THE CITY RECORD

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THE CITY RECORD **MICHAEL R. BLOOMBERG, *Mayor***

EDNA WELLS HANDY, Commissioner, Department of Citywide Administrative Services.
ELI BLACHMAN, Editor of The City Record.

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PUBLIC HEARINGS AND MEETINGS

See Also: Procurement; Agency Rules

BANKING COMMISSION

■ **MEETING**

PLEASE TAKE NOTICE THAT there will be a Quarterly Meeting of the Banking Commission on Wednesday, March 30, 2011 at 12:30 P.M. in the Executive Conference Room at 66 John Street, 12th Floor, Manhattan.

☛ **m23-29**

CITY COUNCIL

■ **HEARINGS**

HEARING BY THE COMMITTEE ON RULES, PRIVILEGES AND ELECTIONS

THE COMMITTEE ON RULES, PRIVILEGES AND ELECTIONS WILL HOLD A HEARING ON WEDNESDAY, MARCH 23, 2011 AT 10:00 A.M. IN THE 14TH FLOOR HEARING ROOM AT 250 BROADWAY, NEW YORK, NY 10007 ON THE FOLLOWING MATTERS:

Advice and Consent

- **Preconsidered M,** Communication from the Mayor submitting the name of Charles McFaul for appointment as a member of the New York City Civil Service Commission pursuant to §§ 31 and 813 of the *New York City Charter*. Should Mr. McFaul receive the advice and consent of the Council, he will be eligible to serve the remainder of a six-year term that expires on March 21, 2015.

Designation

- **Preconsidered-M, Anna Kril,** Council candidate for re-designation and subsequent re-appointment by the Mayor to the New York City Health and Hospitals Corporation Board of Directors to serve for the remainder of a five-year term that will expire on March 20, 2015.

- **Preconsidered-M,** Alphonzo A. Grant, a candidate for designation by the Council to the Civilian Complaint Review Board, pursuant to § 440(b)(1) of the *New York City Charter*. If Mr. Grant, a resident of Brooklyn, is designated by the Council and subsequently appointed by the Mayor, he will be eligible to serve for the remainder of an existing three-year term that expires on July 4, 2011, as well as for a new three-year term commencing on July 5, 2011. Mr. Grant will fill the vacant position formerly held by William ("Bill") Kuntz.

Rules of The Council

- Rules change concerning the Council's procurement policy.

AND SUCH OTHER BUSINESS AS MAY BE NECESSARY

A Calendar of speakers will be established in advance.

Persons interested in being heard should write to the Honorable Christine C. Quinn, Speaker of the City Council, City Hall, New York, New York 10007, setting forth their name, representation and viewpoints.

Michael M. McSweeney
City Clerk, Clerk of the Council

m18-23

CITY PLANNING COMMISSION

■ **PUBLIC HEARINGS**

NOTICE IS HEREBY GIVEN THAT RESOLUTIONS have been adopted by the City Planning Commission Scheduling public hearings on the following matters to be held at Spector Hall, 22 Reade Street New York, New York, on Wednesday, March 30, 2011 at 10:00 A.M.

BOROUGH OF MANHATTAN
No. 1
LOWER MANHATTAN ARCADES TEXT
CD 1 **N 110193 ZRM**

IN THE MATTER OF an application submitted by the Department of City Planning pursuant to Section 201 of the New York City Charter, for an amendment of the Zoning Resolution of the City of New York, concerning arcades within the Special Lower Manhattan District in Community District 1, Borough of Manhattan.

LOWER MANHATTAN ARCADES TEXT AMENDMENT

Matter in underline is new, to be added;
Matter in ~~strikeout~~ is to be deleted;
Matter within # # is defined in Section 12-10
*** indicates where unchanged text appears in the Zoning Resolution

* * *

Article IX: Special Purpose Districts

Chapter 1: Special Lower Manhattan District

* * *

91-03
District Maps

District maps are located in Appendix A of this Chapter and are hereby incorporated and made an integral part of this Resolution. They are incorporated for the purpose of specifying locations where special regulations and requirements, as set forth in the text of this Chapter, apply.

Map 1 Special Lower Manhattan District
Map 2 Street Wall Continuity Types 1, 2A, 2B & 3
Map 3 Street Wall Continuity Types 4 & 5
Map 4 Designated Retail Streets
Map 5 Curb Cut Prohibitions
Map 6 South Street Seaport Subdistrict (Section 91-63)
Map 7 Subway Station Improvement Areas
Map 8 Public Access Modification Areas

* * *

91-80
PUBLIC ACCESS AREAS

91-81
Certification to modify existing arcades in certain areas

For the purposes of this Section, 'arcade' shall refer to an #arcade# or #through-block arcade# provided in accordance to the provisions of Section 12-10 (DEFINITIONS) and 37-80 (ARCADES); an arcade provided in accordance with paragraphs (a) of Section 37-53 (Design Standards for Pedestrian Circulation Spaces); or an open space provided on a #zoning lot# between the #building street wall# and the #street line# where tables and chairs would otherwise not be allowed as permitted obstructions.

The provisions of this Section shall apply to existing #buildings# providing an arcade within the boundary designated by Map 8 in Appendix A of this Chapter.

Any underlying provisions restricting the placement of tables and chairs within such arcades may be modified where the Chairperson of the City Planning Commission certifies to the Commissioner of Buildings that such modifications are consistent with the provisions of this Section, as follows:

(a) Seating

Moveable seating in the form of public seating and open air café seating, as well as associated moveable tables, umbrellas and other furnishings, shall be permitted obstructions within an arcade, provided that such obstructions conform to the provisions listed below, as applicable. No plastic material shall be permitted in tables or chairs provided within an arcade.
Where an open air cafe is provided, it shall be a permanently unenclosed establishment and may have waiter or table service.

(1) Amount and size of tables and chairs

A minimum of four tables and sixteen chairs shall be provided within an arcade. For the purpose of calculating the percentage of required public seating or open air café seating, every table required by a calculation shall be required to have four chairs.

(i) Public seating

Publicly accessible tables, and associated chairs, shall constitute a minimum of 40 percent of the total amount of tables provided within an arcade. Fractions resulting from such calculation shall be rounded to the nearest whole table.

All tables shall have a minimum diameter of two feet. All publicly accessible chairs shall have seat backs, and the seats shall have a minimum depth of twelve inches and a maximum depth of 20 inches.

(ii) Open air café

Open air café tables, and associated chairs, shall constitute a maximum of 60 percent of the total amount of tables provided within an arcade. Fractions resulting from such calculation shall be rounded to the nearest whole table.

(2) Location restrictions and other prohibitions

No tables or chairs shall be permitted within five feet of any #building# entrance. For arcades with a depth of ten feet or less, as measured from the column face furthest from the #street line# to the #street wall#, a clear pedestrian circulation pathway shall be provided in an amount not less than three feet. For arcades with a depth greater than ten feet, such required clear pedestrian pathway shall be increased to an amount not less than six feet. In addition, for #through-block arcades#, a continuous clear path of ten feet shall be provided, connecting each #street# on which the public access area fronts.

(i) Public seating

Where a proposed modification to an arcade is located on a #zoning lot# with frontage along Water Street, a minimum of 50 percent of the aggregate amount of

tables and chairs provided pursuant to paragraph (a)(1)(i) of this Section shall be located within 25 feet of the Water Street #street line#.

(ii) Open air café

Open air cafes shall be located at the same elevation as the adjoining sidewalk area or #publicly accessible open area#, except that platforms may be provided, provided that they do not exceed a height of six inches.
Fences, planters, walls, fabric dividers or other barriers that separate open air cafe areas from other portions of the arcade, or adjacent sidewalks or #publicly accessible open areas# shall be prohibited. No kitchen equipment shall be installed within an open air café.

(3) Hours of operation

(i) Public seating

Tables and chairs shall not be chained, fixed, or otherwise secured during the hours of 7:00 am to 9:00 pm. However, during the nighttime hours of 9:00 pm to 7:00 am such tables and chairs may be removed, or secured within the arcade.

Where public seating and open air cafe seating are provided within an arcade, such public seating shall be subject to the hours of operation of an open air café, as set forth in paragraph (a)(3)(ii) below.

(ii) Open air café

Open air cafes must be in operation and provide service a minimum of 225 days per year.

All furnishings of an open air cafe, including tables, chairs, bussing stations, and heating lamps, shall be completely removed from the arcade when the open air cafe is not in active use, except that tables and chairs may remain in such arcade if they are unsecured and may be used by the public without restriction.

(4) Locating public seating within an adjacent #publicly accessible open area#
Where tables and chairs are provided in an arcade located on the same #zoning lot# as an existing #publicly accessible open area# that fronts upon Water Street, the Chairperson of the City Planning Commission may certify public seating provided pursuant to paragraph (a)(2)(i) of this Section to be located within such a #publicly accessible open area#. The area within such #publicly accessible open area# occupied by public seating provided pursuant to this paragraph shall not be included in calculating the maximum #lot coverage# which permitted obstructions may occupy within such #publicly accessible open area#. Such public seating shall not constitute a design change pursuant to the provisions of Section 37-62 (Changes to Existing Publicly Accessible Open Areas) provided the Chairperson finds that:

(i) no more than 50 percent of the aggregate amount of public seating required pursuant to paragraph (a)(2)(i) above is located within such #publicly accessible open area#;

(ii) such public seating shall in no event constitute required seating for such existing #publicly accessible open area#; and

(iii) such public seating complies with the hours of operation provisions of paragraph (a)(3) above.

Any proposed design change to an existing #publicly accessible open area# beyond the findings permitted in this Section shall be subject to the requirements of Section 37-62 (Changes to Existing Publicly Accessible Open Areas).

(b) Litter receptacles

Litter receptacles shall be permitted obstructions within an arcade pursuant to the provisions set forth in Section 37-744 (Litter receptacles).

In order to certify the proposed modification to an existing arcade is consistent with the provisions of this Section, the applicant shall submit to the Chairperson:

(1) a site plan demonstrating the proposed obstructions within the existing arcade, and where applicable, the adjacent #publicly accessible open area#; and

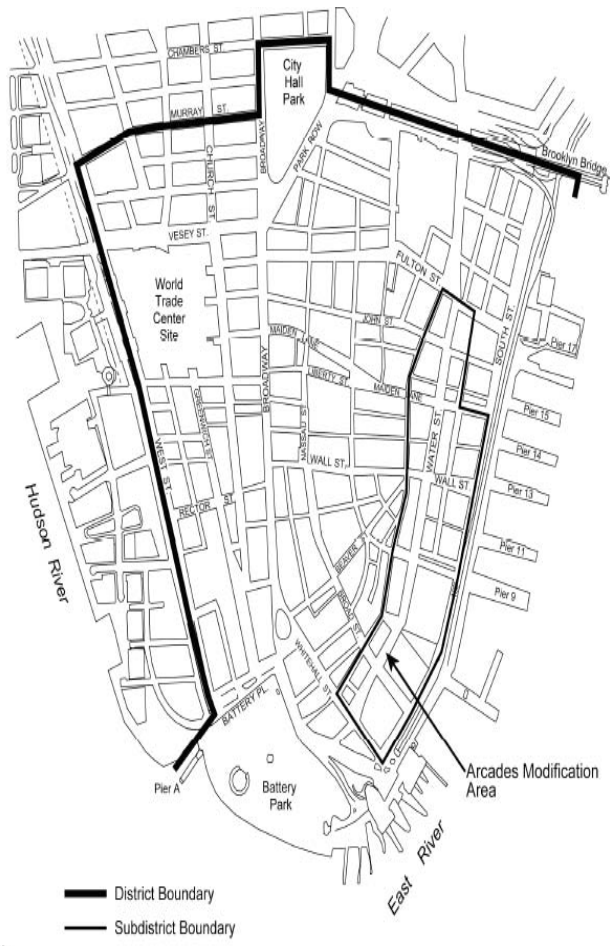
(2) a detailed seating plan illustrating conformance with paragraph (a) of this Section.

All plans for arcades or other #publicly accessible open areas# that are the subject of a certification pursuant to this Section shall be filed and duly recorded in the Borough Office of the City Register of the City of New York, indexed against the property in the form of a legal instrument, in a form satisfactory to the Chairperson, providing notice of the certification of the arcade, pursuant to this Section. Such filing and recording of such instrument shall be a precondition to certification. The recording information shall be included on the certificate of occupancy for any #building#, or portion thereof, on the #zoning lot# issued after the recording date.

* * *

Appendix A
District Maps
Map 8
Public Access Modification Areas

* * *



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BOROUGH OF QUEENS
No. 2
10-24 154th *STREET*

CD 7 **C 100457 ZMQ**

IN THE MATTER OF an application submitted by 10-24 Associates, LLC pursuant to Sections 197-c and 201 of the New York City Charter for an amendment of the Zoning Map, Section No. 7d:

1. changing from an R2A District to an R3-1 District property bounded by 10th Avenue, 154th Street, 11th Avenue and a line 100 feet westerly of 154th Street; and

2. establishing within an existing and proposed R3-1 District a C2-2 District bounded by 10th Avenue, 154th Street, 11th Avenue and a line 135 feet westerly of 154th Street;

as shown on a diagram (for illustrative purposes only) dated December 13, 2010.

BOROUGH OF MANHATTAN
No. 3
101 SPRING STREET

CD 2 **C 100267 ZSM**

IN THE MATTER OF an application submitted by the Judd Foundation pursuant to Sections 197-c and 201 of the New York City Charter for the grant of a special permit pursuant to Section 74-711 of the Zoning Resolution to modify the use regulations of Sections 42-11 (Use Groups 4A, 4B, 4C, 5, 6C, 6E, 7A, 9A, and 12B) and 42-14(D)(2)(b) (Special uses in M1-5A and M1-5B Districts) to allow a non-profit institution without sleeping accommodations (Use Group 4A) within an existing 5-story building on property located at 101 Spring Street (Block 498, Lot 27), in an M1-5B District, within the SoHo-Cast Iron Historic District.

Plans for this proposal are on file with the City Planning Commission and may be seen at 22 Reade Street, Room 3N, New York, NY 10007.

YVETTE V. GRUEL, Calendar Officer
City Planning Commission
22 Reade Street, Room 2E
New York, New York 10007
Telephone (212) 720-3370

m17-30

COMMUNITY BOARDS

■ **PUBLIC HEARINGS**

PUBLIC NOTICE IS HEREBY GIVEN THAT the following matters have been scheduled for public hearing by Community Boards:

BOROUGH OF THE BRONX

COMMUNITY BOARD NO. 12 - Thursday, March 24, 2011, 6:30 P.M., Town Hall, 4101 White Plains Road, Bronx, NY

A public hearing regarding the Mayor's FY 2012 Preliminary Budget and responses to Community Board 12's budget priorities.

m18-24

PUBLIC NOTICE IS HEREBY GIVEN THAT the following matters have been scheduled for public hearing by Community Boards:

BOROUGH OF THE BRONX

COMMUNITY BOARD NO. 10 - Tuesday, March 29, 2011 at 7:00 P.M., Hutch Metro Center, Conference Room, 1200 Waters Place, Bronx, NY

Public Hearing concerning the establishment of a Business Improvement District (BID) for the Westchester Square community in the Bronx.

☛ **m23-29**

PUBLIC NOTICE IS HEREBY GIVEN THAT the following matters have been scheduled for public hearing by Community Boards:

BOROUGH OF QUEENS

COMMUNITY BOARD NO. 08 - Monday, March 28, 2011, 7:30 P.M., Hillside Manor, 188-11 Hillside Avenue, Jamaica Estates, NY

BSA #16-11-BZ
181-30 Aberdeen Road, Queens
An application to permit the interior enlargement to an existing single-family home at the 2nd floor and at the attic level. The proposed development change is contrary to Sections 23-141(a) Floor Area and to 23-141(a) Open Space Ratio and therefore requires a special permit.

m22-28

PUBLIC NOTICE IS HEREBY GIVEN THAT the following matters have been scheduled for public hearing by Community Boards:

BOROUGH OF BROOKLYN

COMMUNITY BOARD NO. 15 - Tuesday, March 29, 2011, 7:00 P.M., Kingsborough Community College, 2001 Oriental Boulevard, Rm. U112, Brooklyn, NY

A Public Hearing on the Fiscal Year 2012 Preliminary Budget.

☛ **m23-29**

OFFICE OF EMERGENCY MANAGEMENT

■ **NOTICE**

The NYC Local Emergency Planning Committee will reconvene on Thursday, March 31st, 2011 at 10:00 A.M. at the New York City Office of Emergency Management, North Conference Room, 165 Cadman Plaza East, Brooklyn, NY 11201.

m21-23

LANDMARKS PRESERVATION COMMISSION

■ **PUBLIC HEARINGS**

NOTICE IS HEREBY GIVEN that pursuant to the provisions of Title 25, chapter 3 of the Administrative Code of the City of New York (Sections 25-307, 25-308, 25,309, 25-313, 25-318, 25-320) (formerly Chapter 8-A, Sections 207-6.0, 207-7.0, 207-12.0, 207-17.0, and 207-19.0), on Tuesday, **April 05, 2011 at 9:30 A.M.** in the morning of that day, a public hearing will be held in the Conference Room at 1 Centre Street, 9th Floor, Borough of Manhattan with respect to the following properties and then followed by a public meeting. Any person requiring reasonable accommodation in order to participate in the hearing or attend the meeting should call or write the Landmarks Commission no later than five (5) business days before the hearing or meeting.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF BROOKLYN 11-6088 - Block 30, lot 19-
54 Jay Street - DUMBO Historic District
A residential building with a commercial storefront built c. 2000. Application is to install storefront infill.
Community District 2.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF BROOKLYN 11-0148 - Block 224, Lot 2-
113 Columbia Heights - Brooklyn Heights Historic District
A Greek Revival style rowhouse built c. 1837-40. Application is to legalize the construction of a stair bulkhead without Landmarks Preservation Commission permits.
Community District 2.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF BROOKLYN 11-4358 - Block 221, lot 18-
68 Cranberry Street - Brooklyn Heights Historic District
An Anglo-Italianate style rowhouse built in 1852. Application is to demolish a rear addition and construct a new rear addition. Community District 2.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF BROOKLYN 11-2119 - Block 215, lot 21-
27 Cranberry Street - Brooklyn Heights Historic District
A vacant lot. Application is to construct a new building.
Zoned R6B-LH7. Community District 2.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF BROOKLYN 11-1398 - Block 1945, lot 8-
357 Waverly Avenue - Clinton Hill Historic District
A vernacular 19th century carriage house and residence. Application is to modify security grilles installed without Landmarks Preservation Commission permits and windows and doors installed in non-compliance with Certificate of No Effect 02-6008. Community District 2.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF BROOKLYN 11-5904 - Block 292, lot 32-
156 Court Street - Cobble Hill Historic District
A Classical Revival style house built in 1848-55 and altered with a storefront. Application is to install new storefront infill. Community District 6.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF BROOKLYN 11-5045 - Block 1062, lot 1-
49 8th Avenue, aka 253 Berkeley Place – Park Slope Historic District

A house designed by J. Doherty & Son and built in 1882-1886. Application is to install a garden fence, stoop ironwork and a rear deck, and modify a window opening to accommodate a door. Community District 6.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF BROOKLYN 11-2648 - Block 1151, lot 54-620 Vanderbilt Avenue - Prospect Heights Historic District
An Italianate style rowhouse built in 1872 and altered in the early 20th century to accommodate storefronts. Application is to legalize the installation of a storefront and awnings without Landmarks Preservation Commission permits. Community District 8.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-6415 - Block 215, lot 7503-151 Hudson Street - Tribeca North Historic District
A Romanesque Revival style store and loft building designed by Julius Kastner and built in 1894. Application is to replace the sidewalk. Community District 1.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-6340 - Block 189, lot 41-228 West Broadway - Tribeca West Historic District A Renaissance Revival style store and loft building designed by Maynard and Wistairr and built in 1892. Application is to construct an elevator bulkhead. Community District 1.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-6798 - Block 486, lot 11-84 Wooster Street - SoHo-Cast Iron Historic District
A Beaux-Arts/Classical style mercantile building designed by Albert Wagner and built in 1895-96. Application is to replace diamond plate at the sidewalk with concrete.
Community District 2.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-6468 - Block 530, lot 58-20 Bond Street - NoHo Historic District
A Romanesque Revival/Renaissance Revival style store and loft building, designed by Cleverdon & Putzel and built in 1894-95. Application is to install a painted wall sign.
Community District 2.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-2769 - Block 521, lot 79-306 Bowery - NoHo East Historic District A Federal Style house built in 1820. Application is to legalize the replacement of dormers in non-compliance with Certificate of Appropriateness 06-7270. Community District 2.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-7194- Block 524, lot 66-100-110 Bleecker Street- University Village- Individual Landmark
A Brutalist style residential complex designed by James Ingo Freed of I. M. Pei & Associates and built in 1964-67. Application is to modify the landscape and install a playground and assorted fixtures. Community District 2.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-6742- Block 615, lot 68- 16 Jane Street- Greenwich Village Historic District
A building designed by A. B. Ogden & Son in 1887 and altered in 1939. Application is to replace the areaway fence, install a new garbage enclosure, doors, and install new expansion joints and planters on the facade.
Community District 2.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-5320 - Block 619, lot 74-75 Christopher Street, aka 116-18 7th Avenue, aka 218-224 West 4th Street – Greenwich Village Historic District
A two-story commercial building designed by Phelps Barnum and built in 1932. Application is to install storefront infill.
Community District 2.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-6758 - Block 575, lot 48-9 West 11th Street - Greenwich Village Historic District
A Gothic Revival style church complex, comprised of the church, designed by Joseph G. Wells, and built in 1844-46; the Gothic Revival style chapel, designed by McKim, Mead and White, and built in 1893-94; and the Prairie School style church house, designed by Edgar Tafel, and built in 1958-60. Application is to replace bluestone sidewalks.
Community District 2.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-5181 - Block 575, lot 48-12 West 12th Street - Greenwich Village Historic District
A Gothic Revival style church complex, comprised of the church, designed by Joseph G. Wells, and built in 1844-46; the Gothic Revival style chapel, designed by McKim, Mead and White, and built in 1893-94; and the Prairie School style church house, designed by Edgar Tafel, and built in 1958-60. Application is to construct additions on the ground floor and roof of the church house, and alter an existing ramp and a path in the garden between the church and church house. Zoned R10. Community District 2.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-4465 - Block 609, lot 164-139 West 13th Street- Greenwich Village Historic District
A Greek Revival style rowhouse built in 1845. Application is to legalize the installation of a stoop gate without Landmarks Preservation Commission permits. Community District 2.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-4942 - Block 609, lot 70-149 West 13th Street - Greenwich Village Historic District
A Greek Revival style house built in 1847-48, and altered c. 1920's. Application is to reconstruct the stoop, install a new entrance, areaway ironwork, and a new cornice, and construct a rooftop addition. Zoned R6.
Community District 2.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-6623 - Block 634, lot 7501-765 Greenwich Street - Greenwich Village Historic District
A Greek Revival style rowhouse built in 1838. Application is to install a roof deck and railings. Community District 2.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-5377 - Block 583, lot 38-28 7th Avenue South - Greenwich Village Historic District
A one-story brick building built in 1921. Application is to enlarge masonry openings, install new storefront infill and alter the roof. Community District 2.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-7192 - Block 527, lot 58-48 Carmine Street - Greenwich Village Historic District Extension II
An altered Renaissance Revival style tenement building with a commercial ground floor designed by Marshall L. Emery and built in 1894. Application is to replace storefront infill and a bracket sign. Community District 2.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-5102 - Block 628, lot 1-1-3 Little West 12th Street - Gansevoort Market Historic District
A neo-Grec style store and loft building, designed by Peter J. Zabriskie, and built in 1887, and a vernacular style warehouse, designed by John G. Michel, and built in 1918-19. Application is to modify parapets and install storefront infill.
Community District 2.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-6175 - Block 645, lot 44-27 9th Avenue - Gansevoort Market Historic District
A Greek Revival style rowhouse, built circa 1844-1846 and altered in the 20th and 21st centuries. Application is to install a painted wall sign. Zoned M1-5.
Community District 2.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 10-9388 - Block 712, lot 14, 21-413-435 West 14th Street - Gansevoort Market Historic District
An Arts and Crafts style market building designed by James S. Maher and built in 1914, and altered by William P. Seaver in 1922. Application is to install storefront infill.
Community District 4.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-4311 - Block 859, lot 34-141-147 East 39th Street, aka 145 East 39th Street- The Allerton 39th Street House - Individual Landmark
A Northern Italian Renaissance style hotel designed by Arthur Loomis Harmon and built in 1916-18. Application is to install rooftop mechanical equipment.
Community District 6.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 10-8244 - Block 824, lot 54-132 East 19th Street - Gramercy Park Historic District
A small apartment building designed by Frederick J. Stevens, built in 1910. Application is to establish a Master Plan governing the future replacement of windows and the installation of through-window air conditioning units.
Community District 6.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-6485 - Block 1146, lot 32-306-316 Columbus Avenue, aka 100-102 West 75th Street - Upper West Side/Central Park West Historic District
A Renaissance/Romanesque Revival style flats building, designed by Gilbert A. Schellenger, and built in 1891-92. Application is to install a bracket sign. Zoned R8B/C1-8A.
Community District 7.

