Quality Assurance Requirements for Medical Use of Radioactive Materials and Radiation Therapy

Effective date: 5/8/13

Summary of Express Terms

The regulatory proposal would revise Part 16 of 10 NYCRR as described in more detail below.

Subdivision (c) of section 16.1 is revised to update the address and phone number of the Department of Health's Bureau of Environmental Radiation Protection and to allow certain reports to be filed electronically with the Department.

Paragraph (15) of subdivision (a) of section 16.2 is amended to make the definition of "byproduct material" comparable to the definition of byproduct material in NRC regulations.

Paragraph (134) of subdivision (a) of section 16.2, which contains an outdated definition of the term "tutelage," is repealed.

Subdivision (a) of section 16.24 is repealed and replaced with a new subdivision (a), which includes updated quality assurance standards for licensees or registrants authorized to administer external beam therapy or brachytherapy to human beings. 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 (a) 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 section requires licensees and registrants to credential individuals involved in quality assurance testing, treatment planning, and radiation treatment of patients. Finally, new subdivision (a) 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 regulation.

Section 16.100 is repealed and replaced with a new section 16.100 to update the licensing requirements for licensure of radioactive materials.

Sections 16.120 and 16.121 are repealed and replaced with a new section 16.120 which sets forth the licensing requirements for human use of radioactive material.

Section 16.122 is repealed. The requirements for teletherapy units are included in the proposed new section 16.123.

Current section 16.123 is repealed and replaced with a new section 16.123. The new version updates the standards for the medical use of radioactive materials, consistent with the federal Nuclear Regulatory Commission (NRC) regulations governing the medical use of radioactive materials; updates definitions to be consistent with federal regulatory definitions; updates the training and experience requirements for physicians, pharmacists and medical physicists who use radioactive materials for medical purposes; and revises and creates new categories of medical

use licenses. The new section 16.123 incorporates certain federal regulatory requirements by reference; it also establishes regulatory requirements specific to New York State that are consistent with the federal regulatory requirements.

The proposed section 16.2 will have a significant impact on physicians who wish to use radiopharmaceuticals for diagnostic nuclear medicine and nuclear cardiology. The current section requires 200 hours of classroom training. By removing this requirement and incorporating the federal classroom training requirements set forth in 10 CFR Part 35, the required classroom and laboratory training hours will be reduced to 80 hours for physicians applying for authorized user status for diagnostic uses. In addition, these physicians would be allowed to obtain the practical training component in a private medical practice setting. Currently such training can be obtained only at a medical institution (hospital). By incorporating the training requirements established in 10 CFR Part 35, the total number of training hours for physicians who use radioactive materials will remain at 700 hours.

Relative to the new categories of medical use licenses, the new section 16.123 includes a category that covers gamma knife radiosurgery units and high dose rate remote afterloaders. Quality assurance requirements are modified to reflect the revised and new categories. The dose limits for members of the public and occupationally exposed individuals are modified to exclude exposure from individuals administered radioactive material and released in accordance with regulations.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 225 of the Public Health Law, Sections 16.1, 16.2, 16.24, 16.100, 16.120, 16.121, 16.122 and 16.123 of Part 16 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York are amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Subdivision (c) of Section 16.1 is REPEALED and new subdivision (c) of Section 16.1 is added as follows:

(c) Communications. Except as otherwise provided for in this Part or authorized by the Department, all applications, notifications or other communications filed pursuant to this Part shall be addressed to the New York State Department of Health Bureau of Environmental Radiation Protection, Empire State Plaza, Albany, New York 12237, or by telephone (518) 402-7550. Registrants and licensees that are authorized pursuant to Article 28 of the Public Health Law to operate a hospital may comply with adverse event reporting required by this Part by electronic filing with the Department via the New York Patient Occurrence and Tracking System (NYPORTS).

Paragraph (15) of subdivision (a) of Section 16.2 is amended as follows:

(15) Byproduct material [means] <u>shall include</u>:

(i) Any radioactive material, except special nuclear material, yielded in, or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; [and]

(ii) the tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes[. Underground]; however, ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition[.];

(iii) any discrete source of radium-226 that is produced, extracted, or converted after extraction for use for a commercial, medical, or research activity;

(iv) any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or converted after extraction for use for a commercial, medical, or research activity.

