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

BRONX BOROUGH PRESIDENT

■ **PUBLIC HEARINGS**

A PUBLIC HEARING IS BEING CALLED by the President of the Borough of the Bronx, Honorable Ruben Diaz Jr. on Tuesday, December 21, 2010 commencing at 1:00 P.M. (please note later start time) in the offices of the Borough President Room 206, 851 Grand Concourse the Bronx, New York 10451 on the following items:

CD #3-ULURP APPLICATION NO: C 110114 HUX -
IN THE MATTER OF an application submitted by the Department of Housing Preservation and Development (HPD) pursuant to Section 505 of the General Municipal (Urban Renewal) Law of New York State and Section 197-c of the New York City Charter for the second amendment to the Melrose Commons Urban Renewal Plan for the Melrose Commons Urban Renewal Area, Borough of the Bronx, Community District 3.

CD #3-ULURP APPLICATION NO: C 110115 ZMX -
IN THE MATTER OF AN application submitted by the New York City Department of Housing Preservation and Development (HPD) pursuant to Sections 197-c and 201 of the New York City Charter for an amendment of the Zoning Map, Section No. 6a:

1. changing from an R7-2 District to an R7A District property bounded by East 163rd Street, a line 100 feet northwesterly of Melrose Avenue, East 162nd Street, and Courtlandt Avenue;

2. changing from an R7-2 District to an R8 District property bounded by East 163rd Street, Melrose Avenue, East 162nd Street, and a line 100 feet northwesterly of Melrose Avenue; and

3. establishing within the proposed R8 District a C1-4 District bounded by East 163rd Street, Melrose avenue, East 162nd Street, and a line 100 feet northwesterly of Melrose Avenue;

Borough of the Bronx, Community District 3, as shown on a diagram (for illustrative purpose only) dated October 25, 2010.

CD #5 - ULURP APPLICATION NO: C 110091 HAX -
IN THE MATTER OF AN application submitted by the NYC Department of Housing Preservation and Development (HPD):

Pursuant to Article 16 of the General Municipal Law of New York State for:

a) the designation of property located at 2311 Tiebout Avenue (Block 3146, Lot 67) as an Urban Development Action Area; and

b) an Urban Development Action Area Project for such area; and

2) pursuant to Section 197-c of the New York City Charter for the disposition of such property to a developer selected by HPD;

To facilitate development of a 7-story building with approximately 20 dwelling units.

CD #6 - ULURP APPLICATION NO: C 110100 ZSX -
IN THE MATTER OF an application submitted by the NYC Department of Housing Preservation and Development (HPD) pursuant to Sections 197-c and 201 of the New York City Charter for the grant of a special permit pursuant to Section 74-681(a)(2) of the Zoning Resolution to allow that portion of the right-of-way or yard where a railroad or transit use ahs been permanently discontinued or terminated to be included in the lot area for a proposed mixed-use development on property located at 1175 East Tremont Avenue a.k.a. 1160 Lebanon Street (Site A, Block 4007, Lot 15), in an M1-1 District, Borough of the Bronx, Community District 6.

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

CD #6 - ULURP APPLICATION NO: C 110101 HAX -
IN THE MATTER OF an application submitted by the NYC Department of Housing Preservation and Development (HPD):

1. Pursuant to Article 16 of the General Municipal Law of New York State for:

   a) the designation of properties located at 1157-1167 East 178th Street a.k.a. 1172 East Tremont Avenue (Site B, Block 3909, Lot 8 and 1160 Lebanon Street a.k.a. 1175 East Tremont Avenue (Site A, Block 4007, Lot 15) as an Urban Development Action Area; and

   b) an Urban Development Action Area Project for such area; and

2. Pursuant to Section 197-c of the New York City Charter for the disposition of such property to a developer selected by HPD;

To facilitate development of three mixed use building with a total of approximately 141 dwelling units.

CD #6-ULURP APPLICATION NO: C 110103 ZSX-
IN THE MATTER OF an application submitted by the New York City Department of Housing Preservation and Development (HPD) pursuant to Sections 197-c and 201 of the New York City Charter for the grant of a special permit pursuant to Section 74-681 (a)(2) of the Zoning Resolution to allow that portion of the right-of-way or yard where railroad or transit use has been permanently discontinued or terminated to be included in the lot area for a proposed mixed-use development on property located at 1157-1167 East 178th Street a.k.a. 1172 East Tremont Avenue (Site B, Block 3909, Lot 8) in an M1-1 District, Borough of the Bronx, Community District 6.

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

ANYONE WISHING TO SPEAK AT THIS PUBLIC HEARING MAY REGISTER AT THE HEARING. PLEASE DIRECT ANY QUESTIONS CONCERNING THESE MATTERS TO THE BRONX BOROUGH PRESIDENT'S OFFICE 718-590-6124

d14-20

CITY COUNCIL

■ **HEARINGS**

HEARING CANCELLATION NOTICE
BY THE COMMITTEE ON RULES, PRIVILEGES AND ELECTIONS

THE COMMITTEE ON RULES, PRIVILEGES AND ELECTIONS HAS CANCELLED A PREVIOUSLY SCHEDULED HEARING FOR MONDAY, DECEMBER 20, 2010, AT 10:30 A.M. IN THE 16TH FLOOR HEARING ROOM AT 250 BROADWAY, NEW YORK, NY 10007.

Michael M. McSweeney
City Clerk, Clerk of the Council

☛ **d17-20**

COMMUNITY BOARDS

■ **PUBLIC HEARINGS**

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

BOROUGH OF MANHATTAN

COMMUNITY BOARD NO. 03 - Tuesday, December 21, 2010, 6:30 P.M., Public School 20, 166 Essex Street (E. Houston and Stanton Sts.), New York, NY

#110140HAM
Application for UDAAP designation and project approval, related disposition of city-owned property, to facilitate the construction of a new 12-story mixed-use building with approximately 16 residential units.

#110141PQM
Acquisition of property to facilitate the proposed new construction.

#110165ZRM
Amendment to the Zoning Resolution, Section 23-962, to enable the proposed new building to be constructed on property which is currently city-owned.

#110124ZCM
Certification, pursuant to Zoning Resolution Section 95-04, as to whether a transit easement volume is required.

d15-21

COMPTROLLER

■ **PUBLIC HEARINGS**

NOTICE IS HEREBY GIVEN that a Public Hearing will be held in the Municipal Building, One Centre Street, Room 650 Conference Room, on Thursday, December 30, 2010 at 10:30 A.M. on the following item:

IN THE MATTER of a proposed contract between the New York City Office of the Comptroller, and Aksia LLC, with its principal place of business at 599 Lexington Avenue, 46th Floor, New York, NY 10022, for Hedge Fund Investment Consulting Services for the New York City Employees' Retirement System, the New York City Police Pension Fund, Subchapter 2, and the New York City Fire Department Pension Fund, Subchapter Two. The term of the contract will commence as of January 1, 2011 for a period of three years with one or more additional renewal periods not to exceed four years. The cost of the services will be paid from the corpus of the Systems and total $2,800,000.

The proposed contractor was selected pursuant to a competitive sealed proposal process in accordance with Section 3-03 of the PPB Rules.

A copy of the contract, or excerpts thereof, can be seen at the Office of the Comptroller, One Centre Street, Room 650, New York, New York 10007, Monday through Friday, excluding holidays commencing on December 17, 2010 through December 29, 2010 between 10:00 A.M. - Noon and 1:30 P.M. - 4:30 P.M.

☛ **d17**

CONSUMER AFFAIRS

■ **PUBLIC HEARINGS**

NOTICE IS HEREBY GIVEN, PURSUANT TO LAW, that the New York City Department of Consumer Affairs will hold a Public Hearing on Wednesday, Decemeber 22, 2010, at 2:00 P.M., at 66 John Street, 11th floor, in the Borough of Manhattan, on the following petitions for sidewalk café revocable consent:

1) 172 Bleeker St. Rest., Inc.
172 Bleecker Street, in the Borough of Manhattan
(To continue to, maintain, and operate an unenclosed sidewalk café for a term of two years.)

2) 172 Bleeker St. Rest., Inc.
190 Sullivan Street, in the Borough of Manhattan
(To continue to, maintain, and operate an unenclosed sidewalk café for a term of two years.)

3) 30 E. 30 Zana Inc.
30 East 30th Street, in the Borough of Manhattan
(To continue to, maintain, and operate an unenclosed sidewalk café for a term of two years.)

4) 44th and Ninth Restaurant, Inc.
623 Ninth Avenue, in the Borough of Manhattan
(To continue to, maintain, and operate an unenclosed sidewalk café for a term of two years.)

5) 62nd & 1st LLC
1125 First Avenue, in the Borough of Manhattan
(To continue to, maintain, and operate an unenclosed sidewalk café for a term of two years.)

6) Canz Suffolk 1 Inc.
40-11 30th Avenue, in the Borough of Queens
(To establish, maintain, and operate an unenclosed sidewalk café for a term of two years.)

7) Chelsea Park LLC
118 Tenth Avenue, in the Borough of Manhattan
(To establish, maintain, and operate an unenclosed sidewalk café for a term of two years.)

8) Cucina Romana Inc.
1429 Fifth Avenue, in the Borough of Manhattan
(To continue to, maintain, and operate an unenclosed sidewalk café for a term of two years.)

9) Delillo Pastry Shop, Inc.
610 East 187th Street, in the Borough of Bronx
(To establish, maintain, and operate an unenclosed sidewalk café for a term of two years.)

10) La Traviata Corp.
139 Montague Street, in the Borough of Brooklyn
(To continue to, maintain, and operate an enclosed sidewalk café for a term of two years.)

11) Masaniello Restaurant Corp.
72 Fifth Avenue, in the Borough of Brooklyn
(To continue to, maintain, and operate an unenclosed sidewalk café for a term of two years.)

12) Meath Trails, Inc.
61 Second Avenue, in the Borough of Manhattan
(To continue to, maintain, and operate an unenclosed sidewalk café for a term of two years.)

13) Mezcals of 5th Ave. Rest Corp.
223 5th Avenue, in the Borough of Brooklyn
(To continue to, maintain, and operate an unenclosed sidewalk café for a term of two years.)

14) New Store Restaurant Corp.
447 Amsterdam Avenue, in the Borough of Manhattan
(To continue to, maintain, and operate an unenclosed sidewalk café for a term of two years.)

15) S.A.V. Associates Inc.
2637 Broadway, in the Borough of Manhattan
(To continue to, maintain, and operate an unenclosed sidewalk café for a term of two years.)

16) Sibeca Corporation
40-18 Broadway, in the Borough of Queens
(To continue to, maintain, and operate an enclosed sidewalk café for a term of two years.)

Individuals requesting Sign Language Interpreters should contact the Department of Consumer Affairs, Licensing division, 42 Broadway, 5th Floor, New York, NY 10004, (212) 487-4379, no later than five (5) business days before the hearing.

☛ **d17**

LANDMARKS PRESERVATION COMMISSION

■ **PUBLIC HEARINGS**

NOTICE IS HEREBY GIVEN THAT PURSUANT to the provisions of 3020 of the New York City Charter and Chapter 3 of Title 24 of the Administrative Code of the City of New York (Sections 25-303 and 25-313) that on **Tuesday, January 4, 2011 at 9:30 A.M.,** at the Landmarks Preservation Commission will conduct a *public hearing* in the Public Meeting Room of the Landmarks Preservation Commission, located at The Municipal Building, 1 Centre Street, 9th Floor North, City of New York with respect to the following proposed Landmark and Landmark Site. Any person requiring reasonable accommodation in order to participate in the hearing should call or write the Landmarks Preservation Commission, [Municipal Building, 1 Centre Street, 9th Floor North, New York, NY 10007, (212) 669-7700] no later than five (5) business days before the hearing. There will also be a public meeting on that day.

ITEM TO BE HEARD

BOROUGH OF BROOKLYN

PUBLIC HEARING ITEM NO. 1
LP-2465
FRANKLIN BUILDING, 186 Remsen Street (aka 184-188 Remsen Street), Brooklyn.
Landmark Site: Borough of Brooklyn Tax Map Block 255, Lot 42

d16-j3

LOFT BOARD

■ **PUBLIC HEARINGS**

NOTICE IS HEREBY GIVEN PURSUANT TO ARTICLE 7 OF THE PUBLIC OFFICERS LAW that the New York City Loft Board will have its monthly Board meeting and a public hearing on the amendments to Sections 2-05 and 2-08 to comport with Multiple Dwelling Law 281(5) on **Thursday, January 20, 2011. The meeting will be held at 2:00 P.M. at Spector Hall, 22 Reade Street, 1st Floor.** The proposed agenda will include cases and general business.

The general public is invited to attend and observe the proceedings. Written comments regarding the proposed amended rules may be sent to the New York City Loft Board at 100 Gold Street, 2nd Floor, New York, NY 10038 to the attention of Ms. Alexander on or before January 14, 2011. Persons seeking to testify are requested to notify Ms. Alexander at 100 Gold Street, 2nd Floor, New York, NY 10038 or by telephone at (212) 566-5663.

d15-17

TRANSPORTATION

■ **PUBLIC HEARINGS**

NOTICE IS HEREBY GIVEN, pursuant to law, that the following proposed revocable consents, have been scheduled for a public hearing by the New York City Department of Transportation. The hearing will be held at 55 Water Street, 9th Floor, Room 945 commencing at 2:00 P.M. on Wednesday, December 22, 2010. Interested parties can obtain copies of proposed agreements or request sign-language interpreters (with at least seven days prior notice) at 55 Water Street, 9th Floor SW, New York, NY 10041, or by calling (212) 839-6550.

#1 In the matter of a proposed revocable consent authorizing 122 Washington Place LLC to continue to maintain and use a stoop on the north sidewalk of Washington Place, east of Barrow, in the Borough of Manhattan. The proposed revocable consent is for a term of ten years from July 1, 2010 to June 30, 2020 and provides among other terms and conditions for compensation payable to the city according to the following schedule:

For the period from July 1, 2010 to June 30, 2020 - $25/annum

the maintenance of a security deposit in the sum of $1,200 and the filing of an insurance policy in the minimum amount of $250,000/$1,000,000 for bodily injury and property damage for each occurrence in the aggregate amount of $100,000.

#2 In the matter of a proposed revocable consent authorizing Farid Jaber to maintain and use a fenced-in planted area on the south sidewalk of Jewel Avenue, east of 112th Street and on the east sidewalk of 112th Street, south of Jewel Avenue, in the Borough of Queens. The proposed revocable consent is for a term of ten years from the date of approval by the Mayor to June 30, 2021 and provides among other terms and condition for compensation payable to the city according to the following schedule:

For the period from the date of Approval by the Mayor to June 30, 2021 - $936/annum.

the maintenance of a security deposit in the sum of $10,000 and the filing of an insurance policy in the minimum amount of $250,000/$,1,000,000 for bodily injury and property damage for each occurrence in the aggregate amount of $100,000.

#3 In the matter of a proposed revocable consent authorizing 346 West 17th Street, LLC to construct, maintain and use a snowmelt system, under the north sidewalk of West 16th Street, east of Ninth Avenue, in the Borough of Manhattan. The proposed revocable consent is for a term of ten years from the date of approval by the Mayor to June 30, 2021 and provides among other terms and conditions for compensation payable to the following schedule:

From the date of Approval by the Mayor to June 30, 2011 - $8,823/annum

For the period July 1, 2011 to June 30, 2012 - $ 9,093
For the period July 1, 2012 to June 30, 2013 - $ 9,363
For the period July 1, 2013 to June 30, 2014 - $ 9,633
For the period July 1, 2014 to June 30, 2015 - $ 9,903
For the period July 1, 2015 to June 30, 2016 - $10,173
For the period July 1, 2016 to June 30, 2017 - $10,443
For the period July 1, 2017 to June 30, 2018 - $10,713
For the period July 1, 2018 to June 30, 2019 - $10,983
For the period July 1, 2019 to June 30, 2020 - $11,253
For the period July 1, 2020 to June 30, 2021 - $11,523

the maintenance of a security deposit in the sum of $12,000 and the filing of an insurance policy in the minimum amount of $250,000/$1,000,000 for bodily injury and property damage for each occurrence in the aggregate amount of $100,000.