BINDING REPORT
BOROUGH OF MANHATTAN 11-6714- Block 1130, lot 1-200 Central Park West - Theodore Roosevelt Memorial, The American Museum of Natural History - Individual Landmark
A Classical style addition designed by John Russell Pope, and built in 1929-1935, to the American Museum of Natural History, a group of museum exhibition and support buildings constructed within a park beginning in 1874. Application is to install banners, lighting, and alter the porte cochere entrance and paving. Community District 7.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-6336 - Block 1199, lot 36-2-6 West 86th Street, aka 255-259 Central Park West - Upper West Side/Central Park West Historic District
A Beaux-Arts style apartment building designed by Mulliken & Moeller and built in 1905-06. Application is to construct a barrier-free access ramp. Community District 7.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-4759 - Block 1412, lot 62-122 East 78th Street - Upper East Side Historic District
A neo-Georgian style residence designed by Foster, Gade and Graham and built in 1911-12. Application is to alter window openings to create entrances, demolish the rear extension, and construct a new rear facade. Zoned R8B.
Community District 8.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-5490 - Block 2050, lot 42-351 Convent Avenue - Hamilton Heights Historic District
A neo-Gothic style church designed by Lamb & Rich and built in 1897-99. Application is to construct an addition. Zoned R7-2.
Community District 9.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF MANHATTAN 11-2982 - Block 1720, lot 8-19 West 120th Street - Mount Morris Park Historic District
A rowhouse, designed by Alfred Barlow, built in 1887-88. Application is to construct a rear yard addition. Zoned R7-2.
Community District 10.

BINDING REPORT
BOROUGH OF MANHATTAN 11-7067 - Block 2106, lot 1-High Bridge - High Bridge, Aqueduct and Pedestrian Walk - Individual Landmark
A Roman style aqueduct and bridge designed by John B. Jervis and completed in 1848, modified in 1861-64, and modified with the installation of the steel arch in 1923. Application is to install barrier-free access ramps, viewing platforms, safety fencing, and lighting.
Community District 12.

CERTIFICATE OF APPROPRIATENESS
BOROUGH OF BRONX 11-6506 - Block 2739, lot 15-1201 Lafayette Avenue - American Bank Note Company Printing Plant - Individual Landmark
A Gothic inspired printing plant building designed by Kirby, Petit & Green, and built in 1911. Application is to install an entrance canopy, signage, and a flagpole.
Community District 2.

m22-a5

TRANSPORTATION

■ NOTICE

COMMUTER VAN SERVICE AUTHORITY APPLICATION
Queens

Notice is hereby given that the Department of Transportation has received an application for a new commuter van service authority in the Borough of Queens. From a residential area of Queens on the north by Astoria Blvd. from Brooklyn Queens Expressway east to 82nd Street, bounded on the east by 82nd Street from Astoria Blvd. to Roosevelt Avenue, by Roosevelt Avenue from 82nd Avenue to Junction Blvd., by Junction Blvd. from Roosevelt Avenue to Long Island Expressway. Bounded on the south by Long Island Expressway from Junction Blvd. to 69th Street. Bounded on the west by 69th Street from Long Island Expressway to Brooklyn Queens Expressway, by Brooklyn Queens Expressway from 69th Street to Brooklyn Queens Expressway East, by Brooklyn Queens Expresway East from Brooklyn Queens Expressway to Astoria Blvd. to a Commercial area of Queens bounded on the north by 32nd Avenue from College Point Blvd. from Parsons Blvd. Bounded on the east by Parsons Blvd. from 32nd Avenue to Oak Avenue, by Oak Avenue from Parsons Blvd. to Rose Avenue, by Rose Avenue from Oak Avenue to Kissena Blvd., by Kissena Blvd. from Rose Avenue to Long Island Expressway. Bounded on the south by Long Island Expressway from Kissena Blvd. to College Point Blvd. Bounded on the west by College Point Blvd. from Long Island Expressway to 32nd Avenue. The applicant is QQ Van Service, Inc. They can be reached at 32-27 Leavitt Street, Flushing, NY 11354. The applicant is proposing to use 15 vans to provide this service Monday through Sunday.

There will be a public hearing held on Thursday, April 28, 2011 at Queens Borough Hall, 120-55 Queens Blvd. - Room 213, Part 2, Kew Gardens, NY 11424 from 2:00 P.M. - 4:00 P.M. for an opportunity to voice your position on this application. In addition, written comments in support or in opposition to this application may be sent to Ms. Dorothy Szorc at the New York City Department of Transportation, Division of Planning and Sustainability, 55 Water Street - 9th Floor, New York, NY 10041, no later than April 28, 2011. Any written comments received after this date may not be considered. Those opposing the application must clearly specify why the proposed additional van service will not meet present and/or future public convenience and necessity.

m21-25

COURT NOTICES

SUPREME COURT

■ NOTICE

RICHMOND COUNTY
IA PART 74
NOTICE OF ACQUISITION
INDEX NUMBER (CY) 4002/11

In the Matter of the Application of the CITY OF NEW YORK, relative to acquire title in fee simple to all or parts of,

ALBEE AVENUE

from Amboy Road to approximately 155 feet north of Amboy Road,

AMBOY ROAD

from Alvine Avenue to approximately 20 feet east of Poillon Avenue,

ANNADALE ROAD

from Amboy Road to Approximately 104 feet northeast of Furman Street,

COMMUNITY LANE

from Amboy Road to approximately 10 feet south of Amboy Road,

FURMAN STREET

from Annadale Road to approximately 18 feet southeast of Annadale Road,

PHILIP AVENUE

from Amboy Road to approximately 10 feet south of Amboy Road,

POILLON AVENUE

from Annadale Road to approximately 97 feet southeast of Annadale Road,

POILLON AVENUE

from Amboy Road to approximately 8 feet south of Amboy Road,

in the Borough of Staten Island, City of State of New York

PLEASE TAKE NOTICE, that by order of the Supreme Court of the State of New York, County of Richmond, IA Part 74 (Hon. Wayne P. Saitta, J.S.C.), duly entered in the office of the Clerk of the County of Richmond on March 2, 2011, the

application of the City of New York to acquire certain real property, for all or parts of **Albee Avenue, Amboy Road, Annadale Road, Community Lane, Furman Street, Philip Avenue, and Poillon Avenue**, was granted and the City was thereby authorized to file an acquisition map with the Office of the Clerk of Richmond County.
Said map, showing the property acquired by the City, was filed with the Clerk of Richmond County on March 4, 2011. Title to the real property vested in the City of New York on March 4, 2011.

PLEASE TAKE FURTHER NOTICE, that the City has acquired the following parcels of real property:

Damage Parcel	Block	Part of Lot
1	6511	111
2	6469	30
3	6469	37
4	6469	39
5	6469	43
6	6469	46
7	6247	1
8	6247	10
9	6247	20
10	6247	29
11	6247	34
12 & 14	6247	37
13	6247	40
15	6246	21
16	6246	30
17	6245	108
18	6249	222
19	6249	174
20	6249	214
21	6249	207
22 & 23	6249	200
24	6249	38
25	6249	33
26	6249	30
27	6249	25
28	6249	21
1A, 1B, 1C, 1D & 1E	Bed of Amboy Road	
1F	Bed of Amboy Road and Poillon Avenue	
1G	Bed of Amboy Road	
2A	Bed of Albee Avenue	
2B	Bed of Philip Avenue	
3A	Bed of Community Lane	
4A, 4B, 4C, 4D, 4E, 4F & 4G	Bed of Annadale Road	
5A	Bed of Poillon Avenue	
6A	Bed of Furman Street	

PLEASE TAKE FURTHER NOTICE, that pursuant to said Order, each and every person interested in the real property acquired in the above-referenced proceeding and having any claim or demand on account thereof, shall have a period of one calendar year from the date of service of the Notice of Acquisition of title vesting, to file a written claim with the Clerk of the Court of Richmond County, and to serve within the same time a copy thereof on the Corporation Counsel of the City of New York, Tax and Bankruptcy Litigation Division, 100 Church Street, New York, New York 10007. Pursuant to § 504 of the Eminent Domain Procedure Law of the State of New York, the claim shall include:

A) the name and post office address of the condemnee;
B) reasonable identification by reference to the acquisition map, or otherwise, of the property affected by the acquisition, and the condemnee's interest therein;
C) a general statement of the nature and type of damages claimed, including a schedule of fixture items which comprise part or all of the damages claimed; and,
D) if represented by an attorney, the name, address and telephone number of the condemnee's attorney.

Pursuant to EDPL § 503(C), in the event a claim is made for fixtures or for any interest other than the fee in the real property acquired, a copy of the claim, together with the schedule of fixture items, if applicable, shall also be served upon the fee owner of said real property.

PLEASE TAKE FURTHER NOTICE, that, pursuant to § 5-310 of the New York City Administrative Code, proof of title shall be submitted to the Corporation Counsel of the City of New York, Tax and Bankruptcy Litigation Division, 100 Church Street, New York, New York 10007 on or before March 4, 2012 (which is two (2) calendar years from the title vesting date).

Dated: March 7, 2011, New York, New York
MICHAEL A. CARDOZO
Corporation Counsel of the City of New York
Attorney for the Condemnor
100 Church Street
New York, New York 10007
Tel. (212) 788-0710

m15-28

PROPERTY DISPOSITION

CITYWIDE ADMINISTRATIVE SERVICES

MUNICIPAL SUPPLY SERVICES

■ **AUCTION**

PUBLIC AUCTION SALE NUMBER 11001-M

NOTICE IS HEREBY GIVEN of a public auction of City fleet vehicles consisting of cars, vans, light duty vehicles, trucks, heavy equipment and miscellaneous automotive equipment to be held on Wednesday, April 13, 2011 (SALE NUMBER 11001-M). Viewing is on auction day only from 8:30 A.M. until 9:00 A.M. The auction begins at 9:00 A.M.
LOCATION: 570 Kent Avenue, Brooklyn, NY (in the Brooklyn Navy Yard between Taylor and Clymer Streets).

A listing of vehicles to be offered for sale in the next auction can be viewed on our website, on the Friday prior to the sale date at:
http://www.nyc.gov/autoauction
OR
http://www.nyc.gov/autoauctions

Terms and Conditions of Sale can also be viewed at this site.

For further information, please call (718) 417-2155 or (718) 625-1313.

m3-a13

■ **SALE BY SEALED BID**

SALE OF: 3 LOTS OF MISCELLANEOUS EQUIPMENT AND SUPPLIES, USED/UNUSED.

S.P.#: 11019 **DUE:** March 29, 2011

Use the following address unless otherwise specified in notice, to secure, examine or submit bid/proposal documents, vendor pre-qualification and other forms; specifications/ blueprints; other information; and for opening and reading of bids at date and time specified above.
DCAS, Division of Municipal Supply Services, 18th Floor Bid Room, Municipal Building, New York, NY 10007.
For sales proposal contact Gladys Genoves-McCauley (718) 417-2156.

m16-29

POLICE

OWNERS ARE WANTED BY THE PROPERTY CLERK DIVISION OF THE NEW YORK CITY POLICE DEPARTMENT.

The following listed property is in the custody, of the Property Clerk Division without claimants.

Recovered, lost, abandoned property, property obtained from prisoners, emotionally disturbed, intoxicated and deceased persons; and property obtained from persons incapable of caring for themselves.
Motor vehicles, boats, bicycles, business machines, cameras, calculating machines, electrical and optical property, furniture, furs, handbags, hardware, jewelry, photographic equipment, radios, robes, sound systems, surgical and musical instruments, tools, wearing apparel, communications equipment, computers, and other miscellaneous articles.

INQUIRIES
Inquiries relating to such property should be made in the Borough concerned, at the following office of the Property Clerk.

FOR MOTOR VEHICLES
(All Boroughs):
* **College Auto Pound, 129-01 31 Avenue, College Point, NY 11354, (718) 445-0100**
* **Gowanus Auto Pound, 29th Street and 2nd Avenue, Brooklyn, NY 11212, (718) 832-3852**
* **Erie Basin Auto Pound, 700 Columbia Street, Brooklyn, NY 11231, (718) 246-2029**

FOR ALL OTHER PROPERTY
* **Manhattan - 1 Police Plaza, New York, NY 10038, (212) 374-4925.**
* **Brooklyn - 84th Precinct, 301 Gold Street, Brooklyn, NY 11201, (718) 875-6675.**
* **Bronx Property Clerk - 215 East 161 Street, Bronx, NY 10451, (718) 590-2806.**
* **Queens Property Clerk - 47-07 Pearson Place, Long Island City, NY 11101, (718) 433-2678.**
* **Staten Island Property Clerk - 1 Edgewater Plaza, Staten Island, NY 10301, (718) 876-8484.**

j1-d31

PROCUREMENT

"The City of New York is committed to achieving excellence in the design and construction of its capital program, and building on the tradition of innovation in architecture and engineering that has contributed to the City's prestige as a global destination. The contracting opportunities for construction/construction services and construction-related services that appear in the individual agency listings below reflect that commitment to excellence."

CITYWIDE ADMINISTRATIVE SERVICES

MUNICIPAL SUPPLY SERVICES

■ **SOLICITATIONS**

Goods

SOUND SYSTEM (BRAND SPECIFIC) – Competitive Sealed Bids – PIN# 8571100559 – DUE 04-07-11 AT 10:30 A.M.

Use the following address unless otherwise specified in notice, to secure, examine or submit bid/proposal documents, vendor pre-qualification and other forms; specifications/ blueprints; other information; and for opening and reading of bids at date and time specified above.
Department of Citywide Administrative Services, 1 Centre Street, Room 1800, New York, NY 10007.
Anna Wong (212) 669-8610; Fax: (212) 669-7603; dcasdmssbids@dcas.nyc.gov

☛ **m23**

■ **AWARDS**

Goods

COMPUTER SOFTWARE – Intergovernmental Purchase – PIN# 8571100606 – AMT: $995,881.25 – TO: Curam Software Inc., 13800 Coppermine Road, Suite 410, Herndon, VA 20171. NYS Contract #PT62193.

Suppliers wishing to be considered for a contract with the Office of General Services of New York State are advised to contact the Procurement Services Group, Corning Tower, Room 3711, Empire State Plaza, Albany, NY 12242 or by phone: 518-474-6717.

☛ **m23**

■ **VENDOR LISTS**

Goods

ACCEPTABLE BRAND LIST – In accordance with PPB Rules, Section 2-05(c)(3), the following is a list of all food items for which an Acceptable Brands List has been established.

1. Mix, Biscuit - AB-14-1:92
2. Mix, Bran Muffin - AB-14-2:91
3. Mix, Corn Muffin - AB-14-5:91
4. Mix, Pie Crust - AB-14-9:91
5. Mixes, Cake - AB-14-11:92A
6. Mix, Egg Nog - AB-14-19:93
7. Canned Beef Stew - AB-14-25:97
8. Canned Ham Shanks - AB-14-28:91
9. Canned Corned Beef Hash - AB-14-26:94
10. Canned Boned Chicken - AB-14-27:91
11. Canned Corned Beef - AB-14-30:91
12. Canned Ham, Cured - AB-14-29:91
13. Complete Horse Feed Pellets - AB-15-1:92
14. Canned Soups - AB-14-10:92D
15. Infant Formula, Ready to Feed - AB-16-1:93
16. Spices - AB-14-12:95
17. Soy Sauce - AB-14-03:94
18. Worcestershire Sauce - AB-14-04:94

Application for inclusion on the above enumerated Acceptable Brand Lists for foods shall be made in writing and addressed to: Purchase Director, Food Unit, Department of Citywide Administrative Services, Division of Municipal Supply Services, 1 Centre Street, 18th Floor, New York, NY 10007, (212) 669-4207.

j5-d31

EQUIPMENT FOR DEPARTMENT OF SANITATION – In accordance with PPB Rules, Section 2.05(c)(3), an acceptable brands list will be established for the following equipment for the Department of Sanitation:
A. Collection Truck Bodies
B. Collection Truck Cab Chassis
C. Major Component Parts (Engine, Transmission, etc.)

Applications for consideration of equipment products for inclusion on the acceptable brands list are available from: Vendor Relations, Department of Citywide Administrative Services, Division of Municipal Supply Services, 1 Centre Street, 18th Floor, New York, NY 10007. (212) 669-8610.

j5-d31

OPEN SPACE FURNITURE SYSTEMS - CITYWIDE – In accordance with PPB Rules, Section 2.05(c)(3), an Acceptable Brands List, #AB-17W-1:99, has been established for open space furniture systems.

Application for consideration of product for inclusion on this acceptable brands list shall be made in writing and addressed to: Vendor Relations, Department of Citywide Administrative Services, Division of Municipal Supply Services, 1 Centre Street, 18th Floor, New York, NY 10007, (212) 669-8610.

j5-d31

DESIGN & CONSTRUCTION

CONTRACT SECTION

■ **SOLICITATIONS**

Construction / Construction Services

FORT GREENE HEALTH CENTER BASEMENT RENOVATION/HVAC UPGRADE – Competitive Sealed Bids – PIN# 85011B0104 – DUE 04-28-11 AT 2:00 P.M. – PROJECT NO.: HL82FGHVC/8502011HL0004C. There will be an optional pre-bid conference on Thursday, April 14, 2011 at 10:00 A.M. at the Fort Greene Health Center located at 295 Flatbush Avenue Extension, Brooklyn, New York, NY 11201.

Special Experience Requirements.

Bid documents are available at: http://www.nyc.gov/ddc
This Bid Solicitation includes M/WBE participation goals for subcontracted work. For the M/WBE goals, please visit our website at www.ddc.nyc.gov/buildnyc see "Bid Opportunities." For more information about M/WBE Certification, please call 311 or go to www.nyc.gov/getcertified.

Bidders are hereby advised that this contract is subject to the Project Labor Agreement ("PLA") entered into between the City and the Building and Construction Trades Council of Greater New York ("BCTC") affiliated Local Unions. Refer to Volume 2 of the Bid Documents for further information.

This contract is part of a Multi-Agency Pilot Program in which the City's Standard Construction Contract provisions concerning Delay Damages have been revised altering the allocation of the risk of projects delays, to allow contractors appropriate compensation for certain delays that are reasonably considered to be the City's responsibility.
Vendor Source ID#: 73403.

Use the following address unless otherwise specified in notice, to secure, examine or submit bid/proposal documents, vendor pre-qualification and other forms; specifications/ blueprints; other information; and for opening and reading of bids at date and time specified above. Bid Documents Deposit - $35.00 per set. Company check or money order. No cash accepted. Late bids will not be accepted.
Department of Design and Construction, 30-30 Thomson Avenue, 1st Floor, Long Island City, NY 11101. Ben Perrone (718) 391-2614; Fax: (718) 391-2615.

☛ **m23**

HEALTH AND HOSPITALS CORPORATION

The New York City Health and Hospitals Corporation is regularly soliciting bids for supplies and equipment at its Central Purchasing Offices, 346 Broadway, New York City, Room 516, for its Hospitals and Diagnostic and Treatment Centers. All interested parties are welcome to review the bids that are posted in Room 516 weekdays between 9:00 a.m. and 4:30 p.m. For information regarding bids and the bidding process, please call (212) 442-4018.

j1-d31

■ **SOLICITATIONS**

Construction Related Services

CONSTRUCTION TO REHABILITATE THE WIC PROGRAM – Competitive Sealed Bids – PIN# 332-11-004 – DUE 04-18-11 AT 9:30 A.M. – Mandatory site-visits scheduled for April 8, 2011 at 10:00 A.M. or 11:00 A.M. at Cumberland Diagnostic and Treatment Center, 100 North Portland Avenue, 1st Floor WIC Program, Brooklyn, NY 11205. Bid document fee $25.00 per set (check or money order) made payable to NYCHHC for hard copy. Copy of bid document can also be obtained free of charge by emailing Millicent. Thompson@nychhc.org. Bid package request deadline is 04-05-11 at 4:00 P.M.

Use the following address unless otherwise specified in notice, to secure, examine or submit bid/proposal documents, vendor pre-qualification and other forms; specifications/ blueprints; other information; and for opening and reading of bids at date and time specified above.
North Brooklyn Health Network, 100 North Portland Avenue, Rm. C-32, Brooklyn, NY 11205.
Millicent Thompson (718) 260-7686; Fax: (718) 260-7619; Millicent.Thompson@nychhc.org

☛ **m23**

HEALTH AND MENTAL HYGIENE

■ **INTENT TO AWARD**

Services (Other Than Human Services)

MAINTENANCE FOR BLOOD PRESSURE KIOSKS – Sole Source – Available only from a single source - PIN# 11CR095401R0X00 – DUE 04-04-11 AT 5:00 P.M. – The Department intends to enter into a sole source contract with New York Blood Pressure Inc., to provide service to 96 Pharmacy Kiosks, Lifeclinic model LC300-15 monitors. These kiosks were purchased by the department's Cardio Vascular Disease Program to be utilized throughout NYC by residents to check their blood pressure. The term of this contract would be from 7/1/10 - 6/30/12, and the maximum contract amount would be $91,728.00. Any vendor that believes it can also provide these services is invited to indicate an expression of interest by letter which must be received no later than April 4, 2011 at 5:00 P.M. Expressions of interest should be sent to: Office of the Chief Agency Contracting Officer, 93 Worth Street, Room 812, New York, NY 10013. Attn: Jeannette Soto-Pacheco, (212) 219-5518 or e-mail jsoto@health.nyc.gov

Use the following address unless otherwise specified in notice, to secure, examine or submit bid/proposal documents, vendor pre-qualification and other forms; specifications/ blueprints; other information; and for opening and reading of bids at date and time specified above.
Health and Mental Hygiene, 2 Lafayette Street, 20th Floor, New York, NY 10007. Cynthia Mont-Burbon (212) 341-0161; cmontbur@health.nyc.gov

m22-28

AGENCY CHIEF CONTRACTING OFFICER

■ **SOLICITATIONS**

Human / Client Services

NEW YORK/NY III SUPPORTED HOUSING CONGREGATE – Competitive Sealed Proposals – Judgment required in evaluating proposals - PIN# 81608PO076300R0X00-R – DUE 03-22-12 AT 4:00 P.M. – The Department is issuing a RFP to establish 3,000 units of citywide supportive housing in newly constructed or rehabilitated single-site buildings for various homeless populations pursuant to the New York III Supported Housing agreement. The subject RFP will be open-ended and proposals will be accepted on an on-going basis. The RFP is available on-line at http://www.nyc.gov/html/doh/html/acco/acco-rfp-nynycongregate-20070117-form.shtml. A pre-proposal conference was held on March 6, 2007 at 2:00 P.M. at 125 Worth Street, 2nd Floor Auditorium, New York, N.Y. Any questions regarding this RFP must be sent in writing in advance to Contracting Officer at the above address or fax to (212) 219-5865. All proposals must be hand delivered at the Agency Chief Contracting Officer, 93 Worth Street, Room 812, New York, NY 10013, no later than March 22, 2012.

As a minimum qualification requirement for (1) the serious and persistent mentally ill populations, the proposer must be incorporated as a not-for-profit organization, and (2) for the young adult populations, the proposer must document site control and identify the source of the capital funding and being used to construct or renovate the building.

Use the following address unless otherwise specified in notice, to secure, examine or submit bid/proposal documents, vendor pre-qualification and other forms; specifications/ blueprints; other information; and for opening and reading of bids at date and time specified above.
Health and Mental Hygiene, 93 Worth Street, Room 812, New York, NY 10013. Huguette Beauport (212) 219-5883, fax: (212) 219-5890, hbeaupor@health.nyc.gov

o1-m21

HOMELESS SERVICES

CONTRACTS AND PROCUREMENT

■ **SOLICITATIONS**

Human / Client Services

CORRECTION: TRANSITIONAL RESIDENCES FOR HOMELESS/ DROP-IN CENTERS – Competitive Sealed Proposals – Judgment required in evaluating proposals - PIN# 071-00S-003-262Z – DUE 06-27-11 AT 10:00 A.M. – CORRECTION: The Department of Homeless Services is soliciting proposals from organizations interested in developing and operating transitional residences for homeless adults and families including the Neighborhood Based Cluster Residence and drop-in centers for adults. This is an open-ended solicitation; there is no due date for submission.

Use the following address unless otherwise specified in notice, to secure, examine or submit bid/proposal documents, vendor pre-qualification and other forms; specifications/ blueprints; other information; and for opening and reading of bids at date and time specified above.
Department of Homeless Services, 33 Beaver Street, 13th Floor, New York, NY 10004.
Marta Zmoira (212) 361-0888, mzmoira@dhs.nyc.gov

j6-20

HOUSING AUTHORITY

■ **SOLICITATIONS**

Goods & Services

GSD_TREE PRUNING FOR CLEARANCE OF CCTV CAMERA LOCATIONS – Competitive Sealed Bids – DUE 04-12-11 –
PIN# 27986 - Various Queens Developments Due at 10:35 A.M.
PIN# 27987 - Various Staten Island Developments Due at 10:40 A.M.
PIN# 27988 - Various Bronx Developments Due at 10:45 A.M.
PIN# 27989 - Various Manhattan Developments Due at 10:50 A.M.
PIN# 27990 - Various Brooklyn Developments Due at 10:55 A.M.
Tree Removal and Crown Reduction-NYCHA Developments, Queens and Staten Island. Two (2) Year Requirement contract. Please ensure that bid response includes documentation as required and attached/included in electronic bid proposal submittal. Failure to comply will result in your bid being deemed non-responsive.

● **GSD_SERVICE OF INTERCOM SYSTEMS - VARIOUS QUEENS DEVELOPMENTS** – Small Purchase – PIN# 28010 – DUE 04-05-11 AT 10:00 A.M.

● **GSD_THIRD PARTY WITNESSING SERVICES FOR CATEGORY 1 AND CATEGORY 5 ELEVATOR INSPECTION - VARIOUS DEVELOPMENTS** – Competitive Sealed Bids – DUE 04-12-11.
PIN# 27999 - Various Manhattan Developments Due at 11:00 A.M.
PIN# 28000 - Various Bronx Developments Due at 11:05 A.M.
Bid Security in the amount of five percent (5 percent) is required; term of contract (2) years. The work to be performed under this contract consists of providing witnessing services for Category 1 and Category 5 elevator inspections City-wide, in all five (5) boroughs as required by Article 304 of Title 28 of the NYC Administrative Code.

