New York City Radioactive Materials Regulations (Proposed)

Section 1: General provisions, communications

1(a) As used in this Code, "Department" means the New York City Department of Health and Mental Hygiene. "State" means the State of New York and/or its agencies, unless the context clearly indicates a different meaning. "CFR" means Code of Federal Regulations. "NRC" means the United States Nuclear Regulatory Commission.

1(b) Except for the removal of source material from its place of origin in nature or as otherwise provided in this Code, no person shall transfer, receive, produce, possess or use in New York City any radioactive material except pursuant to a license issued by the Department.

1(c) (1) This Code does not apply to any person with respect to any radiation source subject to regulation, as provided for by law, by the NRC or the State. This exclusion does not apply to: (A) the use of such sources in places where the general public may be exposed in New York City; or (B) to persons with respect to radiation sources used at industrial or commercial establishments for the application of radiation to human beings in New York City.
(2) This Code does not apply to any common or contract carrier or any shipper operating within New York City to the extent that such carrier or shipper is subject to regulation as provided for by law by the U.S. Department of Transportation or other agencies of the United States or agencies of the State or City of New York, except for compliance with provisions relating to transportation of radioactive materials set forth in [§*175.105 or equivalent] in the incorporated regulations of 10 CFR Part 71.

1(d) Any person exempt pursuant to 10 CFR Part 30 sections 30.11 through 30.22 or 10 CFR Part 40 section 40.13 is exempt to the same extent from the requirements of this Code.

1(e) Fees for each license shall be paid pursuant to section 5.07 of this Code. Inspection fees shall be paid pursuant to [*§175.05 or equivalent] of this Code.

1(f) Except as authorized by the Department, all applications, notifications, reports, or other communications required pursuant to this Code shall be submitted to the Department at the following address:

[ORH mailing address]

1(g) Nothing in this code relieves the licensee with requirements of other applicable Federal, State and Local regulations. In particular, licensees must abide by the New York State Department of Environmental Conservation requirements regarding waste minimization and disposal as codified in 6 NYCRR part 380 or any successor law or regulation.

1(h) Any reference to a specific section of Article 175 in a license issued by the Department shall be understood to refer to the version of Article 175 as of [January 1 2016] and shall be read as referring to the equivalent section of 10CFR.

Section 2 Incorporation of NRC regulations

All persons subject to the requirements of this Code are required to comply with the specific regulations of Title 10 of the Code of Federal Regulations (CFR) as incorporated into this Code pursuant to subdivision (a) of this section.

2(a) Except as set forth in subdivision (b) of this section, Title 10 of the Code of Federal Regulations, Chapter I (Nuclear Regulatory Commission) Parts 19, 20, 30, 31, 33, 35, 37, 71 and §§ 40.13, 40.21, and 40.22 are hereby incorporated by reference with the same force and effect as if fully set forth herein this Code. The CFR provisions incorporated by reference herein may be obtained from the Department at the address provided in section 1f above, or from the following:

(1) The United States Government Publishing Office (GPO), 710 North Capitol Street, N.W., Washington, DC 20401 (866) 512-1800, or, GPO online at http://www.gpo.gov/fdsys, or

(2) The U.S. Nuclear Regulatory Commission online at http://www.nrc.gov/reading-rm/doc-collections/cfr/

2(b) The following sections from Title 10 Chapter I of the CFR are not incorporated:

(1) Part 19: §§ 19.1, 19.2, 19.4, 19.5, 19.8, 19.18, 19.30, 19.31, 19.32, and 19.40.

(2) Part 20: §§ 20.1001, 20.1002, 20.1006 through 20.1009, 20.1405, 20.1406(b), 20.1905(g), 20.2203(c), 20.2401, 20.2402, Part 20 Appendix D.

(3) Part 30: §§ 30.1, 30.2, 30.5 through 30.8, 30.21(c), 30.37 through 30.39, 30.41(b)(6), 30.53, 30.55, 30.62, 30.63, 30.64.

(4) Part 31: §§ 31.1, 31.2, 31.4, 31.22, and 31.23.

(5) Part 33: §§ 33.1, 33.8, 33.11(b-c), 33.14, 33.15, 33.16, 33.21, 33.23, 33.100 Schedule A.

(6) Part 35: §§ 35.1, 35.8, 35.4001, and 35.4002.

(7) Part 37: §§ 37.1, 37.3, 37.7, 37.9, 37.11(a-b), 37.13, 37.105, 37.107, and 37.109.

(8) Part 71: §§ 71.2, 71.6, 71.11, 71.14(b), 71.19, 71.31 through 71.45, 71.51 through 71.77, 71.99, 71.100, 71.101(c)(2), 71.101(d)-(f), 71.107 through 71.125.