(v) any discrete source of naturally occurring radioactive material, other than source material, that is extracted or converted after extraction for use in a commercial medical or research activity that the Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security.

Paragraph (134) of subdivision (a) of Section 16.2 is REPEALED and reserved.

Subdivision (a) of section 16.24 is REPEALED and a new subdivision 16.24(a) is added to read as follows:

(a) External beam therapy and brachytherapy. Each licensee or registrant authorized to administer external beam therapy or brachytherapy to human beings shall 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 tissues, minimal exposure to personnel and adequate patient monitoring aimed at determining the end result of the treatment. Each such licensee or registrant shall meet or exceed all quality assurance criteria described in this subdivision.

(1) Each licensee or registrant shall adopt and maintain a quality assurance manual that includes policies and procedures that require the following:

(i) Each patient's medical record shall be complete, accurate, legible and shall 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 shall 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 shall be made for each patient in accordance with subdivisions (b) and (c) of section

16.19 of this Part. The order or prescription shall 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 shall be verified by qualified clinical staff prior to patient treatment.

(iv) A radiation therapy technologist, physician or other qualified health practitioner shall 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 shall 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 shall be verified by at least two different means by qualified clinical staff prior to each treatment.

(vii) Each patient's response to treatment shall 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 shall 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 shall be checked for completeness and accuracy by qualified clinical staff at intervals not to exceed six fractions.

(ix) Radiation treatment plans and related calculations shall 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 shall 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 paragraph (1) of subdivision (d) of section 16.123 of this Part, 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 subparagraph (2) of this paragraph, and who has received training in use of the manual pursuant to subparagraph (2) of this paragraph.

(x) All equipment and other technology used in planning and administering radiation therapy shall function properly and safely, and shall 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, shall 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 shall 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 shall be immediately reported to the authorized medical physicist.

(xiii) Records for all maintenance, repairs and upgrades of equipment and technology shall be maintained for at least five years.

(xiv) Errors or defects in technology or equipment, including computer hardware and software, shall 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 shall be maintained for review by the Department for at least three years.

(xv) External beam therapy equipment calibration/output required by section16.60(c)(1) of this Part shall be verified by an independent means and records of such measurements shall be retained for review by the Department for at least three years.

(xvi) Patients with permanent brachytherapy implants shall be provided with instructions to take radiation safety precautions, as required by section 16.123(e)(4) (incorporating 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 shall be credentialed. Credentialing shall include verifying that all professional staff are appropriately licensed, including medical physicists and radiation therapy technologists. Records of

credentialing shall be maintained during the period in which the credentialed person provides services to the licensee or registrant and for three years thereafter.

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

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

(2) Each licensee or registrant shall adopt and maintain a radiation treatment manual that includes 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 paragraph (1) of this subdivision. The radiation treatment manual shall be included in training given pursuant to subdivision (c) of section 16.13 of this Part to facility staff who will participate in treatment planning. Each licensee or registrant shall ensure that an authorized medical physicist possessing the qualifications specified in paragraph (1) of subdivision (d) of section 16.123 of this Part 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.

(3) Each licensee or registrant shall 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.

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

(i) Audits shall be conducted at intervals not to exceed 12 months by an authorized medical physicist possessing the qualifications specified in paragraph (1) of subdivision (d) of section 16.123 of this Part, 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.

(ii) The licensee or registrant shall 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 shall 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 shall document the reasons therefor and also alternative actions taken to address the audit findings.

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

(6) Accreditation in Radiation Oncology.

(i) Effective 90 days from the effective date of this regulation, each registrant or licensee shall 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) Effective 18 months from the effective date of this regulation, each registrant and licensee shall 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 shall 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 shall be maintained for at least 6 years.

Section 16.100 is REPEALED and new Section 16.100 is added to read as follows:

§16.100 Licensing requirements for use of radioactive materials.

(a) A person may manufacture, produce, acquire, receive, possess, prepare, use or transfer any radioactive materials only in accordance with a specific license issued by the Department or as allowed in paragraphs (b) or (c) of this section.

(b) A specific license is not required for persons who comply with all applicable requirements for a general license as set forth in section 16.101 of this Part.

(c) A specific license is not required for persons who comply with all applicable requirements to qualify for an exemption as set forth in section 16.4 of this Part or other exemptions provided for in this Part or for the removal of source material from its place of deposit in nature.