Bid Security in the amount of five (5) percent is required. Bid Security shall be in the form of either a certified check made out to the Housing Authority for five percent (5 percent) of the amount of the proposal or a bid bond, which shall be in the form prescribed by the Authority.

● **GSD_MOSQUITO CONTROL - CATCH BASIN LARVICIDING - VARIOUS CITY-WIDE** – Small Purchase – PIN# 28008 – DUE 04-05-11 AT 10:05 A.M. Treat approximately 7,900 catch basins located within the grounds of all Authority Developments city-wide. See attached Exhibit "A" for locations of developments and catch basins. One application shall be applied during the active season for mosquito larvae. Method of treatment and materials utilized shall conform to all rules and regulations governing the application of pesticides. The cost for this service shall be billed at the unit rates as indicated in the Contractors form of proposal to the Authority.

● **GSD_MAINTENANCE PAINTING OF APARTMENTS** – Competitive Sealed Bids – DUE 04-19-11.
PIN# 27991 - Roosevelt I and II-Brooklyn Due at 10:00 A.M.
PIN# 27992 - South Jamaica I and II Houses - Queens Due at 10:05 A.M.
PIN# 27993 - Union Avenue Consolidated - Bronx Due at 10:10 A.M.
PIN# 27994 - Various Bronx Developments Due at 10:15 A.M.
PIN# 27995 - Various Brooklyn Developments Due at 10:20 A.M.
PIN# 28001 - Marcy Houses Due at 10:25 A.M.
PIN# 28002 - Seth Low Houses Due at 10:30 A.M.
Maintenance Painting of Apartments. Term One (1) Year; six month renewal option and (50 percent) increase funding clause. Pre-qualification: Bidder must be established "approved" supplier via NYCHA-Technical Services Paint Program and appear on the active approved vendor list; non-compliance will result in the bid/bidder being deemed non-responsive. Please ensure that bid response includes documentation as required and attached/included in electronic bid proposal submittal. Failure to comply will result in your bid being deemed non-responsive.

Interested firms may obtain a copy and submit it on NYCHA's website: Doing Business With NYCHA. Http://www.nyc.gov/nychabusiness; vendors are instructed to access the Register Here" link for "New Vendors"; if you have supplied goods or services to NYCHA in the past and you have your log-in credentials, click the "Log into iSupplier" link under "Existing Vendor". If you do not have your log-in credentials, click the "Request a Log-in ID" using the link under "Existing Vendor". Upon access, reference applicable RFQ number per solicitation.

Vendors electing to submit a non-electronic bid (paper document) will be subject to a $25.00 non-refundable fee; payable to NYCHA by USPS-Money Order/Certified Check only for each set of RFQ documents requested. Remit payment to NYCHA Finance Department at 90 Church Street, 6th Floor; obtain receipt and present it to 12th Floor, General Services Procurement Group. A bid package will be generated at time of request.

Use the following address unless otherwise specified in notice, to secure, examine or submit bid/proposal documents, vendor pre-qualification and other forms; specifications/ blueprints; other information; and for opening and reading of bids at date and time specified above.
Housing Authority, 90 Church Street, 12th Floor, New York, NY 10007. Sabrina Steverson (212) 306-6771; sabrina.steverson@nycha.nyc.gov

☛ **m23**

HUMAN RESOURCES ADMINISTRATION

■ **AWARDS**

Human / Client Services

SCATTER SITE HOUSING AND SUPPORTIVE SERVICES AIDS – Negotiated Acquisition – Judgment required in evaluating proposals - PIN# 06910H074009 – AMT: $680,990.00 – TO: Discipleship Outreach Ministries Inc. d/b/a Turning Point, 5220 4th Avenue, Brooklyn, NY 11220. The contract term shall be from 4/1/10 - 3/31/11 and E-PIN: 06909X0073CNVN003.

☛ **m23**

JUVENILE JUSTICE

■ **SOLICITATIONS**

Human / Client Services

PROVISION OF NON-SECURE DETENTION GROUP HOMES – Negotiated Acquisition – Judgment required in evaluating proposals - PIN# 13010DJJ000 – DUE 06-30-11 AT 5:00 P.M. – ACS Division of Youth and Family Justice is soliciting applications from organizations interested in operating non-secure detention group homes in New York City. This is an open-ended solicitation; applications will be accepted on a rolling basis until 5:00 P.M. on 6/30/11.

Use the following address unless otherwise specified in notice, to secure, examine or submit bid/proposal documents, vendor pre-qualification and other forms; specifications/ blueprints; other information; and for opening and reading of bids at date and time specified above.
Department of Juvenile Justice, 150 William Street, 9th Floor, New York, NY 10038. Patricia Chabla (212) 341-3505, fax: (212) 341-3625, Patricia.chabla@dfa.state.ny.us

d15-j29

PARKS AND RECREATION

CAPITAL PROJECTS DIVISION

■ **INTENT TO AWARD**

Construction Related Services

CONSTRUCTION AND CONSTRUCTION MANAGEMENT SERVICES FOR VARIOUS HISTORIC HOUSES IN NYC – Sole Source – Available only from a single source - PIN# 8462011C000DC2 – DUE 04-04-11 AT 4:30 P.M. – The Department of Parks and Recreation, Capital Projects Division, intends to enter into Sole Source negotiations with the Historic House Trust of New York City, Inc., to provide Construction and Construction Services of historic house properties within its collection of 22 historic sites, in the Boroughs of Staten Island, Queens, Brooklyn, Bronx, and Manhattan. The contractor must have unique knowledge of the site, the ability to address curatorial issues, secure funding guide restoration and interpretation of the historic house museums.

Any firm which believes that it is also qualified to provide these services or that would like to express their interest in providing services for similar projects in the future may do so. All expressions of interest must be in writing to the address listed here and received by April 4, 2011. You may join the City Bidders list by filling out "NYC-FMS Vendor Enrollment Application" available on-line at "NYC.gov/selltonyc" and in hard copy by calling the Vendor Enrollment Center at (212) 857-1680.

Use the following address unless otherwise specified in notice, to secure, examine or submit bid/proposal documents, vendor pre-qualification and other forms; specifications/ blueprints; other information; and for opening and reading of bids at date and time specified above.
Parks and Recreation, Olmsted Center Flushing Meadows-Corona Park, Room 60, Flushing, NY 11368. Grace Fields-Mitchell (718) 760-6687; Fax: (718) 760-6885; grace.fieldsmitchell@parks.nyc.gov

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CONTRACT ADMINISTRATION

■ **SOLICITATIONS**

Construction / Construction Services

RECONSTRUCTION OF THE BALL FIELD IN MEMORIAL FIELD OF FLUSHING AND RECONSTRUCTION OF PAVEMENTS, FENCES AND GENERAL SITE WORK AT VARIOUS LOCATIONS, THE BRONX – Competitive Sealed Bids – DUE 04-22-11 AT 10:30 A.M. –
PIN# 8462011Q086C01 - Memorial Field in Flushing
PIN# 8462010Q000C10 - Various location in The Bronx Queens, known as Contract #Q086-109M.
E-PIN: 84611B0142.
The Bronx, known as Contract #XG-510M.
E-PIN: 84611B0098.
This procurement is subject to participation goals for MBEs and/or WBEs as required by Local Law 129 of 2005.

● **RECONSTRUCTION OF BOILERS AND HEATING SYSTEMS AT VARIOUS DEPARTMENT OF PARKS AND RECREATION FACILITIES** – Competitive Sealed Bids – PIN# 8462011Q000C03 – DUE 04-20-11 AT 10:30 A.M. - Queens, known as Contract #QG-110M. E-PIN: 84611B0128.
This procurement is subject to participation goals for MBEs and/or WBES as required by Local Law 129 of 2005.

"Bidders are hereby advised that this contract is subject to the Project Labor Agreement ("PLA") covering specified renovation and rehabilitation of city owned buildings and structures entered into between the City and the Building and Construction Trades Council of Greater New York ("BCTC") affiliated local unions. Please refer to the bid documents for further information."

A pre-bid meeting is scheduled for Monday, April 4, 2011 at 11:30 A.M. at the Forest Park Shop.

Bid documents are available for a fee of $25.00 in the Blueprint Room, Room #64, Olmsted Center, from 8:00 A.M. to 3:00 P.M. The fee is payable by company check or money order to the City of NY, Parks and Recreation. A separate check/money order is required for each project. The Company

name, address and telephone number as well as the project contract number must appear on the check/money order. Bidders should ensure that the correct company name, address, telephone and fax numbers are submitted by your company/messenger service when picking up bid documents.

Use the following address unless otherwise specified in notice, to secure, examine or submit bid/proposal documents, vendor pre-qualification and other forms; specifications/ blueprints; other information; and for opening and reading of bids at date and time specified above.
Parks and Recreation, Olmsted Center, Room 64, Flushing Meadows Corona Park, Flushing, NY 11368. Juan Alban (718) 760-6771, Juan.Alban@parks.nyc.gov

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AGENCY RULES

HEALTH AND MENTAL HYGIENE

■ **NOTICE**

NOTICE OF ADOPTION OF AMENDMENTS TO ARTICLE 7 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 public hearing and notice of proposed amendment of Article 7 (Administrative Tribunal) of the New York City Health Code (the "Health Code") was published in the City Record on December 17, 2010 and a public hearing was held on January 21, 2011. No persons testified, and one written comment was received. In response to this comment and a comment from Department staff, several changes were made to the proposal. At a meeting on March 15, 2011, the Board of Health adopted the following resolution.

STATUTORY AUTHORITY

These amendments to the New York City Health Code (the "Health Code") are promulgated pursuant to §§556, 558 and 1043 of the New York City Charter (the "Charter"). Section 556 of the Charter provides the Department of Health and Mental Hygiene (the "Department") with jurisdiction to regulate all matters affecting the health in the city of New York. Section 558(b) and (c) of the Charter empower the Board of Health (the "Board") 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 the Department rulemaking powers.

STATEMENT OF BASIS AND PURPOSE

As part of a comprehensive review of the Health Code, the Board of Health repealed and recodified Article 7 by resolution adopted June 18, 2008. The recodified Article went into effect July 26, 2008. The Board of Health is further amending §7.09 (Appearances) and §7.11 (Hearings and mail adjudication) of this Article to authorize telephone or electronic adjudications and to facilitate settlements.

Support for the amendments was received in a comment from the Director of Operations of the New York State Restaurant Association Greater New York City Chapters. The comment requested that the following additional changes be made: allowing respondents to cross-examine inspectors during telephone or electronic hearings; vacating defaults when respondents request adjudications by mail postmarked the day before a scheduled hearing and the request is received after the date of hearing; extending the proposed deadline for vacating a default from 60 days to 120 days; and imposition of penalties for food service establishment violations in accordance with the recommended penalty schedule of the Department's Bureau of Food Safety and Community Sanitation (BFSCS). The Department agrees that the resolution should be amended to allow cross-examination of witnesses during telephone or other electronic hearings and to permit defaults to be vacated when written requests for mail adjudication with timely postmarks are received after the date of the hearing. In addition, in response to a request from Department staff, the term "reconsider" or "reconsideration" has been amended in §7.09 and §7.17 (c) with respect to reopening defaults.

Allowing hearings to take place by means of telephone and other electronic media will make the Administrative Tribunal more accessible to respondents. Currently, respondents are required to travel from all parts of the City to the Tribunal's single hearing location at 66 John Street in downtown Manhattan. The travel and waiting times associated with appearing in person at the Tribunal can significantly increase the time that respondents are able to devote to their businesses. Allowing the Department to offer telephone hearings could relieve that burden. Telephone and electronic hearings would be optional. They would be conducted only in cases where the Department and the respondent were willing to engage in them, and anyone wishing to appear in person at the Tribunal could still do so. The rules of several New York State government agencies currently authorize telephone hearings. Accordingly, subdivision (a) of §7.09 is being amended, and a new subdivision (h) of §7.11 has been added to authorize such hearings. The Department originally proposed that telephone and electronic hearings only be authorized in cases where no witnesses other than the respondent would testify. However, in response to a comment received from the New York State Restaurant Association, the Department has deleted this restriction. Respondents can still knowingly waive the right to cross examine Department witnesses in person, and a hearing examiner can, in a particular case, require the parties to appear in person if he or she determines that it is necessary to see a witness in order to assess credibility. The Department agrees that there is no reason to categorically exclude cases in which other witnesses are going to testify. In addition, paragraph (4) of §7.09 (a) has been further amended to allow all parties, not only respondent to request an adjournment. Subdivision (a) of §7.09 has also been amended to reference appearances by representatives in §7.21.

Subdivision (d) of §7.09 has been amended to extend the time for reopening a default as of right from thirty days to sixty days. In response to a comment from Department staff, the term "reconsider a default" has been amended throughout Article 7 by substituting the term "motion to vacate a default" since the latter term more accurately describes Tribunal procedures. Extending the time for reopening a default will benefit respondents who inadvertently miss the current deadline of thirty days after mailing or receipt of a notice of default decision. It should also facilitate operations at the Administrative Tribunal, reducing the time spent by hearing examiners in reviewing second requests to reopen defaults and enable hearing examiners to devote more of their time to adjudication of notices of violations on the merits. The New York State Restaurant Association suggested in its comment that the sixty days proposed be extended even longer, to 120 days. The Department, however, believes that sixty days is sufficiently long and that it is in the interest of public health that respondents correct cited violations as promptly as possible. Prolonging the time for notices of violations to be adjudicated would not serve this interest.

Article 7 authorizes the Department to make offers to settle notices of violation. Currently §7.09 (e) requires that settlement offers be made by certified mail, an excessively burdensome procedure for the Department and for respondents. Accordingly, this provision has been amended, authorizing the Department to make settlement offers in a more efficient manner, including online.

STATEMENT PURSUANT TO CHARTER §1043.

This resolution was not included in the Department's Regulatory Agenda for 2009-2010 because the need for the amendment was not known until after the Regulatory Agenda was promulgated.

The resolution is as follows.

Matter deleted is in brackets [ ].

New matter is underlined.

RESOLVED, that subdivisions (a), (d) and (e) of §7.09 of Article 7 of the New York City Health Code, found in Title 24 of the Rules of the City of New York, be, and the same hereby is amended, to be printed together with explanatory notes to read as follows:

§7.09 **Appearances.**
(a) A respondent may appear for a hearing by:
(1) appearing in person [on the date and] at the place and on the date scheduled for the hearing[,];
(2) sending an authorized representative [specified herein] to appear on behalf of such person [on the date and] at the place and on the date scheduled for the hearing [is scheduled] who is:
(i) an attorney admitted to practice law in New York State,
(ii) a representative registered to appear before the Tribunal pursuant to §7.21, or
(iii) any other person, subject to the provisions of §7.21;
(3) making a written request [before the scheduled hearing] for an adjudication by mail, provided that the request is received by the Tribunal before the scheduled date of the hearing or bears a postmark indicating that it was mailed to the Tribunal before the scheduled date of a hearing. If the request bearing such a postmark is received by the Tribunal after a decision on default has been issued, such default shall be vacated automatically; or
(4) participating in a hearing conducted by telephone or other electronic media when the opportunity to do so is offered by the Department, provided, however, that a telephone or electronic hearing may be adjourned for a live hearing if the hearing officer determines that such an adjournment is necessary, or if any party requests an adjournment.

* * *

(d) [Failure by the respondent to appear in person, by sending an attorney or other authorized representative, or by mail] A respondent who fails to appear or to make a timely request for an adjournment shall [constitute a waiver of the right] not be entitled to a hearing. [and shall authorize the hearing examiner, without] Without further notice to the respondent, [to] a hearing examiner may find that the respondent is in default if the respondent has failed to appear and [that the facts are as alleged in the notice of violation, and to] render a default decision sustaining the [allegations] violations cited in the notice of violation, subject to findings the hearing examiner must make with respect to the service of the notice of violation and the sufficiency of the factual allegations contained therein, and imposing a penalty pursuant to Article 3 of this Code or as authorized by other applicable law. If, before [issuing] a default decision is issued, [the Tribunal finds] it is determined that the failure of the party to appear was caused by circumstances beyond the party's reasonable control, [the Tribunal may choose to not issue] a default decision may not be issued and [instead adjourn] the matter may be adjourned [for] to a new hearing date. A decision that is adverse to a respondent [by reason of the respondent's default] shall be issued on default only after the hearing examiner has determined that the notice of violation was served as required by applicable law, and that the notice of violation alleges sufficient facts to support the violations charged. The Tribunal shall notify a defaulting respondent of the issuance of a default decision by mailing a copy of the decision by certified mail or by providing a copy to a respondent or respondent's representative who appears personally at the Tribunal and requests a copy. A respondent may make a motion in writing requesting [request in writing] that a default [decision be reconsidered,] be vacated, if the [request to reconsider] motion to vacate is postmarked or received by the Tribunal within [thirty] sixty days of the date of mailing of the default decision to the respondent or the date a copy was provided to the respondent or the respondent's representative at the Tribunal, whichever date is earlier. One such request shall be granted administratively as of right provided that the Tribunal's records show that there have been no other failures to appear in relation to the particular notice of violation. [In all other cases a] A [request to reconsider] motion to vacate a default [decision] that is received more than sixty days after mailing or personal receipt of the default decision shall be accompanied by a statement setting forth good cause for the respondent's failure to appear. [and either a meritorious defense to any violation found in the decision or a jurisdictional defect in the notice of violation.] Such statement, and any [supporting documentary evidence deemed necessary by a hearing examiner] documents to support the [request for reconsideration of] motion to vacate the default, shall be reviewed by a hearing examiner who shall determine if it establishes a reasonable excuse for the default. [However, under no circumstances shall more than two requests to reconsider default decisions be entertained in relation to a particular notice of violation.] Denial of a [request] motion to vacate a default decision shall not be subject to review by the Review Board.
(e) [Where the notice of violation or an accompanying document, or a related document served on the respondent by certified mail, sets forth a monetary amount that may be paid in full satisfaction of the notice of violation, a respondent may, in lieu of attending a scheduled hearing, pay said amount by mail in the manner and time provided for in such notice.] The Department may extend an offer to settle any notice of violation by setting forth a monetary amount that a respondent may pay in full satisfaction of the violations cited in the notice of violation. A respondent may, in lieu of attending a hearing, pay the department the monetary amount. Such payment shall constitute an admission of liability for the violations charged and no further hearing or appeal shall be allowed.

Notes: Subdivisions (a) and (d) of §7.09 were amended by resolution on March 15, 2011 to authorize the Administrative Tribunal to conduct hearings by telephone conference call and other electronic media, and subdivision (e) was amended to facilitate making settlement offers. Subdivision (d) was amended to extend the time for respondents to make a motion to vacate an initial default from thirty to sixty days after mailing or receipt of a notice of default decision.

RESOLVED, that subdivision (c) of §7.11 of Article 7 of the New York City Health Code be amended, that subdivision (h) of such section be amended and relettered as subdivision (i), and that a new subdivision (h) be added, to be printed together with explanatory notes to read as follows:

§7.11 **Hearings and mail adjudications.**

* * *

(c) Each party to a proceeding shall have the right to be represented by counsel or other authorized representative as set forth in [§7.09(a) hereof,] §§7.09 (a) and 7.21 of this Article, to present evidence, to examine and cross-examine witnesses and to have other rights essential for due process and a fair and impartial hearing.

* * *

(h) With the consent of all parties, a hearing examiner may conduct a hearing by telephone or other electronic media.
[(h)] (i) A written decision sustaining or dismissing each charge in the notice of violation shall be promptly rendered by the hearing examiner who presided over the hearing, or who conducted the adjudication by mail, or who rendered a default decision. Each decision, other than a default decision, shall contain findings of fact and conclusions of law [and,]. [where] Where a violation is sustained, the hearing examiner shall impose a penalty. A copy of the decision, other than a default decision mailed or otherwise provided in accordance with §7.09(d) hereof, shall be served forthwith on the respondent or on the respondent's counsel, registered representative or other authorized representative, either personally or by certified mail. Any fines imposed shall be paid within thirty days of service of the decision. If full payment of fines is not made within thirty days, an additional penalty may be imposed per NOV in an amount of fifty dollars, if paid between thirty-one and sixty days after service of the decision, and one hundred dollars if paid more than sixty days after service of the decision.

Notes: A new subdivision (h) was added, and former subdivision (h) was relettered as subdivision (i), §7.11 on March 15, 2011 to authorize the conduct of hearings by means of telephone or other electronic media, and subdivision (c) was amended to add a reference to representatives in §7.21.

RESOLVED, that subdivision (c) of §7.17 of Article 7 of the New York City Health Code, found in Title 24 of the Rules of the City of New York, be and the same hereby is, amended, to be printed together with explanatory notes as follows:

§7.17 Review Board

* * *

(c) A respondent may seek to review, in whole or in part, any final decision of a hearing examiner, other than a decision rendered on default by the respondent. However, neither a denial [to reconsider] of a motion to vacate a default decision nor a plea admitting the violations charged shall be subject to review by the Review Board. Within thirty days of the Tribunal delivering or mailing the decision to the respondent or authorized representative, such respondent may file a notice of appeal on a form prescribed by the department, accompanied by a brief statement setting forth the specific reasons why the decision should be reversed, remanded or modified. Filing a notice of appeal shall not stay the collection of any fine or other the penalty imposed by the decision. No appeal shall be permitted unless the fine or penalty imposed has been paid prior to or at the time of the filing of the notice of appeal, or the respondent may post a cash or recognized surety company bond in the full amount imposed by the decision and order appealed from. Appeals decisions shall be made upon the entire record of the hearing and the evidence before the hearing examiner. Appeals may be decided without the appearance of the respondent, but the respondent may make a request to appear before the Review Board at the time of filing the notice of appeal.

* * *

Notes: Subdivision (c) of §7.17 was amended by Board of Health resolution adopted March 15, 2011 to substitute the term "motion to vacate" for "to reconsider" in the provision that neither a denial *to reconsider* a default decision nor a plea admitting the violations charged shall be subject to review by the Review Board.

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NOTICE OF ADOPTION OF AMENDMENTS TO ARTICLE 151 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 the Charter, notice of a public hearing and intention to amend Article 151 (Pest Prevention and Management) of the New York City Health Code was published in the City Record on December 17, 2010. A public hearing was held on January 24, 2011. No persons testified and no comments were received. At a meeting on March 15, 2011, the Board of Health adopted the following resolution.

STATUTORY AUTHORITY

These amendments to the New York City Health Code ("Health Code") are promulgated pursuant to §§556, 558 and 1043 of the New York City Charter (the "Charter"). Section 556 of the Charter provides the Department of Health and Mental Hygiene (the "Department" or "DOHMH") with jurisdiction to regulate all matters affecting the health in the city of New York. Section 558(b) and (c) of the Charter empower the Board of Health (the "Board") to amend the Health Code and to include in the Health Code all matters to which the DOHMH's authority extends. Section 1043 of the Charter grants the DOHMH rulemaking powers.

STATEMENT OF BASIS AND PURPOSE

As part of a comprehensive review of the Health Code to assess the efficacy of the articles in protecting public health,

the Board of Health repealed and recodified Article 151 (Pest Prevention and Management) of the Health Code by resolution adopted at its December 16, 2008 meeting.

One of the provisions of the recodified Article is §151.03 (Elimination of standing water), which authorizes the Department to issue orders to property owners to fill in or drain property or otherwise control the accumulation of standing water, which is a breeding area for mosquitos. This provision does not, however, impose a duty on the owners of such properties to maintain the property free of standing water, and thereby establish an explicit violation of this provision if conditions conducive to breeding of mosquitoes are observed. To clarify that there is an explicit duty of owners of such properties, the Board of Health has amended §151.03 by adding a new subdivision (a), preserving the current provision as subdivision (b). In addition, an explanatory note provides examples of places and things that promote conditions conducive to mosquito breeding and indicates that violations are usually written for these conditions during periods of the year when mosquitos breed.

Charter §1049-a (c)(2) provides that the Environmental Control Board ("ECB") shall have concurrent jurisdiction with the Board of Health to "enforce those provisions of the health code … which the board of health shall designate." At its meeting in September, 2010, the Board of Health authorized the Department of Sanitation to enforce Article 151, in addition to the Department and the Departments of Housing Preservation and Development and Buildings. Notices of violations issued by the Departments of Sanitation and Buildings are adjudicated at the ECB, and the Department plans to bring the notices of violation it issues of Article 151 to ECB to reduce the numbers of notices of violation currently being heard at the Department's Administrative Tribunal. The Board of Health has therefore further amended Article 151 to add a new §151.05 designating ECB to hear such violations and providing for the service of notices of violations of provisions of Article 151 returnable to ECB. The table of section headings in Article 151 has also been amended.

Statement Pursuant to Charter §1043

This proposal was not included in the Department's regulatory agenda because the need for the amendment became known after publication of the regulatory agenda.

The amendment is as follows:

Matter underlined is new.

Matter to be deleted is indicated by [brackets].

RESOLVED, that §151.03 of Article 151 of the New York City Health Code, found in Title 24 of the Rules of the City of New York, be, and the same hereby is amended, to be printed together with explanatory notes to read as follows:

§151.03 Elimination of standing water.
(a) Persons in control of premises other than a wetland regulated by federal, state or local law shall keep such premises free of accumulations of standing water.
(b)Except for a wetland regulated by federal, state or local law, the Department may order the person(s) in control of any property including, but not limited to, a sunken lot, property below grade, excavation or any other place where [stagnant] standing water may collect, to fill in or drain such property or to employ other methods to prevent conditions conducive to the breeding or harborage of mosquitoes and other pests in a manner consistent with federal, state and local law.