#4 In the matter of a proposed revocable consent authorizing Roswell Avenue Homeowners Association, Inc. to construct, maintain and use a force main, together with a manhole, under, across and along the roadway of Melvin Avenue, northeasterly of Wild Avenue, in the Borough of Staten Island. The proposed revocable consent is for a term of ten years from the date of approval by the Mayor to June 30, 2021 and provides among other terms and condition for compensation payable to the city according to the following schedule:

From the date of Approval by the Mayor to June 30, 2011 - $5,942 /annum

For the period July 1, 2011 to June 30, 2012 - $6,124
For the period July 1, 2012 to June 30, 2013 - $6,306
For the period July 1, 2013 to June 30, 2014 - $6,488
For the period July 1, 2014 to June 30, 2015 - $6,670
For the period July 1, 2015 to June 30, 2016 - $6,852
For the period July 1, 2016 to June 30, 2017 - $7,034
For the period July 1, 2017 to June 30, 2018 - $7,216
For the period July 1, 2018 to June 30, 2019 - $7,398
For the period July 1, 2019 to June 30, 2020 - $7,580
For the period July 1, 2020 to June 30, 2021 - $7,762

the maintenance of a security deposit in the sum of $10,000 and the filing of an insurance policy in the minimum amount of $250,000/$1,000,000 for bodily injury and property damage for each occurrence in the aggregate amount of $100,000.

#5 In the matter of a proposed revocable consent authorizing Central Park Properties, LLC to construct, maintain and use a fenced-in planted areas and a trash enclosure on the north sidewalk of West 85th Street, between Amsterdam and Columbus Avenues, in the Borough of Manhattan. The proposed revocable consent is for a term of ten years from the date to June 30, 2021 and provide among other terms and conditions for compensation payable to the city according to the following schedule:

For the period from the date of Approval by the Mayor to June 30, 2021 - $100/annum.

the maintenance of a security deposit in the sum of $1,500 and the filing of an insurance policy in the minimum amount of $250,000/$1,000,000 for bodily injury and property damage for each occurrence in the aggregate amount of $100,000.

#6 In the matter of a proposed revocable consent authorizing United Jewish Appeal-Federation of Jewish Philanthropies of New York, Inc. to construct, maintain and use security bollards and a subsurface security wall on and under the south sidewalk of East 59th Street between Park Avenue and Lexington Avenue, in the Borough of Manhattan. The proposed revocable consent is for a term of ten years from the date of approval by the Mayor to June 30, 2021.

There shall be no compensation required for this revocable consent.

the maintenance of a security deposit in the sum of $20,000, and the filing of an insurance policy in the minimum amount of $250,000/$1,000,000 for bodily injury and property damage for each occurrence in the aggregate amount of $100,000.

d1-22

PROPERTY DISPOSITION

CITYWIDE ADMINISTRATIVE SERVICES

MUNICIPAL SUPPLY SERVICES

■ **SALE BY AUCTION**

PUBLIC AUCTION SALE NUMBER 11001-K

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, January 5, 2011 (SALE NUMBER 11001-K). 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.

d8-j5

■ **SALE BY SEALED BID**

SALE OF: 7 LOTS OF MISCELLANEOUS EQUIPMENT, USED/UNUSED.

S.P.#: 11014 **DUE:** December 21, 2010

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.

d8-21

HEALTH AND HOSPITALS CORPORATION

■ SALE BY SEALED BID

FOR SALE 9" TELEVISIONS – Competitive Sealed Bids – PIN# 000041211012 – DUE 01-11-11 AT 3:00 P.M. – Note: If you have any questions regarding this bid, please call Ray Pastorello at (212) 318-4320.

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.
Coler-Goldwater Memorial Hospital, 1 Main Street, Roosevelt Island, New York, NY 10044. Starr Kollore (212) 318-4260, Fax: (212) 318-4253, starr.kollore@nychhc.org

☛ **d17**

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."

CITY UNIVERSITY

■ SOLICITATIONS

Goods

LENS EDGER AND TRACER BLOCKER EQUIPMENT – Sole Source – Available only from a single source - PIN# 041004121006 – DUE 12-28-10 AT 3:00 P.M. – New York City College of Technology will be entering into a purchase order contract with Gerber Coburn Optical, Inc. for the purchase of a Mr. Blue Tracer/Blocker and Mr. Blue Edger. These equipment facilitates automatic and manual binocular tracing of lenses, automatic and manual centering, drilling, milling, beveling and grooving of high base optical lenses. This notice is not an invitation for competition or interest, but is intended to meet the requirement to give public notie of a Soles Source purchase. This is as per New York State Finance Law, Section 163 which authorizes Sole Source purchases without a formal competitive process in certain circumstances.

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.
New York City College of Technology, 11th Fl., 25 Chapel St., Brooklyn, NY 11201. Paula Morant (718) 473-8960, fax: (718) 473-8997, pmorant@citytech.cuny.edu

d14-20

NOBEL PROCERA CAD/CAM RESTORATIVE DENTISTRY SYSTEM – Sole Source – Available only from a single source - PIN# 041004121005 – DUE 12-27-10 AT 3:00 P.M. – New York City College of Technology will be entering into a purchase order contract with Nobel Biocare USA, LLC for the purchase of a NobelProcera CAD/CAM System. NobelProcera CAD/CAM System facilitates design of a full range of prosthetics, from highly esthetic crowns and bridges to complex inplant related restorations. This system adds a new level of efficiency, precision and cost-effectiveness to dental laboratories. This notice is not an invitation for competition or interest, but is intended to meet the requirement to give public notice of a Sole Source purchase without a formal competitive process in certain circumstances.

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.
New York City College of Technology, 11th Fl., 25 Chapel St., Brooklyn, NY 11201. Paula Morant (718) 473-8960, fax: (718) 473-8997, pmorant@citytech.cuny.edu

d13-17

Construction / Construction Services

ELECTRICAL WORK IN LIBRARY CARRELS – Competitive Sealed Bids – PIN# 2011069121310 – DUE 01-27-11 AT 2:00 P.M. – For electrical work in the library to install electrical outlets in carrels at LaGuardia Community College. Winning contractor shall provide all labor, materials, power panels, circuit breakers, receptacles, wires, raceways, supports, wiring devices, as necessary to complete the work as specified in the specifications.

A mandatory site visit and walk through is scheduled for January 18, 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.
City University, 31-10 Thomson Avenue, Room E-405, Purchasing, Long Island City, NY 11101.
Tawanikka Smith (718) 482-5590, fax: (718) 609-2166, purchasing@lagcc.cuny.edu

☛ **d17**

CITYWIDE ADMINISTRATIVE SERVICES

MUNICIPAL SUPPLY SERVICES

■ SOLICITATIONS

Goods

VALVE, RADIATOR – Competitive Sealed Bids – PIN# 8571100270 – DUE 01-07-11 AT 10:30 A.M.
● **WATER METER, POSITIVE DISPLACEMENT** – Competitive Sealed Bids – PIN# 8571100369 – DUE 01-07-11 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, 18th Floor, New York, NY 10007.
Anna Wong (212) 669-8610, fax: (212) 669-7603, dcasdmssbids@dcas.nyc.gov

☛ **d17**

GROCERIES - DJJ – Competitive Sealed Bids – PIN# 8571100307 – DUE 12-22-10 AT 10:00 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, 18th Floor, New York, NY 10007.
Anna Wong (212) 669-8610, fax: (212) 669-7603, dcasdmssbids@dcas.nyc.gov

☛ **d17**

■ 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.

jy17-j4

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.

jy17-j4

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.

jy17-j4

COMPTROLLER

AUDIT

■ VENDOR LISTS

Services (Other Than Human Services)

PREQUALIFIED LIST - CPA FIRMS – NOTICE OF INVITATION TO APPLY FOR PREQUALIFIED LIST - CPA FIRMS

The New York City Office of Comptroller maintains a LIST OF PREQUALIFIED CPA FIRMS to provide auditing services and other services to City agencies. Agencies are required to solicit external CPA audit services from firms on this list.

In order to be considered for placement on the List, firms must:

1. Be registered with the New York State Education Department to practice in the State of New York, under the firm's current organizational status.

2. Have had a System peer review of the firm's auditing practice within the last 3 years, in accordance with AICPA Standards, and received an unmodified opinion.

3. Submit completed City Vendex Vendor and Principal Questionnaires to both the Comptroller's Office and Mayor's Office of Contract Services.

Applications to be considered for placement on the List may be downloaded from the New York City Office of the Comptroller's website at http:www.comptroller.nyc.gov/bureaus/audit/cpaquestionaire.shtm (Application for the CPA List). You may also contact Mr. Dennis J. Hochbaum, Director Quality Assurance, at (212) 669-8887, or write to his attention at: The City of New York, Office of the Comptroller Bureau of Audit, One Centre Street, Room 1100 North, New York, NY 10007.

PPB Rule Section 3-10 (E)(K)

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.
Comptroller's Office, 1 Centre Street, Room 1100N
New York, NY 10007. Dennis Hochbaum (212) 669-8887
fax: (212) 669-8652, DHochba@comptroller.nyc.gov

d13-17

FINANCIAL INFORMATION SERVICES AGENCY

■ AWARDS

Services (Other Than Human Services)

INFOPRINT PRINTER MAINTENANCE AND USAGE – Contract Change – PIN# 12711EX0007 – AMT: $181,496.70 – TO: InfoPrint Solutions Company, LLC, Bldg. 4, E9-28, 6300 Diagonal Highway, Boulder, CO 80301.

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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

HEALTH AND MENTAL HYGIENE

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

■ **AWARDS**

Human / Client Services

VICINATAS HALL SUPPORTED SRO, NY/NY III – Competitive Sealed Proposals – Judgment required in evaluating proposals - PIN# 08PO076325R0X00 – AMT: $1,786,000.00 – TO: Lantern Community Services, Inc., 49 West 37th Street, New York, NY 10018.

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HOMELESS SERVICES

OFFICE OF 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

PROCUREMENT

■ **SOLICITATIONS**

Construction Related Services

WINDOW REPLACEMENT AT 2155 DEAN STREET, BROOKLYN, N.Y. – Competitive Sealed Bids – PIN# 07111S021494 – DUE 01-18-11 AT 11:00 A.M. – Mandatory pre-bid conference has been scheduled on January 4, 2011 at 10:00 A.M. at 2155 Dean Street, Brooklyn, NY 11233.

The Exterior Window Replacement of Dean Street Family Residence bid package and drawing will be available for pick up on December 20, 2010 at the Bid Desk of 33 Beaver Street, New York, NY 10004.

"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. Please refer to the bid documents for further information.

Bidders are further advised that the Agency has established a 15 percent Subcontractor Utilization Plan for Minority Women Business Enterprise (M/WBE) for this contract.

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, New York, NY 10004. Anthony Salako (212) 361-8445 fax: (917) 637-7069, asalako@dhs.nyc.gov

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HUMAN RESOURCES ADMINISTRATION

■ **AWARDS**

Human / Client Services

SCATTER SITE HOUSING – Renewal – PIN# 06911H046515 – AMT: $5,855,625.00 – TO: St. Nicks Alliance Corp., 11 Catherine Street, Brooklyn, NY 11211. E-PIN: 06907P0033CNVR001. Contract Period: 07/01/2010 - 06/30/2013.

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INFORMATION TECHNOLOGY AND TELECOMMUNICATIONS

AGENCY CHIEF CONTRACTING OFFICER

■ **AWARDS**

Services (Other Than Human Services)

MAINTENANCE AND TECHNICAL SERVICES FOR SOFTWARE AG LICENSES – Sole Source – Available only from a single source - PIN# 85810S0009001 – AMT: $14,127,600.00 – TO: Software AG USA, Inc., 11700 Plaza America Drive, Suite 700, Reston, VA 20190. DOITT is purchasing maintenance and technical services for software AG licenses. The city owns software AG perpetual licenses and the contractor is the only entity that can provide software maintenance services for its proprietary licensed software applications. The notice of intent to enter sole source negotiations was published from June 29, 2010 through July 6, 2010 in the City Record.

This award was procured through the Sole Source Procurement method pursuant to Section 3-05 of the Procurement Policy Board Rules.

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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

■ **AWARDS**

Construction Related Services

RECONSTRUCTION OF THE TENNIS HOUSE – Sole Source – Available only from a single source - PIN# 8462009B073D04 – AMT: $94,373.68 – TO: Prospect Park Alliance, 95 Prospect Park West, Brooklyn, New York 11215.

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CONTRACT ADMINISTRATION

■ **SOLICITATIONS**

Construction / Construction Services

CONSTRUCTION AND RECONSTRUCTION OF PLAYGROUNDS IN SCHOOLS YARDS AND CONSTRUCTION OF A HORSE RIDING ARENA – Competitive Sealed Bids – DUE 01-19-11 AT 10:30 A.M. –
PIN# 8462011C000C04 - Const./reconst. of playgrounds in school yards
PIN# 8462010R149C01 - Const. of a horse riding arena
At PS 123K and 239Q, known as Contract #CNYG-109MA2. Located West of Father Capodanno Boulevard and North of Seaview Avenue, in Ocean Breeze Park, Staten Island, known as Contract #R149-608M.
This procurement is subject to participation goals for MBEs and/or WBES as required by Local Law 129 of 2005.

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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SCHOOL CONSTRUCTION AUTHORITY

CONTRACT SERVICES

■ **SOLICITATIONS**

Construction / Construction Services

FLOOD ELIMINATION, EXTERIOR MASONRY, ROOFS AND PARAPETS – Competitive Sealed Bids – PIN# SCA11-13528D-1 – DUE 1-11-11 AT 2:30 P.M. – PS 85 (Queens). Project Range: $3,640,000.00 to $3,835,000.00. Non-refundable document fee.

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.
School Construction Authority, 30-30 Thomson Avenue, First Floor, Long Island City, NY 11101.
Ricardo Forde (718) 752-5288, fax: (718) 472-0477, rforde@nycsca.org

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AGENCY RULES

HEALTH AND MENTAL HYGIENE

■ **NOTICE**

NOTICE OF INTENTION TO AMEND ARTICLE 151 OF THE NEW YORK CITY HEALTH CODE

In compliance with Section 1043(b) of the New York City Charter and pursuant to the authority granted to the Board of Health by Section 558 of the Charter, notice is hereby given of intention to amend Article 151 (Pest Prevention and Management) of the New York City Health Code.

NOTICE IS HEREBY GIVEN THAT THE DEPARTMENT WILL HOLD A PUBLIC HEARING ON THE PROPOSAL ON MONDAY, JANUARY 24, 2011 FROM 10:00 A.M. TO 12:00 NOON IN THE THIRD FLOOR BOARDROOM (ROOM 330) AT 125 WORTH STREET, NEW YORK, NEW YORK 10013.

PERSONS INTERESTED IN PRE-REGISTERING TO SPEAK SHOULD NOTIFY, IN WRITING, RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, 125 WORTH STREET, CN-31, NEW YORK, NEW YORK; (212) 788-5010 BY 5:00 P.M., FRIDAY, JANUARY 21, 2011. PLEASE INCLUDE A TELEPHONE NUMBER WHERE, IF NECESSARY, YOU MAY BE REACHED DURING NORMAL WORKING HOURS. SPEAKERS WILL BE LIMITED TO FIVE (5) MINUTES.

