

Computed Tomography (CT) Quality Assurance

Effective date: 1/20/16

Summary of Express Terms

The regulatory proposal would revise Part 16 of 10 NYCRR as described in more detail below. Section 16.59 is added to cover radiation safety and quality assurance on Computed Tomography (CT) equipment. Section 16.59 (a) of the proposed regulation specifies a number of definitions used to describe CT systems and their operations. The next four sections, respectively, describe: physical and system requirements (16.59(b)); patient communication and viewing requirements (16.59(c)); CT system calibration requirements (16.59(d)); and quality assurance testing requirements (16.59(e)). Part 16.59(f) contains requirements for operations including a requirement for accreditation. One of the requirements is accreditation by a nationally recognized accrediting body that is acceptable to the Department. Currently the American College of Radiology (ACR), the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) or the Intersocietal Accreditation Commission (IAC) are considered acceptable to the Department. This is consistent with the accrediting bodies that CMS accepts. This accreditation requires the registered facility to have one of these three organizations perform a review that includes the physical layout of the facility, policy and procedures, quality assurance and image assessment. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) required the Center for Medicare and Medicaid Services (CMS) to designate accrediting bodies for imaging centers that perform CT (as well as certain other imaging studies). Accreditation is now a requirement under CMS regulation for all non-

hospital providers to receive the technical component payment, and these three organizations (ACR, JCAHO, and IAC) are approved by CMS.

Section 16.25 is that subsection of Part 16 that requires the recording or reporting of medical misadministrations. This part is amended to include an additional reporting requirement for CT misadministrations when the wrong patient is scanned, when the wrong part of the body is scanned or when there is damage to an organ or organ system including erythema and/or hair loss.

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, Section 16.25 of Part 16 is amended and Section 16.59 is added to Part 16 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Section 16.25(a) is amended to add the following to the existing section:

16.25 Misadministrations.

(a) A medical misadministration shall be the administration of:

* * *

(9) A CT scan in which any of the following occur:

(a) A CT scan is performed on the wrong person;

(b) A CT scan is performed on the wrong body part.

(10) a CT scan that results in damage to an organ, organ system or results in hair loss or erythema as determined by a physician.

16.25 (b) Records and Reports of Misadministrations.

(5) A misadministration described in 16.25 (a) (9) or (10) shall be reported to the Department in writing within 15 days of occurrence.

A new section 16.59 is added to read as follows:

16. 59 USE OF COMPUTED TOMOGRAPHY EQUIPMENT

(a) Definitions

(1) “Computed tomography (CT)” scan and “computerized axial tomography (CAT)” scan refer to an imaging procedure that uses x-rays to create cross-sectional images of the human body.

(2) “Computed tomography dose index” (CTDI) means the integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan where the dose profile is centered around $z = 0$ and for a multiple tomogram system, the scan increment between adjacent scans is nT ;

$$CTDI = 1/nT \int_{-T}^{+T} D(z) dz$$

z = position along a line perpendicular to the tomographic plane;

$D(z)$ = Dose at position z ;

T = Nominal tomographic section thickness;

n = Number of tomograms produced in a single scan

(3) “CT x-ray system” is technology that is used to perform CT scans and includes but is not limited to, a control panel, image display device, gantry, x-ray tube, collimating device with filters, high voltage transformer and a data acquisition system.

(4) “CT scanner” refers to technology used to perform and interpret CT scans and includes, but is not limited to, a control panel, gantry, high voltage generator, x-ray tube, table and display devices that are used for image interpretation.

(5) “CTDI₁₀₀” is the dose measurement made with a 16cm diameter (head/pediatric body) or a 32cm diameter (body) acrylic phantom. The measurements are made utilizing a 100mm long pencil ionization chamber. Readings are made with the ion chamber in both the center (axial or central dose) position and near surface slots of the phantom (the peripheral dose).

(6) “CTDI_w”, the weighted or blended dose, is calculated by adding together two-thirds of the CTDI₁₀₀ peripheral dose with one-third of the CTDI₁₀₀ axial or center dose. ($CTDI_w = 2/3 CTDI_{100} \text{ peripheral} + 1/3 CTDI_{100} \text{ axial or center}$). CTDI_w represents an average dose in the x and y planes.

(7) “CTDI_{VOL}” represents the integrated dose over the total volume that is irradiated, $CTDI_{VOL} = (1/PITCH) \times (CTDI_w)$, where “Pitch” is defined as the table travel per rotation divided by the collimation of the x-ray beam. CTDI_{VOL} represents the average dose in the x, y and z planes.

(8) "CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including nominal tomographic section thickness, filtration, and the technique factors.

(9) "CT dosimetry phantom" means the phantom used for determination of the dose delivered by a CT x-ray system. The phantom shall be a right circular cylinder of polymethyl-methacrylate of density 1.19 ± 0.01 grams per cubic centimeter. The phantom shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing any CT system designed to image any section of the body (whole body scanners) and 16.0 centimeters for any system designed to image the head (head scanners) or for any whole body scanner operated in the head scanning mode. The phantom shall provide means for the placement of a dosimeter(s) along its axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom.

(10) "Dose length product" (DLP) is defined as the $CTDI_{vol}$ times the irradiated length of the body for the whole series of images that are taken during a CT scan.

(11) "Picture Archiving and Communication System (PACS)" is a medical imaging technology that provides access to and storage for medical images from multiple modalities. It is comprised of an image acquisition system, display, network and data storage or archiving system.

(12) "Reference plane" means a plane which is displaced from and parallel to the tomographic plane.