Notes: §151.03 was amended by resolution of the Board of Health adopted on March 15, 2011, adding a new subdivision (a) imposing a duty on persons in control of property to maintain such property free of accumulations of standing, stagnant water, and relettering the existing provision as subdivision (b). Locations identified as having accumulations of standing water include, but are not limited to, discarded tires, clogged exterior drains and roof gutters, bird baths, garden accessories, potted plants, swimming and wading pools, pool covers with algae or other unusual vegetation. Violations for such conditions are generally issued during mosquito breeding seasons.

RESOLVED, that Article 151 of the New York City Health Code, found in Title 24 of the Rules of the City of New York, be, and the same hereby is amended, to add a new §151.05, to be printed together with explanatory notes to read as follows:

§151.05 **Notices of violation**.
(a) *Designation of Environmental Control Board.* In accordance with §1049-a (c)(2) of the Charter, a notice of violation ("NOV") citing a violation of any provision of this Article may be made returnable to the Environmental Control Board in addition to the Administrative Tribunal established pursuant to Article 7 of this Code.
(b) *Service of a notice of violation.* A notice of violation shall be served by delivery to an owner or other person in control of property or premises, upon a member of the partnership, limited liability company or other group, upon an officer, director or managing agent of a corporation, or upon any other person of suitable age and discretion owning or in control of such property. Service may be made to such person(s) at the address of the premises that is the subject of the NOV or at such person's last known residence or business address,
(1) By personal delivery in accordance with Article 3 of the New York Civil Practice Law and Rules or Article 3 of the Business Corporation Law; or
(2) By certified or registered mail delivered by the U.S. Postal Service or by any other type of mailing or delivery service that provides proof of mailing or receipt by the respondent. Documentation of delivery or receipt provided by the delivery or mailing service shall be proof of service of the notice of violation.

Notes: §151.05 was added by resolution adopted on March 15, 2011 to designate the Environmental Control Board to hear notices of violation of Article 151, and to provide for service of such notices of violation.

RESOLVED, that the table of section headings of Article 151 of the New York City Health Code, found in Title 24 of the Rules of the City of New York, be, and the same hereby is amended, to be printed together with explanatory notes to read as follows:

ARTICLE 151
PEST PREVENTION AND MANAGEMENT

§151.01 Definitions
§151.02 Prevention of pests and pest management measures.
§151.03 Elimination of standing water.
§151.04 Enforcement by the Department and other City agencies.
§151.05 Notices of violation.

Notes: Article 151 was amended by resolution on March 15, 2011, adding a new §151.05 designating the Environmental Control Board to hear notices of violation of Article 151, and to provide for service of such notices of violation.

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NOTICE OF ADOPTION OF AMENDMENTS TO ARTICLE 173 OF THE NEW YORK CITY HEALTH CODE

In compliance with §1043(b) of the New York City Charter and pursuant to the authority granted to the Board of Health by §558 of said Charter, notice public hearing and of intention to amend Article 173 (Hazardous Substances) of the New York City Health Code was published in the City Record on December 17, 2010, and a hearing was held January 24, 2011. No written comments were received and no testimony was given at the hearing. At its meeting on March 15, 2011, the Board of Health adopted the following resolution.

STATUTORY AUTHORITY

These amendments to the New York City Health Code ("Health Code") are promulgated pursuant to §§556, 558 and 1043 of the New York City Charter (the "Charter"). Section 556 of the Charter provides the Department of Health and Mental Hygiene ("DOHMH") with jurisdiction to regulate all matters affecting the health in the city of New York. Section 558(b) and (c) of the Charter empower the Board of Health (the "Board") to amend the Health Code and to include in the Health Code all matters to which the DOHMH's authority extends. Section 1043 of the Charter grants the DOHMH rulemaking powers.

STATEMENT OF BASIS AND PURPOSE

The Board of Health has amended §173.13 (Lead paint) of Article 173 (Hazardous Substances), updating its provisions for the acceptable limits of lead in paint and other leaded surface-coating materials and harmonizing this section with related provisions of the Federal Consumer Product Safety Act, found in 15 USC §§2051-2089, and regulations of the Consumer Product Safety Commission, found in 16 CFR Part 1303 (Ban of lead-containing paint and certain consumer products bearing lead-containing paint).

Effective January 1, 1960, Health Code §173.13 prohibited use of paint containing more than 1.05% of metallic lead based on the non-volatile content of the paint for covering toys, furniture or interior surfaces of dwellings. At the time, there were no federal or state limitations on the amount of lead in paint to be used for dwellings or in consumer products. The Board amended this section in 1997, reducing the percentage of lead to 0.06%, consistent with the then current federal standard.

Effective August 14, 2009, the Consumer Product Safety Improvement Act (CPSIA) of 2008 (Public Law 110-314) and 16 CFR §1303.1 (c) limit the amount of lead in paint and similar surface-coating materials for consumer household and similar uses to no more than 0.009 percent. Accordingly, the Board of Health has amended paragraph (1) of subdivision (a) and subdivisions (b) and (c) of Health Code §173.13 to incorporate these current federal standards for the maximum levels of lead that can be found in paint and similar surface-coating materials intended for use in residences and other facilities accessible to consumers, and for covering furnishings, toys and other articles intended for use by children, reducing the levels in these Health Code provisions from the current 0.06 percent standard to 0.009 percent.

Statement pursuant to Charter §1043

This resolution was not included in the DOHMH Regulatory Agenda because the need for the proposal was not anticipated at the time the Regulatory Agenda was promulgated.

The resolution is as follows.

Deleted matter is in [brackets].

New matter is underlined.

RESOLVED, that §173.13 (Lead paint) of Article 173 of the New York City Health Code, found in Title 24 of the Rules of the City of New York, be, and the same hereby is amended, to be printed with explanatory notes, to read as follows:

§173.13 **Lead Paint.**
(a)(1) *Lead-based paint prohibited.* No person shall possess, sell, hold for sale or give away paint or other similar surface-coating material which is intended or packaged in a form suitable for use in or around the household or otherwise for consumer use within the meaning of 15 U.S.C. Section 2057 et seq. and 16 Code of Federal Regulations (C.F.R.) Part 1303 or its successor regulations, containing more than [0.06] 0.009 percent of metallic lead, based upon the total non-volatile content of the paint or other similar surface-coating material.
* * *
(b) No person shall manufacture, sell, hold for sale, give away or leave toys, children's furniture or any other articles or things intended for use by children which have a paint or other similar surface-coating material containing more than [0.06] 0.009 percent of metallic lead based on the total non-volatile content of the paint or other similar surface-coating material.
(c) No person shall use a paint or other similar surface-coating material containing more than [0.06] 0.009 percent of metallic lead, based on the total non-volatile content of the paint or other similar surface-coating material on the interior or exterior surfaces of a dwelling. As used in this section, dwelling means any building or structure or portion thereof, including the property occupied by and appurtenant to such dwelling, which is occupied in whole or in part as the home, residence or sleeping place of one or more human beings. This subsection shall also apply to places where children reside, or are boarded, or where they receive regular care and/or education, such as [day] child care services, schools and children's institutions.
* * *
Notes: Paragraph (1) of subdivision (a) and subdivisions (b) and (c) of §173.13 were amended by resolution adopted on March 15, 2011 to reflect the lower federal standard of 0.009 percent of metallic lead that may be contained in lead based paints or similar surface coating materials sold for use or used in consumer goods, children's toys and dwelling

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NOTICE OF PUBLIC HEARING

Subject: Opportunity to Comment on Proposed Repeal of Article 27 (Compressed Air in Tanks for Underwater Breathing) of the New York City Health Code, Found in Title 24 of the Rules of the City of New York.

Date / Time: April 29, 2011 from 10:00 A.M. to 12:00 P.M.

Location: New York City Department of Health and Mental Hygiene
2 Gotham Plaza
42-09 28th Street
14th Floor, Room 14-33
Long Island City, NY 11101

Contact: Rena Bryant
(212) 788-4308

Proposed Rule

The Department of Health and Mental Hygiene is proposing that the Board of Health repeal Article 27 of the Health Code.

Instructions

Prior to the hearing, you may submit written comments about the proposed amendment by mail to:

New York City Department of Health and Mental Hygiene
Board of Health
Office of the Secretary to the Board
Attention: Rena Bryant
2 Gotham Plaza
42-09 28th Street
14th Floor, Room 14-33
Long Island City, NY 11101

or electronically through NYCRULES at www.nyc.gov/nycrules or by e-mail to 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 April 29, 2011. Comments received after this date will be considered to the extent practicable.

To request a sign language interpreter or other form of reasonable accommodation for a disability at the hearing, please contact Rena Bryant at the phone number shown above by April 15, 2011.

Copies of written comments received by the Secretary to the Board of Health and transcript of the public hearing will be available for public inspection within a reasonable time after receipt, between the hours of 9:00 A.M. and 5:00 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 Plaza
42-09 28th Street
14th Floor, Room 14-33
Long Island City, NY 11101

The Department's general policy is to make written comments available for public viewing on the internet. All Comments received, including any personal information provided, will be posted without change to http://www.nyc.gov/html/doh/html/comment/comment.shtml.

Statement of Basis and Purpose

Statutory Authority
These amendments to the New York City Health Code (the "Health Code") are issued according to §§556, 558 and 1043 of the New York City Charter (the "Charter"). Section 556 of the Charter provides the Department of Health and Mental Hygiene (the "Department") with to regulate all matters affecting the health in the city of New York. Section 558(b) and (c) of the Charter empower the Board of Health (the "Board") to amend the Health Code and to include in the Health Code all matters over which the Department has authority. Section 1043 of the Charter gives the Department rulemaking powers.

Basis and purpose of the rule change
As part of a comprehensive review of the Health Code to assess its effectiveness in protecting the public health, the Department of Health and Mental Hygiene (the Department or DOHMH) is requesting that the Board of Health repeal Article 27 (Compressed Air in Tanks for Underwater Breathing). Article 27 was adopted by the Board in 1967, "to protect the health of individuals who participate in underwater diving or swimming activities using air compressed in tanks for underwater breathing," according to the introductory notes to the article. Local Law 14/1966, adding §562-1.0 (renumbered §17-337) to the Administrative Code of the City of New York (Administrative Code), requires a permit to be issued by the Commissioner to sell or distribute compressed air in tanks. It also requires that the Board issue air purity standards, and that such tanks display a certificate indicating compliance with those standards.

By Local Law 21/2010, effective June 1, 2010, the City Council repealed and reenacted Administrative Code §17-337. As reenacted, Administrative Code §17-337 now requires that compressed air filling these tanks comply with the current standard of the Compressed Gas Association (CGA) published in *G-7.1-2004, commodity specification for air* "or a more stringent standard as may be determined by the department." The reenacted Administrative Code provision no longer requires a permit to be issued by the Commissioner or a certificate of compliance attached to each tank of compressed air. In support of the Council's repeal, the Department advised the Council that there have been almost no permits issued for sale or distribution of compressed air tanks during the past two decades, that the Department had no expertise in establishing standards. Also, the Department considers the standards of purity of the CGA to be sufficiently protective. Moreover, the Department has had no reports during this time that any person has suffered an illness, fatality or other negative condition associated with the quality of the compressed air in such tanks. Accordingly, the Department requests that the Board repeal this Article in its entirety.

The resolution is as follows.

RESOLVED, that Article 27 (Compressed Air in Tanks for Underwater Breathing Use) and the list of section headings in Article 27 of the New York City Health Code, found in Title 24 of the Rules of the City of New York, be, and the same hereby are, REPEALED.

NEW YORK CITY LAW DEPARTMENT
100 CHURCH STREET
NEW YORK, NY 10007
212-788-1087

CERTIFICATION PURSUANT TO

CHARTER §1043(d)

RULE TITLE: Repeal of Health Code Article 27

(Storage of Compressed Air in Tanks)

REFERENCE NUMBER: 2011 RG 008

RULEMAKING AGENCY: Department of Health and Mental Hygiene

I certify that this office has reviewed the above-referenced proposed rule as required by section 1043(d) of the New York City Charter, and that the above-referenced proposed rule:

(i) is drafted so as to accomplish the purpose of the authorizing provisions of law;

(ii) is not in conflict with other applicable rules;

(iii) to the extent practicable and appropriate, is narrowly drawn to achieve its stated purpose; and

(iv) to the extent practicable and appropriate, contains a statement of basis and purpose that provides a clear explanation of the rule and the requirements imposed by the rule.

/s/ STEVEN GOULDEN Date: February 22, 2011
Acting Corporation Counsel

NEW YORK CITY MAYOR'S OFFICE OF OPERATIONS
253 BROADWAY, 10th FLOOR
NEW YORK, NY 10007
212-788-1526
CERTIFICATION / ANALYSIS
PURSUANT TO CHARTER SECTION 1043(d)

RULE TITLE: Repeal of Health Code Article 27 (Storage of Compressed Air in Tanks)

REFERENCE NUMBER: DOHMH-1

RULEMAKING AGENCY: DOHMH

I certify that this office has analyzed the proposed rule referenced above as required by Section 1043(d) of the New York City Charter, and that the proposed rule referenced above:

(i) Is understandable and written in plain language for the discrete regulated community or communities;

(ii) Minimizes compliance costs for the discrete regulated community or communities consistent with achieving the stated purpose of the rule; and

(iii) Does not provide a cure period because it does not establish a violation, modification of a violation, or modification of the penalties associated with a violation.

/s/ Matthew Margolin *March 2, 2011*
Mayor's Office of Operations Date

☛ **m23**

NOTICE OF PUBLIC HEARING

Subject: Opportunity to Comment on Proposed Amendment of Article 89 (Mobile Food Vending) of the New York City Health Code, found in Title 24 of the Rules of the City of New York.

Date / Time: April 29, 2011 from 2:00 P.M. to 4:00 P.M.

Location: New York City Department of Health and Mental Hygiene
2 Gotham Plaza
42-09 28th Street
8th Floor, Room 8-17
Long Island City, NY 11101

Contact: Rena Bryant
(212) 788-4308

Proposed Rule

The Department of Health and Mental Hygiene (the Department) is proposing that the Board of Health amend Article 89 of the Health Code to:
1. allow cooked fish and shellfish to be sold on mobile food vending units;
2. prohibit sales of raw meat from mobile food vending units; and
3. clarify procedures for reopening mobile food vending units that are ordered closed by the Department for imminent or public health hazards.

Instructions

Prior to the hearing, you may submit written comments about the proposed amendment by mail to:

New York City Department of Health and Mental Hygiene
Board of Health
Office of the Secretary to the Board
Attention: Rena Bryant
2 Gotham Plaza
42-09 28th Street
8th Floor, Room 8-17
Long Island City, NY 11101

or electronically through NYCRULES at www.nyc.gov/nycrules or by e-mail to 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 April 29, 2011. Comments received after this date will be considered to the extent practicable.

To request a sign language interpreter or other form of reasonable accommodation for a disability at the hearing, please contact Rena Bryant at the phone number shown above by April 15, 2011.

Copies of written comments received by the Secretary to the Board of Health and transcript of the public hearing will be available for public inspection within a reasonable time after receipt, between the hours of 9:00 A.M. and 5:00 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 Plaza
42-09 28th Street
8th Floor, Room 8-17
Long Island City, NY 11101

The Department's general policy is to make written comments available for public viewing on the internet. All Comments received, including any personal information provided, will be posted without change to http://www.nyc.gov/html/doh/html/comment/comment.shtml.

Statement of Basis and Purpose

Statutory Authority

These amendments to the New York City Health Code (the "Health Code") are issued according to §§556, 558 and 1043 of the New York City Charter (the "Charter").

- Section 556 of the Charter provides the Department of Health and Mental Hygiene (the "Department") with authority to regulate all matters affecting health in the city of New York.
- Section 558(b) and (c) of the Charter empowers the Board of Health (the "Board") to amend the Health Code and to include in the Health Code all matters over which the Department has authority.
- Section 1043 of the Charter gives the Department rulemaking powers.

Basis and purpose of the rule change

As part of a comprehensive review of the Health Code, the Board of Health repealed and recodified Article 89 by resolution adopted December 16, 2008. The recodified Article went into effect January 1, 2010. The Department is requesting that the Board further amend this Article to address three issues that arose after the recodified Article went into effect:
1. The preparation, holding and service of raw and cooked fish and shellfish on mobile food vending units, currently prohibited by subdivision (f) of §89.19 ("Food protection and safety);
2. Prohibiting sales of raw meat from mobile food vending units; and
3. Clarifying Department enforcement procedures after a mobile food vendor has been issued an order to cease operating a vending unit in the street, pursuant to §89.29.

Amend §89.19 (f)

Article 89 (Mobile Food Vending) was repealed and recodified by resolution of the Board adopted at its December 16, 2008 meeting. Article 88 (Temporary Food Service Establishments) was also repealed and recodified by resolution adopted on December 17, 2009. Both Article 88 and Article 89 regulate the sale and distribution of foods directly to consumers at places and events that usually occur on City streets.

Article 88 regulates such sales by temporary food service establishments at events of relatively limited duration such as flea markets or street fairs, whereas Article 89 regulates the year round or seasonal sale of food from mobile food vending units. Since it was amended in 2009, Article 88 restricts the sale of raw fish or shellfish at street fairs, flea markets and other events, but allows properly cooked fish or shellfish to be sold at such events. Article 89, however, prohibits the sale of all fish and other aquatic animal food products, whether raw or not, from mobile food vending units.

The Department believes that, when properly stored and prepared, most cooked fish and other aquatic animal food products may be safely sold from either a temporary or a mobile vending establishment. Because there is therefore no basis for prohibiting the sale of properly cooked fish and other aquatic animal food products from mobile food vending units while allowing it for other street vendors, the Department is requesting that the Board amend paragraph (2) of subdivision (f) to permit the sale of properly cooked fish and other aquatic animal food products and to prohibit only the sale of raw fish and other raw aquatic animal food products from mobile vending units.

In addition, the Department is requesting that the Board amend paragraph (1) ("Meat") of subdivision (f) of §89.19 to prohibit the sale of raw meat in or from a mobile food vending unit. Currently, the Code prohibits butchering and dressing of raw meat on a mobile food vending unit, since such processing should only be done at a properly equipped Code-compliant commissary facility. Since mobile food vending units generally cannot be equipped with adequate storage and cleaning facilities, as are retail outlets that are inspected and licensed by the State Department of Agriculture and Markets, the Department is proposing that the sale of raw meat from such units also be prohibited.

Amend §89.29

The Administrative Code of the City of New York (the "Administrative Code") §17-317 (c) authorizes the pre-hearing suspension "for good cause" of a license or permit for up to ten days. If the Department determines before the ten days have elapsed that the permittee or operator of the suspended unit has corrected the infractions and that the infractions resulting in the suspension will not be repeated, the Department may allow the unit to resume operating. In such cases, the Department will meet with the vendor and offer to restore the permit and/or license seized before ten business days have elapsed provided that the vendor agrees to conditions intended to avoid recurrence of imminent or public health hazards. This is consistent with Department practice in dealing with similar conditions at food service establishments, and the Department is requesting that the Board amend §89.29 accordingly.

STATEMENT PURSUANT TO CHARTER §1043.

This resolution was not included in the Department's Regulatory Agenda for 2010-2011 because the need for the amendment was not known until after the Regulatory Agenda was promulgated.

The resolution is as follows:

Matter deleted is in brackets [ ].

New matter is underlined.

RESOLVED, that subdivision (f) of §89.19 of Article 89 of the New York City Health Code, found in Title 24 of the Rules of the City of New York, be, and the same hereby is amended, to be printed together with explanatory notes to read as follows:

§89.19 Food protection and safety.
* * *
(f) *Prohibitions on sale or service of specific foods.* The Commissioner may by rule prohibit the sale or service of specific potentially hazardous foods or types of foods by mobile food vending units.
(1) *Meat.* All meat shall be processed and prepared for cooking at a mobile food commissary. No raw meat shall be sold, butchered, de-boned, dressed, or cut into portion size in or on a mobile food vending unit.
(2) *Fish and other aquatic animals.* No raw fish, raw shellfish, or any other raw food products consisting of or made with an aquatic animal, as defined in Article 81, shall be [prepared, stored,] held for service or sold from a mobile food vending unit. No raw fish, raw shellfish, or any other raw food products consisting of or made with an aquatic animal shall be cleaned, de-boned, dressed, scaled, eviscerated, or cut into portion sizes in or on a mobile food vending unit. Such food products may be cooked or reheated on a mobile food vending unit, provided that the food products have been commercially manufactured, or processed and prepared for cooking at a mobile food commissary or at another duly licensed and approved facility.

Notes: Paragraphs (1) and (2) of subdivision (f) of §89.19 were amended by resolution adopted on XXX to clarify restrictions on preparation, service and sale of raw meat and raw fish, shellfish and other aquatic animal food products by mobile food unit vendors.

RESOLVED, that §89.29 of Article 89 of the New York City Health Code, found in Title 24 of the Rules of the City of New York, be, and the same hereby is amended, to be printed together with explanatory notes to read as follows:

§89.29 Imminent health hazards.
(a) *Cessation of operations of a mobile food vending unit for imminent health hazards.* The Department may order any person operating a mobile food vending unit to immediately cease operations and serving food if the continued operation of the unit presents an imminent hazard to public health. Any person ordered to cease operations and service of food pursuant to this section shall comply with such order immediately[, and].
(b) *Seizure of permit and license(s) authorized.* When the Department determines that a vending unit is operating with imminent health hazards and has ordered the vendor to cease operation, the Department may seize the permit document, and the operator's license document and badge, and may apply a seal or sign to cover the mobile food vending unit's decal, or remove the decal, thereby suspending the license and/or permit.
(c) *Suspension of the vendor's license and permit.* In the event a license or permit has been seized, the licensee or permittee shall, within 10 business days thereafter, be provided with a hearing as to why the cessation order should be rescinded and as to why the mobile food vendor's license and the permit for the unit should not be further suspended or revoked.
[(b) *Seizure of permit and license(s) authorized.* In such cases, the Department shall seize the permit document, and the operator's license document and badge, and may apply a seal or sign to cover the mobile food vending unit's decal, or remove the decal.
(c)](d) *Restoration of the vendor's license or permit.* If the Department determines within 10 business days after issuing the cessation order that the imminent hazard resulting in the order has been corrected, and that public health will not be adversely affected by the resumed operation of the vending unit, the Department may return or reissue any license and/or permit that it has seized pursuant to this section. The Department may condition such return on the licensee and/or permittee agreeing to take any steps necessary so that the hazard does not recur.
(e) *Operation prohibited until after hearing.* [No] Unless otherwise provided in this section, no person shall operate the unit until there has been a hearing at OATH followed by expeditious adoption by the Commissioner of the report and recommendation of an OATH administrative law judge, setting forth a finding that continued operation of the unit by or on behalf of the permittee does not present a continuing hazard to the public health. If the administrative law judge finds that continued operation of the mobile food vending unit by the permittee and the licensee presents a continuing hazard to the public health, the permittee and licensee may request that the Commissioner provide them with an opportunity to correct the violations and to demonstrate that they are willing and able to operate the mobile food vending unit in compliance with all applicable law. If such request is not received the Commissioner shall issue an order suspending or revoking the permittee's mobile food vending unit permit and license and the operator's mobile food vending license.
[(d)] (f) *Service of cessation order.* If the operator of the mobile food vending unit is not the permit holder, the order issued pursuant to this section shall be served upon the permittee by delivery to the person operating the mobile food vending unit, and by mailing the order to the permittee's address, as maintained in Department records, pursuant to §3.05 (b) of this Code.
[(e)] (g) *Cessation signs not to be removed.* Cessation signs or seals affixed by the Department shall not be removed except by order of the Commissioner or designee.
Notes: Section 89.29 was amended by resolution adopted on XXXX, to provide for return of a vending license and permit to the operator of a mobile food vending unit within 10 days, without scheduling a hearing, where the Department determines that although a vendor's conduct may be considered an "imminent health hazard," justifying the seizure of permit documents, the continuing operation of a mobile food vending unit will not endanger public health

NEW YORK CITY LAW DEPARTMENT
DIVISION OF LEGAL COUNSEL
100 CHURCH STREET
NEW YORK, NY 10007
212-788-1087

CERTIFICATION PURSUANT TO

CHARTER §1043(d)

RULE TITLE: Amendment of Health Code Article 89 (Food Vendors)

REFERENCE NUMBER: 2011 RG 10

RULEMAKING AGENCY: Department of Health and Mental Hygiene

I certify that this office has reviewed the above-referenced proposed rule as required by section 1043(d) of the New York City Charter, and that the above-referenced proposed rule:

(i) is drafted so as to accomplish the purpose of the authorizing provisions of law;

(ii) is not in conflict with other applicable rules;

(iii) to the extent practicable and appropriate, is narrowly drawn to achieve its stated purpose; and

(iv) to the extent practicable and appropriate, contains a statement of basis and purpose that provides a clear explanation of the rule and the requirements imposed by the rule.

/s/ STEVEN GOULDEN Date: March 7, 2011
Acting Corporation Counsel

NEW YORK CITY MAYOR'S OFFICE OF OPERATIONS
253 BROADWAY, 10th FLOOR
NEW YORK, NY 10007
212-788-1526

CERTIFICATION / ANALYSIS
PURSUANT TO CHARTER SECTION 1043(d)

RULE TITLE: Amendment of Health Code Article 89 (Food Vendors)

REFERENCE NUMBER: DOHMH-2

RULEMAKING AGENCY: DOHMH

I certify that this office has analyzed the proposed rule referenced above as required by Section 1043(d) of the New York City Charter, and that the proposed rule referenced above:

(i) Is understandable and written in plain language for the discrete regulated community or communities;

(ii) Minimizes compliance costs for the discrete regulated community or communities consistent with achieving the stated purpose of the rule; and

(iii) Does not provide a cure period because a cure period would run counter to the proposed rule's goal of preventing risks to public health in a timely manner.