PERSONS WHO REQUEST THAT A SIGN LANGUAGE INTERPRETER OR OTHER FORM OF REASONABLE ACCOMMODATION FOR A DISABILITY BE PROVIDED AT THE HEARING ARE ASKED TO NOTIFY RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, 125 WORTH STREET CN-31, NEW YORK, NEW YORK 10013; (212) 788-5010 BY MONDAY, JANUARY 10, 2011.

REGISTRATION WILL BE ACCEPTED AT THE DOOR UNTIL 12:00 NOON. HOWEVER, PREFERENCE WILL BE GIVEN TO THOSE WHO PREREGISTER.

WRITTEN COMMENTS REGARDING THE PROPOSAL ADDRESSED TO THE ATTENTION OF THE BOARD OF HEALTH MUST BE SUBMITTED TO RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, BY MAIL TO 125 WORTH STREET CN-31, NEW YORK, NEW YORK 10013, BY FAX TO (212) 788-4315, BY E-MAIL TO RESOLUTIONCOMMENTS@HEALTH.NYC.GOV OR ELECTRONICALLY (WITHOUT ATTACHMENTS) THROUGH www.nyc.gov/nycrules OR http://www.nyc.gov/html/doh/html/notice/notice.shtml ON OR BEFORE 5:00 P.M., MONDAY, JANUARY 24, 2011. ATTACHMENTS TO ONLINE COMMENTS MUST BE MAILED OR FAXED. COMMENTS RECEIVED AFTER JANUARY 24, 2011 WILL BE CONSIDERED TO THE EXTENT POSSIBLE.

WRITTEN COMMENTS RECEIVED BY THE SECRETARY TO THE BOARD OF HEALTH AND A 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 THE OFFICE OF THE SECRETARY. 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.

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 Department is requesting that the Board amend §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 Department is therefore requesting that the Board further amend 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. If the Board approves this new section, the table of section headings would also require amendment.

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 XXX, 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 XXX 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 XXX, 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 INTENTION TO AMEND 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, notice is hereby given of the proposed amendment of Article 7 (Administrative Tribunal) of the New York City Health Code (the "Health Code").

NOTICE IS HEREBY GIVEN THAT THE DEPARTMENT OF HEALTH AND MENTAL HYGIENE WILL HOLD A PUBLIC HEARING ON THE PROPOSAL FROM 10:00 A.M. to 12:00 P.M. ON FRIDAY, JANUARY 21, 2011 IN THE THIRD FLOOR BOARD ROOM (ROOM 330) AT 125 WORTH STREET, NEW YORK, NEW YORK 10013.

PERSONS INTERESTED IN PRE-REGISTERING TO SPEAK SHOULD NOTIFY, IN WRITING, RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, 125 WORTH STREET CN-31, NEW YORK, NEW YORK; (212) 788-5010 BY 5:00 P.M. THURSDAY, JANUARY 20, 2011. PLEASE INCLUDE A TELEPHONE NUMBER WHERE, IF NECESSARY, YOU MAY BE REACHED DURING NORMAL BUSINESS HOURS. SPEAKERS WILL BE LIMITED TO FIVE (5) MINUTES.

PERSONS WHO REQUEST THAT A SIGN LANGUAGE INTERPRETER OR OTHER FORM OF REASONABLE ACCOMMODATION FOR A DISABILITY BE PROVIDED AT THE HEARING ARE ASKED TO NOTIFY RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, 125 WORTH STREET CN-31, NEW YORK, NEW YORK 10013; (212) 788-5010 BY JANUARY 14, 2011. REGISTRATION WILL BE ACCEPTED AT THE DOOR UNTIL 12:00 P.M. HOWEVER, PREFERENCE WILL BE GIVEN TO THOSE WHO PREREGISTER.

WRITTEN COMMENTS REGARDING THE PROPOSAL ADDRESSED TO THE ATTENTION OF THE BOARD OF HEALTH MUST BE SUBMITTED TO RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, BY MAIL TO 125 WORTH STREET CN-31, NEW YORK, NEW YORK 10013, BY FAX TO (212) 788-4315, BY E-MAIL TO RESOLUTIONCOMMENTS@HEALTH.NYC.GOV OR ONLINE (WITHOUT ATTACHMENTS) AT http://www.nyc.gov/html/doh/html/notice/notice.shtml OR www.nyc.gov/nycrules ON OR BEFORE 5:00 P.M., FRIDAY, JANUARY 21, 2011.ATTACHMENTS TO ONLINE COMMENTS MUST BE MAILED OR FAXED. COMMENTS RECEIVED AFTER JANUARY 21, 2011 WILL BE CONSIDERED TO THE EXTENT POSSIBLE.

WRITTEN COMMENTS RECEIVED BY THE SECRETARY TO THE BOARD OF HEALTH AND A 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 THE OFFICE OF THE SECRETARY. 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.

STATUTORY AUTHORITY
These amendments to the New York City Health Code (the "Health Code") are promulgated pursuant to Sections 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 Department is requesting that the Board further amend §7.09 (Appearances) and §7.11 (Hearings and mail adjudication) of this Article to authorize telephone or electronic adjudications and to facilitate settlements.

The Department believes that allowing hearings to take place by means of telephone and other electronic media would make access to the Administrative Tribunal proceedings much less burdensome to respondents. Currently, respondents are required to travel from all parts of the City to the single Tribunal hearing location at 66 John Street in downtown Manhattan. Travel and waiting times can significantly reduce the time respondents spend attending to their immediate business operations. Authorizing respondents the opportunity to participate in telephone hearings when offered by the Department could relieve that burden. No respondent would be required to participate in a telephone hearing; they would be conducted only in cases where the Department and the respondent were willing to engage in them. While a respondent would waive the right to participate in a public hearing and to cross examine Department witnesses for the benefit of not having to appear in person at the Tribunal, telephonic hearings could be adjourned to and continued at the Tribunal if the respondent changes his or her mind. The rules of several New York State government agencies currently authorize telephone hearings. Subdivision (a) of §7.09 would be amended, and a new subdivision (h) of §7.11 would be added to authorize such hearings. In addition, the Department requests that subdivision (a) be further amended to reference appearances by representatives in §7.21, that the language describing defaults in §7.09 (d) be clarified, and that subdivision (d) be further amended to extend the time for reopening a default as of right from thirty days to sixty days.

Extending the time for reopening a default would benefit respondents, who inadvertently miss the current deadline of thirty days after mailing or receipt of a notice of default decision. It would also be expected to facilitate operations at the Administrative Tribunal, reducing the time spent by hearing examiners on reviewing second requests to reopen defaults and enable hearing examiners to devote more of their time to adjudications of notices of violations on the merits.

Recodified 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. The Department also requests that the Board authorize 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 or bears a postmark indicating that it was mailed before the scheduled date of a hearing; or
(4) participating in a hearing conducted by telephone or other electronic media when the opportunity to do so is offered by the Department. The respondent, by agreeing to participate in such a hearing rather than appearing in person at the Tribunal, shall waive his or her rights to a public hearing and to cross-examine the Department's inspectors, except that a telephonic or electronic hearing may be adjourned to the Tribunal for a live hearing if the hearing officer determines that the testimony of a Department witness is necessary or if the respondent makes a request for such 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 request in writing that a default decision be reconsidered, if the request to reconsider 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 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 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 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 XXX 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 request reconsideration of 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. Subject to the provisions of § 7.09(a)(4), a respondent who participates in such a hearing shall waive the right to appear personally at the hearing and to cross-examine the Department inspector who issued the notice of violation.
[(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 XXX 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.

☛ **d17**

NOTICE OF INTENTION TO AMEND ARTICLE 175 OF THE NEW YORK CITY HEALTH CODE

In compliance with §1043(b) of the New York City Charter (the "Charter") and pursuant to the authority granted to the Board of Health by §558 of said Charter, notice is hereby given of the proposed amendment of Article 175 of the New York City Health Code (the "Health Code").

NOTICE IS HEREBY GIVEN THAT THE DEPARTMENT OF HEALTH AND MENTAL HYGIENE (THE "DEPARTMENT") WILL HOLD A PUBLIC HEARING ON THE PROPOSAL ON JANUARY 21, 2011 FROM 2:00 P.M. TO 4:00 P.M. IN THE THIRD FLOOR BOARDROOM (ROOM 330) AT 125 WORTH STREET, NEW YORK, NY 10013.

PERSONS INTERESTED IN PRE-REGISTERING TO SPEAK SHOULD NOTIFY, IN WRITING, RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, 125 WORTH STREET, CN-31, NEW YORK, NY; (212) 788-5010 BY 5:00 P.M. ON JANUARY 20, 2011. PLEASE INCLUDE A TELEPHONE NUMBER WHERE, IF NECESSARY, YOU MAY BE REACHED DURING NORMAL BUSINESS HOURS. SPEAKERS WILL BE LIMITED TO FIVE (5) MINUTES.

PERSONS WHO REQUEST THAT A SIGN LANGUAGE INTERPRETER OR OTHER FORM OF REASONABLE ACCOMMODATION FOR A DISABILITY BE PROVIDED AT THE HEARING, ARE ASKED TO NOTIFY RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, 125 WORTH STREET CN-31, NEW YORK, NY 10013; (212) 788-5010 BY JANUARY 14, 2011. REGISTRATION WILL BE ACCEPTED AT THE DOOR UNTIL 4:00 P.M. HOWEVER, PREFERENCE WILL BE GIVEN TO THOSE WHO PREREGISTER.

WRITTEN COMMENTS REGARDING THE PROPOSAL ADDRESSED TO THE ATTENTION OF THE BOARD OF HEALTH SHALL BE SUBMITTED TO RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, BY MAIL TO 125 WORTH STREET CN-31, NEW YORK, NEW YORK 10013, BY FAX TO (212) 788-4315, OR BY E-MAIL TO RESOLUTIONCOMMENTS@HEALTH.NYC.GOV OR WWW.NYC.GOV/NYCRULES OR ONLINE (WITHOUT ATTACHMENTS) AT http://www.nyc.gov/html/doh/html/notice/notice.shtml ON OR BEFORE 5:00 P.M., JANUARY 21, 2011. ATTACHMENTS TO ONLINE COMMENTS SHALL BE MAILED OR FAXED. COMMENTS RECEIVED AFTER JANUARY 21, 2011 WILL BE CONSIDERED TO THE EXTENT POSSIBLE.

WRITTEN COMMENTS RECEIVED BY THE SECRETARY TO THE BOARD OF HEALTH AND A 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 THE OFFICE OF THE SECRETARY. 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

STATUTORY AUTHORITY

These amendments to the New York City Health Code ("Health Code") are proposed pursuant to Sections 556, 558 and 1043 of the New York City Charter ("Charter") and applicable state and federal law. Section 556 of the Charter grants the New York City Department of Health and Mental Hygiene ("Department") jurisdiction to regulate matters affecting health in New York City. Specifically, Section 556 (c)(11) of the Charter authorizes the Department to regulate all aspects of ionizing radiation within the five boroughs of New York City. Sections 558 (b) and (c) of the Charter empower the Board of Health to amend the Health Code and to include in the Health Code all matters to which the Department's authority extends. Section 1043 of the Charter grants rule-making powers to the Department. The New York State Sanitary Code, in 10 NYCRR §16.1(b)(3), states that localities that have a population of more than 2,000,000 may establish their own radiation licensure requirements in place of State regulations, provided that the local requirements are consistent with Sanitary Code requirements. Section 274 of the federal Atomic Energy Act of 1954 (codified at 42 USC §2021) authorizes "Agreement States" to regulate byproduct material, source material and special nuclear material in quantities not sufficient to form a critical mass. New York State is an "Agreement State" within the meaning of the Atomic Energy Act, and the New York City Department of Health and Mental Hygiene program is a component of and a party to the relevant Agreement.

STATEMENT OF BASIS AND PURPOSE

New York State is an Agreement State, meaning that this State and the United States Nuclear Regulatory Commission (NRC) have entered into an agreement under the Atomic Energy Act through which the NRC has delegated authority to New York State to regulate radioactive material at non-reactor sites within its jurisdiction. The New York State Agreement is comprised of three regulatory programs – 1. the New York State Department of Health, 2. the New York State Department of Environmental Conservation, and 3. the New York City Department of Health and Mental Hygiene. Under this "Agreement State structure", the New York City Department of Health and Mental Hygiene, through the Office of Radiological Health (ORH), regulates radioactive material for medical, research and academic purposes within the five boroughs of New York City.

ORH regulations for radioactive material are contained in Article 175 of the Health Code. ORH licenses and inspects radioactive materials facilities for compliance with Article 175 for the protection of the health and safety of patients, radiation program employees and the general public. There are about 375 licensed sites in New York City possessing radioactive material for medical, academic and research purposes. ORH inspects these facilities at frequencies of once every 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 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 proposed herein for Article 175 can be collectively grouped under the heading "Medical Use of Byproduct Material". The second proposed change 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 proposed clarifying the installation versus the registration requirements of X-ray units, as described below.

I. Medical Use of Byproduct Material

The NRC significantly amended its regulations regarding the use of byproduct material. 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 Department requests that the Board of Health amend Article 175 of the New York City Health Code as indicated below:

- Section 175.02 – A number of new and amended definitions are proposed, particularly with respect to professional practitioners, medical equipment and training.
- Section 175.03 – New requirements proposed with respect to certain records, reports and notifications; move of misadministration requirements from section 175.07.
- Section 175.04 – Proposed renumbering an internal cross-reference.
- Section 175.07 – Revise terminology.
- Section 175.64 – Radiation therapy physicist is renamed authorized medical physicist; instrument calibration methodology is addressed.
- Section 175.103 – Repeal and reenact 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

Currently, section 175.51(b)(1) of the Health Code prohibits 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. 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) is proposed to be moved into 175.51(b)(1) in order to clarify compliance with the Health Code registration process.

The proposal is as follows:

Note - Matter in brackets [ ] is to be 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 or revise certain 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:
…

(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.
…

[(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.
…

(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)(a), 175.103(j)(5)(a), 175.103(j)(6)(a), 175.103(j)(7)(a), 175.103(j)(8)(a), 175.103(j)(10)(a), 175.103(j)(12)(a), or 175.103(j)(13)(a) 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.
...

[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.
…

(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.
...

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

[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.
…

(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.
…

(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.
…

(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.
…

[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.
…

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

[(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)] (144) "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.

(145) "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.
…

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

[(146)] (159) "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.
…

(163) " 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.
…

(168) "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.

(169) "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.
…

(171) "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.
…

(174) "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.

(175) "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.

(176) "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.
…

(185) "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.
…

[(177) "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.]

[(177)](198) "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.
…

(210) "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.

[(202) "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.]

(224) "Sealed source " means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

(225) "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.
…

(243) "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.
…

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

[222](247)"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.
…

[225] (250) "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.

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

(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.
…

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

(269) "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.

(270) "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.
…

(287) "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)(4) of this Code.

***

Notes: The Department proposes that the Board of Health amend §175.02 to add or revise certain definitions in order to maintain compatibility with changes made by the Nuclear Regulatory Commission primarily to Part 35 in Title 10 of the Code of Federal Regulations concerning medical use of byproduct material and other applicable law or regulations.

***

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)(v) 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) of this Code 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, as described in §175.07(e), 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)(210) 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 therapy misadministrations defined in §175.02(a)(210) 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: The Department proposes that the Board of Health amend §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: The Department proposes that the Board of Health amend §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: The Department proposes that the Board of Health amend §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: The Department proposes that the Board of Health amend §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 [scale] 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: The Department proposes that the Board of Health amend §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 another Federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and receive a specific amendment to its NRC 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) When a requirement in this Code differs from the requirement in an existing license condition, the requirement in this Code shall govern.

(vi) 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.