Section 16.120 is REPEALED and new Section 16.120 is added to read as follows:

§16.120 Specific licenses for the use of radioactive materials on human beings.
An application seeking a specific license for use of radioactive materials on human beings shall be approved if all of the following criteria are satisfied:

(a) The application is completed, signed by an appropriate individual, and submitted to the Department.

(b) The applicant is an individual, corporation, partnership or other entity that is legally authorized to do business in New York State. If the applicant is seeking a specific license

pursuant to section 16.123 of this Part, the applicant shall be legally authorized to practice medicine in New York State or operate a hospital as defined in section 2801 of the Public Health Law.

(c) The applicant satisfies the requirements set forth in section 16.103 of this Part.

(d) The applicant demonstrates to the satisfaction of the Department that it has adequate facilities for clinical care of patients.

(e) The applicant demonstrates to the satisfaction of the Department that its facilities will be appropriately equipped and staffed and will be operated as required by this Part.

(f) The applicant provides additional information as requested by the Department.

Section 16.121 is REPEALED and Reserved.

Section 16.122 is REPEALED and Reserved.

Section 16.123 is REPEALED and a new Section 16.123 is added to read as follows:

§16.123 Specific licenses for certain medical uses of byproduct materials.

(a) Purpose and scope. This section contains requirements for the medical uses of byproduct materials that are subject to specific licenses. These requirements are in addition to, and not a substitute for, other requirements in this Part. Any license issued prior to the effective date of this regulation that references paragraph (b) shall be deemed to reference paragraph (d).

(b) Definitions. Whenever used in this section, or in federal regulations incorporated herein, the following terms shall have the following meanings:

(1) "Authorized medical physicist" means an individual who is authorized to practice medical physics pursuant to Article 166 of the Education Law and:

(i) meets the definition and the training requirements for an authorized medical physicist set forth in 10 CFR §§ 35.2, 35.51 and 35.57; or

(ii) is named as a radiation therapy physicist on a medical use radioactive materials license issued by the Department and meets the requirements set forth in 10 CFR § 35.59.

(2) "Authorized nuclear pharmacist" means an individual who is authorized to practice pharmacy pursuant to Article 137 of the Education Law and:

(i) meets the requirements for an authorized nuclear pharmacist in 10 CFR § 35.55(a) and § 35.59; or

(ii) is identified as an authorized nuclear pharmacist on:

(a) a specific license issued by the Nuclear Regulatory Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

(b) a permit issued by a Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(c) a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

(d) a permit issued by a Nuclear Regulatory Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

(iii) is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(iv) was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and the individual practiced at a pharmacy at a federal government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the Nuclear Regulatory Commission.

(3) "Authorized user" means an individual who is authorized to practice medicine pursuant to Article 131 of the Education Law and:

(i) meets the applicable requirements in 10 CFR §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or

(ii) is identified as an authorized user on:

(a) a Nuclear Regulatory Commission or Agreement State license that authorizes the medical use of byproduct material;

(b) a permit issued by a Nuclear Regulatory Commission master material licensee that is authorized to permit the medical use of byproduct material;

(c) a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or

(d) a permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

(4) "Medical use" means the intentional internal or external administration of byproduct material or the radiation from byproduct material to patients or human research subjects under the supervision of an authorized user.

(5) "Positron emission tomography facility" is a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

(6) "Prescribed dosage" means the specified activity or range of activity of unsealed byproduct material as documented in a written directive, or in accordance with the directions of the authorized user for procedures performed pursuant to 10 CFR §§ 35.100 and 35.200. Further details concerning this referenced code are contained in subdivision (c) of this section.

(7) "Prescribed dose" means:

(i) for gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(ii) for teletherapy, the total dose and dose per fraction as documented in the written directive;

(iii) for manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(iv) for remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

(8) "Radiation safety officer" means an individual who:

(i) meets the requirements set forth in 10 CFR §§ 35.50(a) or (c)(1) and 35.59; or

(ii) is identified as a radiation safety officer on a specific medical use license issued by the Nuclear Regulatory Commission or Agreement State or a medical use permit issued by a Nuclear Regulatory Commission master material licensee.

