



**NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE  
BOARD OF HEALTH**

**Notice of Public Hearing and Opportunity to Comment on Proposed Rules**

**What are we proposing?** The New York City Department of Health and Mental Hygiene (DOHMH) is proposing that the New York City Board of Health amend Article 175 of the New York City Health Code to provide updated quality assurance requirements for external beam and brachytherapy radiation treatment to promote a safe and effective treatment dose. The Department is taking this action to remain consistent with similar requirements recently enacted by the New York State Department of Health in the State Sanitary Code.

**When and where is the Hearing?** The New York City Department of Health and Mental Hygiene will hold a public hearing on the proposed rule. The public hearing will take place at 10:00 AM until 12:00 PM on January 23, 2014. The hearing will be at the offices of the New York City Department of Health and Mental Hygiene at 42-09 28<sup>th</sup> Street, 14th Floor, Room 14-45, Long Island City, NY 11101-4132.

**How do I comment on the proposed rules?** Anyone can comment on the proposed rules by:

- **Website.** You can submit comments to the New York City Department of Health and Mental Hygiene through the NYC rules Web site at <http://rules.cityofnewyork.us>.
- **Email.** You can email written comments to [resolutioncomments@health.nyc.gov](mailto:resolutioncomments@health.nyc.gov).
- **Mail.** You can mail written comments to:  
New York City Department of Health and Mental Hygiene  
Board of Health  
42-09 28th Street, 14th Floor, CN31  
Long Island City, NY 11101-4132
- **Fax.** You can fax written comments to New York City Department of Health and Mental Hygiene at (347) 396-6088.
- **By Speaking at the Hearing.** Anyone who wants to comment on the proposed rule at the public hearing must sign up to speak. You can sign up before the hearing by calling Svetlana Burdeynik at (347) 396-6078. You can also sign up in the hearing room before the hearing begins on January 23, 2014. You can speak for up to five minutes.

**Is there a deadline to submit written comments?** Comments submitted or postmarked by 5:00PM on January 23, 2014 will be considered.

**Do you need assistance to participate in the Hearing?** You must tell the DOHMH Office of the General Counsel if you need a reasonable accommodation of a disability at the Hearing. You must tell us if you need a sign language interpreter. You can tell us by mail at the address given above. You may also tell us by telephone at (347) 396-6078. You must tell us by January 9, 2014.

**Can I review the comments made on the proposed rules?** You can review the comments made online at <http://rules.cityofnewyork.us/> on the proposed rules by going to the website at <http://rules.cityofnewyork.us/>.

All written comments and a summary of the oral comments received by DOHMH will be made available to the public within a reasonable period of time by the DOHMH Office of the General Counsel.

**What authorizes the New York City Board of Health to make this rule?** Sections 556, 558 and 1043 of the City Charter authorize the New York City Board of Health to make this proposed rule. This rule was not included in the Department's Fiscal Year 2014 Regulatory Agenda as it is in response to and required by recent State adoption of rules requiring quality assurance for external beam and brachytherapy radiation treatment (see, 10 NYCRR §16.24(a)).

**Where can I find the New York City Health Code?** The New York City Health Code is located in title 24 of the Rules of the City of New York.

**What rules govern the rulemaking process?** The New York City Board of Health must meet the requirements of Section 1043 of the City Charter when creating or changing rules. This notice is made according to the requirements of Section 1043 of the City Charter.

## **Statement of Basis and Purpose of Proposed Rule**

### *Statutory Authority*

This amendment to the New York City Health Code (“Health Code”) is proposed pursuant to Sections 556, 558 and 1043 of the New York City Charter (“Charter”). Section 556 of the Charter grants the New York City Department of Health and Mental Hygiene (“Department”) jurisdiction to regulate all matters affecting health in the City of New York. 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.