(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) or (iii) 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), 175.103(d)(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), (h)(12), (h)(13) and (h)(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, 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 mCi) of radium-226 or 1.85 MBq (50 mCi) 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 mCi) for radium-226 and 1.85 MBq (50 mCi) 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 mCi) 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 mCi) 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) For a unit dosage, this determination shall be made by

(A) Direct measurement of radioactivity; or

(B) A decay correction, based on the activity or activity concentration determined by—

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

(*b*) 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

(*c*) A PET radioactive drug producer licensed under 10 CFR § 30.32(j) or equivalent Agreement State requirements.

(iii) For other than unit dosages, this determination shall be made by—

(A) Direct measurement of radioactivity;

(B) Combination of measurement of radioactivity and mathematical calculations; or

(C) Combination of volumetric measurements and mathematical calculations, based on the measurement made by:

(*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.

(iv) 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.

(v) 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 mSv (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 mSv (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.*

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[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).

(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.

(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 (l200 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 the 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 mSv (10 mrem) per hour and 20 mSv (2 mrem) per hour, respectively; and

(B) with the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:

(a) radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in §175.03 of this Code; and

(b) radiation levels in unrestricted areas do not exceed the limits specified in §175.03 of this Code.

(ii) If the results of the surveys required in §175.103(h)(16)(i) of this Code indicate any radiation levels in excess of the respective limit specified in §175.103(h)(16)(i)(A) or (B), the licensee shall lock the control in the "off" position and not use the unit:

(A) except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding or the treatment room shielding; or

(B) 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 contain spilled byproduct material safely and using proper decontamination procedures; and

(VI) Administering dosages of radioactive drugs to patients or human research subjects; and

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

(5) *Training for imaging and localization studies.*

Except as provided in § 175.103(j)(14) of this Code, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 175.103(d)(2) of this Code to be a physician who—

(i) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in clause (B) of subparagraph (iii) of this paragraph. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC website.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(A) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies that includes the topics listed in items (*a*) through (*b*) of clause (A) of subparagraph (iii) of this paragraph; and

(B) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(ii) Is an authorized user under § 175.103(j)(6) and meets the requirements in § 175.103(j)(5)(iii)(A)(*b*)(VII) of this Code, or equivalent NRC or Agreement State requirements; or

(iii)(A) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience shall include, at a minimum—

(*a*) Classroom and laboratory training in the following areas—

(I) 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;

(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)(5), or 175.103(j)(5)(iii)(A)(*b*)(VII) and 175.103(j)(6) of this Code or equivalent NRC or Agreement State requirements, involving—

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) 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: The Department proposes that the Board of Health repeal and reenact §175.103 of the Health Code in order to maintain compatibility with changes made by the Nuclear Regulatory Commission primarily to Part 35 in Title 10 of the Code of Federal Regulations concerning medical use of byproduct material.

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NOTICE OF INTENTION TO AMEND ARTICLE 173 OF THE NEW YORK CITY HEALTH CODE

In compliance with Section 1043(b) of the New York City Charter and pursuant to the authority granted to the Board of Health by Section 558 of said Charter, notice is hereby given of the proposed amendment of Article 173 (Hazardous Substances) of the New York City Health Code.

NOTICE IS HEREBY GIVEN THAT THE DEPARTMENT WILL HOLD A PUBLIC HEARING ON THE PROPOSAL ON MONDAY, JANUARY 24, 2011 FROM 2:00 P.M. TO 4:00 P.M. IN THE THIRD FLOOR BOARDROOM (ROOM 330) AT 125 WORTH STREET, NEW YORK, NEW YORK 10013.

PERSONS INTERESTED IN PRE-REGISTERING TO SPEAK SHOULD NOTIFY, IN WRITING, RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, 125 WORTH STREET, CN-31, NEW YORK, NEW YORK; (212) 788-5010 BY 5:00 P.M., FRIDAY, JANUARY 21, 2011. PLEASE INCLUDE A TELEPHONE NUMBER WHERE, IF NECESSARY, YOU MAY BE REACHED DURING NORMAL WORKING HOURS. SPEAKERS WILL BE LIMITED TO FIVE (5) MINUTES.

PERSONS WHO REQUEST THAT A SIGN LANGUAGE INTERPRETER OR OTHER FORM OF REASONABLE ACCOMMODATION FOR A DISABILITY BE PROVIDED AT THE HEARING ARE ASKED TO NOTIFY RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, 125 WORTH STREET CN-31, NEW YORK, NEW YORK 10013; (212) 788-5010 BY MONDAY, JANUARY 10, 2011.

REGISTRATION WILL BE ACCEPTED AT THE DOOR UNTIL 4:00 P.M. HOWEVER, PREFERENCE WILL BE GIVEN TO THOSE WHO PREREGISTER.

WRITTEN COMMENTS REGARDING THE PROPOSAL ADDRESSED TO THE ATTENTION OF THE BOARD OF HEALTH MUST BE SUBMITTED TO RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, BY MAIL TO 125 WORTH STREET CN-31, NEW YORK, NEW YORK 10013, BY FAX TO (212) 788-4315, BY E-MAIL TO RESOLUTIONCOMMENTS@HEALTH.NYC.GOV OR ELECTRONICALLY (WITHOUT ATTACHMENTS)THROUGH www.nyc.gov/nycrules OR http://www.nyc.gov/html/doh/html/notice/notice.shtml ON OR BEFORE 5:00 P.M., MONDAY, JANUARY 24, 2011. ATTACHMENTS TO ONLINE COMMENTS MUST BE MAILED OR FAXED. COMMENTS RECEIVED AFTER JANUARY 24, 2011 WILL BE CONSIDERED TO THE EXTENT POSSIBLE.

WRITTEN COMMENTS RECEIVED BY THE SECRETARY TO THE BOARD OF HEALTH AND A 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 THE OFFICE OF THE SECRETARY. 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.

STATUTORY AUTHORITY

These amendments to the New York City Health Code ("Health Code") are promulgated pursuant to Sections 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 DOHMH proposes that the Board amend §173.13 (Lead paint) of Article 173 (Hazardous Substances) to update its provisions for the acceptable limits of lead in paint and other leaded surface-coating materials thereby 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 Department is requesting that the Board amend 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 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 XXX 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 interiors.

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TAXI AND LIMOUSINE COMMISSION

■ **NOTICE**

Notice of Public Hearing and Opportunity to Comment on Proposed Rules

Notice is hereby given in accordance with section 1043(b) of the New York City Charter ("Charter") that the Taxi and Limousine Commission ("TLC") proposes amending the provisions of Title 35 of the Rules of the City of New York to add rules governing the process and requirements for license applications and renewals.

These rules are proposed pursuant to sections 1043 and 2303 of the Charter and section 19-503 of the Administrative Code of the City of New York. The proposed rules were included in the TLC's regulatory agenda for Fiscal Year 2011.

A public hearing on these proposed rules will be held by the TLC at its offices at 40 Rector Street, 5th Floor, New York, New York 10006 on Thursday, January 20, 2011, at 10:00 A.M. Persons wishing to testify at the hearing may notify the TLC in advance, either in writing or by telephone to the TLC's Office of Legal Affairs at the address and telephone given below. Any request for a sign language interpreter or other form of reasonable accommodation for a disability at the hearing must be submitted to the Office of Legal Affairs in writing or by telephone no later than January 13, 2011.

Written comments in connection with these proposed rules must be received no later than January 18, 2011. Comments may be submitted through the NYC Rules website at www.nyc.gov/nycrules, or may be submitted to the Office of Legal Affairs at:

Charles R. Fraser
Deputy Commissioner for Legal Affairs/General Counsel
Taxi and Limousine Commission
40 Rector Street, 5th Floor
New York, New York 10006
Telephone: 212-676-1135
Fax: 212-676-1102
Email: tlcrules@tlc.nyc.gov

Written comments and a transcript of the hearing will be available for public inspection at that office.

New Material is underlined.

[Material inside brackets indicates deleted material.]

Section 1. It is proposed to amend Section 4-04 of Title 35 of the Rules of the City of New York to add a new subdivision (o) to read as follows:

(o) *Payment of Fines and Fees.*

(1) An Applicant, including an applicant for a renewal License, must pay, and provide proof of payment of, any outstanding fines or fees owed by the Applicant to
(i) the Commission,
(ii) NYC Department of Finance's Parking Violations Bureau,
(iii) NYC Department of Finance's Red Light Camera Unit,
(iv) NYS DMV's Traffic Violations Bureau and
(v) any of their successor agencies.

(2) This requirement includes payment of fines and fees owed as of the date of the application by
(i) any Business Entity Persons of the Applicant
(ii) any Business Entity of which the Applicant is a Business Entity Person, and
(iii) any Business Entity of which a Business Entity Person of Applicant is also a Business Entity Person.

Section 2. It is proposed to amend Section 4-06 of Title 35 of the Rules of the City of New York to add new subdivisions (e) and (f) to read as follows:

(e) *When to File for Renewal*.

(1) A renewing Applicant must file a completed application at least 30 days before the expiration date of the License in order to avoid a late fee.

(2) A renewing Applicant can file a completed application less than 30 days before the expiration date as a "late application," if the Applicant pays a late fee of $25.

(3) The postmark date is the date of filing for an application that is filed by mail. The date of submission is the date of filing for an application that is filed in person.

(4) The Commission will not accept a renewal application after the expiration date of the License. If the application is not filed before the expiration date, the License cannot be renewed.

(f) *Suspended Licenses*.

(1) If a License is suspended, the Licensee must apply for renewal as required in (e) above if the Licensee wants to renew the License. Failure to complete the renewal requirements means that the License cannot be renewed.

(2) A License that is suspended is not Valid and cannot be used until the suspension ends. This is true even if the Applicant has filed an application for a renewal.

Section 3. It is proposed to amend Section 4-07(d) of Title 35 of the Rules of the City of New York to read as follows:

(d) *Late Filing Fee.* The Commission will charge an additional fee of $25 for a late filing of a renewal application, [and may choose not to accept it] if it allows the filing at all.

Section 4. It is proposed to amend Section 4-08 of Title 35 of the Rules of the City of New York to add a new subdivision (e) to read as follows:

(e) *Failure to Complete Application Requirements.*

(1) The Commission will deny an application for a new License if the Applicant has not completed all of the requirements of an application within 180 days of the date the application is filed.

(2) The Commission will deny an application for a renewal License if the Applicant has not completed all of the requirements of an application within 30 days after the expiration of the prior License.

(3) The Commission will not deny an application under this Rule if completion is delayed because the Commission has not issued a final decision in any fitness Hearing it requires.

Section 5. It is proposed to amend Section 5-04 of Title 35 of the Rules of the City of New York to add a new subdivision (j) to read as follows:

(j) *Payment of Fines and Fees.*

(1) An Applicant, including an applicant for a renewal License, must pay, and provide proof of payment of, any outstanding fines or fees owed by the Applicant to
(i) the Commission,
(ii) NYC Department of Finance's Parking Violations Bureau,
(iii) NYC Department of Finance's Red Light Camera Unit,
(iv) NYS DMV's Traffic Violations Bureau and
(v) any of their successor agencies.

(2) This requirement includes payment of fines and fees owed as of the date of the application by
(i) any Business Entity Persons of the Applicant
(ii) any Business Entity of which the Applicant is a Business Entity Person, and
(iii) any Business Entity of which a Business Entity Person of Applicant is also a Business Entity Person.

Section 6. It is proposed to amend Section 5-06 of Title 35 of the Rules of the City of New York to add new subdivisions (e) and (f) to read as follows:

(e) *When to File for Renewal*.

(1) A renewing Applicant must file a completed application at least 30 days before the expiration date of the License in order to avoid a late fee.

(2) A renewing Applicant can file a completed application less than 30 days before the expiration date as a "late application," if the Applicant pays a late fee of $25.

(3) The postmark date is the date of filing for an application that is filed by mail. The date of submission is the date of

filing for an application that is filed in person.

(4) The Commission will not accept a renewal application after the expiration date of the License. If the application is not filed before the expiration date, the License cannot be renewed.

(f) *Suspended Licenses*.

(1) If a License is suspended, the Licensee must apply for renewal as required in (e) above if the Licensee wants to renew the License. Failure to complete the renewal requirements means that the License cannot be renewed.

(2) A License that is suspended is not Valid and cannot be used until the suspension ends. This is true even if the Applicant has filed an application for a renewal.

Section 7. It is proposed to amend Section 5-07(d) of Title 35 of the Rules of the City of New York to read as follows:

(d) *Late Filing Fee*. The Commission will charge an additional fee of $25 for a late filing of renewal application,[filing fee for a late submittal,] if it allows the filing at all. [application.]

Section 8. It is proposed to amend Section 5-08 of Title 35 of the Rules of the City of New York to add a new subdivision (c) to read as follows:

(c) *Failure to Complete Application Requirements.*

(1) The Commission will deny an application for a new License if the Applicant has not completed all the requirements of an application within 180 days of the date the application is filed.

(2) The Commission will deny an application for a renewal License if the Applicant has not completed all the requirements of an application within 30 days after the expiration of the prior License.

(3) The Commission will not deny an application under this Rule if completion is delayed because the Commission has not issued a final decision in any fitness Hearing it requires.

Section 9. It is proposed to amend Section 6-04 of Title 35 of the Rules of the City of New York to add a new subdivision (n) to read as follows:

(n) *Payment of Fines and Fees.*

(1) An Applicant, including an applicant for a renewal License, must pay, and provide proof of payment of, any outstanding fines or fees owed by the Applicant to
(i) the Commission,
(ii) NYC Department of Finance's Parking Violations Bureau,
(iii) NYC Department of Finance's Red Light Camera Unit,
(iv) NYS DMV's Traffic Violations Bureau and
(v) any of their successor agencies.

(2) This requirement includes payment of fines and fees owed as of the date of the application by
(i) any Business Entity Persons of the Applicant
(ii) any Business Entity of which the Applicant is a Business Entity Person, and
(iii) any Business Entity of which a Business Entity Person of Applicant is also a Business Entity Person.

Section 10. It is proposed to amend Section 6-06 of Title 35 of the Rules of the City of New York to add new subdivisions (c) and (d) to read as follows:

(c) *When to File for Renewal*.

(1) A renewing Applicant must file a completed application at least 30 days before the expiration date of the License in order to avoid a late fee.

(2) A renewing Applicant can file a completed application less than 30 days before the expiration date as a "late application," if the Applicant pays a late fee of $25.

(3) The postmark date is the date of filing for an application that is filed by mail. The date of submission is the date of filing for an application that is filed in person.

(4) The Commission will not accept a renewal application after the expiration date of the License. If the application is not filed before the expiration date, the License cannot be renewed.

(d) *Suspended Licenses*.

(1) If a License is suspended, the Licensee must apply for renewal as required in (c) above if the Licensee wants to renew the License. Failure to complete the renewal requirements means that the License cannot be renewed.

(2) A License that is suspended is not Valid and cannot be used until the suspension ends. This is true even if the Applicant has filed an application for a renewal.

Section 11. It is proposed to amend Section 6-07(d) of Title 35 of the Rules of the City of New York to read as follows:

(d) *Late Filing Fee*. The Commission will charge an additional fee of $25 for a late filing of a renewal application, if it allows the filing at all.

Section 12. It is proposed to amend Section 6-08(d) of Title 35 of the Rules of the City of New York to read as follows:

(d)[*Representation Before the Commission.* If the Commission denies a new or renewal Driver's License application, the Applicant is entitled to a hearing before the Commission. The Applicant can be represented by an attorney or a non-attorney at the hearing. The Commission can, for cause, refuse to allow a non-attorney to represent the Applicant.] *Failure to Complete Application Requirements.*

(1) The Commission will deny an application for a new License if the Applicant has not completed all the requirements of an application within 180 days of the date the application is filed.

(2) The Commission will deny an application for a renewal License if the Applicant has not completed all the requirements of an application within 30 days after the expiration of the prior License.

(3) The Commission will not deny an application under this Rule if completion is delayed because the Commission has not issued a final decision in any fitness Hearing it requires.

