NOTICE OF PUBLIC HEARING

Subject: Opportunity to comment on proposed amendments of Article 175 (Radiation Control) of

the New York City Health Code concerning new requirements for Cone Beam Computed Tomography (CBCT) units in dental facilities; revised requirements for radiation facility personnel protective lead garments and clarification about medical event reporting.

Date/Time: October 22, 2013/2PM to 4PM

Location: New York City Department of Health and Mental Hygiene

42-09 28th Street

14th Floor, Room 14-45 Queens, NY 11101

Contact: Roslyn Windholz

42-09 28th Street, 14th Floor, CN31 Long Island City, NY 11101-4132

(347) 396-6078/6116

Proposed Rules

These proposed changes for Article 175 of the New York City Health Code concern:

- Establishing standards for Cone Beam Computed Tomography (CBCT), an emerging x-ray technology now being used in dental offices in New York City; and
- Adding specific requirements for the methodology and testing frequency for operator lead protective garments as part of a radiation facility's quality assurance program; and
- Clarification that both licensees and registrants are required to report medical events.

The CBCT and protective lead garments proposals were included in the Department's FY2013 Regulatory Agenda; the medical event reporting clarification was not included in the FY2013 Regulatory Agenda as it is the result of recent analysis.

Instructions

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

New York City Department of Health and Mental Hygiene Board of Health Attention: Roslyn Windholz 42-09 28th Street, 14th Fl., CN31 Oueens, NY 11101-4132

Comments can also be sent electronically through NYCRULES at www.nyc.gov/nycrules, or, by email to resolutioncomments@health.nyc.gov or, online (without attachments) at http://www.nyc.gov/html/doh/html/about/notice.shtml on or before 5:00 P.M., on October 22, 2013.

- If you are interested in pre-registering to speak, please notify Roslyn Windholz by October 22, 2013. Please include a phone number where, if necessary, you may be reached during normal business hours. You can also register at the door until 4 PM; however, preference will be given to those who pre-register. At the public hearing, you can speak up to five minutes.
- To request a sign language interpreter or other form of reasonable accommodation for a disability at the hearing, please contact Roslyn Windholz at the phone number shown above by October 8, 2013.
 - 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/about/comment.shtml.
- Copies of written comments and a summary of oral comments received at the hearing will be available for public inspection within a reasonable time after the hearing between the hours of 9:00 A.M. and 5:00 P.M. at the address above.

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

The New York State Sanitary Code, in 10 NYCRR §16.1(b)(3), states that localities that have a population of more than 2,000,000 may establish their own radiation licensure requirements in place of State regulations, provided that the local requirements are consistent with Sanitary Code requirements.

Section 274 of the federal Atomic Energy Act of 1954 (codified at 42 USC §2021, "Atomic Energy Act") authorizes "Agreement States" to regulate byproduct material, source material and special nuclear material in quantities not sufficient to form a critical mass. New York State is an "Agreement State" within the meaning of the Atomic Energy Act, and the New York City Department of Health and Mental Hygiene is a component of the New York State Agreement. 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.

Statement of Basis and Purpose

ORH regulations for radiation machines and radioactive materials are contained in Article 175 of the Health Code. ORH registers and inspects radiation machines, and 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.

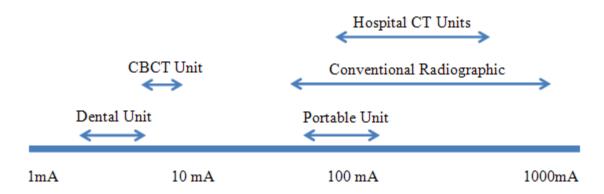
There are about 6500 registered facilities possessing radiation machines and 375 licensed sites in New York City possessing radioactive material for medical, academic and research purposes. Of the registered facilities, approximately 6440 are registered diagnostic X-ray facilities and 60 are therapeutic X-ray

facilities possessing certified registrations. ORH inspects these facilities at frequencies of once every 1, 2 or 3 years depending on the type of usage.