Section 228 of the New York State Public Health Law provides that local enactments like section 175.07 of the Health Code must be consistent with the requirements of the New York State Sanitary Code, as codified at Chapter I of Title 10 of the Codes, Regulations and Rules of New York State. In order to be consistent with recent State Sanitary Code amendments involving updated quality assurance requirements for external beam and brachytherapy radiation treatment, the Department is proposing commensurate changes to the corresponding requirements in the Health Code.

### *Background*

The Department, through its 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 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.

The State Sanitary Code was recently amended to reflect updated quality assurance requirements for external beam and brachytherapy radiation treatment (*see*, 10 NYCRR §16.24(a)). In order to maintain consistency, the Department is proposing to make commensurate changes to its corresponding requirements in §175.07(c) of Article 175 of the Health Code.

### *Proposed Rule Elements and Goals*

The Department proposes that the Board of Health repeal current subdivision (c) of §175.07 and replace it with a new subdivision (c) that includes updated quality assurance standards for radiation materials licensees or radiation equipment registrants who are authorized to administer external beam therapy or brachytherapy to humans. The new subdivision includes quality standards appropriate for newer, more complex radiation therapy treatment systems and also requires additional verification of radiation set-up equipment and treatment plans prior to administering radiation treatments to patients. New subdivision (c) also requires quality assurance programs to cover data communication/transfer between component systems of planning and treatment delivery systems to ensure complete, uncorrupted data transfer. Additionally, the new subdivision requires licensees and registrants to credential individuals involved in quality assurance testing, treatment planning, and radiation treatment of patients. Finally, new subdivision (c) requires licensees and registrants to be accredited in radiation oncology by the American College of Radiology or the American College of Radiation Oncology, or another equivalent accrediting organization, within 18 months of the effective date of the rule.

The New York City Board of Health’s authority for these rules is found in sections 556, 558 and 1043 of the City Charter. This proposed rule implements particular standards set forth in newly enacted state regulations with only minor exercise of the Board’s discretion. Pursuant to section 1043(d)(4)(iii), the analysis required by Section 1043(d) of the Charter was not performed.

New material is underlined.

[Deleted material is in brackets.]

“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.

The proposed rule is as follows:

**RESOLVED**, that subdivision (c) of 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, be REPEALED and new subdivision (c) is added to include updated quality assurance requirements for external beam and/or brachytherapy radiation treatment, to be printed together with explanatory notes, to read as follows:

**§175.07           Quality assurance programs.**

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(c) External beam and brachytherapy. A quality assurance program for external beam therapy and/or 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 authorized to administer external beam therapy and/or brachytherapy to humans must implement a quality assurance program to systematically monitor, evaluate and document radiation therapy services to ensure consistent and safe fulfillment of the dose prescription to the target volume, with minimal dose to normal tissue, minimal exposure to personnel and adequate patient monitoring aimed at determining the end result of the treatment. Each such licensee or registrant must meet or exceed all quality assurance criteria described in this subdivision.

(2) Each licensee or registrant must adopt and maintain a quality assurance program that includes policies and procedures that require the following:

(i) Each patient's medical record must be complete, accurate, legible and must include the patient's initial clinical evaluation, treatment planning data, treatment execution data, clinical assessments during treatment, a treatment summary and plan for subsequent care. Treatment related data must be recorded in the patient's medical record at the time of each treatment.

(ii) A written and dated order or prescription for the medical use of radiation or radioactive material must be made for each patient in accordance with §175.103(b)(7) of this Code. The order or prescription must be signed or approved electronically by a board certified radiation oncologist or qualified physician who restricts his or her practice to radiation oncology.

(iii) The accuracy of treatment plan data and any modifications to treatment plan data transferred to a radiation treatment delivery system must be verified by qualified clinical staff prior to patient treatment.

(iv) A radiation therapy technologist, physician or other qualified health practitioner must verify that the patient set up on the treatment machine is in accordance with the treatment plan prior to the first fraction of a course of treatment and prior to treatment for any changes to the initial treatment plan.