2(c) To reconcile differences between this Code and the incorporated sections of the CFR, the following meanings shall be substituted for certain terms in the incorporated language of the CFR:

(1) Any reference to ‘‘NRC’’ or ‘‘Commission’’ in the incorporated CFR regulations means the Department, unless the context clearly indicates

otherwise. Notifications and correspondence indicated in the incorporated sections of the CFR should be sent to the Department, except as required by 10 CFR §37.27 (relating to requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material), which should be sent to the NRC.

(2) References to forms in the incorporated CFR regulations mean the appropriate forms prescribed by the Department.

(3) Any reference to ‘‘NRC or agreement state’’ in the incorporated CFR regulations means this Department, NRC, or agreement state.

(4) Any reference to “Type A specific license of broad scope” in the incorporated CFR regulations means “specific license of broad scope” as defined in this Code.

(5) Any reference to “byproduct material” in sections 30.31 through 30.62, and 31.9 of the incorporated CFR regulations means “radioactive material” as defined in this Code.

Section 3: Additional New York City Requirements

3(a) [§175.07] **Quality assurance programs.**

(1) *Purpose and scope.* This section establishes requirements for the use of radioactive materials or the radiation therefrom for diagnostic and therapeutic uses in the healing arts. These requirements and provisions provide for the protection of the public health and safety and are in addition to, and not in substitution for, others in this Code. The requirements of this section apply to all licensees subject to this Code.

(2) *Diagnostic facilities.* A quality assurance program is a system of plans, actions, reviews, reports and records, the purpose of which is to ensure that diagnostic facilities achieve consistent high quality imaging and other diagnostic results, while maintaining personnel doses within limits prescribed by the Department.

(i) Each licensee performing diagnostic procedures shall implement a quality assurance program including at a minimum:
(A) The adoption of a manual containing written policies and procedures for radiation protection and describing the facility's quality assurance program. Policies and procedures must be consistent with the types of procedures provided including, but not limited to, identification of patients, personnel monitoring, and protection of pregnant workers and patients. The quality assurance manual must describe the various processing, generator and systems quality control tests appropriate for the types of procedures provided in sufficient detail to ensure that they will be performed properly;
(B) The performance of quality control tests and the correction of deficiencies as specified in the quality assurance manual;

(C) the maintenance of equipment records for each diagnostic imaging system, containing test results, records of equipment repairs and other pertinent information;
(D) The provisions of a formalized in-service training program for employees including, but not limited to, quality assurance and radiation safety procedures;
(E) The measurement of the amount of activity of each dose of a radiopharmaceutical/radiobiologic administered to each patient;
(F) The calculated absorbed dose for diagnostic procedures involving radioactive materials;
(G) The provision of the information described in clauses (E) and (F) of item (i) of paragraph (2) of this subdivision to any patient upon request; and
(H) The performance of an ongoing program of analysis of repeated, rejected or misadministered diagnostic studies which are designed to identify and correct problems and to optimize quality.
(ii) Each licensee shall maintain written records documenting quality assurance and audit activities for review by the Department. Such records shall be maintained by the licensee until after the next scheduled inspection is completed by the Department.
(3) *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 tissues.
(i) Each licensee 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 must meet or exceed all quality assurance criteria described in this subdivision.
(ii) Each licensee must adopt and maintain a quality assurance program that includes policies and procedures that require the following:
(A) 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.
(B) 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 10 CFR §35.41. 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.

(C) 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.
(D) 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.
(E) 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.
(F) Each patient's identification must be verified by at least two different means by qualified clinical staff prior to each treatment.
(G) 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.
(H) 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.
(I) 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 10 CFR §35.51, 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 licensee's treatment planning procedures manual required pursuant to (3)(ii)(S) of this subdivision, and who has received training in use of this manual.
(J) All equipment and other technology used in planning and administering radiation therapy must function properly and safely, and must be calibrated properly and repaired 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.
(K) 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.
(L) Test results that exceed tolerances/limits must be immediately reported to the authorized medical physicist.
(M) Records for all maintenance, repairs and upgrades of equipment and technology must be maintained for at least five years.
(N) 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.
(O) 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.
(P) All personnel involved in planning or implementing radiation therapy must be credentialed. Credentialing must include verifying that all professional staff are 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 and for three years thereafter.
(Q) 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 (3)(ii)(U) of this subdivision and for review by the Department.
(R) There must be a process to ensure quick and effective response to any radiation therapy related recalls, notices, safety alerts and hazards.
(iii) Each licensee must adopt and maintain a radiation treatment manual prepared by an authorized medical physicist possessing the qualifications specified in 10 CFR §35.51. 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 by clause (I) of item (i) of paragraph (3) of this subdivision). The treatment planning manual may be part of the quality assurance manual required by item (i) of paragraph (3) of this subdivision. The radiation treatment manual must be included in training given pursuant to 10 CFR §19.12 to facility staff who will participate in treatment planning. Each licensee must ensure that an authorized medical physicist possessing the qualifications specified in 10 CFR §35.51 prepares or reviews and approves a procedures manual describing how radiation therapy treatment planning is to be performed at the licensee's facility and reviews the treatment planning manual at least annually.