I. Cone Beam Computed Tomography (CBCT)

Cone Beam Computed Tomography (CBCT) units are specialty CT x-ray units that produce radiation levels higher than conventional dental intra-oral x-ray units and are utilized for the imaging of the jaw, specific teeth, and the sinus cavity with high resolution. CBCT is useful for imaging and reconstruction of the human anatomy where speed and accurate reconstruction of structures is essential, but low contrast resolution is not essential. CBCT units were introduced into the dental environment in the early 2000s as an advanced imaging technology for dentists. The dental community has embraced CBCT technology and dental imaging professional organizations have put out position papers on CBCT use in the dental office.

CBCT has the potential to generate radiation exposures outside the range of traditional dental x-ray devices and has increased operational complexity that can result in unintended exposures to the public and workers. The graphic below identifies where the CBCT radiographic units fit in the universe of radiographic units that ORH regulates. The scale below presents the range of exposure in terms of milliamperes (mA) values¹ and shows that CBCT units are outside the range found from common dental x-ray devices:



Another measure of comparison for radiographic units is to compare the typical Entrance Skin Exposure (ESE) or entrance patient dose, which are typically interchangeable for diagnostic x-ray kVps. CBCT manufacturer manuals reviewed indicate that the typical range for CBCT entrance dose is in the range of 2-4.4 mGy (about 0.2-0.44 rads). Data tabulated by the regulatory community in the United Kingdom shows that the effective dose for CBCT units are higher than conventional dental x-ray procedures:

Table: Typical doses from x-ray examinations of the head

Dental Panoramic Exam Effective Dose (uSv) = 24 micro Sieverts CBCT Unit (large Field of View) Effective Dose (uSv) = 68-1073 micro Sieverts CT Scan Dental Program Effective Dose (uSv) = 534-2100 micro Sieverts

¹ The quantity of electron flow (current) in the x-ray tube is described in units of milliamperes (mA). The rate of x-ray production is directly proportional to the x-ray tube current. Higher mA values indicate more electrons are striking the target and therefore producing more x-rays. (Source: http://www.e-radiography.net/radsafety/rad_physics.htm.)

Currently, there are no standards in Article 175 to regulate CBCTs installed in dental offices. ORH estimates that 90 dental facilities employ CBCT in New York City. Dental facilities possessing such CBCT units will be required to register with and allow inspection by the Department and will need to develop a quality assurance program, which will be composed of periodic quality control testing and a radiation safety manual to ensure patient and operator safety. The proposed regulations are needed to protect both the members of the public undergoing such CBCT exams and operators of the CBCT units.

II. Operator protective lead garments

Protective lead garments are an important radiation safety tool for radiation facility operators and their workers conducting fluoroscopic² procedures in order to reduce their occupational radiation exposures. To assure that these lead protective garments retain their integrity over time, these garments should undergo routine testing by a variety of methods, as indicated in these proposed rules. If defective protective garments are used unknowingly, then their users will be subjected to unnecessary radiation exposures.

Currently, there are no standards in Article 175 for the integrity testing of protective lead garments. These proposed rules will provide a uniform standard for testing lead protective garments for registrants of radiation facilities to help ensure that their workers' occupational radiation exposures can be minimized.

III. Medical event reporting

The Department seeks to clarify that reporting of a medical event is required not only of radiation materials licensees, but also by radiation equipment registrants. The internal cross-reference provided in the definition of "medical event" is also being revised.

At its meeting on September 10, 2013, the Board of Health adopted a resolution that amended portions of §§ 175.02 and 175.03 that are further amended in the proposals below. The text of the amendments proposed in this notice reflect Article 175 of the Health Code as it exists at the time this proposal was approved for publication, and do not include the changes adopted on September 10, 2013.

Matter in brackets [] is to be deleted. Matter underlined is new.

"Shall" and "must" denote mandatory requirements and may be used interchangeably in the rules of this Department, unless otherwise specified or unless the context clearly indicates otherwise.