/s/ Francisco Navarro *3/08/11*
Mayor's Office of Operations Date

☛ **m23**

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 the Charter, a notice of public hearing and notice of intention to amend Article 175 of the New York City Health Code (the "Health Code") was published in the City Record on December 17, 2010, and a public hearing was held on January 21, 2011. Seven written comments were submitted, and two individuals testified. Certain typographical errors were corrected and technical changes made to the notice of intention by the Department, on its own initiative, and in response to the testimony and public comments. For example, all definitions located in §175.02(a) have now been included, not just those that were being added or amended in the notice of intention; the definition of "byproduct material" in §175.02(a)(33) was revised to match the federal definition (10 CFR §20.1003); §175.103(a)(4)(vi) was revised to indicate that the stricter requirement governs in case of a conflict between a license condition and the Health Code; §175.103(b)(5)(iii) was changed to make explicit that only New York State Health Department-licensed personnel may medically administer radioactive material; and §175.103(c)(4)(ii) was revised to require direct measurement by a licensee of radiopharmaceutical dosage before medical use. At its meeting on March 15, 2011, the Board of Health adopted the following resolution.

STATUTORY AUTHORITY

These amendments to the New York City Health Code ("Health Code") are made 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 one, two or three 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 (IMPEP) and conducts a quadrennial review of Agreement State programs. The latest IMPEP review of the New York State programs took place in November of 2006.

In 2002, the NRC promulgated extensive changes to Title 10 of the Code of Federal Regulations (CFR) particularly Part 35, which effected changes to Medical Use of Byproduct Material. Further amendments to the Part 35 training and experience requirements, including recognition of specialty board certification processes and certain other conforming changes, became effective in 2005.

New York City must make commensurate changes to Article 175 of the Health Code to remain compatible with federal regulations. The most extensive set of changes made herein for Article 175 can be collectively grouped under the heading "Medical Use of Byproduct Material". The second set of changes concerns x-ray equipment. New York City is responsible for the regulation, registration and inspection of diagnostic X-ray units, which are not overseen by the NRC. An amendment is made clarifying the installation versus the registration requirements of X-ray units, as described below.

I. Medical Use of Byproduct Material

The NRC has significantly amended its regulations regarding the use of byproduct material for medical uses. Most extensively, the NRC amended 10 CFR Part 35, Medical Use of Byproduct Material, largely to remain current with developments in the medical field. These NRC amendments have substantially affected authorized users (physicians), medical physicists, hospitals, suppliers, and others involved in the medical use of byproduct material. To remain compatible with NRC regulations, the Board of Health amended Article 175 of the New York City Health Code as indicated below:

- Section 175.02 – Added a number of new and revised definitions, particularly with respect to professional practitioners, medical equipment and training.
- Section 175.03 – Added new requirements with respect to certain records, reports and notifications.
- Section 175.04 – Renumbered an internal cross-reference.
- Section 175.07 – Revised terminology; moved misadministration requirements from this section to section 175.03.
- Section 175.64 – Radiation therapy physicist is renamed authorized medical physicist; instrument calibration methodology is addressed.
- Section 175.103 – Repealed and reenacted entire section in order to, for example:
- Introduce application of written directives for medical procedures, which is essentially a prescription for the therapeutic use of radioactive material or radiation.
- Significantly change training and experience requirements for human-use radioactive materials procedures, such as reducing classroom hours for imaging studies and recognizing new national certification boards.
- Increase training requirements for Radiation Safety Officers.
- Add safety precautions and instructions for medical use of unsealed byproduct material for which a written directive is required.

II. Registration of X-ray Units

Section 175.51(b)(1) of the Health Code prohibited the placement of x-ray equipment at a facility until an x-ray registration is obtained from ORH. However, section 175.51(d)(1) allows the placement of operable x-ray equipment in a facility for pre-inspections or medical physics testing. The intent of the section is to prohibit only the clinical utilization of such equipment, not its installation. X-ray equipment may be installed in a facility for testing purposes, however such equipment may not be used for diagnostic or treatment purposes without a certificate of registration from ORH. Given the possibility of confusion between the language of section 175.51(b)(1) and (d)(1), certain language from 175.51(d)(1) has been moved into 175.51(b)(1) in order to clarify compliance with the Health Code registration process.

The amended text is as follows:

Note - Matter in brackets [ ] is deleted.
Matter underlined is new.

RESOLVED, that 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 September 17, 2008, be and the same hereby is amended to add and/or revise and renumber definitions, to be printed together with explanatory notes, to read as follows:

§175.02 **Definitions.**

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

(1) "A_1" means the maximum activity of special form radioactive material permitted in a Type A package. "A_2" means the maximum activity of radioactive material, other than special form, LSA and SCO material, permitted in a Type A package. These values are either listed in Table A-1, Appendix A of §175.105 of this Code or may be derived in accordance with the procedure prescribed in such Appendix A.

(2) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

(3) "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 MeV. For purposes of this definition, "particle accelerator" is an equivalent term.

(4) "Accelerator-produced material" means any material made radioactive by a particle accelerator.

(5) "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

(6) "Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

(7) "Added filtration" means any filtration which is in addition to the inherent filtration.

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

[(8)] (9) "Adult" means an individual 18 or more years of age.

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

[(10)] (11) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

[(11)] (12) "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials exist in concentrations:

(i) in excess of the derived air concentrations (DACs) specified in Table 1, Appendix B of §175.03 of this Code, or

(ii) to such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

[(12)] (13) "Aluminum equivalent" means the thickness of aluminum (type 1100 alloy) affording the same attenuation, under specified conditions, as the material in question. The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

[(13)] (14) "Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table 1, Columns 1 and 2, of Appendix B of §175.03 of this Code.

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

[(15)] (16) "As low as is reasonably achievable" (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this Code as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

[(16)] (17) "Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or such person's employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

[(17)] (18) "Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters (8 inches by 8 inches by 1.5 inches), of type 1100 aluminum alloy or other materials having equivalent attenuation.

(19) "Authorized medical physicist" means an individual who—

(i) Is a "professional medical physicist" as provided for in Article 166 of the New York State Education Law (§§ 8700-8709), and meets the requirements of §§175.103(j)(2) and 175.103(j)(15) of this Code; or

(ii) Is identified as an authorized medical physicist or teletherapy physicist on—

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

(B) A medical use permit issued by a Commission master material licensee;

(C) A permit issued by a Commission or Agreement State broad scope medical use licensee; or

(D) A permit issued by a Commission master material license broad scope medical use permittee.

(20) "Authorized nuclear pharmacist" means a pharmacist who-

(i) Is approved by the New York State Department of Education, Office of the Professions, and meets the requirements in §§175.103(j)(3) and 175.103(j)(15) of this Code; or

(ii) Is identified as an authorized nuclear pharmacist on—

(A) A specific license issued by the Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

(B) A permit issued by a Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(C) A permit issued by a Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or (iv) A permit issued by a Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

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

(iv) Is designated as an authorized nuclear pharmacist in accordance with 10 CFR § 32.72(b)(4).

[(18)](21) "Authorized user" means [an individual] a physician, dentist, or podiatrist who —

(i) Meets the requirements in §§ 175.103(j)(15) and 175.103(j)(4)(i), 175.103(j)(5)(i), 175.103(j)(6)(i), 175.103(j)(7)(i), 175.103(j)(8)(i), 175.103(j)(10)(i), 175.103(j)(12)(i), or 175.103(j)(13)(i) of this Code; or

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

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

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

(C) A permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or;

(D) A permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material; or

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

[(19)] (22) "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain a required quantity of radiation at a preselected location(s).

[(20)] (23) "Background radiation" means radiation from cosmic sources; naturally occurring radioactive material, including radon (except as a decay product of source or special nuclear material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include radiation from any regulated sources of radiation.

[(21)] (24) "Barrier" [see "Protective Barrier"].

[(22)] (25) "Beam axis" means a line from the source through the centers of the x-ray fields.

[(23)] (26) "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray beam.

[(24)] (27) "Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.

[(25)] (28) "Becquerel" (Bq) means the SI unit of activity. One becquerel is equal to 1 disintegration (d) or transformation (t) per second ($d\text{-}s^{-1}$ or $t\text{-}s^{-1}$).

[(26)] (29) "Bioassay" means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of this Code, "radiobioassay" is an equivalent term.

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

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

[(28)] (32) "Breast equivalent phantom" means a device which contains test objects of various specified dimensions as speck sets, masses and fibers representing low density areas and microcalcifications related to the imaging of breast lesions and which can be imaged by a mammographic x-ray system to visualize such test objects.

[(29)] (33) "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 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.

(iii) (A) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(B) Any material that—

(*a*) Has been made radioactive by use of a particle accelerator; and

(*b*) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(iv) Any discrete source of naturally occurring radioactive material, other than source material, that—

(A) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(B) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

[(30)] (34) "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method observed by him/her of determining calendar quarters for purposes of this Code except at the beginning of a year.

[(31)] (35) "Calibration" means the determination of:

(i) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or

(ii) the strength of a source of radiation relative to a standard.

[(32)] (36) "C-arm x-ray system" means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

[(33)] (37) "Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

[(34)] (38) "Certified components" means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.

[(35)] (39) "Certified registration" means a registration for any therapeutic radiation machine issued by the Department upon review and approval of an application submitted pursuant to this Code.

[(36)] (40) "Certified system" means any x-ray system which has one or more certified components.

[(37)] (41) "Certified Radiation Equipment Safety Officer" means an individual who holds an unexpired certificate as a radiation equipment safety officer issued by the New York State Department of Health.

[(38)] (42) "CFR" means Code of Federal Regulations.

[(39)] (43) "Chelating agent" means amine polycarboxylic acids, hydroxycarboxylic acids, gluconic acid, and polycarboxylic acids.

[(40)] (44) "City" means the City of New York.

[(41)] (45) "Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days; for Class W, Weeks, from 10 to 100 days; and for Class Y, Years, of greater than 100 days. For purposes of this Code, "lung class" and "inhalation class" are equivalent terms.

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

[(42)] (47) "Coefficient of Variation," or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{X} = \frac{1}{X}\left[\sum_{i=1} \frac{(X_i - X)^2}{(n-1)}\right]^{1/2}$$

where

s = estimated standard deviation of the population.

X = mean value of observations in sample.

$X_i = i^{th}$ observation in sample.

n = number of observations in sample.

[(43)] (48) "Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

[(44)] (49) "Collimator " means a device by which a radiation beam is restricted in size.

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

[(45)] (51) "Commissioner" means the Commissioner of Health and Mental Hygiene of the City of New York.

[(46)] (52) "Committed dose equivalent" ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

[(47)] (53) "Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = S\ w_T, H_{T,50}$).

[(48)] (54) "Computed tomography" or "CT" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

[(49)] (55) "Cone" means a device used to indicate beam direction and to establish a minimum source-surface distance. It may or may not incorporate a collimator.

[(50)] (56) "Contamination" means the presence in or on any animal, food, water supply, building or premises, body of water, municipal sewage disposal system, chattel or thing of a solid, liquid or gas emitting ionizing radiation which may constitute a danger to human beings.

[(51)] (57) "Control panel" means that part of radiation equipment upon which is mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

[(52)] (58) "Conveyance" means: (i) "For transport by public highway or rail" any transport vehicle or large freight container;

(ii) "For transport by water" any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and

(iii) "For transport by aircraft" any aircraft.

[(53)] (59) "Cooling curve" means the graphical relationship between heat units stored and cooling time.

[(54)] (60) "Critical Group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

[(55)] (61) "Curie" means a unit of activity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7E10 transformations per second ($t\text{-}s^{-1}$).

[(56)] (62) "Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

[(57)] (63) "Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

[(58)] (64) "Decommission" means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits-

(i) Release of the property for unrestricted use and termination of the license; or

(ii) Release of the property under restricted conditions and the termination of the license.

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

[(60)] (66) "Deep dose equivalent" (H_d), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2).

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

[(61)] (68) "Department" means the New York City Department of Health and Mental Hygiene.

[(62)] (69) "Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present.

[(63)] (70) "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of this Code, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table 1, Column 3, of Appendix B of §175.03 of this Code.

[(64)] (71) "Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

[(65)] (72) "Deterministic effect" [see "Nonstochastic effect"].

[(66)] (73) "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

[(67)] (74) "Diagnostic type protective tube housing" means an x-ray tube housing so constructed that the leakage radiation at a distance of one meter from the tube housing does not exceed 2.58 E-5 $C\text{-}kg^{-1}$ (100 milliroentgens) in one hour with a beam-limiting device attached and the tube operated at its leakage technique factors as specified by the manufacturer. Measurements may be averaged over an area of 100 cm^2 with no linear dimensions greater than 20 centimeters (8 inches).

[(68)] (75) "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

[(69)] (76) "Diaphragm" means a device or mechanism by which the radiation beam is restricted in size.

[(70)] (77) "Distinguishable from background" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

[(71)] (78) "Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of this Code, "radiation dose" is an equivalent term.

[(72)] (79) "Dose equivalent (H_T)" means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

[(73)] (80) "Dose limits" means the permissible upper bounds of radiation doses established in accordance with this Code. For purposes of this Code, "limits" is an equivalent term.

[(74)] (81) "Dose monitor unit" [See "Monitor unit".]

[(75)] (82) "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

[(76)] (83) "Effective dose equivalent (H_E)" means the sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = S\ w_T H_T$).

[(77)] (84) "Embryo/fetus" means the developing human organism from conception until the time of birth.

[(78)] (85) "Entrance or access point" means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

[(79)] (86) "Entrance exposure rate" means the exposure per unit time at the point where the center of the useful beam enters the patient. For the purposes of this definition, "exposure" is defined in §175.02(a)(80)(ii).

[(80)] (87) "Equipment" means x-ray equipment.

[(81)] (88) "Exclusive use" (also referred to in other regulations as "sole use" or "full load") means the sole use of a conveyance by a single consignor for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier must ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the consignor.

[(82)] (89) "Explosive material" means any chemical compound, mixture, or device which produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

[(83)] (90) "Exposure" means either:

(i) being exposed to ionizing radiation or to radioactive material; or

(ii) the quotient of dQ divided by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The units of exposure are the coulomb per kilogram ($C\text{-}kg^{-1}$) and the roentgen.

[(84)] (91) "Exposure rate" means the exposure per unit of time.

[(85)] (92) "External beam radiation therapy" means a method of radiation therapy utilized to deliver a radiation dose in which the source (sources) of radiation is (are) at a distance from the body. For the purposes of this Code "teletherapy" is an equivalent term.

[(86)] (93) "External dose" means that portion of the dose equivalent received from any source of radiation outside the body.

[(87)] (94) "Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

[(88)] (95) "Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (300 mg/cm^2).

[(89)] (96) "Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

[(90)] (97) "Filter" means material placed in the useful beam to absorb preferentially selected radiations.

[(91)] (98) [Reserved]

[(92)] (99) "Fissile material" means plutonium-239, plutonium-241, uranium-233, uranium-235 or any combination of these radionuclides. Fissile material means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium, and natural uranium or depleted uranium that has been irradiated in thermal reactors only are not included in this definition. Certain exclusions from fissile material controls are provided in 10 CFR 71.15

[(93)] (100) "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

[(94)] (101) "Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

[(95)] (102) "Gantry" means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

[(96)] (103) "General purpose radiographic x-ray system" means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

[(97)] (104) "Generally applicable environmental radiation standards" means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

[(98)] (105) "Gonad or gonadal shield" means a protective barrier for the ovaries or testes.

[(99)] (106) "Gray" (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram. One gray is equal to 100 rads.

[(100)] (107) "Half-value layer (HVL)" means the thickness of specified material which, when introduced into the beam of a given path of radiation, reduces the exposure rate by one-half. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

[(101)] (108) "Hazardous waste" means those wastes designated as hazardous by U.S. Environmental Protection Agency regulations in 40 CFR Part 261.

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

[(102)] (110) "High radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters (12 inches) from any source of radiation or from any surface that the radiation penetrates. For the purposes of this Code, rooms or areas in which diagnostic x-ray systems are used for healing arts purposes are not considered high radiation areas.

[(103)] (111) "Human use" [see "Medical use"].

[(104)] (112) "Image receptor" means any device, such as a fluorescent input phosphor or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformation.

[(105)] (113) "Individual" means any human being.

[(106)] (114) "Individual monitoring" means the assessment of:

(i) dose equivalent

(A) by the use of individual monitoring devices, or
(B) by the use of survey data; or

(ii) committed effective dose equivalent

(A) by bioassay, or

(B) by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours.

[(107)] (115) "Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of this Code, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, and personal air sampling devices.

[(108)] (116) "Inhalation class" [see "Class"].

[(109)] (117) "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

[(110)] (118) "Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the Department.

[(111)] (119) "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

[(112)] (120) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

[(113)] (121) "Kilo electron volt (keV)" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum.

[(114)] (122) "Kilovolt peak (kVp)" means the maximum value in kilovolts of the potential difference of a pulsating generator. When only one-half of the wave is used, the value refers to the useful half of the wave.

[(115)] (123) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

[(116)] (124) "Leakage radiation" means radiation emanating from the diagnostic source assembly except for:

(i) the useful beam, and

(ii) radiation produced when the exposure switch or timer is not activated.

[(117)] (125) "Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

(i) for diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, **i.e.,** 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

(ii) for diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.

(iii) for all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

[(118)] (126) "License" means a radioactive materials license issued by the Department for the transfer, receipt, production, possession or use of radioactive materials pursuant to this Code. There are two types of licenses: general and specific. A "general license" means a license to transfer, receive, possess, or use radioactive material in certain forms or quantities which is issued pursuant to the terms and conditions of this Code. General licenses are effective without the filing of an application with or the issuance of a license document by the Department. A "specific license" means a license evidenced by a license document issued by the Department to a licensee upon review and approval of an application submitted pursuant to this Code or a license similarly issued by the New York State Department of Health, the New York State Department of Labor, the U.S. Nuclear Regulatory Commission or any agreement state. Unless otherwise specified, the type of license referred to in this Code shall be a specific license.

[(119)] (127) "Licensed material" means byproduct, source, or special nuclear material received, possessed, produced, used, transferred or disposed of under a general or specific license issued by the Department or any radioactive material which is subject to the licensure requirement of this Code.

[(120)] (128) "Licensee" means any person who is licensed by the Department in accordance with this Code or any person who possesses radioactive material which is subject to the licensure requirements of this Code.

[(121)] (129) "Limits" [See "Dose limits"].

[(122)] (130) "Light field" means the area illuminated by visible light, simulating the radiation field.

[(123)] (131) "Linear accelerator" [See "Accelerator"]. For the purposes of this Code, "linac" is an equivalent term.

[(124)] (132) "Line-voltage regulation" means the difference between the no-load line potentials expressed as a percent of the load line potential; that is,

$$\text{Percent line-voltage regulation} = 100\ \frac{(V_n - V_1)}{V_1}$$

where:

V_n = No-load line potential and

V_1 = Line load potential.

[(125)] (133) "Lost or missing licensed material" means licensed radioactive material whose location is unknown. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

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

[(126)] (135) "Low specific activity (LSA) material" means radioactive material with limited specific activity which is nonfissile or is excepted under §175.105(b)(2) that satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material must be in one of three groups:

(1) LSA-I.

(i) Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radioactive radionuclides that are not intended to be processed for the use of these radionuclides; or

(ii) Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures; or

(iii) Radioactive material, other than fissile material, for which the A_2 value is unlimited; or

(iv) Mill tailings, contaminated earth, concerete, rubble, other debris, and activated material in which the radioactive material is essentially uniformly distributed, and the average specific activity does not exceed 10^{-6} A_2/g.

(2) LSA-II.

(i) Water with tritium concentration up to 0.8 TBq/liter (20.0 Ci/liter); or

(ii) Material in which the radioactive material is essentially uniformly distributed, and the average specific activity does not exceed 10^{-4} A_2/g for solids and gases, and 10^{-5} A_2/g for liquids.

(3) LSA-III. Solids (e.g., consolidated wastes, activated materials) excluding powders, that satisfy the requirements of 10 CFR §71.77 in which:

(i) The radioactive material is essentially uniformly distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.);

(ii) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for 7 days, would not exceed 0.1 A_2; and

(iii) The estimated average specific activity of the solid does not exceed 2×10^{-3} A_2/g.

[(127)] (136) "Lung class" [see "Class"].

[(128)] (137) "Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding 4 times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs.

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

(139) "Manual brachytherapy" means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

[(130)] (140) "Maximum line current" means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

(141) "Medical event" means an event that meets the criteria in §175.03(l)(8) of this Code.

[(131)] (142) "Medical institution" means a facility as defined in Article 28 of the New York State Public Health Law.

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

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

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

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

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

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

(vi) a therapeutic radiation dose from any source other than a radiopharmaceutical, radiobiologic or brachytherapy source such that errors in computation, calibration, time of exposure, treatment geometry or equipment malfunction result in a calculated total treatment dose differing from the final prescribed total treatment dose ordered by more than 10 percent;

(vii) a therapeutic radiation dose from a brachytherapy source such that errors in computation, calibration, treatment time, source activity, source placement or equipment malfunction result in a calculated total treatment dose differing from the final total treatment dose ordered by more than 10 percent; or

(viii) a therapeutic radiation dose in any fraction of a fractionated treatment such that the administered dose in the individual treatment or fraction differs from the dose ordered for that individual treatment or fraction by more than 50 percent.]

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

(144) "Medium dose-rate remote afterloader", means a

brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads) per hour, but less than or equal to 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

[(134)] (145) "Mega electron volt (MeV)" means the energy equal to that acquired by a particle with one electron charge passing through a potential difference of one million volts in a vacuum.

[(135)] (146) "Member of the public" means any individual, except when that individual is receiving an occupational dose.

[(136)] (147) "Minor" means an individual less than 18 years of age.

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

[(137)] (149) "Monitor unit" means a unit response from the beam monitoring system from which the absorbed dose can be calculated. For the purposes of this Code, "Dose monitor unit" is an equivalent term.

[(138)] (150) "Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of this Code, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

[(139)] (151) "NARM" means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.

[(140)] (152) "Natural radioactivity" means radioactivity of naturally occurring nuclides.

[(141)] (153) "Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of this Code, "deterministic effect" is an equivalent term.

[(142)] (154) "Normal form radioactive material" means radioactive material which has not been demonstrated to qualify as special form radioactive material.

[(143)] (155) "Nuclear Regulatory Commission" (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

[(144)] (156) "Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under §175.103(c)(9), from voluntary participation in medical research programs, or as a member of the public.

[(145)] (157) "Operator" means any person conducting the business or activities carried on within a radiation installation or having by law the administrative control of a radiation source whether as owner, lessee, contractor, user or otherwise.

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

[(147)] (159) "Package" means the packaging together with its radioactive contents as presented for transport.

(i) "Fissile material package" or Type AF package, Type BF package, Type BF package, or Type B(U)F package, or Type B(M)F package means a fissile material packaging together with its fissile material contents.

[(2)] (ii) "Type A package" means a Type A packaging together with its radioactive contents. A Type A package is defined and must comply with DOT regulations in 49 CFR Part 173.

[(ii)] (iii) "Type B package" means a Type B packaging together with its radioactive contents. On approval by the NRC, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kPa (100 lb/in^2) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in 10 CFR 71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see USDOT regulations in 49 CFR Part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in 10 CFR 71.13.

[(148)] (160) "Packaging" means the assembly of components necessary to ensure compliance with the packaging requirements of 10 CFR Part 71. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

[(149)] (161) "Particle accelerator" [See "Accelerator"].

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

[(150)] (163) "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

[(151)] (164) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, public authority or political subdivision of this State, any other State of the United States or political subdivision or agency thereof, and any legal successor, representative, agent or agency of the foregoing, but shall not include federal government agencies.

[(152)] (165) "Personnel monitoring equipment" [See "Individual monitoring devices"].

[(153)] (166) "Phantom" means an object behaving in essentially the same manner as tissue with respect to absorption or scattering of the ionizing radiation in question.

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

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

[(154)] (169) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

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

[(155)] (171) "Position indicating device (PID)" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance.

[(156)] (172) "Positive collimating device" means a device which is permanently affixed to the x-ray tube housing and is intended to confine the emerging x-ray beam to the image receptor or area of clinical interest, whichever is smaller.

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

(174) "Prescribed dosage" means the specified activity or range of activity of unsealed byproduct material as documented—

(i) In a written directive; or

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

(175) "Prescribed dose" means—

(i) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(ii) For teletherapy, the total dose and dose per fraction as documented in the written directive;

(iii) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(iv) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

[(157)] (176) "Primary protective barrier" [See "Protective barrier "].

[(158)] (177) "Probabilistic effect" [See "Stochastic effect"].

[(159)] (178) "Professional practice" means the practice of medicine, dentistry, podiatry, osteopathy, chiropractic or veterinary medicine.

[(160)] (179) "Professional practitioner" means any person licensed or otherwise authorized under the New York State Education Law to practice a professional practice.

[(161)] (180) "Protective apron" means an apron made of radiation attenuating material(s), used to reduce radiation exposure.

[(162)] (181) "Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

(i) "Primary protective barrier" means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure.

(ii) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

[(163)] (182) "Protective glove" means a glove made of radiation attenuating material(s) used to reduce radiation exposure.

[(164)] (183) "Public dose" means the dose received by a member of the public from exposure to sources of radiation. It 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.

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

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

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

[(165)] (185) "Pyrophoric liquid" means any liquid that ignites spontaneously in dry or moist air at or below 54.4°C (130°F). A pyrophoric solid is any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

[(166)] (186) "Qualified expert" means an individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs, e.g., individuals certified in the appropriate field by the American Board of Radiology or the American Board of Health Physics, or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy, e.g., individuals certified by the American Board of Medical Physics or in therapeutic Radiological Physics or X-Ray and Radium Physics by the American Board of Radiology.

[(167)] (187) "Quality factor" (Q) means the modifying factor that is used to derive dose equivalent from absorbed dose.