Section 13. It is proposed to amend Section 7-04 of Title 35 of the Rules of the City of New York to add a new subdivision (l) to read as follows:

(l) *Payment of Fines and Fees.*

(1) An Applicant, including an applicant for a renewal License, must pay, and provide proof of payment of, any outstanding fines or fees owed by the Applicant to
(i) the Commission,
(ii) NYC Department of Finance's Parking Violations Bureau,
(iii) NYC Department of Finance's Red Light Camera Unit,
(iv) NYS DMV's Traffic Violations Bureau and
(v) any of their successor agencies.

(2) This requirement includes payment of fines and fees owed as of the date of the application by
(i) any Business Entity Persons of the Applicant
(ii) any Business Entity of which the Applicant is a Business Entity Person, and
(iii) any Business Entity of which a Business Entity Person of Applicant is also a Business Entity Person.

Section 14. It is proposed to amend Section 7-06 of Title 35 of the Rules of the City of New York to add new subdivisions (c) and (d) to read as follows:

(c) *When to File for Renewal*.

(1) A renewing Applicant must file a completed application at least 30 days before the expiration date of the License in order to avoid a late fee.

(2) A renewing Applicant can file a completed application less than 30 days before the expiration date as a "late application," if the Applicant pays a late fee of $25.

(3) The postmark date is the date of filing for an application that is filed by mail. The date of submission is the date of filing for an application that is filed in person.

(4) The Commission will not accept a renewal application after the expiration date of the License. If the application is not filed before the expiration date, the License cannot be renewed.

(d) *Suspended Licenses*.

(1) If a License is suspended, the Licensee must apply for renewal as required in (d) above if the Licensee wants to renew the License. Failure to complete the renewal requirements means that the License cannot be renewed.

(2) A License that is suspended is not Valid and cannot be used until the suspension ends. This is true even if the Applicant has filed an application for a renewal.

Section 15. It is proposed to amend Section 7-07(d) of Title 35 of the Rules of the City of New York to read as follows:

(d) *Late Filing Fee.* The Commission will charge an additional fee of $25 for a late filing of a renewal application, if it allows the filing at all.

Section 16. It is proposed to amend Section 7-08(d) of Title 35 of the Rules of the City of New York to read as follows:

(d) [*Commission Failure to Approve Within 180 Days*] *Failure to Complete Application Requirements*.

(1) [The Commission will approve or disapprove applications for a Commuter Van Driver's License within 180 days of receiving the completed application.

(2) Failure to approve or disapprove application within this time frame will be considered a denial of the application.]

(1) The Commission will deny an application for a new License if the Applicant has not completed all the requirements of an application within 180 days of the date the application is filed.

(2) The Commission will deny an application for a renewal License if the Applicant has not completed all the requirements of an application within180 days after the expiration of the prior License.

(3) The Commission will not deny an application under this Rule if completion is delayed because the Commission has not issued a final decision in any fitness Hearing it requires.

Section 17. It is proposed to amend Section 8-04 of Title 35 of the Rules of the City of New York to add a new subdivision (h) to read as follows:

(h) *Payment of Fines and Fees.*

(1) An Applicant, including an applicant for a renewal License, must pay, and provide proof of payment of, any outstanding fines or fees owed by the Applicant to
(i) the Commission,
(ii) NYC Department of Finance's Parking Violations Bureau,
(iii) NYC Department of Finance's Red Light Camera Unit,
(iv) NYS DMV's Traffic Violations Bureau and
(v) any of their successor agencies.

(2) This requirement includes payment of fines and fees owed as of the date of the application by
(i) any Business Entity Persons of the Applicant
(ii) any Business Entity of which the Applicant is a Business Entity Person, and
(iii) any Business Entity of which a Business Entity Person of Applicant is also a Business Entity Person.

Section 18. It is proposed to amend subdivision (c) of Section 8-06 of Title 35 of the Rules of the City of New York, renumber subdivision (d) as subdivision (e) and add a new subdivision (d), to read as follows:

(c) *Filing for Renewal*.

(1) [Unless the time to renew the License has been extended by the Chairman, a renewal] A renewing Applicant must file a completed application [must be filed] by no later than April 30th of each year in which a License is scheduled to expire.

(2) A renewing Applicant can file a completed application after April 30 as a "late application," if the Applicant pays a late fee of $25. This fee is in addition to any penalties specified for a violation of this Rule.

(3) The postmark date is the date of filing for an application that is filed by mail. The date of submission is the date of filing for an application that is filed in person.

(4) A License for which a renewal application has not been filed by April 30 is not Valid and cannot be used until the renewal is approved. This is in addition to any penalties specified for a violation of this Rule.

([2]5) It is the Owner's responsibility to obtain a renewal application in order to comply with the filing deadline.

§8-06(c)	Fine: $[50-$350]1,000 and[/or] suspension up to 30 days for failure to file by April 30.	Appearance NOT REQUIRED

(d) *Suspended Licenses*.

(1) If a License is suspended, the Licensee must apply for renewal as required in (c) above if the Licensee wants to renew the License. Failure to complete the renewal requirements means that the License cannot be renewed.

(2) A License that is suspended is not Valid and cannot be used until the suspension ends. This is true even if the Applicant has filed an application for a renewal.

[(d)](e) *Advertising Permits.* A permit to display exterior advertising runs for one year or less and each permit will expire on the 31st day of August.

Section 19. It is proposed to amend Section 8-07 of Title 35 of the Rules of the City of New York to add a new subdivision (i) to read as follows:

(i) *No Refund if Application Denied.* The Commission will not refund fees if it denies or disapproves the application.

Section 20. It is proposed to amend Section 8-08 of Title 35 of the Rules of the City of New York to add new subdivisions (g) and (h) to read as follows:

(g) *Failure to Complete Application Requirements.*

(1) The Commission will deny an application for a new License if the Applicant has not completed all the requirements of an application within 180 days of the date the application is filed.

(2) The Commission will not deny an application under this Rule if completion is delayed because the Commission has not issued a final decision in any fitness Hearing it requires.

(h) *Late Filing Fee*. The Commission will charge an additional fee of $25 for a late filing of a renewal application, if it allows the filing at all.

Section 21. It is proposed to amend subdivisions (1)-(5) of Section 9A-04(f) of Title 35 of the City of New York to read as follows:

(f) *Inspection Required to Renew a Vehicle License.*

(1) An Applicant for renewal of a For-Hire Vehicle License must have the vehicle inspected at the Commission's Safety and Emissions Division and demonstrate that the Vehicle has passed an inspection within [thirty]60 days after the date of the first scheduled inspection.

(2) The maximum number of inspections allowed in this [30]60-day period is four.

(3) The maximum limit of four inspections applies whether the Applicant submits only the original vehicle, or also submits a replacement vehicle.

(4) After the License expiration date, the vehicle must not operate until it passes inspection and meets all other requirements for Licensure.

(5) Failure of the original vehicle or any replacement vehicle to pass an inspection after four tries within the [30]60-day period will result in denial of the renewal application.

Section 22. It is proposed to amend Section 9A-04 of Title 35 of the Rules of the City of New York to add a new subdivision (l) to read as follows:

(l) *Payment of Fines and Fees.*

(1) An Applicant, including an applicant for a renewal License, must pay, and provide proof of payment of, any outstanding fines or fees owed by the Applicant to
(i) the Commission,
(ii) NYC Department of Finance's Parking Violations Bureau,
(iii) NYC Department of Finance's Red Light Camera Unit,
(iv) NYS DMV's Traffic Violations Bureau and
(v) any of their successor agencies.

(2) This requirement includes payment of fines and fees owed as of the date of the application by
(i) any Business Entity Persons of the Applicant
(ii) any Business Entity of which the Applicant is a Business Entity Person, and
(iii) any Business Entity of which a Business Entity Person of Applicant is also a Business Entity Person.

Section 23. It is proposed to amend Section 9A-06(c) of Title 35 of the Rules of the City of New York to read as follows:

(1) A renewing Applicant must file a completed application at least 30 days before the expiration date of the License in order to avoid a late fee.

(2) [The Commission will allow a]A renewing Applicant [to]can file a completed application less than 30 days before the expiration date as a "late application," [provided]if the Applicant pays a late fee of $25.

(3) [No renewal application will be accepted and the License cannot be renewed after the expiration date of the For-Hire Vehicle License.] The postmark date is the date of filing for an application that is filed by mail. The date of submission is the date of filing for an application that is filed in person.

(4) The Commission will not accept a renewal application after the expiration date of the License. If the application is not filed before the expiration date, the License cannot be renewed.

Section 24. It is proposed to amend Section 9A-06 of Title 35 of the Rules of the City of New York to add a new subdivision (f) to read as follows:

(f) *Suspended Licenses*.

(1) If a License is suspended, the Licensee must apply for renewal as required in (c) above if the Licensee wants to renew the License. Failure to complete the renewal requirements means that the License cannot be renewed.

(2) A License that is suspended is not Valid and cannot be used until the suspension ends. This is true even if the Applicant has filed an application for a renewal.

Section 25. It is proposed to amend Section 9A-07(b) of Title 35 of the Rules of the City of New York to read as follows:

(b) *Late Filing Fee.* [There will be an additional fee of $25 for a "late filing" of a License renewal application.] The Commission will charge an additional fee of $25 for a late

filing of a renewal application, if it allows the filing at all.

Section 26. It is proposed to amend Section 9A-08 of Title 35 of the Rules of the City of New York to add a new subdivision (e) to read as follows:

(e) *Failure to Complete Application Requirements.*

(1) The Commission will deny an application for a new License if the Applicant has not completed all the requirements of an application within 120 days of the date the application is filed.

(2) The Commission will deny an application for a renewal License if the Applicant has not completed all the requirements of an application within 120 days after the expiration of the prior License.

(3) The Commission will not deny an application under this Rule if completion is delayed because the Commission has not issued a final decision in any fitness Hearing it requires.

Section 27. It is proposed to amend Section 9B-04 of Title 35 of the Rules of the City of New York to add a new subdivision (f) to read as follows:

(f) *Payment of Fines and Fees.*

(1) An Applicant, including an applicant for a renewal License, must pay, and provide proof of payment of, any outstanding fines or fees owed by the Applicant to
(i) the Commission,
(ii) NYC Department of Finance's Parking Violations Bureau,
(iii) NYC Department of Finance's Red Light Camera Unit,
(iv) NYS DMV's Traffic Violations Bureau and
(v) any of their successor agencies.

(2) This requirement includes payment of fines and fees owed as of the date of the application by
(i) any Business Entity Persons of the Applicant
(ii) any Business Entity of which the Applicant is a Business Entity Person, and
(iii) any Business Entity of which a Business Entity Person of Applicant is also a Business Entity Person.

Section 28. It is proposed to amend Section 9B-06(c) of Title 35 of the Rules of the City of New York to read as follows:

(1) A renewing Applicant must file a completed application *at least* 60 days before the expiration date of the License in order to avoid a late fee.

(2) [The Commission will allow a]A renewing Applicant [to]can file a competed application less than 60 days before the expiration date as a "late application," [provided] if the Applicant pays a late fee of $25.

(3) [No renewal application will be accepted and the License cannot be renewed after the expiration date of the For-Hire Base License.] The postmark date is the date of filing for an application that is filed by mail. The date of submission is the date of filing for an application that is filed in person.

(4) The Commission will not accept a renewal application after the expiration date of the License. If the application is not filed before the expiration date, the License cannot be renewed.

Section 29. It is proposed to amend Section 9B-06 of Title 35 of the Rules of the City of New York to add a new subdivision (e) to read as follows:

(e) *Suspended Licenses*.

(1) If a License is suspended, the Licensee must apply for renewal as required in (c) above if the Licensee wants to renew the License. Failure to complete the renewal requirements means that the License cannot be renewed.

(2) A License that is suspended is not Valid and cannot be used until the suspension ends. This is true even if the Applicant has filed an application for a renewal.

Section 30. It is proposed to amend Section 9B-07(b) of Title 35 of the Rules of the City of New York to read as follows:

(b) *Late Filing Fee.* [There will be an additional fee of $25 for a "late filing" of a License renewal application.] The Commission will charge an additional fee of $25 for a late filing of a renewal application, if it allows the filing at all.

Section 31. It is proposed to amend Section 9B-08 of Title 35 of the Rules of the City of New York to add a new subdivision (f) to read as follows:

(f) *Failure to Complete Application Requirements.*

(1) The Commission will deny an application for a new Black Car Base or Luxury Limousine Base License if the Applicant has not completed all the requirements of an application within 120 days of the date the application is filed.

(2) The Commission will deny an application for a renewal Black Car Base or Luxury Limousine Base License if the Applicant has not completed all the requirements of an application within 30 days after the expiration of the prior License.

(3) The Commission will not deny an application under this Rule if completion is delayed because the Commission has not issued a final decision in any fitness Hearing it requires.

Section 32. It is proposed to amend Section 10A-04 of Title 35 of the Rules of the City of New York to add a new subdivision (l) to read as follows:

(l) *Payment of Fines and Fees.*

(1) An Applicant, including an applicant for a renewal License, must pay, and provide proof of payment of, any outstanding fines or fees owed by the Applicant to
(i) the Commission,
(ii) NYC Department of Finance's Parking Violations Bureau,
(iii) NYC Department of Finance's Red Light Camera Unit,
(iv) NYS DMV's Traffic Violations Bureau and
(v) any of their successor agencies.

(2) This requirement includes payment of fines and fees owed as of the date of the application by
(i) any Business Entity Persons of the Applicant
(ii) any Business Entity of which the Applicant is a Business Entity Person, and
(iii) any Business Entity of which a Business Entity Person of Applicant is also a Business Entity Person.

Section 33. It is proposed to amend subdivision (d) of Section10A-05 of Title 35 of the Rules of the City of New York and to add a new subdivision (e) to read as follows:

(d) *When to File Application for Renewal*. [A renewing Applicant must file on or before the expiration date of the current License.]

(1) A renewing Applicant must file a completed application at least 30 days before the expiration date of the License in order to avoid a late fee.

(2) A renewing Applicant can file a completed application less than 30 days before the expiration date as a "late application," if the Applicant pays a late fee of $25.

(3) The postmark date is the date of filing for an application that is filed by mail. The date of submission is the date of filing for an application that is filed in person.

(4) The Commission will not accept a renewal application after the expiration date of the License. If the application is not filed before the expiration date, the License cannot be renewed.

(e) *Suspended Licenses*.

(1) If a License is suspended, the Licensee must apply for renewal as required in (d) above if the Licensee wants to renew the License. Failure to complete the renewal requirements means that the License cannot be renewed.

(2) A License that is suspended is not Valid and cannot be used until the suspension ends. This is true even if the Applicant has filed an application for a renewal.

Section 34. It is proposed to amend Section 10A-06(c) of the Title 35 of the Rules of the City of New York to read as follows:

(c) The Commission will charge an additional fee of $25 for a late filing of a renewal application, if it allows the filing at all.

Section 35. It is proposed to amend Section 10A-07 of Title 35 of the Rules of the City of New York to add a new subdivision (f) to read as follows:

(f) *Failure to Complete Application Requirements.*

(1) The Commission will deny an application for a new License if the Applicant has not completed all the requirements of an application within 120 days of the date the application is filed.

(2) The Commission will deny an application for a renewal License if the Applicant has not completed all the requirements of an application within 120 days after the expiration of the prior License.

(3) The Commission will not deny an application under this Rule if completion is delayed because the Commission has not issued a final decision in any fitness Hearing it requires.

Section 36. It is proposed to amend Section 10B-04 of Title 35 of the Rules of the City of New York to add a new subdivision (g) to read as follows:

(g) *Payment of Fines and Fees.*

(1) An Applicant, including an applicant for a renewal License, must pay, and provide proof of payment of, any outstanding fines or fees owed by the Applicant to
(i) the Commission,
(ii) NYC Department of Finance's Parking Violations Bureau,
(iii) NYC Department of Finance's Red Light Camera Unit,
(iv) NYS DMV's Traffic Violations Bureau and
(v) any of their successor agencies.