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 July 9, 2013, is amended to update the definitions of medical event and protective garment, to be printed together with explanatory notes, to read as follows:

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² Fluoroscopy is a type of medical imaging that shows a continuous x-ray image on a monitor. It is used to diagnose or treat patients by displaying the movement of a body part or of an instrument or dye (contrast agent) through the body. During a fluoroscopy procedure, an x-ray beam is passed through the body. The image is transmitted to a monitor so that the body part and its motion can be seen in detail. (Source: http://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandproceduresmedicalimaging/medicalx-rays/ucm115354.htm)

§ 175.02 Definitions

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

(145) "Medical event" means an event that meets the criteria in [\$175.03(1)(8)] \(\frac{\xi}{2}\)175.03(1)(9) of this Code.

(185) "Protective [apron] <u>garment</u>" means an apron, <u>glove, thyroid shield or other protective barrier worn by a professional practitioner or licensed radiographic technologist or patient</u> made of radiation attenuating material(s), used to reduce radiation exposure.

Notes: The Department proposes that the Board of Health amend §175.02(a) of the Health Code to update the definitions of medical event and protective garment.

RESOLVED, that clause (B) of subparagraph (iii) of paragraph 1 of subdivision (c), clauses (B) and (C) of subparagraph (ii) of paragraph 2 of subdivision (f), and paragraphs 9 and 10 of subdivision (l), of Section 175.03 of Article 175 of the New York City Health Code, as set forth in Title 24 of the Rules of the City of New York, subparagraph (iii) of paragraph 1 of subdivision (c) as last amended by resolution on September 29, 2006, and paragraphs 9 and 10 of subdivision (l) as last amended by resolution on March 13, 2012, are amended to clarify requirements about the reporting of a medical event and doses to an embryo/fetus or a nursing child, to be printed together with explanatory notes, to read as follows:

§175.03 Standards for protection against radiation.

(c) Occupational dose limits. (1) Occupational dose limits for adults.

(iii) The assigned deep dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure:

- (B) when a protective [apron] garment is worn during x-ray fluoroscopic procedures to be in compliance with §175.62(i) of this Code and monitoring is conducted as specified in §175.03(f)(2)(ii), the effective dose equivalent for external radiation may be determined for these individuals as follows:
- (a) when only one individual monitoring device is used and it is located at the neck outside the protective [apron] garment, the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or
- (b) when individual monitoring devices are worn, both under the protective [apron] garment at the waist and outside the protective [apron] garment at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective [apron] garment multiplied by 1.5 and the deep dose

equivalent reported for the individual monitoring device located at the neck outside the protective [apron] garment multiplied by 0.04.

(f) Surveys and monitoring.

(2) Personnel monitoring.

(ii) A person supplying personnel monitoring devices to individuals pursuant to §175.03(f)(2)(i) shall ensure that the individuals wear such devices as follows:

- (B) An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman pursuant to §175.03(c)(8) shall be located at the waist under any protective [apron] garment worn by the woman.
- (C) An individual monitoring device used for monitoring the eye dose equivalent shall be located at the neck outside any protective [apron] garment worn by the individual, or at an unshielded location closer to the eye.

(1) Reports.

- (9) Report and notification of a medical event.
- (i) A licensee <u>or registrant</u> shall report any event, except for an event that results from patient intervention, in which the administration of <u>radiation</u>, byproduct material or radiation from byproduct material results in-

- (10) Report and notification of a dose to an embryo/fetus or a nursing child.
- (i) A licensee <u>or registrant</u> 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 <u>radiation</u>, 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 <u>or registrant</u> shall report any dose to a nursing child that is a result of an administration of radiation or, byproduct material to a breast-feeding individual that-

- (iii) The licensee <u>or registrant</u> 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] <u>subparagraphs (i) or (ii) of this paragraph</u>.
- (iv) The licensee <u>or registrant</u> 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 or registrant's name;

(g) Certification that the licensee <u>or registrant</u> notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

- (v) The licensee or registrant 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 or registrant either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee or registrant 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 or registrant shall make the appropriate notifications as soon as possible thereafter. The licensee or registrant 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 or registrant 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 or registrant upon request. The licensee or registrant shall provide such a written description if requested.
- (vi) A licensee or registrant shall:

(B) Provide a copy of the annotated report to the referring physician, if other than the licensee <u>or registrant</u>, no later than 15 days after the discovery of the event.