(v) Clinical staff must obtain clarification before beginning a patient's treatment if any element of the order or other record is confusing, ambiguous, erroneous or suspected of being erroneous.

- (vi) Each patient's identification must be verified by at least two different means by qualified clinical staff prior to each treatment.
- (vii) Each patient's response to treatment must be assessed by a board certified radiation oncologist or other qualified physician in the active practice of external beam therapy and/or brachytherapy. Unusual responses must be evaluated as possible indications of treatment errors and recorded in the patient's medical record.
- (viii) The medical records of patients undergoing fractionated treatment must be checked for completeness and accuracy by qualified clinical staff at intervals not to exceed six fractions.
- (ix) Radiation treatment plans and related calculations must be checked by qualified clinical staff for accuracy before 25 percent of the prescribed dose for external beam therapy or 50 percent of the prescribed dose for brachytherapy is administered, except the check must be performed prior to treatment for: any single fraction treatment; any fractional dose that exceeds 300cGy or 700 monitor units; or when the output of a medical therapy accelerator exceeds 600 monitor units per minute during treatment. If a treatment plan and related calculations were originally prepared by a board certified radiation oncologist or an authorized medical physicist possessing the qualifications specified in §175.64(c)(2) or §175.103(j)(2) of this Code, it may be rechecked by the same individual using a different calculation method. Treatment plans and related calculations prepared by other qualified clinical personnel must be checked by a second qualified person using procedures specified in the registrant's or licensee's treatment planning procedures manual required pursuant to §175.07(c)(2) of this Code, and who has received training in use of this manual.
- (x) All equipment and other technology used in planning and administering radiation therapy must function properly and safely, and must be calibrated properly and re-paired and maintained in accordance with the manufacturer's instructions. The equipment and technology that is subject to such quality control includes but is not limited to: computer software and hardware including upgrades and new releases; equipment used to perform simulation; dosimetry equipment; equipment used to guide treatment delivery, including but not limited to ultrasound units, kV and mV imaging equipment and monitors that are used to view patient imaging studies; and personnel radiation safety equipment. Data communication between various systems, including but not limited to treatment planning systems, treatment delivery systems and data networks/storage media, must be evaluated and tested to ensure accurate and complete data transfer.
- (xi) Quality control tests performed on equipment and technology used in planning and implementing radiation treatment must be documented, including:
- (A) detailed procedures for performing each test;
  - (B) the frequency of each test;
  - (C) acceptable results for each test;
  - (D) corrective actions taken;
  - (E) record keeping and reporting procedures for test results including the tester's name, signature and date of the test; and
  - (F) the qualifications are specified for the individual(s) conducting the test and for the person who reviews test data.
- (xii) Test results that exceed tolerances/limits must be immediately reported to the au-thorized medical physicist.
- (xiii) Records for all maintenance, repairs and upgrades of equipment and technology must be maintained for at least five years.
- (xiv) Errors or defects in technology or equipment, including computer hardware and software, must be reported to the technology or equipment manufacturer and to the United States Food and Drug Administration (MedWatch) as soon as possible and in no event more than 30 days of discovery, and records of equipment errors and reports required by this clause must be maintained for review by the Department for at least three years.
- (xv) External beam therapy equipment calibration/output required by §175.64(g) of this Code, must be verified by an independent means and records of such measurements must be retained for review by the Department for at least three years.

(xvi) Patients with permanent brachytherapy implants must be provided with instructions to take radiation safety precautions, as required by 10 CFR 35.75 and the licensee's radioactive materials license, after being released from the licensee's facility.

(xvii) All personnel involved in planning or implementing radiation therapy must be credentialed. Credentialing must include verifying that all professional staff is appropriately licensed, including medical physicists and radiation therapy technologists. Records of credentialing must be maintained during the period in which the credentialed person provides services to the licensee or registrant and for three years thereafter.

(xvii) Any unintended deviation from the treatment plan that is identified must be evaluated and corrective action to prevent recurrence must be implemented. Records of unintended deviations and corrective action must be maintained for audits required by paragraph (4) of this subdivision and for review by the Department.