(2) This requirement includes payment of fines and fees owed as of the date of the application by
(i) any Business Entity Persons of the Applicant
(ii) any Business Entity of which the Applicant is a Business Entity Person, and
(iii) any Business Entity of which a Business Entity Person of Applicant is also a Business Entity Person.

Section 37. It is proposed to amend subdivision (c) of Section 10B-05 of Title 35 of the Rules of the City of New York and to add a new subdivision (d) to read as follows:

(c) *When to Application File for Renewal*. [A renewing Appplicant must file a complete application on or before the expiration date of the current License.]

(1) A renewing Applicant must file a completed application at least 60 days before the expiration date of the License in order to avoid a late fee.

(2) A renewing Applicant can file a completed application less than 60 days before the expiration date as a "late application," if the Applicant pays a late fee of $25.

(3) The postmark date is the date of filing for an application that is filed by mail. The date of submission is the date of filing for an application that is filed in person.

(4) The Commission will not accept a renewal application after the expiration date of the License. If the application is not filed before the expiration date, the License cannot be renewed.

(d) *Suspended Licenses*.

(1) If a License is suspended, the Licensee must apply for renewal as required in (c) above if the Licensee wants to renew the License. Failure to complete the renewal requirements means that the License cannot be renewed.

(2) A License that is suspended is not Valid and cannot be used until the suspension ends. This is true even if the Applicant has filed an application for a renewal.

Section 38. It is proposed to amend Section 10B-06(d) of the Rules of the City of New York to read as follows:

(d) The Commission will charge an additional fee of $25 for a late filing of a renewal application, if it allows the filing at all.

Section 39. It is proposed to amend Section 10B-07 of Title 35 of the Rules of the City of New York to add a new subdivision (d) to read as follows:

(d) *Failure to Complete Application Requirements*

(1) The Commission will deny an application for a new License if the Applicant has not completed all the requirements of an application within 120 days of the date the application is filed.

(2) The Commission will deny an application for a renewal License if the Applicant has not completed all the requirements of an application within 30 days after the expiration of the prior License.

(3) The Commission will not deny an application under this Rule if completion is delayed because the Commission has not issued a final decision in any fitness Hearing it requires.

Section 40. It is proposed to amend Section 11A-04 of Title 35 of the Rules of the City of New York to add a new subdivision (h) to read as follows:

(h) *Payment of Fines and Fees.*

(1) An Applicant, including an applicant for a renewal License, must pay, and provide proof of payment of, any outstanding fines or fees owed by the Applicant to
(i) the Commission,
(ii) NYC Department of Finance's Parking Violations Bureau,
(iii) NYC Department of Finance's Red Light Camera Unit,
(iv) NYS DMV's Traffic Violations Bureau and
(v) any of their successor agencies.

(2) This requirement includes payment of fines and fees owed as of the date of the application by
(i) any Business Entity Persons of the Applicant
(ii) any Business Entity of which the Applicant is a Business Entity Person, and
(iii) any Business Entity of which a Business Entity Person of Applicant is also a Business Entity Person.

Section 41. It is proposed to amend Section 11A-05 of Title 35 of the Rules of the City of New York to add new subdivisions (c) and (d) to read as follows:

(c) *When to File for Renewal*.

(1) A renewing Applicant must file a completed application at least 30 days before the expiration date of the License in order to avoid a late fee.

(2) A renewing Applicant can file a completed application less than 30 days before the expiration date as a "late application," if the Applicant pays a late fee of $25.

(3) The postmark date is the date of filing for an application that is filed by mail. The date of submission is the date of filing for an application that is filed in person.

(4) The Commission will not accept a renewal application after the expiration date of the License. If the application is not filed before the expiration date, the License cannot be renewed.

(d) *Suspended Licenses*.

(1) If a License is suspended, the Licensee must apply for renewal as required in (c) above if the Licensee wants to renew the License. Failure to complete the renewal requirements means that the License cannot be renewed.

(2) A License that is suspended is not Valid and cannot be used until the suspension ends. This is true even if the Applicant has filed an application for a renewal.

Section 42. It is proposed to amend Section 11A-06 of the Rules of the City of New York to add a new subdivision (f) to read as follows:

(f) *Late Filing Fee.* The Commission will charge an additional fee of $25 for a late filing of a renewal application, if it allows the filing at all.

Section 43. It is proposed to amend Section 11A-07 (c) of Title 35 of the Rules of the City of New York to read as follows:

(c) [*Commission's*] *Failure to*[*Approve*]*Complete Application Requirements*. [Any application that the Commission does not approve or disapprove within 180 days after the completed application is filed will be considered disapproved.]
(1) The Commission will deny an application for a new License if the Applicant has not completed all the requirements of an application within 180 days of the date the application is filed.

(2) The Commission will deny an application for a renewal License if the Applicant has not completed all the requirements of an application within 180 days after the expiration of the prior License.

(3) The Commission will not deny an application under this Rule if completion is delayed because the Commission has not issued a final decision in any fitness Hearing it requires.

Section 44. It is proposed to amend Section11B-04 of Title 35 of the Rules of the City of New York to add a new subdivision (j) to read as follows:

(j) *Payment of Fines and Fees.*

(1) An Applicant, including an applicant for a renewal License, must pay, and provide proof of payment of, any outstanding fines or fees owed by the Applicant to
(i) the Commission,
(ii) NYC Department of Finance's Parking Violations Bureau,
(iii) NYC Department of Finance's Red Light Camera Unit,
(iv) NYS DMV's Traffic Violations Bureau and
(v) any of their successor agencies.

(2) This requirement includes payment of fines and fees owed as of the date of the application by
(i) any Business Entity Persons of the Applicant
(ii) any Business Entity of which the Applicant is a Business Entity Person, and
(iii) any Business Entity of which a Business Entity Person of Applicant is also a Business Entity Person.

Section 45. It is proposed to amend Section 11B-05 of Title 35 of the Rules of the City of New York to add new subdivisions (d) and (e) to read as follows:

(d) *When to File for Renewal*.

(1) A renewing Applicant must file a completed application at least 60 days before the expiration date of the Authorization in order to avoid a late fee.

(2) A renewing Applicant can file a completed application less than 60 days before the expiration date as a "late application," if the Applicant pays a late fee of $25.

(3) The postmark date is the date of filing for an application that is filed by mail. The date of submission is the date of filing for an application that is filed in person.

(4) The Commission will not accept a renewal application after the expiration date of the Authorization. If the application is not filed before the expiration date, the Authorization cannot be renewed.

(e) *Suspended Licenses*.

(1) If an Authorization is suspended, the Licensee must file for renewal as required in (c) above if the Licensee wants to renew the Authorization. Failure to complete the renewal requirements means that the Authorization cannot be renewed.

(2) An Authorization that is suspended is not Valid and cannot be used until the suspension ends. This is true even if the Applicant has filed an application for a renewal.

Section 46. It is proposed to amend Section 11B-06 of the Rules of the City of New York to read as follows:

§ 11B-06 Authorization Fees

(a) [***Reserved*** (Commuter Service Authorization Fee)]*Fee for Authorization.* The fee for a Commuter Van Service Authorization will be $275 annually.

(b) *When Fee is Paid.* The fee for an original or renewal Authorization must be paid at the time the application is filed.

(c) *No Refund if Application Denied.* The Commission will not refund fees if it denies or disapproves the application.

([b]d) *Authorization Replacement Fee*. The fee to replace any lost, damaged or destroyed Authorization is $25.

(e) *Late Filing Fee.* The Commission will charge an additional fee of $25 for a late filing of a renewal application, if it allows the filing at all.

Section 47. It is proposed to amend Section 11B-07(d) of Title 35 of the Rules of the City of New York to read as follows:

(d) *Failure to* [*Approve.*]*Complete Application Requirements.* [Any application that the Commission, after consultation with the NYS Department of Transportation, does not approve or disapprove within 180 days after the completed application is filed will be considered disapproved.]
(1) The Commission will deny an application for a new Authorization if the Applicant has not completed all the requirements of an application within 180 days of the date the application is filed.

(2) The Commission will deny an application for a renewal Authorization if the Applicant has not completed all the requirements of an application within 180 days after the expiration of the prior Authorization.

(3) The Commission will not deny an application under this Rule if completion is delayed because the Commission has not issued a final decision in any fitness Hearing it requires.

Section 48. It is proposed to amend Section 12-04 of Title 35 of the Rules of the City of New York to add a new subdivision (g) to read as follows:

(g) *Payment of Fines and Fees.*

(1) An Applicant, including an applicant for a renewal License, must pay, and provide proof of payment of, any outstanding fines or fees owed by the Applicant to
(i) the Commission,
(ii) NYC Department of Finance's Parking Violations Bureau,
(iii) NYC Department of Finance's Red Light Camera Unit,
(iv) NYS DMV's Traffic Violations Bureau and
(v) any of their successor agencies.

(2) This requirement includes payment of fines and fees owed as of the date of the application by
(i) any Business Entity Persons of the Applicant
(ii) any Business Entity of which the Applicant is a Business Entity Person, and
(iii) any Business Entity of which a Business Entity Person of Applicant is also a Business Entity Person.

Section 49. It is proposed to amend Section 12-06 of Title 35 of the Rules of the City of New York to add subdivisions (c), (d) and (e) to read as follows:

(c) *No Refund if Application Denied.* The Commission will not refund fees if it denies or disapproves the application.

(d) *License Replacement Fee*. The fee to replace any lost, damaged or destroyed License is $25.

(e) *Late Filing Fee.* The Commission will charge an additional fee of $25 for a late filing of a renewal application, if it allows the filing at all.

Section 50. It is proposed to amend Section 12-09 of Title 35 of the Rules of the City of New York to read as follows:

(a) *Term of License.* Taxicab Broker's Licenses will be issued as of January 1st and will expire on the next December 31st unless suspended or revoked before then by the Commission.

(b)) *When to File for Renewal*.

(1) A renewing Applicant must file a completed application at least 60 days before the expiration date of the License in order to avoid a late fee.

(2) A renewing Applicant can file a completed application less than 60 days before the expiration date as a "late application," if the Applicant pays a late fee of $25.

(3) The postmark date is the date of filing for an application that is filed by mail. The date of submission is the date of filing for an applications that is filed in person.

(4) The Commission will not accept a renewal application after the expiration date of the License. If the application is not filed before the expiration date, the License cannot be renewed.

(c) *Suspended Licenses*.

(1) If a License is suspended, the Licensee must apply for renewal as required in (b) above if the Licensee wants to renew the License. Failure to complete the renewal requirements means that the License cannot be renewed.

(2) A License that is suspended is not Valid and cannot be used until the suspension ends. This is true even if the Applicant has filed an application for a renewal.

Section 51. It is proposed to amend Section 12-10 of Title 35 of the Rules of the City of New York to add a new subdivision (d) to read as follows:

(d) *Failure to Complete Application Requirements*

(1) The Commission will deny an application for a new License if the Applicant has not completed all the requirements of an application within 120 days of the date the application is filed.

(2) The Commission will deny an application for a renewal License if the Applicant has not completed all the requirements of an application within 30 days after the expiration of the prior License.

(3) The Commission will not deny an application under this Rule if completion is delayed because the Commission has not issued a final decision in any fitness Hearing it requires.

Section 52. It is proposed to amend Section 13-04 of Title 35 of the Rules of the City of New York to add a new subdivision (g) to read as follows:

(g) *Payment of Fines and Fees.*

(1) An Applicant, including an applicant for a renewal License, must pay, and provide proof of payment of, any outstanding fines or fees owed by the Applicant to
(i) the Commission,
(ii) NYC Department of Finance's Parking Violations Bureau,
(iii) NYC Department of Finance's Red Light Camera Unit,
(iv) NYS DMV's Traffic Violations Bureau and
(v) any of their successor agencies.

(2) This requirement includes payment of fines and fees owed as of the date of the application by
(i) any Business Entity Persons of the Applicant
(ii) any Business Entity of which the Applicant is a Business Entity Person, and
(iii) any Business Entity of which a Business Entity Person of Applicant is also a Business Entity Person.

Section 53. It is proposed to amend Section 13-05 of Title 35 of the Rules of the City of New York to add new subdivisions (c) and (d) to read as follows:

(c) *When to File for Renewal*.

(1) A renewing Applicant must file a completed application at least 60 days before the expiration date of the License in order to avoid a late fee.

(2) A renewing Applicant can file a completed application less than 60 days before the expiration date as a "late application," if the Applicant pays a late fee of $25.

(3) The postmark date is the date of filing for an application that is filed by mail. The date of submission is the date of filing for an application that is filed in person.

(4) The Commission will not accept a renewal application after the expiration date of the License. If the application is not filed before the expiration date, the License cannot be renewed.

(d) *Suspended Licenses*.

(1) If a License is suspended, the Licensee must apply for renewal as required in (c) above if the Licensee wants to renew the License. Failure to complete the renewal requirements means that the License cannot be renewed.

(2) A License that is suspended is not Valid and cannot be used until the suspension ends. This is true even if the Applicant has filed an application for a renewal.

Section 54. It is proposed to amend Section 13-06 of Title 35 of the Rules of the City of New York to add new subdivisions (d), (e) and (f) to read as follows:

(d) *No Refund if Application Denied.* The Commission will not refund fees if it denies or disapproves the application.

(e) *License Replacement Fee*. The fee to replace any lost, damaged or destroyed License is $25.

(f) *Late Filing Fee.* The Commission will charge an additional fee of $25 for a late filing of a renewal application, if it allows the filing at all.

Section 55. It is proposed to amend Section 13-07 of Title 35 of the Rules of the City of New York to add a new subdivision (f) to read as follows:

(f) *Failure to Complete Application Requirements.*

(1) The Commission will deny an application for a new License if the Applicant has not completed all the requirements of an application within 120 days of the date the application is filed.

(2) The Commission will deny an application for a renewal License if the Applicant has not completed all the requirements of an application within 30 days after the expiration of the prior License.

(3) The Commission will not deny an application under this Rule if completion is delayed because the Commission has not issued a final decision in any fitness Hearing it requires.

Section 56. It is proposed to amend Section 14-04 of Title 35 of the Rules of the City of New York to add a new subdivision (k) to read as follows:

(k) *Payment of Fines and Fees.*

(1) An Applicant, including an applicant for a renewal License, must pay, and provide proof of payment of, any outstanding fines or fees owed by the Applicant to
(i) the Commission,
(ii) NYC Department of Finance's Parking Violations Bureau,
(iii) NYC Department of Finance's Red Light Camera Unit,
(iv) NYS DMV's Traffic Violations Bureau and
(v) any of their successor agencies.

(2) This requirement includes payment of fines and fees owed as of the date of the application by
(i) any Business Entity Persons of the Applicant
(ii) any Business Entity of which the Applicant is a Business Entity Person, and
(iii) any Business Entity of which a Business Entity Person of Applicant is also a Business Entity Person.

Section 57. It is proposed to amend Section 14-07 of Title 35 of the Rules of the City of New York to read as follows:

(a) *Annual Fee.* Every application for a Taximeter License must be accompanied by a non-refundable application fee of $500 for each location to be Licensed.

(b) *Half-Year Fee.* The application fee for any Taximeter License to be issued for a period of six months or less will be one-half of the annual fee.

(c) *Form of Payment.* The application fee must be paid by credit card, money order, or certified check.

(d) *No Refund if Application Denied.* The Commission will not refund fees if it denies or disapproves the application.

(e) *License Replacement Fee*. The fee to replace any lost, damaged or destroyed License is $25.

(f) *Late Filing Fee.* The Commission will charge an additional fee of $25 for the late filing of a renewal application, if it allows the filing at all.

