



DEPARTMENT OF HEALTH AND MENTAL HYGIENE

BOARD OF HEALTH

**NOTICE OF ADOPTION OF AMENDMENTS TO ARTICLE 175
OF THE NEW YORK CITY HEALTH CODE**

In compliance with §1043(b) of the New York City Charter (the “Charter”) and pursuant to the authority granted to the Board of Health by §558 of said Charter, a notice of intention to amend Article 175 of the New York City Health Code (the “Health Code”) was published in the City Record on December 19, 2013 and a public hearing was held on January 23, 2014. No written comments were received and no individuals testified at the public hearing. The Department has made no changes to the rule since presentation to the Board or since publication in the City Record. At its meeting on March 11, 2014, the Board of Health adopted the following resolution.

Statement of Basis and Purpose of Rule

Statutory Authority

This amendment to the New York City Health Code (“Health Code”) is made 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 Board of Health is effecting 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 Board of Health is making commensurate changes to the corresponding requirements in §175.07(c) of Article 175 of the Health Code.

Rule Elements and Goals

The Board of Health is repealing current subdivision (c) of §175.07 and replacing 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 publication of this rule.

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 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.

(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 authorized 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.

Notes: On March 11, 2014, the Board of Health amended §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.