(T) Each licensee 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 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.

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

(*a*) Audits must be conducted at intervals not to exceed twelve (12) months by an authorized medical physicist possessing the qualifications specified in 10 CFR §35.51, and also by a physician, both of whom are in the active practice of the type of radiation therapy conducted by the licensee. These must be individuals who are not involved in the therapy program being audited; and

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

(*c*) The licensee 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 must document the reasons therefor and also any alternative actions taken to address the audit findings.

(4) Each licensee 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.

(5) *Unsealed byproduct material for which a written directive is required.* A quality assurance program for 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.

(i) Each licensee who uses unsealed byproduct material for which a written directive is required in humans shall implement a quality assurance program which includes at a minimum:
(A) 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;
(*b*) A written, signed and dated order for medical use of radioactive material is made in accordance with 10 CFR §35.40;
(*c*) Each patient is positively identified;
(*d*) All orders and other treatment records are clear and legible;
(*e*) staff will be instructed to obtain clarification before treating a patient if any element of the order or other record is confusing, ambiguous or suspected of being erroneous;
(*e*) 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 unsealed byproduct material for which a written directive is required and that unusual responses are evaluated as possible indications of treatment errors; and
(*f*) Complete treatment records containing data recorded at the time of each treatment are maintained.
(ii) Each licensee shall ensure that all equipment used in planning and administering 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 quality assurance manual.
(iii) Each licensee shall audit the 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.
(6) Accreditation in Radiation Oncology.
(i) Each 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.
(ii) The 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 licensee. Records must be maintained for at least 6 years.

3(b) [§175.103(b)(5)(iii)] **Qualifications for nuclear medicine technologists.**

Personnel, duly licensed by the New York State Department of Health to practice nuclear medicine technology, other than physicians or registered professional nurses, at licensees involved in the performance of diagnostic procedures utilizing radioactive material which includes performing parenteral administration of radioactive material by intravenous, intramuscular or subcutaneous methods, shall:
(1) 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
(2) Possess certification as a nuclear medicine technologist by the American Registry of Radiologic Technologists or certification by the Nuclear Medicine Technology Board; and
(3) 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:
(i) Procedures to assure that the nuclear medicine technologist possesses the education and training or certification set forth in this subdivision and is proficient in the competent performance of parenteral administration; and
(ii) Requirements for authorized user physician which at a minimum shall require supervision by such physician when parenteral administration of radioactive material for diagnostic testing is performed by a qualified nuclear medicine technologist.

3(c) [§175.101(h)(4)] **License termination requirements.**

(1) If a licensee does not submit an application for renewal of a radioactive materials license pursuant to 10 CFR §30.32, then the licensee shall on or before the expiration date stated in the license:
(i) terminate use of radioactive material;
(ii) Dispose of all radioactive material in accordance with all applicable regulations in effect at the time of disposal;
(iii) Submit a written certification of the disposition of all radioactive materials authorized by the license on forms prescribed by the Department;
(iv) Remove radioactive contamination to the extent practicable; and
(v) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a copy of this survey to the Department. Such survey shall be subject to approval by the Department and shall include:
(A) Levels of radiation in units (or multiples) of $Gy\text{-}hr^{-1}$ ($millirads\text{-}hr^{-1}$) at one (1) cm for beta-gamma radiation or at one (1) m for gamma radiation;