Notes: The Department proposes that the Board of Health amend $\S\S175.03(c)(1)(iii)(B)$, 175.03(f)(2)(ii)(B) and (C), and 175.03(l)(9) and (10) of the Health Code to update the term "protective garment," and to clarify that both licensees and registrants must report a medical event and doses to an embryo/fetus or a nursing child.

RESOLVED, that subparagraph (iii) of paragraph 2 of subdivision (c) of Section 175.54 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, is amended and new paragraphs 4, 5 and 6 are added to such subdivision to provide requirements for the methodology and testing frequency for operator lead protective garments as part of a radiation facility's quality assurance program to reduce radiation exposures, to be printed together with explanatory notes, to read as follows:

§175.54 Surveys, shielding requirements and operator protection for diagnostic radiation machines.

(c) Operator protection.

(2) Mobile, portable, podiatric and dental radiographic installations, excluding mammographic systems.

(iii) Each operator of a mobile or portable radiographic x-ray unit, excluding dental and podiatric units, shall be provided with personnel monitoring as provided in §175.03 and shall wear a protective [apron] garment of at least 0.25 mm lead equivalent.

- (4) The facility must include a written policy and procedure in the quality assurance manual, as required by Section 175.07 (b)(1)(i), that conforms to the manufacturer's recommended care and use policy for lead protective garments and is adhered to on a continuing basis. This policy, at a minimum, must describe the training of Licensed Radiographic Technologists (LRTs) on the proper care and usage of protective garments; how storage sites for lead protective garments will be evaluated and maintained and procedures for how LRTs report lead protective garment problems to the Radiation Safety Officer.
- (5) Protective garments that are not used by operators conducting fluoroscopic procedures or not used for protection in veterinary offices for x-ray radiographic procedures on animals must be checked annually for defects such as holes, cracks and tears by using one of the following methods: visual investigation, tactile investigation, or x-ray imaging. If a defect is found, the lead protective garment must be removed from service and either replaced or repaired to conform to the manufacturers' specifications.
- (6) Protective garments that are used by operators conducting fluoroscopic procedures or used for protection in veterinary offices for x-ray radiographic procedures on animals must be checked annually for defects such as holes, cracks and tears by using all of the following methods: visual investigation, tactile investigation, and x-ray imaging. If a defect is found, the lead protective garment must be removed from service and either replaced or repaired to conform to the manufacturers' specifications.

Notes: The Department proposes that the Board of Health amend §175.54(c) of the Health Code to update the term "protective garment" and to add requirements for the methodology and testing frequency for operator lead protective garments as part of a radiation facility's quality assurance program to reduce radiation exposures.

RESOLVED, that Section 175.58 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, is amended to add new subdivisions (c) and (d) providing requirements for the use of Cone Beam Computed Tomography (CBCT) x-ray equipment in dental offices to reduce radiation exposures, to be printed together with explanatory notes, to read as follows:

§175.58 Dental radiography.

- (c) Facilities possessing a Cone Beam Computed Tomography (CBCT) unit.
- (1) Notwithstanding any provision of this Code to the contrary, dental facilities possessing a CBCT unit will be subject to the requirements of Section 175.07(b) of this Code, which requires a written quality assurance program for all dental equipment possessed by the facility, including a written quality control manual and a written radiation safety policy and procedures manual for the facility.
- (i) For all intraoral, panoramic and cephalometric dental x-ray units (except CBCT units), the registrant must establish annual quality control testing of x-ray parameters sufficient to maintain patient doses and image quality consistent over time. The annual tests will evaluate, at a minimum, collimation, filtration,

patient dose, accuracy and reproducibility of X-ray techniques and the operational status of x-ray safety features.