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

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

(c) Approved medical uses of byproduct materials. A licensee may use byproduct materials on human beings for the particular uses set forth below, provided that the licensee meets all applicable requirements of this Part:

(1) Use of unsealed byproduct material for uptake, dilution and excretion studies;

(2) Use of unsealed byproduct material for imaging and localization studies;

(3) Use of unsealed byproduct material for which a written directive is required;

(4) Use of sources for manual brachytherapy;

(5) Use of sealed sources for diagnosis;

(6) Use of sealed source in a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit; or

(7) Other specific medical uses of byproduct material or radiation from byproduct material, as licensed by the Department.

(d) Federal standards. All licensees shall comply with the provisions of the following federal regulations, which are hereby incorporated by reference, with the same force and effect as if fully set forth at length herein: Title 10 of the Code of Federal Regulations, Part 35, Medical Use of Byproduct Material. This code is published by the Office of the Federal Register National Archives and Records Administration. Copies may be obtained from the Superintendent of Documents, United States Government Printing Office, Washington D.C. 20402. This code is available for copying and inspection at the Regulatory Affairs Unit, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, New York 12237. Notwithstanding any provision herein to the contrary, if a conflict occurs between the above referenced CFR and other provisions in this Part, compliance with the more restrictive regulation is required.

(e) General requirements applicable to all licensees authorized to use byproduct materials for medical purposes.

(1) Record Keeping Requirements. A licensee shall comply with all record keeping requirements set forth in Subpart L (Records) of Part 35 of 10 CFR. Further details concerning this referenced code are contained in subdivision (c) of this section.

(2) Reporting requirements: A licensee shall comply with all reporting requirements set forth in Subpart M (Reports) of Part 35 of 10 CFR as revised herein as follows: (i) in § 35.3045(c) and §35.3047(c), replace phrase "NRC Operations Center" with "Department"; (ii) in §35.3045(d) and § 35.3047(d), replace “By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter” with “shall submit a written report to the Department”; (iii) in § 35.3045(g)(1) and § 35.3047(f)(1), replace the term "NRC" with "Department"; and, (iv) in § 35.3067 replace “The report must be filed with the appropriate NRC Regional Office listed in § 30.6 of this chapter, by an appropriate method listed in § 30.6(a) of this chapter, with a copy to the Director, Office of Federal and State Materials and Environmental Management Programs.” with “The report shall be filed with the Department”.

(3) Training and experience requirements. A licensee shall ensure that all staff who are involved in the use of byproduct material pursuant to a specific license have the training and experience required by this Part.

(4) Other General Requirements. A licensee shall comply with requirements set forth in 10 CFR § 35.5, §35.6, §35.11(a)and (b), §35.24(b), (e), (f) and (g), §35.27, §35.40, §35.41, §35.49,

§35.60, §35.61, §35.63, §36.67, §35.69, §35.70, §35.75, §35.80, §35.92 as modified herein as follows: in § 35.27(a)(1) and (b)(1), replace “19.12 of this chapter” with “16.13(c) of this Part”.

(f) Requirements for the use of unsealed byproduct material for uptake, dilution and excretion studies. A licensee shall use unsealed byproduct material for uptake dilution and excretion studies only if authorized to do so by a specific license issued by the Department and provided that the licensee complies with10 CFR §§ 35.100 and 35.190 and all applicable provisions of this Part.

(g) Requirements for the use of unsealed byproduct material for imaging and localization studies. A licensee shall use unsealed byproduct material for imaging and localization studies only if authorized to do so by a specific license issued by the Department and provided that the licensee complies with 10 CFR §§ 35.200, 35.204 and 35.290 and other applicable provisions of this Part.

(h) Requirements for the use of unsealed byproduct material for which a written directive is required. A licensee shall use unsealed byproduct material for which a written directive is required only if authorized to do so by a specific license issued by the Department and provided that the licensee complies with Subpart E (Unsealed Byproduct Material-Written Directive Required) of Part 35 of 10 CFR and other applicable provisions of this Part.

(i) Requirements for the use of sources for manual brachytherapy. A licensee may use sources for manual brachytherapy only if authorized to so by a specific license issued by the Department

and provided that the licensee complies with Subpart F (Manual Brachytherapy) of Part 35 of 10 CFR.

(j) Requirements for the use of sealed sources for diagnosis. A licensee may use sealed sources for diagnosis only if authorized to do so by a specific license issued by the department and provided that the licensee complies with Subpart G (Sealed Sources for Diagnosis) of Part 35 of 10 CFR and other applicable provision of this Part.