(B) Levels of removable and fixed contamination, including alpha, in units of disintegrations (transformations) per min (becquerels) per 100 cm^2 for surfaces;
(C) Becquerels-ml^{-1} (mCi-ml^{-1}) for water;
(D) Becquerels-g^{-1} (pCi-ml^{-1}) for solids such as soil or concrete; and
(E) A description of the survey or other measuring instrument(s) used, including manufacturer(s) and model number(s) and date of most recent calibration.
(vi) If the information submitted pursuant to item (v) of this subdivision does not adequately demonstrate that the premises are suitable for unrestricted use, the Department shall inform the licensee of the appropriate further actions required for the termination of the license, including, but not limited to, decontamination of the licensed premises to such levels and within such time frames as the Department may prescribe.
(2) Each specific license shall continue in effect, beyond the expiration date if necessary, with respect to the presence of any residual radioactive materials that may be present as contamination until the Department terminates the license. During this time, the licensee shall:
(i) Limit activities involving radioactive material to those related to decommissioning; and
(ii) Continue to control entry to restricted areas until the Department determines they are suitable for release for unrestricted use and the Department terminates the license.
(3) The Department will terminate a specific license only when the Department determines that:
(i) All licensed radioactive material has been properly transferred or disposed; and
(ii) A radiation survey has been performed which describes all radiation levels and levels of fixed and removable contamination; and
(iii) The licensee submits sufficient documentation to support a determination that the requirements of items (i) through (ii) of paragraph (3) of this subdivision have been met.

3(d) [§175.06] **Professional practitioners.**

(1) Nothing in this Code shall limit any human use of radiation in diagnostic and therapeutic procedures pursuant to this Code, provided that with respect to human use of radioactive materials, such use is in accordance with a specific license issued pursuant to this Code, or an exemption therefrom, or under a license issued by the New York State Department of Health or the U.S. Nuclear Regulatory Commission or other agreement states.
(2) Each professional practitioner who treats or diagnoses any alleged or proven case of radiation illness or radiation injury to any individual, except that which can be expected in the normal course of radiation therapy, shall report to the Commissioner in writing within seven (7) days such treatment or diagnosis, the full name, address, social security number, and age of such individual.

(3) No person other than a professional practitioner shall direct or order the application of radiation to a human being; nor shall any person other than a professional practitioner or a person working under the direction, order, or direct supervision of a professional practitioner apply radiation to a human being. Such direction, order to apply, application of, or administration of radiation shall be in the course of the practitioner's professional practice and shall comply with the following:
(i) The provisions of the license or other authorization of the professional practitioner under the New York State Education Law, or any successor law and regulations pertinent thereto, including, but not limited to, provisions as to those parts of the human body and those persons which the professional practitioner may diagnose, analyze or treat, or to which he/she may direct or order the application of, or apply, radiation, and provisions as to the type of radiation which the professional practitioner may use and the purpose for which the professional practitioner may use it; and
(ii) The applicable provisions of Article 35 of the New York State Public Health Law and Part 89 of Title 10 of the Codes, Rules and Regulations of the State of New York, or any successor law or regulation, relating to the practice of radiologic technology, including licensure requirements and the limitations under which radiologic technologists and other persons, other than professional practitioners, may apply x-rays to human beings.
(iii) A professional medical practitioner shall be responsible for the supervision of any radiation employee who administers radiation to human beings to assure that each exposure is given consistent with expected medical benefit and in accordance with any standards or requirements relating to the practice for which he/she is licensed.
(iv) A radiologic technologist shall be responsible for complying with the requirements of such technologist's license and the limitations established by the New York State Department of Health, Bureau of Radiologic Technology. Each activity carried out as a radiologic technologist shall be such as to assure the maximum medical benefit with the minimum radiation exposure to patients and employees.

3(e) [§175.103(b)(1)] **ALARA program.**

(1) 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.
(2) To satisfy the requirement of paragraph (1) of this subdivision:
(i) 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

(ii) For licensees that are not medical institutions, management and all authorized users shall participate in the program as requested by the radiation safety officer.
(3) The ALARA program shall include notice to workers of the program's existence and workers' responsibility to help keep dose equivalents ALARA.
(4) 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.
(5) The purpose of the review required by paragraph (4) of this subdivision is to ensure that every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material to unrestricted areas, that are as low as reasonably achievable, taking into account the state of technology and the cost of improvements in relation to benefits.
(6) The licensee shall retain a current written description of their ALARA program for the duration of the license. The written description shall include:
(i) A commitment by management to keep occupational doses as low as reasonably achievable;
(ii) A requirement that the radiation safety officer brief management once each year on the radiation safety program;
(iii) personnel exposure investigational levels that, when exceeded, will initiate an investigation by the radiation safety officer of the cause of the exposure (ALARA I); and 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 to be taken to reduce the probability of recurrence (ALARA II).

3(f) [§175.03(h)(3)(i)(D)] **Written policy statement on respirator use.**

If the licensee uses respiratory protection equipment to limit intakes pursuant to 10 CFR §§ 20.1701 through 20.1705, the licensee shall issue a written policy statement on respirator usage covering:
(1) The routine, non-routine, and emergency use of respirators and
(2) Limitations on periods of respirator use and relief from respirator use; and
(3) The use of process or other engineering controls, instead of respirators.