- (ii) For all CBCT units, the quality control tests must follow the manufacturer's recommended tests and frequency and utilize the manufacturer's quality control phantom. The quality control test results will be retained for review by the Department until after the next scheduled inspection is completed by the Department. If manufacturer guidance is absent or recommendations do not include quarterly or more frequent quality control testing, the facility must establish quality control testing that includes, at a minimum, the following:
- (A) Quarterly quality control tests to determine image noise, image uniformity, reconstructed image measurement accuracy, high contrast spatial resolution of the CBCT unit; and,
- (B) Annual quality control tests to measure accuracy of imaging parameters (kVp, exposure time and dimensions of the scan beam), reproducibility of exposure per the most common scan, and beam filtration (HVL); and
- (C) Annually, the facility will determine the patient radiation dose for the most common CBCT scan used at the facility as conducted by a medical physicist.
- (d) Conditions of operation for the CBCT unit.
- (1) Facilities possessing a CBCT unit must adhere to the requirements of Section 175.54 regarding the shielding requirements and operator protection for all CBCT units possessed by the dental facility.
- (2) All operators of the CBCT must undergo training on the proper operation of the CBCT units and documentation of this training will be retained by the dental facility for review by the Department until after the next scheduled inspection is completed by the Department.
- (3) All operators must be able to communicate with and visually observe the patient during the CBCT examination from the operator's protected position.
- (4) CBCT patient exams will not be conducted solely for cosmetic purposes with no diagnostic value to the patient.
- (5) The logbook for CBCT exams must contain all relevant diagnostic examination information, including but not limited to, x-ray technique, scan time, anatomical exam site and reason for examination.

Notes: The Department proposes that the Board of Health amend §175.58 of the Health Code to add new subdivisions (c) and (d) providing requirements for the use of Cone Beam Computed Tomography (CBCT) x-ray equipment in dental offices to reduce radiation exposures.

RESOLVED, that paragraphs 1 and 2 of subdivision (b) of Section 175.60 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, is amended to revise the reference for protective garment, to be printed together with explanatory notes, to read as follows:

§175.60 Fixed radiography (excluding dental, veterinary and podiatric radiography).

- (b) Conditions for operation of equipment. (1) No person shall be regularly employed to hold patients or films during exposures nor shall such duty be performed by an individual occupationally exposed to radiation in the course of that individual's other duties. When it is necessary to restrain the patient, mechanical supporting or restraining devices should be used. If patients or films must be held by an individual, that individual shall be protected with appropriate shielding devices such as protective gloves and a protective [apron] garment of at least 0.25 mm lead equivalent. No part of the holding individual's body shall be in the useful beam. The exposure of any individual used for holding patients shall be monitored. Pregnant women and individuals under 18 years of age shall not hold patients under any conditions.
- (2) Only persons required for the radiographic procedure shall be in the radiographic room during the exposure and, except for the patient, all such persons shall be equipped with appropriate shielding devices such as protective gloves and a protective [apron] garment of at least 0.25 mm lead equivalent.

Notes: The Department proposes that the Board of Health amend §175.60(b) of the Health Code to revise the reference for protective garment.

RESOLVED, that paragraph 1 of subdivision (b) of Section 175.61 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, is amended to revise the reference for protective garment, to be printed together with explanatory notes, to read as follows:

§175.61 Portable, bedside or mobile equipment (excluding dental, veterinary and podiatric radiography).

(b) Conditions for operation of equipment. (1) No person shall be regularly employed to hold patients or films during exposures, nor shall such duty be performed by an individual occupationally exposed to radiation in the course of that individual's other duties. When it is necessary to restrain the patient, mechanical supporting or restraining devices should be used. If patient or films must be held by an individual, that individual shall be protected with appropriate shielding devices such as protective gloves and a protective [apron] garment of at least 0.25 mm lead equivalent. No part of the holding individual's body shall be in the useful beam. The exposure of any individual used for holding patients shall be monitored. Pregnant women and individuals under 18 years of age shall not hold patients under any conditions.