(i) As used in this Code, the quality factors for converting absorbed dose to dose equivalent are shown in Table 1.

Table 1

Quality Factors and Absorbed Dose Equivalents

Type of Radiation	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent*
X, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

*Absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

(ii) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in Table 1, 0.01 Sv (1 rem) of neutron radiation of unknown energies may, for purposes of this Code, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table 2 to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

Table 2

Mean Quality Factors, Q, and Fluence per Unit Dose Equivalent for Monoenergetic NeutronsEquivalent for Monoenergetic Neutrons

Neutron Energy (MeV)	Quality Factor[a] (Q)	Fluence per Unit Dose Equivalent[b] (neutrons cm-2 rem-1)	Fluence per Unit Dose Equivalent[b] (neutrons cm-2 Sv-1)
(thermal) 2.5E-8	2	980E6	980E8
1E-7	2	980E6	980E8
1E-6	2	810E6	810E8
1E-5	2	810E6	810E8
1E-4	2	840E6	840E8
1E-3	2	980E6	980E8
1E-2	2.5	1010E6	1010E8
1E-1	7.5	170E6	170E8
5E-1	11	39E6	39E8
1	11	27E6	27E8
2.5	9	29E6	29E8
5	8	23E6	23E8
7	7	24E6	24E8
10	6.5	24E6	24E8
14	7.5	17E6	17E8
20	8	16E6	16E8
40	7	14E6	14E8
60	5.5	16E6	16E8
1E2	4	20E6	20E8
2E2	3.5	19E6	19E8
3E2	3.5	16E6	16E8
4E2	3.5	14E6	14E8

[a] Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.

[b] Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

[(168)] (188) "Quarter" [See "Calendar quarter"].

[(169)] (189) "Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs per gram or 0.01 joule per kilogram (0.01 gray).

[(170)] (190) "Radiation" means alpha particles, beta particles, gamma rays, x rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of this Code, ionizing radiation is an equivalent term. Radiation, as used in this Code, does not include non-ionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

[(171)] (191) "Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters (12 inches) from the source of radiation or from any surface that the radiation penetrates.

[(172)] (192) "Radiation detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

[(173)] (193) "Radiation dose" [See "Dose"].

[(174)] (194) "Radiation equipment" means any equipment or device which can emit radiation by virtue of the application thereto of high voltage.

[(175)] (195) "Radiation installation" means any place or facility, including vehicles such as a van or truck, where:

(i) radiation equipment, in operable condition or assembles and intended to be used, is located or used; or

(ii) radioactive material is transferred, received, produced, possessed or used.

Such installation shall include generally a hospital; medical, dental, chiropractic, osteopathic, podiatric, or veterinarian institution, clinic or office; van or truck providing services at non-permanent locations; educational institution; commercial, private or research laboratory performing diagnostic procedures or handling equipment or material for medical use; or any trucking, storage, messenger or delivery service establishment. Radiation installation shall include, whether or not it is specifically stated above, any place, facility or vehicle such as a van or truck where radiation is applied intentionally to a human. The limits of the radiation installation shall be as designated by the operator.

[(176)] (196) "Radiation machine" means any device capable of producing radiation except those devices with radioactive material as the only source of radiation.

[(177)] (197) "Radiation safety officer" means an individual who: [under the authorization of the operator of a radiation installation, administers a radiation protection program in accordance with § 175.03 of this Code and who is qualified by training and experience in radiological health to evaluate the radiation hazards of such installation and administer such radiation protection program.]

(i) Meets the requirements in §§ 175.103(j)(1)(i) and 175.103(j)(15) of this Code; or

(ii) Is identified as a Radiation Safety Officer on—

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

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

[(178)] (198) "Radiation source" means any radioactive material or any radiation equipment.

[(179)] (199) "Radiation therapy physicist" means the individual identified as the qualified radiation therapy physicist on a Department license or certified registration.

[(180)] (200) "Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

[(181)] (201) "Radioactive material" means any solid, liquid, or gas which emits radiation spontaneously.

[(182)] (202) "Radioactive material site" means a location, or contiguous and adjacent locations, under a single license in which radioactive materials are authorized to be received, produced, used, possessed (stored), or transferred and in which a specific use of said radioactive materials may be evaluated by a single set of Departmental inspection criteria concerning the procedures, equipment or shielding utilized by the licensee.

[(183)] (203) "Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

[(184)] (204) "Radiobioassay" [See "Bioassay"].

[(185)] (205) "Rated line voltage" means the range of potentials, in volts, of the supply line specified by the manufacturer at which the x-ray machine is designed to operate.

[(186)] (206) "Rated output current" means the maximum allowable load current of the x-ray high-voltage generator.

[(187)] (207) "Rated output voltage" means the allowable peak potential, in volts, at the output terminals of the x-ray high-voltage generator.

[(188)] (208) "Rating" means the operating limits specified by the manufacturer.

(209) "Recordable therapy medical event" means the administration of:

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

(ii) a therapeutic radiation dose from any source other than a radiopharmaceutical, radiobiologic or brachytherapy source such that errors in computation, calibration, time of exposure, treatment geometry or equipment malfunction result in a calculated total treatment dose differing from the final prescribed total treatment dose ordered by more than 10 percent;

(iii) a therapeutic radiation dose from a brachytherapy source such that errors in computation, calibration, treatment time, source activity, source placement or equipment malfunction result in a calculated total treatment dose differing from the final total treatment dose ordered by more than 10 percent; but in which the percentage error in all cases is equal to or less than 20 percent.

[(189)] (210) "Recording" means producing a permanent form of an image resulting from x-ray photons (e.g., film, video tape).

[(190)] (211) "Reference Man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

[(191)] (212) "Registrant" means any person who is registered with the Department or who is legally obligated to register with the Department pursuant to this Code.

[(192)] (213) "Registration" means registration with the Department in accordance with this Code.

[(193)] (214) "Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor. One rem is equal to 0.01 sievert.

[(194)] (215) "Research and development" means:

(i) theoretical analysis, exploration, or experimentation; or

(ii) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes.

Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

[(195)] (216) "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of 10 CFR Part 20.

[(196)] (217) "Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

[(197)] (218) "Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

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

[(199)] (220) "Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58E-4 coulomb per kilogram of air (see "Exposure").

[(200)] (221) "Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

[(201)] (222) "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction. (The radiation also may have been modified by a decrease in energy.)

[(202)] (223) "Sealed source" means [radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.] any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

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

[(203)] (225) "Secondary protective barrier" [See "Protective barrier"].

[(204)] (226) "Shallow dose equivalent" (H_S), which applies to the external exposure of the skin of the whole body or the skin of an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

[(205)] (227) "Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

[(206)] (228) "SI" means the abbreviation for the International System of Units (Systeme Internationale).

[(207)] (229) "Sievert" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor. One sievert is equal to 100 rem.

[(208)] (230) "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

[(209)] (231) "Source" means, for the purposes of radiation equipment, the focal spot of the x-ray tube.

[(210)] (232) "Source-image receptor distance (SID)" means the distance from the source to the center of the input surface of the image receptor.

[(211)] (233) "Source material" means:

(i) Uranium or thorium, or any combination thereof, in any physical or chemical form; or

(ii) Ores that contain by weight one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium or any combination of uranium and thorium. Source material does not include special nuclear material.

[(212)] (234) "Source material milling" means any activity that results in the production of byproduct material as defined in §175.02(a)([29]33)(ii).

[(213)] (235) "Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

[(214)] (236) "Source-skin distance or source-surface distance (SSD)" means the distance measured along the central ray from the center of the front surface of the source of the x-ray focal spot or sealed radioactive source to the surface of the irradiated object.

[(215)] (237) "Special form radioactive material" means radioactive material which satisfies the following conditions:

(i) it is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(ii) the piece or capsule has at least one dimension not less than 5 mm (0.2 inch); and

(iii) it satisfies the requirements of 10 CFR 71.75. A special form encapsulation designed in accordance with the requirements of 10 CFR 71.4 in effect on June 30, 1983, (see 10 CFR Part 71, revised as of January 1, 1983), and constructed prior to July 1, 1985, and a special form encapsulation designed in accordance with the requirements of 10 CFR 71.4 in effect on March 31, 1996, (see 10 CFR Part 71, revised as of January 1, 1983), and constructed before April 1, 1998, may continue to be used. Any other special form encapsulation must meet the specifications of this definition.

[(216)] (238) "Special nuclear material" means:

(i) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the U.S. Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

(ii) Any material artificially enriched by any of the foregoing, but does not include source material.

[(217)] (239) "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

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

[(218)] (240) "Specific activity" of a radionuclide means the radioactivity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

[(219)] (241) "State" means the State of New York, unless the context of this Code clearly indicates that a different meaning is intended.

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

[(220)] (243) "Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of this Code, "probabilistic effect" is an equivalent term.

[(221)] (244) "Stray radiation" means the sum of leakage and scattered radiation.

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

[(222)] (246) "Supervision" means:

(i) for radioactive materials licenses which do not authorize human use, the training of persons in the use of radioactive materials in other than medical procedures. Such training shall include at least thirty (30) hours of instruction in the principles and practices of radiation protection, radioactivity measurement, standardization and monitoring techniques and instruments, mathematics and calculations basic to the use and measurement of radioactivity, and biological effects of radiation; and

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

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

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

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

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

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

[(224)] (248) "Technique factors" means the conditions of operation of radiation equipment. They are specified as follows:

(i) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs.

(ii) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses.

(iii) For CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

(iv) For CT x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

(v) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

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

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

[(226)] (251) "Test" means the process of verifying compliance with an applicable regulation.

[(227)] (252) "Therapeutic-type protective tube housing" means:

(i) for x-ray therapy equipment not capable of operating at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that the leakage radiation averaged over any 100 cm^2 (15.5 inches^2) at a distance of 1 meter (3 feet) from the source does not exceed 2.58 E-4 C-kg^{-1} (1 roentgen) in an hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential.

(ii) For x-ray therapy equipment capable of operation at 500

kVp or above, the following definition applies: An x-ray tube housing so constructed that the leakage radiation averaged over an 100 cm^2 (15.5 $inches^2$) area at a distance of 1 meter (3 feet) from the source does not exceed 0.10 percent of the useful beam dose rate at 1 meter (3 feet) from the source for any of its operating conditions.

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

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

[(228)] (255) "This Code" means Article 175 and all other parts of the New York City Health Code applicable to licensees and registrants or other persons subject to the provisions of Article 175.

[(229)] (256) "Total effective dose equivalent" (TEDE) means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

[(230)] (257) "Total organ dose equivalent" (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in §175.03(k)(7)(i)(F) of this Code.

[(231)] (258) "Traceable to a national standard" means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

[(232)] (259) "Transport index (TI)" means the dimensionless number, rounded up to the next tenth, placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is determined by multiplying the maximum radiation level in millisievert (mSv) per hour at 1 meter (3.3ft) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at 1 meter (3.3 ft)).

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

[(233)] (261) "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when they are contained within the tube housing.

[(234)] (262) "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

[(235)] (263) "Type A package" means a packaging that, together with its radioactive contents limited to A_1 or A_2 as appropriate, meets the requirements of U.S. DOT 49 CFR 173.410 and 173.412 and is designed to retain the integrity of containment and shielding required by this part under normal conditions of transport as demonstrated by the tests set forth in 49 CFR 173.465 or 173.466, as appropriate.

[(236)] (264) "Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material. A_1 and A_2 are given in Appendix A of §175.105 or may be determined by procedures described in such Appendix A.

[(237)] (265) [Reserved]

[(238)] (266) [Reserved]

[(239)] (267) "Type B quantity" means a quantity of radioactive material greater than a Type A quantity.

(268) "Type of use" means use of byproduct material under §§10 CFR 35.100; 35.200; 35.300; 35.400; 35.500; 35.600; or 35.1000.

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

[(240)] (270) "U.S. Department of Energy" means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, 42 U.S.C. 5814, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977.)

[(241)] (271) "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

[(242)] (272) "Unrestricted area" means an area, access to which is not controlled by the licensee or registrant for purposes of radiation protection.

[(243)] (273) "Use" as used in radioactive materials licenses means to employ or apply radioactive materials for the licensed purpose. It shall include instruction of, and responsibility for, technical and support staff members. It does not include training others in the techniques of use of radioactive materials for the purpose of qualifying for licensure.

In licenses authorizing medical use of radioactive materials, "use" shall also include:

(i) ordering or directing the administration of radiation or radioactive materials to humans, including the method or route of administration;

(ii) actual use of, or direction of technologists or other paramedical personnel in the use of, radioactive material;

(iii) interpretation of results of diagnostic procedures; and

(iv) regular review of the progress of patients receiving therapy and modification of the originally prescribed dose as warranted by the patient's reaction to radiation therapy.

[(244)] (274) "Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the system to produce radiation.

[(245)] (275) "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.

[(246)] (276) "Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in 1 hour at 1 meter (3 feet) from a source of radiation or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose (gray and rad) are appropriate, rather than units of dose equivalent (sievert and rem).

[(247)] (277) "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons produce a visible image.

[(248)] (278) "Waste" means those low-level radioactive wastes that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level 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, radioactive waste (a) not classified as high-level radioactive 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.

[(249)] (279) "Waste handling licensees" mean persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive waste.

[(250)] (280) "Week" means 7 consecutive days starting on Sunday.

[(251)] (281) "Weighting factor" w_T for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of W_T are:

Organ Dose Weighting Factors

Organ or Tissue	W_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30[a]
Whole Body	1.00[b]

[a] 0.30 results from 0.06 for each of 5 "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

[b] For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

[(252)] (282) "Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

[(253)] (283) "Worker" means an individual engaged in work under a license or registration issued by the Department and controlled by a licensee or registrant, but does not include the licensee or registrant.

[(254)] (284) "Working level" (WL) means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of 1.3E5 MeV of potential alpha particle energy. The short-lived radon daughters are:

(i) for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and

(ii) for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

[(255)] (285) "Working level month" (WLM) means an exposure to 1 working level for 170 hours (2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month).

(286) "Written directive" means an authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject, as specified in § 175.103(b)(6) of this Code.

[(256)] (287) "X-ray control" means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

[(257)] (288) "X-ray equipment" means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

(i) "Mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

(ii) "Portable x-ray equipment" means x-ray equipment designed to be hand carried.
(iii) "Stationary x-ray equipment" means x-ray equipment which is installed in a fixed location.

[(258)] (289) "X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

[(259)] (290) "X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

[(260)] (291) "X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

[(261)] (292) "X-ray subsystem" means any combination of two or more components of an x-ray system for which there are requirements specified in this Article.

[(262)] (293) "X-ray tube" means any electron tube which is designed for the conversion of electrical energy into x-ray energy. For the purposes of permit fee requirements in Article 5 of this Code, an x-ray tube means any electrical device which produces x-rays of intensity exceeding 1.29 E-4 $C\text{-}kg^{-1}$ (0.5 milliroentgen) per hour when measured 5 centimeters (2 inches) from any accessible surface thereof, and averaged over an area of 10 cm^2 (1.55 square inches).

[(263)] (294) "Year" means the period of time beginning in January used to determine compliance with the provisions of this Code. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

***

Notes: On March 15, 2011, the Board of Health amended §175.02 to add, delete , revise and/or renumber its definitions in order primarily to maintain compatibility with changes made by the Nuclear Regulatory Commission to Part 35 in Title 10 of the Code of Federal Regulations concerning medical use of byproduct material and to update supervision requirements promulgated by the New York State Department of Health.

***

RESOLVED, that 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 September 26, 2006, be and the same hereby is amended to add new requirements with respect to certain records, reports and notifications, to be printed together with explanatory notes, to read as follows:

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

(b) *Radiation protection programs.*

(1) *Radiation Protection Programs.*
…

(2) *Radiation protection program changes.*

(i) A licensee may revise its radiation protection program without Departmental approval if—

(A) The revision does not require a license amendment under § 175.103(a)(7) of this Code;

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

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

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

(ii) A licensee shall retain a record of each change in accordance with § 175.03(k)(4) of this Code.
…

[(2)] (3) *Radiation safety officer.*
…

(k) *Records.*

(1) *General provisions.*
…

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

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

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

(4) *Records of radiation protection program changes.*

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

[(3)](5) *Records of receipt, use and disposition of radioactive material.* (i) Each licensee shall maintain records of the receipt, use and disposition of radioactive material in units of becquerels or microcuries and shall include from whom such materials were received and the ultimate disposition.

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

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

[(5) Records of tests for leakage or contamination of sealed sources Records of tests for leakage or contamination of sealed sources required by §175.03(e)(1) shall be kept in units of becquerel or microcurie and maintained for inspection by the Department for 5 years after the records are made.]

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

[(7)](8) *Records of planned special exposures.* (i) For each use of the provisions of §175.03(c)(6) of this Code for planned

special exposures, the licensee or registrant shall maintain records that describe:

…

[(8)](9) *Records of individual monitoring results.* (i) Recordkeeping Requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to §175.03(f)(2) of this Code, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before the effective date of these requirements need not be changed. These records shall include, when applicable:

…

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

…

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

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

…

(12) *Records of written directives.*

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

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

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

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

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

(15) *Records of radiation survey instrument calibrations.*

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

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

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

(ii) The record shall contain—

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

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

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

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

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

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

(i) A licensee shall retain records of leak tests required by §175.03(e)(1) and § 175.103(c)(6)(ii) of this Code for inspection by the Department for 5 years after the records are made. The records shall include the model number, and serial number if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test in units of becquerel or microcurie; the date of the test; and the name of the individual who performed the test.

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

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

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

(19) *Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material.*
(i) A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with § 175.103(c)(9) of this Code, if the total effective dose equivalent is calculated by—

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

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

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

(D) Considering the shielding by tissue.

(ii) A licensee shall retain a record that the instructions required by §175.103(c)(9)(ii) of this Code were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

(iii) The records required by subparagraphs (i) and (ii) of this paragraph shall be retained for 3 years after the date of release of the individual.

(20) *Records of mobile medical services.*

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

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

(21) *Records of decay-in-storage.*

A licensee shall maintain records of the disposal of licensed materials, as required by §175. 103(c)(11) of this Code for 3 years. The record shall include the date the radioactive material was placed in storage, the date of the disposal, the model and serial number of the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

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

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

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

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

(23) *Records of safety instruction.*

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

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

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

(25) *Records of brachytherapy source accountability.*

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

(ii) For temporary implants, the record shall include—

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

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

(iii) For permanent implants, the record shall include—

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

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

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

(26) *Records of calibration measurements of brachytherapy sources.*

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

(ii) The record shall include—

(A) The date of the calibration;

(B) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;
(C) The source output or activity;
(D) The source positioning accuracy within the applicators; and

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

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

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

(ii) The record shall include—

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

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

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

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

(29) *Records of safety procedures*

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

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

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

(ii) For each calibration, intercomparison, or comparison, the record shall include—

(A) The date;

(B) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by subparagraphs (i) and (ii) of § 175.103(h)(8) of this Code;

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

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

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

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

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

(ii) The record shall include—

(A) The date of the calibration;

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

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

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

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

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

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

(ii) The record shall include—

(A) The date of the spot-check;

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

(C) An assessment of timer linearity and constancy;

(D) The calculated on-off error;

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

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

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

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

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

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

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

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

(ii) The record shall include, as applicable—

(A) The date of the spot-check;

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

(C) An assessment of timer accuracy;

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

(E) The name of the individual who performed the periodic spot-check and the signature of the authorized medical

physicist who reviewed the record of the spot-check.

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

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

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

(ii) The record shall include—

(A) The date of the spot-check;

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

(C) An assessment of timer linearity and accuracy;

(D) The calculated on-off error;

(E) A determination of trunnion centricity;

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

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

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

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

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

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

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

(ii) The record shall include—

(A) The date of the check;

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

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

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

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

(36) *Records of surveys of therapeutic treatment units.*

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

(ii) The record shall include—

(A) The date of the measurements;

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

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

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

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

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

(ii) The record shall contain—

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

(B) The date of inspection;

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

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

(E) The signature of the inspector.

[(11)] (38) [*Form*] *Maintenance of records.*

(i) Each record required by this section shall be legible throughout the retention period specified by each Departmental regulation. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, shall include all pertinent information such as stamps, initials, and signatures.

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

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

(l) *Reports.*

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

…

(7) Report[s] of a leaking [or contaminated sealed] source[s].

[The licensee or registrant shall file a report within five (5) days with the Department if the test for leakage or contamination required pursuant to §175.03(e)(1) indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results and the corrective action taken.]

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

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

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

(i) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in —

(A) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

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

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

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

(B) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following—

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

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

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

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

(*e*) A leaking sealed source.

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

(D) A therapeutic radiation dose in any fraction of a fractionated treatment such that the administered dose in the individual treatment or fraction differs from the dose ordered for that individual treatment or fraction by more than 50 percent.

(ii) A licensee/certified registrant shall be required to make a record of, but not report, a therapeutic radiation dose from any source other than a radiopharmaceutical, radiobiologic or brachytherapy source such that errors in computation, calibration, time of exposure, treatment geometry or equipment malfunction result in a calculated total treatment dose differing from the final prescribed total treatment dose ordered by more than 10 percent.

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

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

(v) The licensee/certified registrant shall submit a written report to the Department within 15 days after discovery of the medical event. This reporting requirement may be satisfied by submitting to the Department a copy of the incident report filed with the New York State Department of Health pursuant to 10 NYCRR §405.8, provided, however, that such report contains all information required by this Code.

(A) The written report shall include—

(*a*) The licensee's/certified registrant's name;

(*b*) The name of the prescribing physician;

(*c*) A brief description of the event;

(*d*) Why the event occurred;

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

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

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

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

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

(vii) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees/certified registrants and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

(viii) A licensee/certified registrant shall:

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

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

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

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

(ix) Records and reports of medical events.

(A) Diagnostic medical events.

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

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

(B) Therapy medical events.

(*a*) When a recordable therapy medical event as defined in §175.02(a)(209) of this Code is discovered, in which the percentage of error is equal to or less than 20 percent,, the licensee or registrant shall immediately investigate the cause and take corrective action; and

(*b*) the licensee or registrant shall make and retain a record of all recordable therapy medical events as defined in §175.02(a)(209) of this Code. The record shall contain all the information required by §175.103 of this Code and shall be retained for six (6) years.

(C) Records and reports of diagnostic and therapy medical events

The record shall contain the names of all individuals involved in the event (including the treating physician, allied health personnel, the patient and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a description of the event, the effect on the patient (including sequelae, prognosis and follow-up actions) and actions taken to prevent recurrence.

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

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

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

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

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

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

(iv) The licensee shall submit a written report to the Department within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in subparagraphs (i) and (ii) of this paragraph.

(A) The written report shall include—

(*a*) The licensee's name;

(*b*) The name of the prescribing physician;

(*c*) A brief description of the event;

(*d*) Why the event occurred;

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

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

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

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

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

(vi) A licensee shall:

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

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

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

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

***

Notes: On March 15, 2011, the Board of Health amended §175.03 to add new requirements with respect to certain records, reports and notifications in order to maintain compatibility with changes made by the Nuclear Regulatory Commission to Part 35 in Title 10 of the Code of Federal Regulations concerning medical use of byproduct material.

***

RESOLVED, that Section 175.04 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 renumber an internal cross-reference, to be printed together with explanatory notes, to read as follows:

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

…

(d) *Notification and reports to workers.* (1) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified herein. The information reported shall include data and results obtained pursuant to this Code or license or certified registration conditions as shown in records maintained by the licensee and/or registrant pursuant to §175.03(k)[(8)](9) of this Code. Each notification and report shall:

…

(2) Each licensee and/or registrant shall advise each worker annually of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee and/or registrant pursuant to §175.03(k)[(8)](9) of this Code.

***

Notes: On March 15, 2011, the Board of Health amended §175.04 to renumber an internal cross-reference.

***

RESOLVED, that Section 175.07 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 21, 2001, be and the same hereby is amended to move misadministration requirements to Section 175.03 and to revise certain terminology, to be printed together with explanatory notes, to read as follows:

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

…

(c) *External beam and brachytherapy.* A quality assurance program for external beam therapy and brachytherapy is a system of plans, actions, reviews, reports and records, the purpose of which is to ensure a consistent and safe fulfillment of the dose prescription to the target volume, with minimal dose to normal tissue.
(1) Each licensee or registrant who uses external beam therapy and/or brachytherapy in humans shall implement a quality assurance program which includes at a minimum:
(i) the adoption of a quality assurance manual containing written policies and procedures designed to ensure effective supervision, safety, proper performance of equipment, effective communication and quality control. These must include policies and procedures to ensure that:

…

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

…

(2) Each licensee or registrant shall ensure that [a radiation therapy] an authorized medical physicist possessing the qualifications specified in §175.64(c)(2) or §175.103(j)(2) of this Code, prepares a procedures manual describing how radiation therapy treatment planning is to be performed at the licensee's or registrant's facility. The treatment planning manual may be part of the quality assurance manual required by §175.07(c)(1) of this Code and shall include the calculation methods and formulas to be used at the facility, including the methods for performing the checks of treatment plans and related calculations as required by §175.07(c)(1) of this Code. The treatment planning manual shall be reviewed annually by [a radiation therapy] an authorized medical physicist and shall be included in training given pursuant to §175.04(c) of this Code to facility staff who will participate in treatment planning.

…

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

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

…

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

(1) Each licensee who uses [radiopharmaceuticals and/or radiobiologics for therapy] unsealed byproduct material for which a written directive is required in humans shall implement a quality assurance program which includes at a minimum: (i) the adoption of a manual containing written policies and procedures designed to assure effective supervision, safety, proper performance of equipment, effective communication and quality control. These must include procedures to assure that:

(A) each patient's evaluation and intended treatment is documented in the patient's record;

…

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

…

(2) Each licensee shall ensure that all equipment used in planning and administering [radiopharmaceutical/radiobiologic therapy] unsealed byproduct material for which a written directive is required is designed and used for the intended purpose and is properly functioning, is properly calibrated and is maintained in accordance with the manufacturer's instructions and the quality assurance program described in the licensee's or registrant's quality assurance manual.