3(g) [§175.03(l)(9)(ix) **Reports and records of medical events.**

(A) *Diagnostic medical events involving radioactive material*.
(*a*) Records of medical events which involve diagnostic procedures and the corrective actions taken pursuant to 3(a)(2)(i)(H) of this Code shall be retained for 6 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 shall notify the Department in writing within fifteen (15) days and make and retain a record of such event for six (6) years.

(B) *Diagnostic medical events involving diagnostic radiation equipment*.

(a) Records of medical events which involve diagnostic radiation equipment and the corrective actions taken pursuant to 3(a)(2)(i)(H) of this Code shall be retained for six (6) years; and

(b) If such a medical event results in an unintended dose to the skin of the patient greater than 2 Sv (200 rem) to the same anatomical area, or results in an unintended dose to any organ greater than 0.5 Sv (50 rem), or results in an unintended dose to the whole body greater than 0.05 Sv (5 rem) total effective dose, the licensee shall notify the Department in writing within fifteen (15) days and make and retain a record of such event for six (6) years.

(c) If a diagnostic medical event involving diagnostic radiation equipment results in the wrong patient, the wrong exam or the wrong anatomical site being imaged, the licensee shall notify the Department in writing within fifteen (15) days and make and retain a record of such event for six (6) years.

(C) *Therapy medical events*.

(*a*) When a recordable therapy medical event as defined in § this Code is discovered, in which the percentage of error is equal to or less than 20 percent, the licensee shall immediately investigate the cause and take corrective action; and

(*b*) The licensee shall make and retain a record of all recordable therapy medical events as defined this Code. The record shall contain all the information required by this Code and shall be retained for six (6) years.

(D) *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.

3(h) [§175.103(c)(10)] **Storage of volatiles and gases.**

(1) A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.

(2) After drawing the first dosage, a licensee shall store and use a multidose container in a properly functioning fume hood.

3(i) [§175.103(c)(1)] **Dose calibrator possession, calibration and checks.**

(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 (10mCi) of radium-226 or 1.85 MBq (50mCi) 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 (10mCi) for radium-226 and 1.85 MBq (50mCi) 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 (10mCi) 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 item (ii)) of this subdivision, a licensee that uses a dose calibrator to measure the activity of beta-emitting radioactive materials to be administered to a patient shall perform additional checks specified in clauses (A) and (B) of item (ii) of this subdivision 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 item (vi) of paragraph (1) of this subdivision.
(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 (10mCi) 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 by3(i)(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 items (ii), (iii) and (v) of paragraph (1) of this subdivision for 3 years. Such records shall include:

(A) For clause (A) of item (ii) of paragraph (1) of this subdivision, 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 clause (B) of item (ii) of paragraph (1) of this subdivision, 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 clause (C) of item (ii) of paragraph (1) of this subdivision, 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 clause (D) of item (ii) of paragraph (1) of this subdivision, 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.

3(j) Survey instrument calibration requirements for medical use.[§175.103(c)(3)] Survey instrument calibration requirements for medical use.

(1) A licensee shall calibrate the survey instruments used to show compliance with this Code and before first use, annually, and following a repair that may affect the calibration.

(2) To satisfy the requirements of paragraph (1) of this subdivision, the licensee shall:

(i) Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source, the intensity of which is determined to be within 10 percent accuracy;

(ii) 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

(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.

(3) To satisfy the requirements of 10 CFR §35.60(b), the licensee shall:

(i) Consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 10 percent; and

(ii) 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.

(iii) 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.

(4) To satisfy the requirements of paragraphs (1) through (3) of this subdivision, 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.

(5) 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.

(6) A licensee shall retain a record of each survey instrument calibration in accordance with 10 CFR §35.2061.

3(k) [§175.03(i)(2)] **Storage of radioactive material.**

Radioactive material shall not be stored with either food or beverages.

3(l) [§175.104(d)(2)] **Prohibition on burial.**

No person shall bury any licensed radioactive material within

New York City.

3(m) [§175.101(k)(1)(iv)] **Prohibition on advertisement.**

No person, in any advertisement or public posting, expressly or by implication, shall refer to the fact that a radiation installation is licensed by the Department, and no person shall state or imply that a radiation installation or its activities have been approved by the Department, the Board of Health or the Commissioner.

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* Citations to sections of Article 175 of the New York City Health Code in this document are to its current section numbers and layout as of December 2015. These section numbers and layout are subject to change pending the repeal and reenactment of Article 175, which is anticipated to occur on or about September 2016.