(k) Use of sealed source in a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit. A licensee may use a sealed source in a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit only if authorized to so by a specific license issued by the department and provided that the licensee complies with Subpart H (Photon Emitting Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units) of Part 35 of 10 CFR and other applicable provisions of this Part.

(l) Other medical uses of byproduct material or radiation from byproduct material. A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in paragraphs 1 through 6 of subdivision (b) of this section if the licensee submits to the department information required by 10 CFR §35.12(b) through (d) and the licensee has received written approval from the Department in a specific license or license amendment and uses the material in accordance with specific conditions that the department deems necessary or desirable for the safest medical use of the material.

(m) General Use License. Any licensee who is licensed for one or more of the types of medical uses specified in paragraphs (1) through (6) of subdivision (b) of this section also is authorized to use radioactive material under the general license in Appendix 16-A, Table 6, Item (i) infra, for the specified "in vitro" uses without filing Form GEN 373 as required by Appendix 16-A, Table 6, Item (i), subdivision (2), infra, provided, however, that the licensee is subject to the other provisions of Appendix 16-A, Table 6, Item (i), infra.

Regulatory Impact Statement

Statutory Authority:

The Public Health and Health Planning Council is authorized by § 225(4) of the Public Health Law (PHL) to establish, amend and repeal provisions of the State Sanitary Code (SSC), subject to the approval of the Commissioner of Health. PHL §§ 225(5)(p) and (q) and 201(1)(r) authorize the Commissioner to promulgate SSC regulations to protect the public from the adverse effects of ionizing radiation. Pursuant to these regulations, as set forth in 10 NYCRR Part 16, the Department of Health (Department), licenses or registers health care providers to use radioactive materials and ionizing radiation emitting equipment on patients.

The federal Atomic Energy Act of 1954 (the Act), codified at 42 USC §§ 2021, et. seq. authorizes the United States Nuclear Regulatory Commission (NRC) to regulate the use of radioactive materials. The Act also authorizes "Agreement States" to regulate the use of radioactive materials in lieu of the NRC, provided that the "Agreement State" promulgates regulations that are comparable to or exceed NRC's regulatory standards. New York State is an "Agreement State" within the meaning of the Act. New York's regulatory standards for the use of radioactive materials in 10 NYCRR Part 16 must therefore meet or exceed comparable NRC regulatory standards. The Act governs only to the use of radioactive materials; it does not apply to x-rays or radiation therapy equipment that emit only x-rays.

Legislative Objectives:

The legislative intent of PHL §§ 225(5) and 201(1)(p) and (q) is to protect the public from the adverse effects of ionizing radiation. Promulgating regulations to ensure safe and effective clinical uses of radioactive material and radiation producing equipment is consistent with this legislative objective.

Needs and Benefits:

The NRC has relinquished its authority to regulate the use of radioactive materials in New York State to the Department. The Act requires New York to adopt and enforce regulatory standards for the use of radioactive materials that are comparable to or exceed federal regulatory standards that apply to the use of radioactive materials. The Department regulates the use of radioactive material at approximately 1100 facilities, including approximately 450 health care facilities. The Department's regulations are designed to require the delivery of quality care while protecting people and the environment from the harmful effects of radiation. In order to ensure that New York retains its authority under federal law to regulate the use of radioactive material, the Department's regulations must be amended to conform more closely to current federal regulatory standards. The proposed regulations incorporate by reference many of the NRC regulatory standards that govern the medical use of radioactive materials. In areas where the NRC regulations are not incorporated, the Department has promulgated comparable regulations.

In recent years, technology and equipment used to deliver radiation therapy to cancer patients, including systems used to plan and execute radiation therapy treatment, have become significantly more complex. Recently developed radiation therapy systems more effectively

deliver high dose rate treatments to precisely defined three-dimensional tumor volumes while sparing dose to healthy tissue. Patients benefit significantly when, as is the case in the vast majority of such radiation treatments, the dose is delivered as intended. However, radiation treatment errors can cause serious consequences for patients and in extreme cases, death. An analysis of the causes of medical adverse events (radiation therapy misadministrations) reported to the Department within the past eight years has identified common errors and causes of errors that may be preventable with the implementation of more comprehensive quality assurance programs. When the current regulations for quality assurance for external beam and brachytherapy were implemented in 1993, radiation therapy equipment was much simpler in design and function, and there were fewer units in service. Most radiation therapy treatments were delivered in a hospital setting. Today there are greater numbers of patients receiving radiation therapy, and more patients are treated in freestanding radiation therapy centers. There are more medical therapy accelerators in use. Newer radiation treatment systems are very complex; these systems rely on computer networks and electronic data storage and movement. DOH regulates approximately 120 medical facilities that provide radiation therapy. The current regulations need to be revised to effectively address quality assurance requirements for newer systems, to ensure implementation of strategies to prevent the occurrence of misadministrations and ensure those facilities meet current standards of care.