(3) Each licensee shall audit the [radiopharmaceutical/radiobiologic] unsealed byproduct material for which a written directive is required quality assurance program at intervals not to exceed twelve (12) months to assess the effectiveness of the program, document the audit and any modifications or improvements found to be needed and institute corrective actions and improvements as indicated by the audit findings.

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

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

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

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

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

(ii) When a therapy misadministration described in 175.02(a)(129)(i), (ii), (iii) or (viii) is discovered, or when a misadministration described in §175.02(a)(129)(v), (vi) or (vii) is discovered in which the percentage of error is greater than 20 percent, the licensee or registrant shall notify the Department by telephone within 24 hours. The licensee or registrant shall also notify the referring physician of the affected patient and the patient of any therapy misadministration described herein, with the exception of the misadministration defined in §175.02(a)(129)(viii). When it is not medically advisable to give such information to the patient, the information shall be made available to the patient's responsible relative or guardian on the patient's behalf. These notifications shall be made within 24 hours after the misadministration is discovered. If the referring physician, patient or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee or registrant shall notify them as soon as practicable. It is not required that the patient be notified without first consulting the referring physician; however, medical care for the patient shall not be delayed because of this.

(iii) Within seven (7) days after an initial therapy misadministration report, the licensee or registrant shall send a written report to the Department. The written report shall contain the name of the licensee or registrant, the information required by §175.07(e)(3) and whether the licensee or registrant notified the patient or the patient's responsible relative or guardian. This reporting requirement may be satisfied by submitting to the Department a copy of the incident report filed with the New York State Department of Health pursuant to 10 NYCRR Part 405 provided, however, that such report contains all information required by this Code.

(3) Each licensee or registrant shall maintain a record of each reportable diagnostic misadministration and each therapy misadministration for six (6) years. The record shall contain the names of all individuals involved in the event (including the treating physician, allied health personnel, the patient and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a description of the event, the effect on the patient (including sequelae, prognosis and follow-up actions) and actions taken to prevent recurrence.

(4) Within seven (7) days after an initial therapy misadministration report made pursuant to §175.07(e)(2)(ii), the licensee or registrant shall provide the patient a written report, with a copy to the patient's referring physician. The report shall contain a brief description of the event, the effect on the patient including any change in the patient's health status which resulted from or could result from the misadministration, and recommendations for the appropriate course of treatment or follow-up. If it is not medically advisable to give such information to the patient, the report shall be made available to the patient's responsible relative or guardian on the patient's behalf. Such action shall be documented in the patient's treatment record.]

***

Notes: On March 15, 2011, the Board of Health amended §175.07 to change its heading and update certain references and to remove misadministration requirements from this section of the Health Code.

***

RESOLVED, that Section 175.51 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 26, 2006, be and the same hereby is amended to clarify the distinction between installation and operation of x-ray equipment, to be printed together with explanatory notes, to read as follows:

§ 175.51. **Registration and inspection of installations with radiation equipment; other permitted activities.**

(a) Applicability.

…

(b) Registration required. (1) Prior to establishing, maintaining or operating any radiation installation at which is located any radiation equipment in operable condition, or prior to installing such equipment which is intended to be used, the owner or operator of such installation shall have obtained a current certificate of registration or, for a therapeutic radiation machine subject to the requirements of § 175.64(b) of this Code, a certified registration from the Department. This shall not prohibit the installation of radiation-producing equipment by a registrant at a facility solely for testing purposes by medical physicists.

(2) For professional practitioners in private practice, registrations shall not be issued to anyone other than natural persons who shall be responsible for the use and operation of the equipment and shall be liable for violations of the conditions of the registration or the provisions of this Code.

(c) Application for a certificate of registration as described in § 175.51(b)(1) of this Code shall be made to the Department on a written form and in a manner prescribed by the Department.

(d) Facilities at which either the operator or location will be changed shall apply for a new registration at least thirty (30) days prior to such change.

(1) Facilities without a current certificate of registration shall apply as follows:

No registrant shall apply x-rays to treat or diagnose any patient's medical condition at a facility that does not possess a current, non-expired Certificate of Registration from the Department. [This shall not prohibit the installation of radiation-producing equipment by a registrant at a facility solely for testing purposes by medical physicists.]

***

Notes: On March 15, 2011, the Board of Health amended §175.51 to clarify the distinction between installation versus operation of x-ray equipment.

***

RESOLVED, that Section 175.64 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 26, 2006, be and the same hereby is amended to revise references to authorized medical physicists and other technical changes, to be printed together with explanatory notes, to read as follows:

§175.64 **Therapeutic radiation machines.**

…

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

(1) *Leakage radiation.*

…

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

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

…

(17) *Periodic quality assurance checks.* (i) Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to the requirements of §175.64(f) of this Code which are capable of operation at greater than 50 kV.

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

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

…

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

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

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

…

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

…

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

…

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

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

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

…

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

…

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

…

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

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

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

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

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

…

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

…

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

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

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

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

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

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

…

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

(i) a description of the calibration procedure;

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

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

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

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

***

Notes: On March 15, 2011, the Board of Health amended §175.64 to revise references to authorized medical physicists and other technical changes.

***

RESOLVED, that 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 June 27, 1994, be and the same hereby is repealed and reenacted, to be printed together with explanatory notes, to read as follows:

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

(a) *General information.*

(1) *Purpose and scope.*

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

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

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

(ii) If the research is conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research—

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

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

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

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

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

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

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

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

(4) *Implementation.*

(i) A Government agency or a Federally recognized Indian Tribe that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a specific medical use license is required by the Atomic Energy Act of 1954, as amended, shall comply with the requirements of 10 CFR Part 35, including provisions that are specific to licensees, on November 30, 2007. All other persons who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for which a specific medical use license is required, shall comply with the requirements of 10 CFR Part 35, including provisions that are specific to licensees, on August 8, 2009, or earlier as noticed by the NRC.
(ii) Reserved

(iii) Reserved

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

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

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

(5) *License required.*

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

(ii) An individual may —

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

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

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

(i) An application for a license for medical use of byproduct material shall be submitted and signed by the applicant or a licensee's management. If the application is for medical use sited in a medical institution, only the institution's management may apply. If the application is for medical use not sited in a medical institution, any professional practitioner may apply.

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

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

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

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

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

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

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

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

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

(*b*) A letter requesting the amendment; and

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

(v) In addition to the requirements in subparagraphs (ii) through (iv) of this paragraph, an application for a license or amendment for medical use of byproduct material as described in § 175.103(i)(1) of this Code shall also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of 10 CFR Part 35.

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

(*a*) Radiation safety precautions and instructions;

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

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

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

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

(7) *License amendments.*

A licensee shall apply for and shall receive a license amendment—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(8) *Notifications*.

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

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

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

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

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

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

(B) The licensee permits an authorized user or an individual qualified to be a Radiation Safety Officer, under §§ 175.103(j)(1) and 175.103(j)(15) of this Code, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer in accordance with § 175.103(b)(2) of this Code.
(C) The licensee's mailing address changes;

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

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

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

(9) *Exemptions regarding specific licenses of broad scope*.

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

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

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

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

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

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

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

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

(10) *License issuance*.

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

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

(B) The applicant has paid any applicable fee;

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

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

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

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

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

(11) *Specific exemptions*

The Department may, upon application of any interested person or upon its own initiative, grant exemptions from the regulations in this Code that it determines are authorized by law and will not endanger life or property and are otherwise in the public interest.

(b) *General administrative requirements.*

(1) *ALARA Program.*

(i) Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas to be As Low As Reasonably Achievable (ALARA) in accordance with this subdivision.

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

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

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

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

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

(v) The purpose of the review required by subparagraph (iv) of this paragraph is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material to unrestricted areas as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

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

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

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

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

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

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

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

(ii) The radiation safety officer shall:

(A) investigate overexposures, medical events, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, and disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

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

(a) authorizing the purchase of radioactive material;

(b) receiving and opening packages of radioactive material;

(c) storing radioactive material;

(d) keeping an inventory record of radioactive material;

(e) using radioactive material safely;

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

(g) performing periodic radiation surveys;

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

(i) disposing of radioactive material;

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

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

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

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

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

(3) *Radiation safety committee.* Each medical institution licensee shall establish a radiation safety committee to oversee the use of radioactive material.

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

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

(B) The committee shall meet at least quarterly.

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

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

(a) the date of the meeting;

(b) members present;

(c) members absent;

(d) summary of deliberations and discussions;

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

(f) document any reviews required by §175.103(b)(1)(iv) and (b)(3)(ii) of this Code.

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

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

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

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

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

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

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

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

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

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

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

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

(iv) A licensee shall retain a record of each change made

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

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

(A) identify radiation safety problems;

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

(C) verify implementation of corrective actions.

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

(5) *Supervision*. (i) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user, as allowed by § 175.103(a)(5)(ii)(A) of this Code, shall—

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

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

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

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

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

(iii) Personnel, duly licensed by the New York State Department of Health to practice nuclear medicine technology, other than physicians or registered professional nurses, at licensees involved in the performance of diagnostic procedures utilizing radioactive material which includes performing parenteral administration of radioactive material by intravenous, intramuscular or subcutaneous methods, shall:

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

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

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

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

(*b*) requirements for authorized user physician which at a minimum shall require supervision by such a physician when parenteral administration of radioactive material for diagnostic testing is performed by a qualified nuclear medicine technologist.

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

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

(A) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive shall be documented as soon as possible in writing in the patient's record. A written directive shall be prepared within 48 hours of the oral directive.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(8) *Suppliers.*

For medical use, a licensee may only use—

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

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

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

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

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

(c) *General technical requirements.*

(1) *Possession, use, calibration, and check of dose calibrators.*

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

(ii) A licensee shall:
(A) check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy this requirement, the check shall be done on a frequently used setting with a sealed source of not less than 370 kBq (10 ?Ci) of radium-226 or 1.85 MBq (50 ?Ci) of any other photon-emitting radionuclide with a half-life greater than 90 days;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) *Calibration of survey instruments*.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(viii) A licensee in possession of a sealed source or brachytherapy source shall survey with a radiation survey instrument at intervals not to exceed 3 months all areas where such sources are stored. This shall not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

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

(7) *Labeling of vials and syringes*.

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).[1]

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

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

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

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

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

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

(B) No person shall commence any autopsy on any cadaver that contains more than 185 MBq (5 mCi) of radioactive material administered/implanted for therapeutic purposes without first having consulted with, and having been advised by, the radiation safety officer of the hospital or the physician responsible for the administration/implantation of the radioactive material. If neither is available, a designated representative may serve.

(C) A radioactivity report on every cadaver containing more than 185 MBq (5 mCi) of radioactive material administered/implanted for therapeutic purposes shall be completed by the radiation safety officer or the physician responsible for the administration of the radioactive material or their designated representative. The report shall include the name, address and radioactive materials license number of the hospital; the name of the deceased; the name, address and telephone number of the next of kin; the name, address and telephone number of the funeral home to which the deceased will be sent; the radionuclide involved; the approximate activity on the date of the report and the physical form; the location(s) of the radioactive materials within the body and the external dose rate at the body surface closest to the source; the precautions to be observed during autopsy or handling of the body by the funeral director; and the name of the person who prepared the form. This report shall accompany the body, whether autopsied or not, when it is surrendered to the funeral director. The Department shall be notified in person, by telephone, by mailgram or by facsimile within 24 hours of the death and a copy of the radioactivity report shall be sent to the Department within fifteen (15) days of the date of death.

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

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

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

(11) *Decay-in-storage*.

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

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

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

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

(12) *Provision of mobile medical service*.

(i) A licensee providing mobile medical service shall—

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

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

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

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

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

(iii) A licensee providing mobile medical services shall retain the letter required in clause (A) of subparagraph (i) of this paragraph and the record of each survey required in clause (D) of subparagraph (i) of this paragraph in accordance with § 175.03(k)(20)(i) and (ii) of this Code, respectively.

(d) *Unsealed Byproduct Material—Written Directive Not Required*

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

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

(i) Obtained from:

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

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

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

(A) An authorized nuclear pharmacist;

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

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

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

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

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

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

(i) Obtained from:

(A) A manufacturer or preparer licensed under 10 CFR §32.72 or equivalent Agreement State requirements; or
(B) A PET radioactive drug producer licensed under 10 CFR § 30.32(j) or equivalent Agreement State requirements; or

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

(A) An authorized nuclear pharmacist;

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

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

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

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

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

(vi) Provided the conditions of §175.103(e)(3) of this Code are met, a licensee may use radioactive aerosols or gases only if specific application is made to and approved by the

Department.

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

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

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

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

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

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

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

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

(4) *Control of aerosols and gases.* (i) A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed by §175.03 of this Code.

(ii) The system shall provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(iii) Before receiving, producing, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the ALI listed in Table 1 of Appendix A of §175.03 of this Code. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

(iv) A licensee shall post the time calculated in §175.103(e)(3)(iii) of this Code at the area of use, as well as safety measures to be instituted in case of a spill at the area of use.

(v) A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed 6 months. Records of these checks and measurements shall be maintained for 3 years.

(vi) A copy of the calculations, including assumptions, measurements and calculations made, required in §175.103(e)(3)(iii) of this Code shall be recorded and retained for the duration of the license.

(5) *Possession of survey instruments.* A licensee authorized to use unsealed byproduct material-written directive not required, shall have in its possession a portable, radiation detection survey instrument capable of detecting dose rates over the range of 1.0 μSv (0.1 mrem) per hour to 1000 μSv (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The instruments shall be operable and calibrated in accordance with §175.103(c)(2) of this Code.

(e) *Unsealed Byproduct Material—Written Directive Required.*

(1) *Use of unsealed byproduct material for which a written directive is required.*

(i) A licensee may use any unsealed byproduct material prepared for medical use and for which a written directive is required that is—

(A) Obtained from:

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

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

(B) Excluding production of PET radionuclides, prepared by:
(*a*) An authorized nuclear pharmacist;

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

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

(C) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

(D) Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

(2) *Safety instruction.*

In addition to the requirements of 10 CFR §19.12,

(i) A licensee shall provide oral and written radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under § 175.103(c)(9) of this Code. To satisfy this requirement, the instruction shall be commensurate with the duties of the personnel and include—

(A) Patient or human research subject control;

(B) Visitor control, including—

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

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

(C) Contamination control;

(D) Waste control; and

(E) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

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

(3) *Safety precautions.*

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

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

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

(*b*) A room, with a private sanitary facility, with another individual who also has received therapy with unsealed byproduct material and who also cannot be released under § 175.103(c)(9) of this Code;

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

(C) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room and authorize visits by individuals under age 18 only on a patient-by-patient basis with the approval of the authorized user after consultation with the radiation safety officer; and

(D) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle the material and items as radioactive waste; and

(E) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of §175.03 of this Code and retain for 3 years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in mSv (mrem) per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

(F) Survey the patient's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room shall not be reassigned until removable contamination is less than 5 Bq (300 disintegrations per minute) per 100 square centimeters.

(G) Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within 3 days after administering the dosage, and retain for the period required by §175.03(k) of this Code a record of each thyroid burden measurement, date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

(ii) A licensee shall notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(4) *Possession of survey instruments.* A licensee authorized to use unsealed byproduct material for which a written directive is required shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 1.0 μSv (0.1 mrem) per hour to 1000 μSv (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The instruments shall be operable and calibrated in accordance with §175.103(c)(2).

(f) *ManualBrachytherapy*

(1) *Use of sources for manual brachytherapy.*

A licensee shall use only brachytherapy sources for therapeutic medical uses:

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

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

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

(i) Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.

(ii) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

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

(3) *Brachytherapy sources accountability.*

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

(ii) As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

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

(4) *Safety instruction.*

In addition to the requirements of 10 CFR §19.12, a licensee shall:

(i) provide oral and written radiation safety instruction, initially and at least annually, to all personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under § 175.103(c)(9) of this Code. To satisfy this requirement, the instruction shall be commensurate with the duties of the personnel and include the—

(A) Size and appearance of the brachytherapy sources;

(B) Safe handling and shielding instructions;

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

(D) Procedures for visitor control, including both:

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

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

(E) Procedures for notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

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

(5) *Safety precautions.*

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

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

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

(C) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room, and authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer.

(D) Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with §175.03 of this Code and retain for 3 years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in mSv (mrem) per hour, the instrument used to make the survey, and the initials of the individual who made the survey; and

(E) Provide the patient with radiation safety guidance that will help to keep the radiation dose to household members and the public as low as reasonably achievable before releasing the patient if the patient was administered a permanent implant.

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

(A) Dislodged from the patient; and

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

(iii) A licensee shall notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(6) *Possession of survey instruments.* A licensee authorized to use sources for manual brachytherapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 1.0 μSv (0.1 mrem) per hour to 1000 μSv (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The instruments shall be operable and calibrated in accordance with §175.103(c)(2).

(7) *Calibration measurements of brachytherapy sources.*

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

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

(B) Determined source positioning accuracy within applicators; and

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

(ii) Instead of a licensee making its own measurements as required in subparagraph (i) of this paragraph, the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with subparagraph (i) of this paragraph.

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

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

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

(i) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay shall be based on the activity determined under § 175.103(f)(7) of this Code.

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

(9) *Therapy-related computer systems.*

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer

systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of:

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

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

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

(iv) The accuracy of the software used to determine sealed source positions from radiographic images.

(g) *Sealed sources for diagnosis*

(1) *Use of sealed sources for diagnosis*. A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

(2) *Availability of survey instrument.* A licensee authorized to use sealed sources for diagnosis shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range 1.0 µSv (0.1 mrem) per hour to 1000 µSv (100 mrem) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 µSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The instrument shall be operable and calibrated in accordance with §175.103(c)(2) of this Code..

(h) *Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units*

(1) *Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit*.

A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

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

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

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

(i) Immediately after removing the last temporary implant source from a patient or a human research subject, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position. The licensee shall not release from confinement for medical care a patient or a human research subject treated by temporary implant until all sources have been removed.

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

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

(i) Only a person specifically licensed by the Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(ii) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

(iii) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Commission or an Agreement State or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(iv) A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with § 175.03(k)(28) of this Code.

(4) *Amendments.* In addition to the requirements specified in §175.103(a)(5) of this Code, a licensee shall apply for and shall have received a license amendment before:

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

(ii) making any change in the location of the teletherapy unit within the treatment room;
(iii) using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

(iv) relocating the teletherapy unit; or

(v) allowing an individual not listed on the licensee's license to perform the duties of the authorized medical physicist.

(5) *Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.*

(i) A licensee shall—

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

(B) Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

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

(D) Develop, implement, and maintain written procedures for ensuring that only approved individuals are present in the treatment room during treatment with the source(s); for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position; or removing the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures shall include—

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

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

(*c*) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

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

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

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

(B) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(iv) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in—

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

(B) The operating procedures for the unit.

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

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

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

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

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

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

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

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

(C) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

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

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

(A) Each radiation monitor shall be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy room.

(B) A licensee shall require any individual entering the treatment room to assure, through the use of the radiation monitors, that radiation levels have returned to ambient levels.

(C) Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

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

(E) A licensee shall maintain a record of the check required by §175.103(i)(7)(iv) of this Code for 3 years. The record shall include the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.

(F) If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in §175.103(i)(7)(v) of this Code.

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

(v) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(vi) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

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

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

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

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

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

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

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

(C) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(D) Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

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

(A) Remaining in the unshielded position; or

(B) Lodged within the patient following completion of the treatment.

(7) *Possession of survey instruments.* A licensee authorized to use a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit shall have in its possession a portable radiation detection survey instrument capable of detecting rates over the range 1.0 µSv (0.1 mrem) per hour to 1000 µSv (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 µSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The instruments shall be operable and calibrated in accordance with §175.103(c)(2) of this Code.

(8) *Dosimetry equipment*.

(i) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met.

(A) The system shall have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration shall have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

(B) The system shall have been calibrated within the previous 4 years. Eighteen to thirty months after that calibration, the system shall have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison shall indicate that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(ii) The licensee shall have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with subparagraph (i) of this paragraph. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in subparagraph (i) of this paragraph.

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

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

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

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

(B) Before medical use under the following conditions:
(*a*) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

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

(*c*) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(C) At intervals not exceeding 1 year.

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

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

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

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

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

(E) On-off error; and

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

(iii) A licensee shall use the dosimetry system described in §

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

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

(v) A licensee shall mathematically correct the outputs determined in clause (A) of subparagraph (ii) of this paragraph for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.

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

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

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

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

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

(B) Before medical use under the following conditions:

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

(*b*) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(C) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

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

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

(A) The output within ± 5 percent;

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

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

(D) Length of the source transfer tubes;

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

(F) Length of the applicators; and

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

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

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

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

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

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

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

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

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

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

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

(B) Before medical use under the following conditions—

(*a*) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(*b*) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(*c*) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(C) At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

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

(A) The output within ±3 percent;

(B) Relative helmet factors;

(C) Isocenter coincidence;

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

(E) On-off error;

(F) Trunnion centricity;

(G) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(H) Helmet microswitches;

(I) Emergency timing circuits; and

(J) Stereotactic frames and localizing devices (trunnions).

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

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

(v) A licensee shall mathematically correct the outputs determined in clause (A) of subparagraph (ii) of this paragraph at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

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

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

(12) *Periodic spot-checks for teletherapy units.*

(i) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month and after making any change for which an amendment is required by §175.103(i)(3) that include determination of—

(A) Timer accuracy, and timer linearity over the range of use;

(B) On-off error;

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

(D) The accuracy of all distance measuring and localization devices used for medical use;

(E) The output for one typical set of operating conditions measured with the dosimetry system described in § 175.103(h)(8)(ii) of this Code; and

(F) The difference between the measurement made in clause (E) of this subparagraph and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(ii) A licensee shall use the dosimetry system described in § 175.103(i)(9) to measurements required in § 175.103(i)(11)(ii)(E) of this Code.

(iii) A licensee shall perform measurements required by subparagraph (i) of this paragraph in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(iv) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check. The licensee shall retain a copy of each such notification for three years.

(v) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of—

(A) Electrical interlocks at each teletherapy room entrance;

(B) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(C) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(D) Viewing and intercom systems;

(E) Treatment room doors from inside and outside the treatment room; and

(F) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(vi) If the results of the checks required in subparagraph (iv) of this paragraph indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(vii) A licensee shall retain a record of each spot-check required by subparagraphs (i) and (iv) of this paragraph, and a copy of the procedures required by subparagraph (ii), in accordance with § 175.03(k)(32) of this Code.

(13) *Periodic spot-checks for remote afterloader units.*

(i) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit—

(A) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

(B) Before each patient treatment with a low dose-rate remote afterloader unit; and

(C) After each source installation.

(ii) A licensee shall perform the measurements required by subparagraph (i) of this paragraph in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(iii) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(iv) To satisfy the requirements of subparagraph (i) of this paragraph, spot-checks shall, at a minimum, assure proper operation of—

(A) Electrical interlocks at each remote afterloader unit room entrance;

(B) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(C) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(D) Emergency response equipment;

(E) Radiation monitors used to indicate the source position;

(F) Timer accuracy;

(G) Clock (date and time) in the unit's computer; and

(H) Decayed source(s) activity in the unit's computer.

(v) If the results of the checks required in subparagraph (iv) of this paragraph indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(vi) A licensee shall retain a record of each check required by subparagraph (iv) of this paragraph and a copy of the procedures required by subparagraph (ii) of this paragraph in accordance with § 175.03(k)(33) of this Code.

(14) *Periodic spot-checks for gamma stereotactic radiosurgery units.*

(i) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit—

(A) Monthly;

(B) Before the first use of the unit on a given day; and

(C) After each source installation.

(ii) A licensee shall—

(A) Perform the measurements required by subparagraph (i) of this paragraph in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(B) Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(iii) To satisfy the requirements of subparagraph (i) of this paragraph, spot-checks shall, at a minimum—

(A) Assure proper operation of—

(*a*) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(*b*) Helmet microswitches;

(*c*) Emergency timing circuits; and

(*d*) Stereotactic frames and localizing devices (trunnions).

(B) Determine—

(*a*) The output for one typical set of operating conditions measured with the dosimetry system described in § 175.103(h)(8)(ii) of this Code;

(*b*) The difference between the measurement made in item (*a*) of this clause (B) and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(*c*) Source output against computer calculation;

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

(*e*) On-off error; and

(*f*) Trunnion centricity.

(iv) To satisfy the requirements of clauses (B) and (C) of subparagraph (i) of this paragraph, spot-checks shall assure proper operation of—

(A) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(B) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(C) Viewing and intercom systems;

(D) Timer termination;

(E) Radiation monitors used to indicate room exposures; and

(F) Emergency off buttons.

(v) A licensee shall arrange for the repair of any system identified in subparagraph (iii) of this paragraph that is not operating properly as soon as possible.

(vi) If the results of the checks required in subparagraph (iv) of this paragraph indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(vii) A licensee shall retain a record of each check required by subparagraphs (iii) and (iv) and a copy of the procedures required by subparagraph (ii) of this paragraph in accordance with § 175.03(k)(34) of this Code.

(15) *Additional technical requirements for mobile remote*

afterloader units.

(i) A licensee providing mobile remote afterloader service shall—

(A) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

(B) Account for all sources before departure from a client's address of use.

(ii) In addition to the periodic spot-checks required by § 175.103(h)(13) of this Code, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks shall be made to verify the operation of—

(A) Electrical interlocks on treatment area access points;

(B) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(C) Viewing and intercom systems;

(D) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

(E) Radiation monitors used to indicate room exposures;

(F) Source positioning (accuracy); and

(G) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(iii) In addition to the requirements for checks in subparagraph (ii) of this paragraph, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(iv) If the results of the checks required in subparagraph (ii) of this paragraph indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(v) A licensee shall retain a record of each check required by subparagraph (ii) of this paragraph in accordance with § 175.03(k)(35) of this Code.