[(d)](g) *Term of License.* The term of a Taximeter License will be one year or less and each License will expire on the 31st day of March.

(h) *When to File for Renewal*.

(1) A renewing Applicant must file a completed application at least 60 days before the expiration date of the License in order to avoid a late fee.

(2) A renewing Applicant can file a completed application less than 60 days before the expiration date as a "late application," if the Applicant pays a late fee of $25.

(3) The postmark date is the date of filing for an application that is filed by mail. The date of submission is the date of filing for an application that is filed in person.

(4) The Commission will not accept a renewal application after the expiration date of the License. If the application is not filed before the expiration date, the License cannot be renewed.

(i) *Suspended Licenses*.

(1) If a License is suspended, the Licensee must apply for renewal as required in (h) above if the Licensee wants to renew the License. Failure to complete the renewal requirements means that the License cannot be renewed.

(2) A License that is suspended is not Valid and cannot be used until the suspension ends. This is true even if the Applicant has filed an application for a renewal.

Section 58. It is proposed to amend Section 14-08 of Title 35 of the Rules of the City of New York to add a new subdivision (c) to read as follows:

(c) *Failure to Complete Application Requirements*

(1) The Commission will deny an application for a new License if the Applicant has not completed all the requirements of an application within 120 days of the date the application is filed.

(2) The Commission will deny an application for a renewal License if the Applicant has not completed all the requirements of an application within 30 days after the expiration of the prior License.

(3) The Commission will not deny an application under this Rule if completion is delayed because the Commission has not issued a final decision in any fitness Hearing it requires.

Statement of Basis and Purpose

These proposed rules make several changes to the Commission's rules regarding the license application and renewal process and requirements. The principal changes are:

- The rules set deadlines by which licensees must file renewal applications. Ordinarily, a renewal application must be submitted by no later than 30 days before expiration of a license. However, applications will be accepted after that date, until the license expiration date upon payment of a $25 late fee. No application will be accepted after the license expiration date and (except for taxicab medallions), the license will expire and cannot thereafter be renewed.
- The rules provide that licensees on suspension who wish to renew their licenses must do so within the time periods that govern all other licensees.
- The rules provide deadlines by which applications must be completed or they will be denied.
- The rules provide that holders of commuter van authorizations must pay a license fee.
- The rules change the 30 day period in which FHVs must pass renewal inspections to a 60 day period, which is the same period permitted for passing inspections on new applications.
- The rules provide that any applicant for a license, including a renewal license, must, as a condition of licensure, pay any outstanding fees and fines owed to any of the Commission, the NYC Department of Finance Parking Violations Bureau, the NYC Department of Finance Red Light Camera Unit, or the NYS DMV Traffic Violations Bureau.
- The rules provide, as permitted by the New York City Administrative Code and where not already included in TLC Rules, that the TLC will impose a $25 late fee on renewal license applicants who seek to file a renewal application after the deadline specified in TLC rules.
- The rules provide, again consistent with the New York City Administrative Code and where not already included in the TLC Rules, that any fees (and that includes late fees where applicable) paid to the TLC are not refundable in the event that a license application is denied or disapproved.

These rules are proposed to simplify and standardize the application and renewal process and requirements across license classes and to give applicants and the TLC staff clear deadlines by which actions must occur. In addition, these rules will assist the Commission in collecting fines that may be owed by a former licensee who applies for a new license. The Commission believes that requiring license applicants to pay fines owed to the Commission and fines owed to other agencies as a result of traffic or parking violations is an important component of its regulatory mission to assure that its licensees comply with Commission and traffic rules and regulations.

This rule amends the version of the Commission's rules that becomes effective April 1, 2011.

☛ **d17**

SPECIAL MATERIALS

CITYWIDE ADMINISTRATIVE SERVICES

MUNICIPAL SUPPLY SERVICES

■ NOTICE

OFFICIAL FUEL PRICE SCHEDULE NO. 6589
FUEL OIL AND KEROSENE

CONTRACT NO.	ITEM NO.	FUEL/OIL TYPE		VENDOR	CHANGE	PRICE EFF. 12/13/2010
2887105	2.0	#1DULS	MANH	SPRAGUE ENERGY CORP	+.0505 GAL.	2.9804 GAL.
2887105	3.0	#1DULS	BRONX	SPRAGUE ENERGY CORP	+.0505 GAL.	2.9804 GAL.
2887105	4.0	#1DULS	BROOKLYN	SPRAGUE ENERGY CORP	+.0505 GAL.	3.0154 GAL.
2887105	5.0	#1DULS	QUEENS	SPRAGUE ENERGY CORP	+.0505 GAL.	3.0154 GAL.
2887105	6.0	#1DULS	S.I.	SPRAGUE ENERGY CORP	+.0505 GAL.	3.0804 GAL.
2887105	7.0	#1DULS	P/U	SPRAGUE ENERGY CORP	+.0505 GAL.	2.8922 GAL.
2887086	3.0	#1DULSB20	CITY WIDE BY TW	SPRAGUE ENERGY CORP	+.0549 GAL.	3.0874 GAL.
2887086	7.0	#1DULSB20	P/U	SPRAGUE ENERGY CORP	+.0549 GAL.	3.0177 GAL.
2887086	1.0	#1DULSB5	CITY WIDE BY TW	SPRAGUE ENERGY CORP	+.0516 GAL.	2.9457 GAL.
2887086	5.0	#1DULSB5	P/U	SPRAGUE ENERGY CORP	+.0516 GAL.	2.8637 GAL.
3087064	1.0	#1DULSB50	CITY WIDE BY TW	METRO FUEL OIL CORP.	+.0615 GAL.	3.8743 GAL.
2887052	1.0	#2	MANH	RAPID PETROLEUM	+.0530 GAL.	2.5102 GAL.
2887052	4.0	#2	BRONX	RAPID PETROLEUM	+.0530 GAL.	2.5100 GAL.
2887052	7.0	#2	BROOKLYN	RAPID PETROLEUM	+.0530 GAL.	2.4996 GAL.
2887052	13.0	#2	S.I.	RAPID PETROLEUM	+.0530 GAL.	2.5431 GAL.
2887053	10.0	#2	QUEENS	METRO FUEL OIL CORP.	+.0530 GAL.	2.5329 GAL.
2887169	1.0	#2B5	CITY WIDE BY TW	METRO FUEL OIL CORP.	+.0539 GAL.	2.9507 GAL.
2887105	8.0	#2DHS	BARGE M.T.F. 111	SPRAGUE ENERGY CORP	+.0530 GAL.	2.7857 GAL.
2887106	9.0	#2DHS	BARGE WI	METRO FUEL OIL CORP.	+.0530 GAL.	2.6971 GAL.
2887301	1.0	#2DLS	BARGE ST. GEORGE	METRO FUEL OIL CORP.	+.0448 GAL.	2.7908 GAL.
2887301	3.0	#2DLS	P/U	METRO FUEL OIL CORP.	+.0448 GAL.	2.6536 GAL.
2887105	1.0	#2DULS	CITY WIDE BY TW	SPRAGUE ENERGY CORP	+.0436 GAL.	2.6524 GAL.
2887105	1.1	#2DULS	P/U	SPRAGUE ENERGY CORP.	+.0436 GAL.	2.6174 GAL.
2887301	2.0	#2DULS	BARGE ST. GEORGE	METRO FUEL OIL CORP.	+.0436 GAL.	2.7321 GAL.
2887086	4.0	#2DULSB20	CITY WIDE BY TW	SPRAGUE ENERGY CORP	+.0494 GAL.	2.9137 GAL.
2887087	8.0	#2DULSB20	P/U	METRO FUEL OIL CORP.	+.0494 GAL.	3.2645 GAL.
2887086	2.0	#2DULSB5	CITY WIDE BY TW	SPRAGUE ENERGY CORP	+.0451 GAL.	2.7420 GAL.
2887105	10.0	#2DULSB5	BARGE ST. GEORGE	SPRAGUE ENERGY CORP	+.0451 GAL.	3.2773 GAL.
2887159	6.0	#2DULSB5	P/U	METRO FUEL OIL CORP.	+.0451 GAL.	2.7897 GAL.
3087065	2.0	#2DULSB50	CITY WIDE BY TW	SPRAGUE ENERGY CORP.	+.0581 GAL.	3.6720 GAL.
2887274	7.0	#2DULSDISP	DISPENSED	SPRAGUE ENERGY CORP.	+.0436 GAL.	2.9793 GAL.
2887052	2.0	#4	MANH	RAPID PETROLEUM	+.0616 GAL.	2.3630 GAL.
2887052	5.0	#4	BRONX	RAPID PETROLEUM	+.0616 GAL.	2.3664 GAL.
2887052	8.0	#4	BROOKLYN	RAPID PETROLEUM	+.0616 GAL.	2.3772 GAL.
2887052	14.0	#4	S.I.	RAPID PETROLEUM	+.0616 GAL.	2.4102 GAL.
2887053	11.0	#4	QUEENS	METRO FUEL OIL CORP.	+.0616 GAL.	2.3820 GAL.
2887052	3.0	#6	MANH	RAPID PETROLEUM	+.0674 GAL.	2.2804 GAL.
2887052	6.0	#6	BRONX	RAPID PETROLEUM	+.0674 GAL.	2.2804 GAL.
2887052	9.0	#6	BROOKLYN	RAPID PETROLEUM	+.0674 GAL.	2.2954 GAL.
2887052	15.0	#6	S.I.	RAPID PETROLEUM	+.0674 GAL.	2.3314 GAL.
2887054	12.0	#6	QUEENS	CASTLE OIL CORPORATION	+.0674 GAL.	2.2995 GAL.
2787347	1.0	JETA	FLOYD BENNETT	SPRAGUE ENERGY CORP	+.0583 GAL.	3.2386 GAL.

OFFICIAL FUEL PRICE SCHEDULE NO. 6590
FUEL OIL, PRIME AND START

CONTRACT NO.	ITEM NO.	FUEL/OIL TYPE		VENDOR	CHANGE	PRICE EFF. 12/13/2010
3087154	1.0	#2	MANH	F & S PETROLEUM CORP.	+.0530 GAL.	2.6167 GAL.
3087154	79.0	#2	BRONX	F & S PETROLEUM CORP.	+.0530 GAL.	2.6167 GAL.
3087154	157.0	#2	BKLYN, QUEENS, SI	F & S PETROLEUM CORP.	+.0530 GAL.	2.6967 GAL.
3087225	1.0	#4	CITY WIDE BY TW	METRO FUEL OIL CORP.	+.0616 GAL.	2.8111 GAL.
3087225	2.0	#6	CITY WIDE BY TW	METRO FUEL OIL CORP.	+.0674 GAL.	2.6854 GAL.

OFFICIAL FUEL PRICE SCHEDULE NO. 6591
FUEL OIL AND REPAIRS

CONTRACT NO.	ITEM NO.	FUEL/OIL TYPE		VENDOR	CHANGE	PRICE EFF. 12/13/2010
3087115	1.0	#2	MANH & BRONX	PACIFIC ENERGY	+.0530 GAL.	2.4421 GAL.
3087115	80.0	#2	BKLYN, QUEENS, SI	PACIFIC ENERGY	+.0530 GAL.	2.4473 GAL.
3087218	1.0	#4	CITY WIDE BY TW	PACIFIC ENERGY	+.0616 GAL.	2.7524 GAL.
3087218	2.0	#6	CITY WIDE BY TW	PACIFIC ENERGY	+.0674 GAL.	2.7383 GAL.

OFFICIAL FUEL PRICE SCHEDULE NO. 6592
GASOLINE

CONTRACT NO.	ITEM NO.	FUEL/OIL TYPE	VENDOR		CHANGE	PRICE EFF. 12/13/2010
2687312	1.0	E70	CITY WIDE BY TW	SPRAGUE ENERGY CORP.	-.0390 GAL.	2.6122 GAL.
2787192	7.0	PREM	CITY WIDE BY TW	METRO TERMINALS	-.0410 GAL.	2.6566 GAL.
2887274	6.0	PREM	CITY WIDE BY VEHICLE	SPRAGUE ENERGY CORP.	-.0410 GAL.	2.8901 GAL.
2787192	1.0	U.L.	CITY WIDE BY TW	METRO TERMINALS	-.0031 GAL.	2.4564 GAL.
2887274	1.0	U.L.	MANH P/U BY VEHICLE	SPRAGUE ENERGY CORP.	-.0031 GAL.	2.8275 GAL.
2887274	2.0	U.L.	BX P/U BY VEHICLE	SPRAGUE ENERGY CORP.	-.0031 GAL.	2.7275 GAL.
2887274	3.0	U.L.	BR P/U BY VEHICLE	SPRAGUE ENERGY CORP.	-.0031 GAL.	2.7275 GAL.
2887274	4.0	U.L.	QNS P/U BY VEHICLE	SPRAGUE ENERGY CORP.	-.0031 GAL.	2.7275 GAL.
2887274	5.0	U.L.	S.I. P/U BY VEHICLE	SPRAGUE ENERGY CORP.	-.0031 GAL.	2.7275 GAL.

☛ **d17**

HEALTH AND MENTAL HYGIENE

■ NOTICE

Notice of Concept Paper

In advance of the release of a Request for Proposals for a School-Located Mass Influenza Vaccination Campaign, the Department of Health and Mental Hygiene (DOHMH) is issuing a concept paper presenting DOHMH's plan for this new citywide service. The concept paper will be posted from 12/13/10 through 1/26/2011 on the Department's website at http://www.nyc.gov/health/contracting and public comment is invited.

d13-17

HOUSING PRESERVATION & DEVELOPMENT

■ NOTICE

OFFICE OF ENFORCEMENT & NEIGHBORHOOD SERVICES
CERTIFICATION OF NO HARASSMENT UNIT

REQUEST FOR COMMENT ON APPLICATION FOR CERTIFICATION OF NO HARASSMENT PURSUANT TO LOCAL LAW 19 OF 1983

DATE OF NOTICE: December 10, 2010

TO: OCCUPANTS, FORMER OCCUPANTS AND OTHER INTERESTED PARTIES OF

Address	Application #	Inquiry Period
79 West 119th Street, Manhattan	100/10	November 15, 2007 to Present
122 West 130th Street, Manhattan	101/10	November 16, 2007 to Present
608 8th Avenue, Manhattan	102/10	November 18, 2007 to Present
56 West 130 Street, Manhattan	103/10	November 18, 2007 to Present
136 West 123 Street, Manhattan	106/10	November 22, 2007 to Present
449 51st Street, Brooklyn	99/ 10	November 10, 2007 to Present
1234 Dean Street, Brooklyn	104/10	November 19, 2007 to Present
312 Alexander Avenue, Bronx	105/10	November 22, 2007 to Present

The Department of Housing Preservation and Development has received an application for a certification that during the inquiry period noted for the premises above, that no harassment has occurred at such premises in the form of threats, use of physical force, deprivation of essential services such as heat, water, gas or electric, or by any other conduct intended to cause persons to vacate the premises or waive rights related to their occupancy. Upon the issuance of a Certification, an owner can legally convert the premises to non-single room occupancy use.

Comments as to whether harassment has occurred at the premises should be submitted to the Anti-Harassment Unit, 100 Gold Street, 3rd Floor, New York, NY 10038, by letter postmarked not later than 30 days from the date of this notice or by an in-person statement made within the same period. To schedule an appointment for an in-person statement call (212) 863-5277, (212) 863-8211 or (212) 863-8298.

d10-21

OFFICE OF PRESERVATION SERVICES
CERTIFICATION OF NO HARASSMENT UNIT

REQUEST FOR COMMENT ON APPLICATION FOR CERTIFICATION OF NO HARASSMENT PURSUANT TO THE SPECIAL CLINTON DISTRICT PROVISIONS OF THE ZONING RESOLUTION

DATE OF NOTICE: December 10, 2010

TO: OCCUPANTS, FORMER OCCUPANTS AND OTHER INTERESTED PARTIES OF

Address	Application #	Inquiry Period
313 West 48th Street, Manhattan	97/10	November 9, 1995 to Present

Prior to the issuance of a permit by the Department of Buildings for the alteration or demolition of residential buildings in certain areas of the **Special Clinton District**, the Department of Housing Preservation and Development is required to certify that: 1) prior to evicting or otherwise terminating the occupancy of any tenant preparatory to alteration or demolition, the owner shall have notified HPD of the owner's intention to alter or demolish the building and 2) the eviction and relocation practices followed by the owner of the building satisfy all applicable legal requirements and that no harassment has occurred.