Costs:

The Department estimates that regulated parties that use radioactive materials will not incur any additional costs in order to comply with the proposed changes to 10 NYCRR § 16.123. In most instances, the proposed regulatory amendments will reduce costs and regulatory burdens for

physicians who are required to qualify as "authorized users" of radioactive materials for diagnostic purposes. The current section requires 200 hours of classroom training. By removing this requirement and incorporating the federal classroom training requirements set forth in 10 CFR Part 35, the required classroom and laboratory training hours will be reduced to 80 hours for physicians applying for authorized user status for diagnostic uses. In addition, these physicians would be allowed to obtain the practical training component in a private medical practice setting. Currently such training can be obtained only at a medical institution (hospital). By incorporating the training requirements established in 10 CFR Part 35, the total number of training hours for physicians who use radioactive materials will remain at 700 hours.

This will result in lower costs for classroom training (tuition/course fee) and associated travel/lodging expenses, and will reduce the time a physician would be away from his/her clinical practice to obtain the required classroom training. The current regulations specify that such training must be obtained at a medical institution, or hospital. However, under the training requirements established in 10 CRF Part 35, which will be incorporated by the new regulation, physicians will have the option to obtain the required work experience portion of the training (620 hours) at non-institutional facilities. Costs associated with complying with the quality assurance testing for therapeutic devices, including high-dose rate brachytherapy and teletherapy should not increase or change, because the current license conditions contain these same quality assurance requirements.

The Department estimates that the cost to regulated parties that use external beam therapy or manual brachytherapy to comply with proposed 10 NYCRR § 16.24 will be limited to the fee to

become accredited in radiation oncology by either the American College of Radiology (ACR), the American College of Radiation Oncology (ACRO) or an equivalent organization as approved by the Department. The cost for accreditation is approximately $9,500 for each three-year period. However, approximately half of the affected regulated parties are either currently accredited or have an application pending with ACR or ACRO on their own accord. Many that are not accredited use the services of outside radiation oncologists and medical physicists to audit their radiation therapy quality assurance program on an annual basis. The costs for annual outside audits are estimated to cost several thousands of dollars. The proposed regulation would remove the need for outside audits, although they could be conducted to meet the requirement for an annual audit. Under the proposed rule, either an internal or an external audit may be used to fulfill the annual audit requirement. Costs saved by elimination of the requirement for outside audits are expected to offset a portion of the costs that will be incurred for accreditation. The other proposed changes to 10 NYCRR § 16.24 will impose very little or no cost to regulated parties since existing facility staff can comply with the new quality assurance requirements.

Local Government Mandates:

These proposed regulations apply to two State University hospitals, a Department operated hospital and hospitals operated by public benefit corporations. These hospitals are currently accredited by the ACR. No other additional costs are associated with implementation of these requirements. Registrants and licensees, including the hospitals operated by state and local governments, are currently required to retain all quality assurance documents for review by the department. The additional records and filing is estimated to be a small incremental amount. Affected parties will need to complete an application for accreditation initially and every three

years thereafter. The radiation oncology accrediting bodies are transitioning to an on-line application process to minimize time and effort for parties seeking accreditation.

Paperwork:

Department regulations (10 NYCRR Part 16) require registrants and licensees to maintain a variety of records relating to the use of ionizing radiation for review by the Department. The Department estimates that licensees and registrants may have a small amount of additional documentation to create, maintain or file. Affected parties will have to complete an application for radiation oncology accreditation. However, the accrediting bodies are transitioning to an online application process to minimize time and effort for regulated parties seeking accreditation.

The proposed regulations will not affect license documents issued by the Department to current licensees, registrants or authorized users. The Department plans to provide updated license guidance to new applicants to facilitate completion of an application based on the new requirements.