(xviii) There must be a process to ensure quick and effective response to any radiation therapy related recalls, notices, safety alerts and hazards.

(3) Each licensee or registrant must adopt and maintain a radiation treatment manual prepared by an authorized medical physicist possessing the qualifications specified in §175.64(c)(2) or §175.103(j)(2) of this Code. The manual must 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 in paragraph (1) of this subdivision). The treatment planning manual may be part of the quality assurance manual required by §175.07(c)(1) of this Code. The radiation treatment manual must be included in training given pursuant to §175.04(c) of this Code to facility staff who will participate in treatment planning. Each licensee or registrant must ensure that an authorized medical physicist possessing the qualifications specified in paragraph §175.64(c)(2) or §175.103(j)(2) of this Code prepares or reviews and approves a procedures manual describing how radiation therapy treatment planning is to be performed at the licensee's or registrant's facility and reviews the treatment planning manual at least annually.

(4) Each licensee or registrant must ensure that all equipment used in planning and administering radiation therapy is functioning properly, designed for the intended purpose, properly calibrated, and maintained in accordance with the manufacturer's instructions and the quality assurance program described in the licensee or registrant's quality assurance manual. Such equipment must be calibrated prior to use on patients, at least annually thereafter and following any change, repair or replacement of any component which may alter the radiation output.

(5) Each licensee or registrant must implement written procedures for auditing the effectiveness of the radiation therapy quality assurance program that include the following:

(i) Audits must be conducted at intervals not to exceed twelve (12) months by an authorized medical physicist possessing the qualifications specified in §175.64(c)(2) or §175.103(j)(2) of this Code, and also by a physician, both of whom are in the active practice of the type of radiation therapy conducted by the licensee or registrant. These must be individuals who are not involved in the therapy program being audited; and

(ii) The licensee or registrant must ensure that the individuals who conduct the audit prepare and deliver to the licensee or registrant a report which contains an assessment of the effectiveness of the quality assurance program and makes recommendations for any needed modifications or improvements.

(iii) The licensee or registrant must promptly review the audit findings, address the need for modifications or improvements, and document actions taken. If recommendations are not acted on, the licensee or registrant must document the reasons therefor and also any alternative actions taken to address the audit findings.

(iv) Each licensee or registrant must maintain complete written records relating to quality assurance and audit activities for review and inspection by the Department. Audit records must be maintained for at least six (6) years.

(6) Accreditation in Radiation Oncology.

(i) Ninety (90) days from the effective date of this rule, each registrant or licensee must have an active application with, or be accredited in radiation oncology by, the American College of Radiology, the American

College of Radiation Oncology or another accrediting organization that is equivalent as determined by the Department.

(ii) Eighteen (18) months from the effective date of this rule, each registrant and licensee must maintain accreditation in radiation oncology by the American College of Radiology, the American College of Radiation Oncology or another accrediting organization that is equivalent as determined by the Department.

(iii) The registrant or licensee must maintain a record of accreditation, including a copy of the application, all supplemental application information and all correspondence transmitted between the accrediting body and the registrant or licensee. Records must be maintained for at least 6 years.

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*Notes: The Department proposes that the Board of Health amend §175.07 by repealing and reenacting subdivision (c) to add new quality assurance requirements for external beam and/or brachytherapy radiation treatment to maintain consistency with recently adopted State requirements.*

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**NEW YORK CITY LAW DEPARTMENT  
DIVISION OF LEGAL COUNSEL  
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**CERTIFICATION PURSUANT TO  
CHARTER §1043(d)**

**RULE TITLE: Amendment of Rules Governing Radiation Treatment (Health Code Article 175)**

**REFERENCE NUMBER: 2013 RG 099**

**RULEMAKING AGENCY: Department of Health and Mental Hygiene**

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

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

/s/ STEVEN GOULDEN  
Acting Corporation Counsel

Date: December 4, 2013