Notes: The Department proposes that the Board of Health amend §175.61(b) of the Health Code to revise the reference for protective garment.

RESOLVED, that paragraph 3 of subdivision (i) of Section 175.62 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, is amended to revise the reference for protective garment, to be printed together with explanatory notes, to read as follows:

§175.62 Fluoroscopy.

(i) *Conditions for operation of equipment.*

(3) Unless measurements indicate that they are not needed, protective [gloves and aprons] garments of at least 0.25 mm lead equivalent each shall be worn by any person within the fluoroscopy room.

Notes: The Department proposes that the Board of Health amend $\S175.62(i)(3)$ of the Health Code to revise the reference for protective garment.

RESOLVED, that subparagraph (iv) of paragraph 18 of subdivision (f) of 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, is amended to revise the reference for protective garment, 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.

(18) *Operating procedures.*

(iv) The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective [gloves and apron] garments of not less than 0.5 mm lead equivalency at 100 kV.

Notes: The Department proposes that the Board of Health amend §175.64(f)(18)(iv) of the Health Code to revise the reference for protective garment.

RESOLVED, that subparagraph (iii) of paragraph 2 of subdivision (a) and subparagraph (iii) of paragraph 2 of subdivision (b), of Section 175.65 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, is amended to revise the reference for protective garment, to be printed together with explanatory notes, to read as follows:

§175.65 Veterinary radiography and fluoroscopy.

(a) Fixed radiographic installations.

- (2) *Conditions for operation of equipment.*
- (iii) Animal patients or films shall be held by an individual only under extreme conditions when clinically necessary. Such individuals shall wear protective gloves having at least 0.5 mm lead equivalent, a

protective [apron] garment of at least 0.25 mm lead equivalent, and shall keep all parts of his/her body out of the useful beam.

(b) Portable or mobile radiographic installations.

- (2) *Conditions for operation of equipment.*
- (iii) Animal patients or films shall be held by an individual only under extreme conditions when clinically necessary. Such individuals shall wear protective gloves having at least 0.5 mm lead equivalent, a protective [apron] garment of at least 0.25 mm lead equivalent, and shall keep all parts of his/her body out of the useful beam.

Notes: The Department proposes that the Board of Health amend §175.65(a) and (b) of the Health Code to revise the reference for protective garment.

NEW YORK CITY LAW DEPARTMENT DIVISION OF LEGAL COUNSEL 100 CHURCH STREET NEW YORK, NY 10007 212-356-0428

CERTIFICATION PURSUANT TO

CHARTER §1043(d)

RULE TITLE: Standards for New Radiation Technology (Health Code Article 175)

REFERENCE NUMBER: 2013 RG 042

RULEMAKING AGENCY: Department of Health and Mental Hygiene

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

- (i) is drafted so as to accomplish the purpose of the authorizing provisions of law;
- (ii) is not in conflict with other applicable rules;
- (iii) to the extent practicable and appropriate, is narrowly drawn to achieve its stated purpose; and
- (iv) to the extent practicable and appropriate, contains a statement of basis and purpose that provides a clear explanation of the rule and the requirements imposed by the rule.

Date: August 29, 2013

/s/ STEVEN GOULDEN
Acting Corporation Counsel

NEW YORK CITY MAYOR'S OFFICE OF OPERATIONS 253 BROADWAY, 10th FLOOR NEW YORK, NY 10007 212-788-1400

CERTIFICATION/ANALYSIS PURSUANT TO CHARTER SECTION 1043(d)

RULE TITLE: Standards for New Radiation Technology (Health Code Article 175)

REFERENCE NUMBER: DOHMH-31

RULEMAKING AGENCY: Department of Health and Mental Hygiene

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

- (i) Is understandable and written in plain language for the discrete regulated community or communities;
- (ii) Minimizes compliance costs for the discrete regulated community or communities consistent with achieving the stated purpose of the rule; and
- (iii) Does not provide a cure period because the violations pose a risk to the public health.

<u>/s/ Ruby B. Choi</u>
Mayor's Office of Operations

August 29, 2013
Date