Duplication:

There is no duplication of the proposed regulatory requirements by any federal, state or local agency for licensees, registrants or authorized users subject to 10 NYCRR Part 16. New York State entered into an agreement with the federal government on October 15, 1962, by which the federal government discontinued its regulatory authority over the use of radioactive materials and New York assumed such authority. The Atomic Energy Act does not govern use of x-ray emitting equipment.

Alternatives:

There are no suitable alternatives to the revisions to these proposed regulations. As discussed above, the Atomic Energy Act (42 USC § 2021 et. seq.) requires Agreement States such as New York to adopt and implement regulatory standards that meet or exceed comparable federal standards.

Federal Standards:

These proposed revisions to 10 NYCRR §16.123 incorporate by reference certain federal requirements specified in 10 CFR Part 35.

Compliance Schedule:

The proposed regulatory amendments will be effective upon publication of a Notice of Adoption in the State Register. However, proposed 10 NYCRR §16.24(a)(6) requires that licensees and registrants apply for accreditation in radiation oncology with the American College of Radiology or the American College of Radiation Oncology or another accrediting organization approved by the Department within 90 days of the regulation's effective date and to become accredited and maintain such accreditation within 18 months of such effective date.

Contact Person:

Katherine Ceroalo
New York State Department of Health
Bureau of House Counsel, Regulatory Affairs Unit
Corning Tower Building, Rm. 2438
Empire State Plaza
Albany, New York 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.state.ny.us

Regulatory Flexibility Analysis for Small Businesses and Local Governments

Effect on Small Business:

The Department has issued radioactive materials licenses to approximately 350 private medical practices. These licensees would be affected by the proposed revisions to 10 NYCRR §16.123. The Department estimates that there will be no new costs for these licensees and in some instances, regulated parties may save money by complying with the updated standards in proposed 10 NCRR §16.123. The Department expects the cost to comply with the new training and experience requirements for physicians who wish to become authorized for certain medical uses will be reduced in most situations. Specifically the required classroom and laboratory training hours will be reduced from 200 to 80 hours for physicians applying for authorized user status for diagnostic uses. The total number or training hours will remain at 700 hours. This will result in lower costs for classroom training (tuition/course fee) and associated travel/lodging expenses, and will reduce the time a physician would be away from his/her clinical practice to obtain the required classroom training. Physicians will have the option to obtain the required work experience portion of the training (620 hours) at non-institutional facilities. The current requirements specify that such training must be obtained at a medical institution (hospital).

The proposed changes to 10 NYCRR §16.24 would apply to approximately 60 medical private practices. The draft proposed rule was sent to all medical therapy accelerator facilities, including the small businesses (non-institutions) for comments. One facility manager stated that they support the accreditation requirement although it can be a hardship to practices like hers.

However the manager's facility was already accredited and has application pending to maintain accreditation. No other facility expressed any anticipated hardship with the proposed rule.

Compliance Requirements:

Licensees and applicants will need to become familiar with the new requirements and modify their quality assurance policies and procedures accordingly. Those who are not currently accredited will need to do so within 18 months of the effective date of the rule.

Professional Services:

The vast majority of facilities have in-house staff that perform quality assurance testing and operate radiation emitting technology. The Department does not expect that it would be necessary for licensees to use additional professional services for completion of applications for accreditation or to implement the quality assurance requirements.

Capital Costs and Annual Costs of Compliance:

The amortized annual cost is estimated to be approximately $3,200 per year for accreditation (based on a three-year accreditation cost of $9,500). However, approximately 50 percent of the facilities are either currently accredited or have an application for accreditation pending; therefore, they will not incur any additional costs. There are no capital costs associated with this regulation.

Economic and Technology Feasibility

There are no capital costs or new technology required to comply with the proposed rule.

Minimizing Adverse Impact:

Facilities will have 90 days to apply and 18 months to become accredited. This will allow a facility adequate time to select the accreditation body of their choice, complete an application and budget funds for the accreditation fee. The Department has held several discussions with the proposed accrediting bodies, and has accompanied their auditors during accreditation surveys. These interactions were conducted to ensure that the bodies have the capacity to handle an influx of applications for accreditation and that the organizations operate in a professional and constructive manner, have an efficient process, and have an overall effect of improving patient safety. Further the requirement for external annual audits was eliminated which would offset the cost of accreditation.