The owner of the building located at the above-referenced address seeks the issuance of an HPD Certification. The owner has represented and certified to HPD of the owner's intention to alter or demolish the building and that the eviction and relocation practices followed by the owner satisfy all applicable legal requirements and that no harassment has occurred. For your information HPD considers harassment to include, but not be limited to, the threatened or actual use of physical force, deprivation of essential services such as heat, water, gas or electric, or any other conduct intended to cause persons to vacate the premises or waive rights related to their occupancy.

HPD requests that if you have any comments or evidence of unlawful eviction and relocation practices or harassment occurring at the above referenced premises that you notify the Anti-Harassment Unit, 3rd Floor, 100 Gold Street, New York, NY 10038, by letter postmarked not later than 30 days from the date of this notice or by an in-person statement made within the same period. To schedule an appointment for an in-person statement call (212) 863-5277, (212) 863-8211 or (212) 863-8298.

d10-21

TRANSPORTATION

■ NOTICE

PUBLIC NOTICE OF A CONCESSION OPPORTUNITY FOR THE OPERATION, MANAGEMENT AND MAINTENANCE OF PEDESTRIAN PLAZAS LOCATED AT ASTOR PLACE, LAFAYETTE STREET, EAST 9TH STREET AND 4TH AVENUE, BOROUGH OF MANHATTAN

Pursuant to the Concession Rules of the City of New York, the Department of Transportation ("DOT") intends to enter into a concession for the operation, management, and maintenance of pedestrian plazas located at Astor Place, Lafayette Street, East 9th Street, and 4th Avenue in Manhattan ("Licensed Plaza"), including through DOT-approved events, sponsorships, and subconcessions including but not limited to providing for the sale of any of the following: prepared food, flowers, locally grown produce or locally manufactured products, merchandise (such as souvenirs or T-shirts) that helps brand or promote the neighborhood or the concessionaire, and other similar merchandise.

Subconcessions would be awarded based on solicitations issued by the concessionaire in the basic form of Request for Proposals or Request for Bids, subject to DOT's prior written approval of both solicitation and award.

The concession agreement will provide for one (1) five-year term, with four (4) one-year renewal options. The renewal options shall be exercisable at DOT's sole discretion.

DOT has identified the Village Alliance District Management Association, Inc. as a potential concessionaire, but DOT will consider additional expressions of interest from other potential not-for-profit concessionaires for the operation, management, and maintenance of the Licensed Plaza. In order to qualify, interested organizations should be active in the neighborhood of the Licensed Plaza and have demonstrated experience in the management, operation and maintenance of publicly accessible facilities, including but not limited to programming/events management and concession or retail operation/management.

Not for profit organizations may express interest in the proposed concession by contacting Andrew Wiley-Schwartz, Assistant Commissioner for Public Spaces, by email at awileyschwartz@dot.nyc.gov or in writing at 55 Water Street, 9th Floor, New York, NY 10041 by January 10, 2011. Mr. Wiley-Schwartz may also be contacted with any questions relating to the proposed concession by email or by telephone at (212) 839-6678.

Please note that the New York City Comptroller is charged with the audit of concession agreements in New York City. Any person or entity that believes that there has been unfairness, favoritism or impropriety in the concession process should inform the Comptroller, Office of Contract Administration, 1 Centre Street, New York, New York 10007, telephone number (212) 669-2323.

☛ **d17-j10**

READER'S GUIDE

The City Record (CR) is, published each business day and includes notices of proposed New York City procurement actions, contract awards, and other procurement-related information. Solicitation notices for most procurements valued at or above $100,000 for information technology and for construction and construction related services, above $50,000 for other services, and above $25,000 for other goods are published for at least one day. Other types of procurements, such as sole source, require notice in the City Record for five consecutive days. Unless otherwise specified, the agencies and offices listed are open for business Mondays thru Fridays from 9:00 A.M. to 5:00 P.M. except legal holidays.

NOTICE TO ALL NEW YORK CITY CONTRACTORS

The New York State Constitution ensures that all laborers, workers or mechanics employed by a contractor or subcontractor doing public work are to be paid the same wage rate that prevails in the trade where the public work is being done. Additionally, New York State Labor Law §§ 220 and 230 provide that a contractor or subcontractor doing public work in construction or building service must pay its employees no less than the prevailing wage. Section 6-109 (the Living Wage Law) of the New York City Administrative Code also provides for a "living wage", as well as prevailing wage, to be paid to workers employed by City contractors in certain occupations. The Comptroller of the City of New York is mandated to enforce prevailing wage. Contact the NYC Comptrollers Office at www.comptroller.nyc.gov, click on Labor Law Schedules to view rates.

New York City's "Burma Law" (Local Law No. 33 of 1997) No Longer to be Enforced. In light of the United States Supreme Court's decision in **Crosby v. National Foreign Trade Council,** 530 U.S. 363 (2000), the City has determined that New York City's Local Law No. 33 of 1997 (codified in Administrative Code Section 6-115 and Charter Section 1524), which restricts City business with banks and companies doing business in Burma, is unconstitutional. This is to advise, therefore, that the language relating to Burma contained in existing New York City contracts may not be enforced.

CONSTRUCTION/CONSTRUCTION SERVICES OR CONSTRUCTION RELATED SERVICES

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.

VENDOR ENROLLMENT APPLICATION

New York City procures approximately $7 billion worth of goods, services, construction and construction-related services every year. The NYC Procurement Policy Board Rules require that agencies primarily solicit from established mailing lists called bidder/proposer lists. To register for these lists--free of charge-, prospective suppliers should fill out and submit the NYC-FMS Vendor Enrollment application.

- Online at http://nyc.gov/selltonyc
- To request a hardcopy application, call the Vendor Enrollment Center at (212) 857-1680.

Attention Existing Suppliers:
Even if you already do business with NYC agencies, be sure to fill out an application. We are switching over to citywide, centralized Bidders Lists instead of the agency-specific lists previously used to issue notices about upcoming contract opportunities. To continue receiving notices of New York City contract opportunities, you must fill out and submit a NYC-FMS Vendor Enrollment application.
If you are uncertain whether you have already submitted an application, call us at (212) 857-1680.

SELLING TO GOVERNMENT TRAINING WORKSHOP

New and experienced vendors are encouraged to register for a free training course on how to do business with New York City. "Selling to Government" workshops are conducted by the Department of Small Business Services, 110 William Street, New York, NY 10038. Morning and afternoon sessions are convened on the first Tuesday of each month. For more information, and to register, call (212) 618-8845.

PRE-QUALIFIED LIST

New York City procurement policy permits agencies to develop and solicit from pre-qualified lists of vendors, under prescribed circumstance. When it is decided by an agency to develop a pre-qualified list, criteria for pre-qualification must be clearly explained in the solicitation and notice of the opportunity to pre-qualify for that solicitation must be published in at least five issues of the *CR*.

Information and qualification questionnaires for inclusion on such list may be obtained directly from the Agency Chief Contracting Officer at each agency, (see Vendor Information Manual). A completed qualification Questionnaire may be submitted to the Chief Contracting Officer at any time, unless otherwise indicated and action (approval or denial) shall be taken by the agency within 90 days from the date of submission. Any denial or revocation of pre-qualified status can be appealed to the Office of Administrative Trials and Hearings, (OATH), Section 3-11 of the Procurement Policy Board Rules describes the criteria for the general use of pre-qualified lists.

NON-MAYORAL ENTITIES

The following agencies are not subject to Procurement Policy Board rules and do not follow all of the above procedures: City University, Department of Education, Metropolitan Transportation Authority, Health & Hospitals Corporation, Housing Authority. Suppliers interested in applying for inclusion on bidders list should contact these entities directly (see Vendor Information Manual) at the addresses given.

PUBLIC ACCESS CENTER

The Public Access Center is available to suppliers and the public as a central source for supplier-related information through on-line computer access. The Center is located at 253 Broadway, 9th floor, in lower Manhattan, and is open Monday through Friday from 10:00 A.M to 3:00 P.M. For information, contact the Mayor's Office of Contract Services at (212) 788-0010.

ATTENTION: NEW YORK CITY MINORITY AND WOMEN OWNED BUSINESS ENTERPRISES

Join the growing number of Minority and Women Owned Business Enterprises (M/WBEs) that are competing for New York City's business. In order to become certified for the program, your company must substantiate that it: (1) is at least fifty-one percent (51%) owned, operated and controlled by a minority or woman and (2) is either located in New York City or has a significant tie to New York City's business community. To obtain a copy of the certification application and to learn more about the program, contact the New York City Department of Small Business Services, 110 William Street, 2nd Floor, New York, New York 10038 (212) 513-6311.

PROMPT PAYMENT

It is the policy of the City of New York to pay its bills promptly. The Procurement Policy Board Rules generally require that the City pay its bills within 30 days after the receipt of a proper invoice. The City now pays interest on all late invoices. The grace period that formerly existed was eliminated on July 1, 2000. However, there are certain types of payments that are not eligible for interest. These are listed in Section 4-06 of the Procurement Policy Board Rules. The Comptroller and OMB determine the interest rate on late payments twice a year, in January and in July.

PROCUREMENT POLICY BOARD RULES

The Rules may also be accessed on the City Website, http://nyc.gov/selltonyc

COMMON ABBREVIATIONS USED IN THE CR

The CR contains many abbreviations. Listed below are simple explanations of some of the most common ones appearing in the CR:

AB ..... Acceptable Brands List
AC .....Accelerated Procurement
AMT .....Amount of Contract
BL .....Bidders List
CSB .....Competitive Sealed Bidding (including multi-step)
CB/PQ .....CB from Pre-qualified Vendor List
CP .....Competitive Sealed Proposal (including multi-step)
CP/PQ .....CP from Pre-qualified Vendor List
CR .....The City Record newspaper
DA .....Date bid/proposal documents available
DUE .....Bid/Proposal due date; bid opening date
EM .....Emergency Procurement
IG .....Intergovernmental Purchasing
LBE .....Locally Based Business Enterprise
M/WBE .....Minority/Women's Business Enterprise
NA .....Negotiated Acquisition
NOTICE....Date Intent to Negotiate Notice was published in CR
OLB .....Award to Other Than Lowest Responsible & Responsive Bidder/Proposer
PIN .....Procurement Identification Number
PPB .....Procurement Policy Board
PQ .....Pre-qualified Vendors List
RS .....Source required by state/federal law or grant
SCE .....Service Contract Short-Term Extension
DP .....Demonstration Project
SS .....Sole Source Procurement
ST/FED .....Subject to State &/or Federal requirements

KEY TO METHODS OF SOURCE SELECTION

The Procurement Policy Board (PPB) of the City of New York has by rule defined the appropriate methods of source selection for City procurement and reasons justifying their use. The CR procurement notices of many agencies include an abbreviated reference to the source selection method utilized. The following is a list of those methods and the abbreviations used:

CSB .....**Competitive Sealed Bidding** (including multi-step)
Special Case Solicitations/Summary of Circumstances:
CP .....***Competitive Sealed Proposal*** (including multi-step)
CP/1 .....Specifications not sufficiently definite
CP/2 .....Judgement required in best interest of City
CP/3 .....Testing required to evaluate
CB/PQ/4 ....
CP/PQ/4 ....**CB or CP from Pre-qualified Vendor List/** Advance qualification screening needed
DP .....Demonstration Project
SS .....**Sole Source Procurement/**only one source
RS .....Procurement from a Required Source/ST/FED
NA .....Negotiated Acquisition
For ongoing construction project only:
NA/8 .....Compelling programmatic needs
NA/9 .....New contractor needed for changed/additional work
NA/10 .....Change in scope, essential to solicit one or limited number of contractors
NA/11 .....Immediate successor contractor required due to termination/default
For Legal services only:
NA/12 .....Specialized legal devices needed; CP not advantageous
WA .....**Solicitation Based on Waiver/Summary of Circumstances** (Client Services/BSB or CP only)
WA1 .....Prevent loss of sudden outside funding
WA2 .....Existing contractor unavailable/immediate need
WA3 .....Unsuccessful efforts to contract/need continues
IG .....**Intergovernmental Purchasing** (award only)
IG/F .....Federal
IG/S .....State
IG/O .....Other
EM .....**Emergency Procurement** (award only) An unforeseen danger to:
EM/A .....Life
EM/B .....Safety
EM/C .....Property
EM/D .....A necessary service
AC .....**Accelerated Procurement/**markets with significant short-term price fluctuations
SCE .....**Service Contract Extension/**insufficient time; necessary service; fair price
Award to Other Than Lowest Responsible & Responsive Bidder or Proposer/Reason (award only)
OLB/a .....anti-apartheid preference
OLB/b .....local vendor preference
OLB/c .....recycled preference
OLB/d .....other: (specify)

HOW TO READ CR PROCUREMENT NOTICES

Procurement Notices in the CR are arranged by alphabetically listed Agencies, and within Agency, by Division if any. The notices for each Agency (or Division) are further divided into three subsections: Solicitations, Awards; and Lists & Miscellaneous notices. Each of these subsections separately lists notices pertaining to Goods, Services, or Construction.

Notices of Public Hearings on Contract Awards appear at the end of the Procurement Section. At the end of each Agency (or Division) listing is a paragraph giving the specific address to contact to secure, examine and/or to submit bid or proposal documents, forms, plans, specifications, and other information, as well as where bids will be publicly opened and read. This address should be used for the purpose specified UNLESS a different one is given in the individual notice. In that event, the directions in the individual notice should be followed. The following is a SAMPLE notice and an explanation of the notice format used by the CR.

SAMPLE NOTICE:

POLICE

DEPARTMENT OF YOUTH SERVICES

■ **SOLICITATIONS**

Services (Other Than Human Services)

BUS SERVICES FOR CITY YOUTH PROGRAM – Competitive Sealed Bids – PIN# 056020000293 – DUE 04-21-03 AT 11:00 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.
NYPD, Contract Administration Unit, 51 Chambers Street, Room 310, New York, NY 10007. Manuel Cruz (646) 610-5225.

☛ **m27-30**

ITEM	EXPLANATION
POLICE DEPARTMENT	Name of contracting agency
DEPARTMENT OF YOUTH SERVICES	Name of contracting division
■ SOLICITATIONS	Type of Procurement action
Services (Other Than Human Services)	Category of procurement
BUS SERVICES FOR CITY YOUTH PROGRAM	Short Title
CSB	Method of source selection
PIN # 056020000293	Procurement identification number
DUE 04-21-03 AT 11:00 am	Bid submission due 4-21-03 by 11:00 am; bid opening date/time is the same.
Use the following address unless otherwise specified in notice, to secure, examine-submit bid/proposal documents; etc.	Paragraph at the end of Agency Division listing giving contact information, or submit bid/information or and Agency Contact address
	NYPD, Contract Administration Unit 51 Chambers Street, Room 310 New York, NY 10007. Manuel Cruz (646) 610-5225.
☛	Indicates New Ad
m27-30	Date that notice appears in City Record

NUMBERED NOTES
Numbered Notes are Footnotes. If a Numbered Note is referenced in a notice, the note so referenced must be read as part of the notice. **1.** All bid deposits must be by company certified check or money order made payable to Agency or Company.