(16) *Radiation surveys*.

(i) In addition to the survey requirement in §175.03 of this Code, a person licensed under this section shall make surveys to ensure that:

(A) the maximum and average radiation levels at 1 meter from the teletherapy source with the source in the off position and the collimators set for a normal treatment field do not exceed 100 ? Sv (10 mrem) per hour and 20 ? Sv (2 mrem) per hour, respectively; and

(B) with the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:

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

(b) radiation levels in unrestricted areas do not exceed the limits specified in §175.03 of this Code.

(ii) If the results of the surveys required in §175.103(h)(16)(i) of this Code indicate any radiation levels in excess of the respective limit specified in §175.103(h)(16)(i)(A) or (B), the licensee shall lock the control in the "off" position and not use the unit:

(A) except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding or the treatment room shielding; or

(B) until the licensee has received a specific exemption from the Department.

(iii) The licensee shall make the survey required by subparagraph (i) of this paragraph at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(iv) A licensee shall retain a record of the radiation surveys required by subparagraph (i) of this paragraph in accordance with § 175.03(k)(36) of this Code.

(17) *Reports of teletherapy and gamma stereotactic radiosurgery surveys, checks, tests, and measurements.* A licensee shall furnish a copy of the records required in §175.103(h)(9) and (11) of this Code and the output from the teletherapy source expressed as Sv (rem) per hour at one meter from the source determined during the surveys required in §175.103(h)(16) of this Code to the Office of Radiological Health within 30 days following completion of the action that initiated the record requirement.

(18) *Modification of a teletherapy unit or room before beginning a treatment program.* If the survey required by §175.103(h)(16) of this Code indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by §175.03 of this Code, before beginning the treatment program, the licensee shall:

(i) either equip the unit with stops or add additional radiation shielding to ensure compliance with §175.03 of this Code;

(ii) perform the survey required by §175.103(h)(16) of this Code again; and

(iii) include in the report required by §175.103(h)(17) of this Code the results of the initial survey, a description of the modification made to comply with §175.103(h)(16)(i) of this Code and the results of the second survey; or

(iv) request and receive a license amendment that authorizes radiation levels in unrestricted areas greater than those permitted by §175.03 of this Code.

(19) *Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.*

(i) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(ii) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(iii) A licensee shall keep a record of the inspection and servicing in accordance with § 175.03(k)(37) of this Code.

(20) *Therapy-related computer systems.*

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of:

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

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

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

(iv) The accuracy of the software used to determine sealed source positions from radiographic images; and

(v) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

(i) *Other Medical Uses of Byproduct Material or Radiation From Byproduct Material*

A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in §175.103(d) through (h) of this Code if—

(1) The applicant or licensee has submitted the information required by § 175.103(a)(6)(ii) through (iv) of this Code; and

(2) The applicant or licensee has received written approval from the Commission in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Commission considers necessary for the medical use of the material.

(j) *Training and experience requirements.*

(1) *Radiation safety officer.* Except as provided in § 175.103(j)(14) of this Code, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 175.103(b)(2) of this Code to be an individual who—

(i) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in subparagraphs (iii) and (iv) of this paragraph. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(A)(*a*) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(*b*) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

(*c*) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(B)(*a*) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(*b*) Have 2 years of full-time practical training and/or supervised experience in medical physics—

(I) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(II) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 175.103(j)(14), 175.103(j)(5), or 175.103(j)(6) of this Code;

(C) Pass an examination, administered by diplomates of the specialty board that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(D) Has completed a structured educational program consisting of both:

(*a*) 200 hours of classroom and laboratory training in the following areas—

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Radiation biology; and

(V) Radiation dosimetry; and

(*b*) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license or permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of byproduct material involving the following—

(I) Shipping, receiving, and performing related radiation surveys;

(II) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(III) Securing and controlling byproduct material;

(IV) Using administrative controls to avoid mistakes in the administration of byproduct material;

(V) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(VI) Using emergency procedures to control byproduct material; and

(VII) Disposing of byproduct material; or

(E) [Reserved]

(ii)(A) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under § 175.103(j)(2)(i) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in subparagraphs (iii) and (iv) of this paragraph; or

(B) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities; and,

(iii) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in subparagraph (iv) of this paragraph and in items (*a*) and (*b*) of clause (A) of subparagraph (i) of this paragraph or items (*a*) and (*b*) of clause (B) of subparagraph (i) of this paragraph or clause (D) of subparagraph (ii) of this paragraph or clauses (A) or (B) of subparagraph (ii) of this paragraph, and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and

(iv) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

(2) *Training for an authorized medical physicist.*

Except as provided in § 175.103(j)(14) of this Code, the licensee shall require the authorized medical physicist to be an individual who—

(i) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in clause (B) of subparagraph (ii) and subparagraph (iii) of this paragraph. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC website.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(A) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(B) Have 2 years of full-time practical training and/or supervised experience in medical physics—

(*a*) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(*b*) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements in § 175.103(j)(14), 175.103(j)(10), or 175.103(j)(13) of this Code; and

(C) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(D) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience shall be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and shall include:

(*a*) Performing sealed source leak tests and inventories;
(*b*) Performing decay corrections;

(*c*) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(*d*) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(*e*) Has obtained written attestation that the individual has satisfactorily completed the requirements in item (*f*) of clause (D) of subparagraph (i) and clauses (A) and (B) of subparagraph (i), or clause (D) of subparagraph (i) of this paragraph, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation shall be signed by a preceptor authorized medical physicist who meets the requirements in §§ 175.103(j)(2), 175.103(j)(14), or equivalent NRC or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(*f*) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

(3) *Training for authorized nuclear pharmacist.*

Except as provided in § 175.103(j)(14) of this Code, the

licensee shall require the authorized nuclear pharmacist to be a pharmacist who—

(i) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in item (*f*) of clause (G) of subparagraph (ii) of this paragraph. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC website.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(A) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(B) Hold a current, active license to practice pharmacy;

(C) Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

(D) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(ii) Has completed 700 hours in a structured educational program consisting of both:

(A) 200 hours of classroom and laboratory training in the following areas—

(B) Radiation physics and instrumentation;

(C) Radiation protection;

(D) Mathematics pertaining to the use and measurement of radioactivity;

(E) Chemistry of byproduct material for medical use; and

(F) Radiation biology; and

(G) Supervised practical experience in a nuclear pharmacy involving—

(*a*) Shipping, receiving, and performing related radiation surveys;

(*b*) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(*c*) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(*d*) Using administrative controls to avoid medical events in the administration of byproduct material; and

(*e*) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(*f*) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in clauses (A) through (C) of subparagraphs (i) or clause (A) of subparagraph (ii) of this paragraph and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

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

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

(i) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in clause (B) of subparagraph (iii) of this paragraph. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC website.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(A) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies as described in clause (A) of subparagraph (iii) of this paragraph; and
(B) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(ii) Is an authorized user under §§ 175.103(j)(5), 175.103(j)(6) of this Code, or equivalent NRC or Agreement State requirements;

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

(*a*) Classroom and laboratory training in the following areas—

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Chemistry of byproduct material for medical use; and

(V) Radiation biology; and

(*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 Agreement State requirements, involving—

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(III) Calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(V) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(VI) Administering dosages of radioactive drugs to patients or human research subjects; and

(VII) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(B) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(5), or 175.103(j)(6) and 175.103(j)(5)(iii)(A)(*b*)(VII) of this Code or equivalent NRC or Agreement State requirements, that the individual has satisfactorily completed the requirements in clause (A) of subparagraph (i) or clause (A) of subparagraph (iii) of this paragraph and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 175.103(d)(1) and 175.103(d)(2) of this Code.

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

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

(i) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in number (VII) of item (*b*) of clause (A) and clause (B) of subparagraph (ii) of this paragraph. (Specialty boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC website.) To be recognized, a specialty board shall require all candidates for certification to:

(A) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs shall include 700 hours of training and experience as described in item (*a*) of clause (A) through number (V) of item (*b*) of clause (A) of subparagraph (ii) of this paragraph. Eligible training programs shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(B) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required; or

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

(*a*) Classroom and laboratory training in the following areas—

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Chemistry of byproduct material for medical use; and

(V) Radiation biology; and

(*b*) Work experience, under the supervision of an authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(6) of this Code, or equivalent NRC or Agreement State requirements. A supervising authorized user, who meets the requirements in § 175.103(j)(6)(ii) of this Code, shall also have experience in administering dosages in the same dosage category or categories (*i.e.*, § 175.103(j)(6)(ii)(A)*(b)*(VII) of this Code) as the individual requesting authorized user status. The work experience shall involve—

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(III) Calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(V) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;

(VI) [Reserved]

(VII) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status—

(*1*) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I–131, for which a written directive is required;

(*2*) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-1312;

(*3*) Parenteral administration of any beta emitter, or a photon- emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or

(*4*) Parenteral administration of any other radionuclide, for which a written directive is required; and

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

(7) *Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).*

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

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

(ii) Is an authorized user under § 175.103(j)(6) for uses listed in §175.103(j)(6)(ii)(A)(*b*)(VIII)(*1*) or (*2*), § 175.103(j)(8) of this Code, or equivalent NRC or Agreement State requirements; or

(iii)(A) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training shall include—

(*a*) Radiation physics and instrumentation;

(*b*) Radiation protection;

(*c*) Mathematics pertaining to the use and measurement of radioactivity;

(*d*) Chemistry of byproduct material for medical use; and

(*e*) Radiation biology; and

(B) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(6), 175.103(j)(7), 175.103(j)(8) of this Code, or equivalent NRC or Agreement State requirements. A supervising authorized user who meets the requirements in § 175.103(j)(6)(ii shall also have experience in administering dosages as specified in §§ 175.103(j)(6)(ii)(A)*(b)*(VII)*(1)* or 175.103(j)(6)(ii)(A)*(b)*(VII)*(2)* of this Code. The work experience shall involve—

(*a*) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(*b*) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(*c*) Calculating, measuring, and safely preparing patient or human research subject dosages;

(*d*) Using administrative controls to prevent a medical event involving the use of byproduct material;

(*e*) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(*f*) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(C) Has obtained written attestation that the individual has satisfactorily completed the requirements in clauses (A) and (B) of subparagraph (iii) of this paragraph, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 175.103(e)(1) of this Code. The written attestation shall be signed by a preceptor authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(6), 175.103(j)(7), 175.103(j)(8) of this Code, or equivalent NRC or Agreement State requirements. A preceptor authorized user, who meets the requirement in § 175.103(j)(6)(b), shall also have experience in administering dosages as specified in §§ 175.103(j)(6 ii)(A)*(b)*(VII)*(1)* or 175.103(j)(6)(ii)(A)*(b)*(VII)*(2)* of this Code.

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

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

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

(ii) Is an authorized user under § 175.103(j)(6) for uses listed in § 175.103(j)(6)(ii)(A)*(b)*(VII)*(2)* of this Code or equivalent NRC or Agreement State requirements; or

(iii)(A) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training shall include—

(*a*) Radiation physics and instrumentation;

(*b*) Radiation protection;

(*c*) Mathematics pertaining to the use and measurement of radioactivity;

(*d*) Chemistry of byproduct material for medical use; and

(*e*) Radiation biology; and

(B) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(6), 175.103(j)(8) of this Code, or equivalent NRC or Agreement State requirements. A supervising authorized user, who meets the requirements in § 175.103(j)(6)(ii) of this Code, shall also have experience in administering dosages as specified in § 175.103(j)(6)(ii)(A)*(b)*(VII)*(2)* of this Code. The work experience shall involve—

(*a*) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(*b*) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(*c*) Calculating, measuring, and safely preparing patient or human research subject dosages;

(*d*) Using administrative controls to prevent a medical event involving the use of byproduct material;

(*e*) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(*f*) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(C) Has obtained written attestation that the individual has satisfactorily completed the requirements in clauses (A) and (B) of subparagraph (iii) of this paragraph, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 175.103(e)(1) of this Code. The written attestation shall be signed by a preceptor authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(6), 175.103(j)(8) of this Code, or equivalent NRC or Agreement State requirements. A preceptor authorized user, who meets the requirements in § 175.103(j)(6)(b), shall also have experience in administering dosages as specified in § 175.103(j)(6)(ii)(A)*(b)*(VII)(2) of this Code.

(9) *Training for the parenteral administration of unsealed byproduct material requiring a written directive.*

Except as provided in § 175.103(j)(14) of this Code, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who—

(i) Is an authorized user under § 175.103(j)(6) for uses listed in §§ 175.103(j)(6) (ii)(A)*(b)*(VII)(3) or 175.103(j)(6) (ii)(A)*(b)*(VII)4) of this Code, or equivalent NRC or Agreement State requirements; or

(ii) Is an authorized user under §§ 175.103(j)(10), 175.103(j)(13) of this Code, or equivalent NRC or Agreement State requirements and who meets the requirements in sub paragraph (iv) of this section; or

(iii) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under §§ 175.103(j)(10) or 175.103(j)(13) of this Code, and who meets the requirements in subparagraph (iv) of this section.

(iv)(A) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training shall include—

(*a*) Radiation physics and instrumentation;

(*b*) Radiation protection;

(*c*) Mathematics pertaining to the use and measurement of radioactivity;

(*d*) Chemistry of byproduct material for medical use; and

(*e*) Radiation biology; and

(B) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(6), 175.103(j)(9) of this Code, or equivalent NRC or Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in § 175.103(j)(6) of this Code shall have experience in administering dosages as specified in §§ 175.103(j)(6) (ii)(A)*(b)*(VII)(3) and/or 175.103(j)(6) (ii)(A)*(b)*(VII)(4) of this Code. The work experience shall involve—

(*a*) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

(*b*) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(*c*) Calculating, measuring, and safely preparing patient or human research subject dosages;

(*d*) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(*e*) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and

(*f*) Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

(C) Has obtained written attestation that the individual has satisfactorily completed the requirements in subparagraphs (ii) or (iii) of this paragraph, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation shall be signed by a preceptor authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(6), 175.103(j)(9) of this Code, or equivalent NRC or Agreement State requirements. A preceptor authorized user, who meets the requirements in § 175.103(j)(6) of this Code, shall have experience in administering dosages as specified in §§ 175.103(j)(6) (ii)(A)*(b)*(VII)(3) and/or 175.103(j)(6) (ii)(A)*(b)*(VII)(4) of this Code.

(10) *Training for use of manual brachytherapy sources.*

Except as provided in §175.103(j)(14) of this Code, a licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under §175.103(f)(1) to be a physician who —

(i) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State, and who meets the requirements in clause (C) of subparagraph (ii) of this paragraph. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC website.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(A) Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(B) Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(ii)(A) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes—

(*a*) 200 hours of classroom and laboratory training in the following areas—

(I) Radiation physics and instrumentation;

(II) Radiation protection;
(III) Mathematics pertaining to the use and measurement of radioactivity; and

(IV) Radiation biology; and

(*b*) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(10) of this Code, or equivalent NRC or Agreement State requirements at a medical institution, involving—

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Checking survey meters for proper operation;

(III) Preparing, implanting, and removing brachytherapy sources;

(IV) Maintaining running inventories of material on hand;

(V) Using administrative controls to prevent a medical event involving the use of byproduct material;

(VI) Using emergency procedures to control byproduct material; and

(B) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(10) of this Code, or equivalent NRC or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by item (*a*) of clause (A) of subparagraph (ii) of this paragraph; and

(C) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(10) of this Code, or equivalent NRC or Agreement State requirements, that the individual has satisfactorily completed the requirements in clause (A) of subparagraph (i), or clauses (A) and (B) of subparagraph (ii) of this paragraph and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 175.103(f)(1) of this Code.

(11) *Training for ophthalmic use of strontium-90.*

Except as provided in § 175.103(j)(14) of this Code, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who—

(i) Is an authorized user under § 175.103(j)(10) of this Code or equivalent NRC or Agreement State requirements; or

(ii)(A) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training shall include—

(*a*) Radiation physics and instrumentation;

(*b*) Radiation protection;

(*c*) Mathematics pertaining to the use and measurement of radioactivity; and

(*d*) Radiation biology; and

(B) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training shall involve

(*a*) Examination of each individual to be treated;

(*b*) Calculation of the dose to be administered;

(*c*) Administration of the dose; and

(*d*) Follow up and review of each individual's case history; and

(C) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(10), 175.103(j)(11) of this Code, or equivalent NRC or Agreement State requirements, that the individual has satisfactorily completed the requirements in subparagraphs (i) and (ii) of this paragraph and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

(12) *Training for use of sealed sources for diagnosis.*
Except as provided in § 175.103(j)(14) of this Code, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under § 175.103(g)(1) of this Code to be a physician, dentist, or podiatrist who—

(i) Is certified by a specialty board whose certification process includes all of the requirements in subparagraphs (ii) and (iii) of this paragraph and whose certification has been recognized by the Commission or an Agreement State. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC website.); or

(ii) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training shall include—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(iii) Has completed training in the use of the device for the uses requested.

(13) *Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.*
Except as provided in § 175.103(j)(14) of this Code, the licensee shall require an authorized user of a sealed source for a use authorized under § 175.103(h)(1) of this Code to be a physician who—

(i) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in clause (C) of subparagraph (ii) and subparagraph (iii) of this paragraph. (The names of board certifications which have

been recognized by the Commission or an Agreement State will be posted on the NRC website.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(A) Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(B) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(ii)(A) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes—

(*a*) 200 hours of classroom and laboratory training in the following areas—

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity; and

(IV) Radiation biology; and

(*b*) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(13) of this Code, or equivalent NRC or Agreement State requirements at a medical institution, involving—

(I) Reviewing full calibration measurements and periodic spot-checks;

(II) Preparing treatment plans and calculating treatment doses and times;

(III) Using administrative controls to prevent a medical event involving the use of byproduct material;

(IV) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(V) Checking and using survey meters; and

(VI) Selecting the proper dose and how it is to be administered; and

(B) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(13) of this Code, or equivalent NRC or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required bysub paragraph (ii)(A)(*b*) of this section; and

(C) Has obtained written attestation that the individual has satisfactorily completed the requirements in clause (A) of subparagraph (i) or clauses (A) and (B) of subparagraph (ii) of this paragraph, and subparagraph (iii) of this paragraph, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation shall be signed by a preceptor authorized user who meets the requirements in §§ 175.103(j)(14), 175.103(j)(13) of this Code, or equivalent NRC or Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(iii) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

(14) *Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.*

(i)(A) An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before October 24, 2002, need not comply with the training requirements of §§ 175.103(j)(1), 175.103(j)(2), or 175.103(j)(3) of this Code, respectively.

(B) An individual identified as a Radiation Safety Officer, an authorized medical physicist, or an authorized nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope between October 24, 2002 and April 29, 2005 need not comply with the training requirements of §§ 175.103(j)(1), 175.103(j)(2), or 175.103(j)(3) of this Code, respectively.

(C) A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of § 175.103(j)(1), § 175.103(j)(2) or § 175.103(j)(3) of this Code, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for purposes of this chapter.

(ii)(A) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee before October 24, 2002, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Subparts D through H of 10 CFR Part 35.

(B) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee who perform only those medical uses for which they were authorized between October 24, 2002 and April 29, 2005, need not comply with the training requirements of Subparts D through H of 10 CFR Part 35.

(C) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of subparts D through H of 10 CFR Part 35 when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for purposes of this chapter.

(iii) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on Department licenses for the same uses for which these individuals are authorized.

(15) *Recentness of training.*

The training and experience specified in §175.103(j)(1) through (14) of this Code shall have been obtained within the 7 years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

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Notes: On March 15, 2011, the Board of Health repealed and reenacted §175.103 of the Health Code primarily in order to maintain compatibility with changes made by the Nuclear Regulatory Commission to Part 35 in Title 10 of the Code of Federal Regulations concerning medical use of byproduct material.

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SPECIAL MATERIALS

HEALTH AND MENTAL HYGIENE

■ **NOTICE**

NOTICE OF THE ESTABLISHMENT OF MOBILE FOOD VENDOR PERMIT WAITING LISTS BY THE NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE

On May 9, 2011, the Department of Health and Mental Hygiene (DOHMH) will establish, utilizing a random selection process, three (3) separate waiting lists for Green Cart permits -- two-year, full-term mobile food vendor unit permits authorizing the holders thereof to sell only raw fresh fruits and vegetables within designated areas of the City -- for the Bronx, Brooklyn, and Staten Island. At this time, no lists will be created for Manhattan or Queens.

Application packages with detailed instructions for inclusion in the selection process for the Green Cart permit waiting lists may be obtained via the internet at www.nyc.gov/greencarts, by calling 311, or in person at the New York City Department of Consumer Affairs Licensing Center, located at 42 Broadway, 5th Floor, New York, New York 10004, Monday through Friday from 9:00 A.M. to 5:00 P.M.

In order to be eligible for inclusion in the selection process to establish these waiting lists,
- the applicant must have a valid mobile food vendor license (ID badge) issued by the Department of Health and Mental Hygiene **on or before Friday, April 29, 2011,** and
- the applicant must submit a completed waiting list application form by mail only to the address listed on the application form with a postmark dated **on or before Friday, April 29, 2011.**

All eligible waiting list applications will secure a waiting list position.

In accordance with Local Law No. 9 of 2008, preference or priority for a waiting list position will be given to those applicants who are members of a "preference category" listed in Local Law No.9. This preference or priority will be established by the giving of additional points to those applicants who are:

- already on an existing DOHMH mobile food vending permit waiting list
- United States veterans
- disabled persons

Applicants who do not belong to a preference category/priority group will secure a waiting list position after those who belong to a preference category/priority group.

For each borough list, all applications will be randomly assigned a number on each waiting list. Preference category/priority group applicants will be randomized separately and prioritized accordingly. If the applicant secures a waiting list position based upon a claim of being in one or more of the preference categories/priority groups mentioned above, the applicant will have to provide proof of such claim when the applicant is notified to apply for the Green Cart permit. If an applicant fails to do so, he or she will be disqualified from all Green Cart waiting lists.

Mobile Food Vendor License Applications: Application packages for a mobile food vendor operator's license (ID badge) may also be obtained via the internet at www.nyc.gov/greencarts, by calling 311, or in person at the New York City Department of Consumer Affairs Licensing Center, located at 42 Broadway, 5th Floor, New York, New York 10004, Monday through Friday from 9:00 A.M. to 5:00 P.M. Interested persons should allow at least twenty-five (25) business days to receive the necessary tax documentation and register for and pass the Department's "Mobile Food Vendor Food Protection Course", both of which are required prior to applying for a mobile food vending license.

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LATE NOTICES

ADMINISTRATION FOR CHILDREN'S SERVICES

■ **PUBLIC HEARING**

SHORT NOTICE

NOTICE IS HEREBY GIVEN that a Public Hearing will be held at the Administration for Children's Services, 150 William Street, 9th Floor – Conference Room 9C1, Borough of Manhattan, on March 24, 2011, commencing at 10:00 A.M. on the following:

IN THE MATTER of one proposed contract between the Administration for Children's Services of the City of New York and Abbott House, 100 North Broadway, Irvington, NY 10533, for the provision of non-secure detention group home services at 25-23 99th Street, East Elmhurst, NY 11369. The contract amount is $3,306,905.00. The term of the contract is 3-years from April 1, 2011 to March 31, 2014, with an option to renew for up to three years. The E-PIN is 13011N0001001.

The proposed contractor has been selected by means of the Negotiated Acquisition Method, pursuant to Section 3-04 (d) (2) of the Procurement Policy Board Rules.

A copy of the draft contract is available for public inspection at the New York City Administration for Children's Services, Office of Procurement, 150 William Street, 9th Floor, Borough of Manhattan, on March 23, 2011, between the hours of 10:00 A.M. and 4:00 P.M. Please contract Patricia Chabla, Agency Chief Contracting Officer at (212) 341-3505 to arrange a viewing of the draft contract.

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ECONOMIC DEVELOPMENT CORPORATION

CONTRACTS

■ **SOLICITATIONS**

Goods & Services

SACKMAN STREET INDUSTRIAL – Request for Proposals – PIN# 4862-0 – DUE 04-06-11 AT 4:00 P.M. – NYCEDC is seeking proposals for the sale and development of a site consisting of Lots 19, 21 and 23 on Block 3676 of the Borough of Brooklyn for an as-of-right industrial use.

Companies who have been certified with the New York City Department of Small Business Services as Minority and Women Owned Business Enterprises ("M/WBE") are strongly encouraged to apply. To learn more about M/WBE certification and NYCEDC's M/WBE program, please visit http://www.nycedc.com/opportunitymwdbe.

Respondents may submit questions and/or request clarifications from NYCEDC no later than 4:00 P.M. on Wednesday, March 30, 2011. Questions regarding the subject matter of this RFP should be directed to sackmanstreetrfp@nycedc.com. For all questions that do not pertain to the subject matter of this RFP please contact NYCEDC's Contracts Hotline at (212) 312-3969. Answers to all questions will be posted by Friday, April 1, 2011, to www.nycedc.com/RFP.

To download a copy of the solicitation documents please visit www.nycedc.com/RFP. Please submit three (3) sets of your proposal to NYCEDC.

Use the following address unless otherwise specified in notice, to secure, examine or submit bid/proposal documents, vendor pre-qualification and other forms; specifications/ blueprints; other information; and for opening and reading of bids at date and time specified above.
Economic Development Corp., 110 William Street, 6th Floor, New York, NY 10038. Maryann Catalano (212) 312-3969; Fax: (212) 312-3918; sackmanstreetrfp@nycedc.com

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