Small Business Input:

A copy of the draft proposed rule was sent to all medical therapy accelerator facilities, which includes both private practices and hospital-based radiation therapy treatment clinics. Seven facilities submitted comments. Only one commenter addressed the cost for accreditation, however, she stated that she supports the accreditation requirement. Several comments were in regard to clarification on a few aspects of the proposed language. Guidance, which will assist the affected facilities in implementation and compliance with the new requirements, will be developed and provided to affected facilities.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

There are 105 affected facilities located in 46 rural areas (33 counties with a population of less than 200,000 and 13 counties with certain townships with a population density of more than 150 persons per square mile).

Reporting, Recordkeeping and Other Compliance Requirements and Professional Services:

There are no new reporting requirements contained in the proposed regulations. No additional professional service costs are anticipated. Facilities will be required to maintain records of quality assurance test results and accreditation documents for review by the Department's inspectors. Compliance with the recordkeeping requirements will require only a minor incremental amount of time and effort for affected facilities.

Cost:

The cost to comply with the accreditation requirement will be approximately $9,500 every three years. This will affect approximately 50 percent of the facilities that will be subject to the proposed 10 NYCRR §16.24(e), because approximately 50 percent of the facilities are either currently accredited or have an application for accreditation pending. Facilities that are currently accredited or have an application pending have done so in part to satisfy the current audit requirements in section 16.24. Such facilities have selected the option to conduct annual internal audits (by in-house staff) and have periodic audits performed by the ACR or ACRO. Such facilities will not effectively see an increase in their operating budgets to comply with the new

accreditation requirement as they have already chosen to become accredited and have budgeted for the associated cost.

Minimizing Adverse Impact:

Facilities will have 18 months to become accredited. This will allow a facility adequate time to select the accreditation body of their choice, complete an application and budget funds for the accreditation fee. The Department has held several discussions with the proposed accrediting bodies, and has accompanied their auditors during accreditation surveys. These interactions were conducted to ensure that the bodies have the capacity to handle an influx of applications for accreditation and that the organizations operate in a professional and constructive manner, have an efficient process, and have an overall effect of improving patient safety.

Rural Area Participation:

A copy of a draft proposed rule was sent to all medical therapy accelerator facilities, which includes both private practices and hospital-based radiation therapy treatment clinics. Seven facilities commented. One commenter addressed the cost for accreditation but indicated they understood the value of accreditation. A few commenters requested minor clarification on a few aspects of the proposed language.

Job Impact Statement

Nature of Impact:

It is anticipated that no jobs will be adversely affected by this rule. Radiation therapy providers in New York will need to become familiar with and implement the new regulatory requirements set forth in proposed 10 NYCRR §16.24. The proposed regulations do not significantly change the training or experience requirements of radiation therapy facility staff. Medical providers authorized to use radioactive materials would need to become familiar with and implement the new regulatory requirements set forth in proposed 10 NYCRR §16.123. The Department anticipates that few if any persons will be adversely affected. Licensee staff, specifically those designated as the radiation safety officer, medical physicist, nuclear pharmacist, and authorized user will need to become familiar with the new requirements.

Categories and Numbers Affected:

There are approximately 120 radiation therapy facilities that would be subject to the rule. Half of these are hospitals or their satellite facilities, and the other half are non-institutional entities. There are approximately 450 medical use of radioactive materials licensees.

Regions of Adverse Impact:

No areas will be adversely affected.

Minimizing Adverse Impact:

There are no alternatives to the proposed regulations. The Department will revise guidance to assist all licensees, including those in rural areas, with implementation of the proposed regulations.

Self-Employment Opportunities:

The rule is expected to have minimal impact on self-employment opportunities since the majority of providers that will be affected by the rule are not sole proprietorships.

ASSESSMENT OF PUBLIC COMMENT

The public comment period ended on November 19, 2012. The Department received one comment from Virtual Radiologic (VRad). VRad requested that the Department consider repealing the definition of "use" of radioactive materials under 10 NYCRR 16.2(137)(iii), which provides that "use" includes the interpretation of the results of diagnostic procedures.

It is not necessary to make this change at this time. The proposed regulations relies on the separate definition of "medical use" set forth in section 16.123(b)(4). That section provides: "Medical use means the intentional internal or external administration of byproduct material or the radiation from byproduct material to patients or human research subjects under the supervision of an authorized user." The new definition does not include the interpretation of diagnostic studies as medical use. Accordingly, VRad's concern does not need to be addressed, and a change will not be made to these provisions.