(13) "Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram or a series of tomograms.

(14) "Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

(15) "Technique" means the settings selected on the control panel of the equipment and may include the position of the x-ray tube, image intensifier and patient.

(16) "Technique chart" means a chart that lists the standard settings and positions for a given technique.

(17) "Tomogram" is an image of a tissue plane or section of tissue.

(18) "Tomographic plane" means that geometric plane which the manufacturer identified as corresponding to the output tomogram.

(19) "Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

(b) CT X-Ray System Equipment Requirements.

- (1) Each control panel and gantry of a CT x-ray system shall include visual signals that indicate to the operator of the CT x-ray system whenever x-rays are being produced and when x-ray production is terminated, and, if applicable, whether the shutter is open or closed.
- (2) Each CT x-ray system shall be equipped with a control that allows the operator of the CT x-ray system to terminate the x-ray exposure at any time during a scan, or series of scans, when the exposure time is greater than one-half second duration.
- (3) Each CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence are indicated prior to the initiation of a scan or a scan sequence.
- (4) Each CT x-ray system shall include a clearly and conspicuously labeled emergency shutoff button or switch.
- (5) Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation by the operator prior to the initiation of another scan.

(c) Patient communication and viewing requirements.

- (1) Each CT x-ray system shall be equipped to allow two-way aural communication between the patient and the operator at the control panel.
- (2) Each CT x-ray system shall be equipped with windows, mirrors, closed-circuit television, or an equivalent to permit continuous visual observation of the patient during CT scanning by the CT operator from the control panel.
- (3) When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

(d) Calibration.

- (1) Each registrant shall ensure that the calibration of the radiation output of each CT x-ray system that it operates is performed by, or under the direction of, a licensed medical physicist.
- (2) Each registrant shall maintain and make available for review by the Department, on the premises of its radiation installation where a CT x-ray system is located written procedures for the appropriate calibration of the CT x-ray system.

- (3) After initial installation, the CT x-ray system shall be calibrated prior to its use on human beings and recalibrated at least within every 14 months thereafter. Any change or replacement of components of a CT x-ray system which could cause a change in the radiation output will require a recalibration within 30 days of component installation by a licensed medical physicist operating within their scope of practice.
- (4) The calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. This system shall have been calibrated either by the National Institute of Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL) and traceable to NIST. The calibration shall have been performed within the previous 24 months and after any servicing that might have affected system calibration.
- (5) CT dosimetry phantom(s) shall be used in determining the radiation output of each CT x-ray system. Such phantom(s) shall meet the following specifications and conditions of use:
- (i) Any effects on the doses measured because of the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom; and

(ii) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

(iii) The requirements of subparagraphs (i) and (ii) of this paragraph can also be met by using an alternative method of radiation measurement and calculation published in the peer-reviewed scientific literature and acceptable to the Department.

(6) Records of calibrations performed shall be maintained for a period of three (3) years at the radiation installation where the CT is located.

(e) Quality Assurance Testing

(1) Each registrant shall maintain a Quality Assurance (QA) manual that shall contain written procedures for all testing and shall meet the requirements specified in this section and section 16.23(a)(1). The CT Quality Assurance procedures shall have been developed under the direction of a licensed medical physicist or radiologist.

(2) The QA procedures shall incorporate the use of one or more image quality dosimetry phantoms or the phantom supplied by the original equipment manufacturer which have the capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and

high contrast objects, and measuring the mean CT Number for water or other reference material. All of these image quality parameters shall be evaluated at least annually by a licensed medical physicist.

(3) Written records of the QA checks performed by the registrant shall be maintained for review by the Department for a period of at least three (3) years.

(4) QA checks shall include the following:

(a) Images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations. The images shall be retained as photographic copies or as electronic copies stored within the CT x-ray system or stored on the PACS.

(b) Dose assessment for the most common CT examinations that are performed on the system for which reference levels have been published by the American College of Radiology (ACR), the American Association of Physicists in Medicine (AAPM) or the National Council on Radiation Protection and Measurements (NCRP) for pediatric heads, pediatric abdomens, adult heads and adult abdomens.

(c) An evaluation of image quality.

(f) Operating Procedures and Policies

- (1) The CT x-ray system shall not be operated on a human being except by a physician or by a radiologic technologist licensed pursuant to Article 35 of the Public Health Law who has been specifically trained in its operation.

- (2) The registrant shall ensure that each CT x-ray system has a radiation protection survey or other measurement and assessment of exposure to persons in controlled and non-controlled areas made at the time of installation. Additional radiation protection surveys shall be done after any change in the radiation installation or equipment which might cause a significant increase in radiation hazard.

- (3) Each CT x-ray system shall have available at the control panel written information regarding the operation and calibration of the CT x-ray system. Such information shall include:
 - (i) Dates of the latest calibration and QC checks and the location within the facility where the results of those tests may be obtained;

 - (ii) Instructions on the use of the CT dosimetry phantom(s) including a schedule of QC tests that are appropriate for the system as determined by the manufacturer, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;

- (iii) A current set of default protocols are available at the control panel (either electronically or as a document) which specifies for each routine examination the CT conditions of operation and the slice thickness, spacing between slices and/or pitch;
- (iv) A list of techniques optimized for the body part being imaged to obtain a quality image and to ensure that the lowest amount of radiation is used as consistent with good medical practice.

(4) If the QC testing on the CT x-ray system identifies that a system operating parameter has exceeded a tolerance as specified in the Quality Assurance manual, use of the CT x-ray system on patients shall be limited to those exceptions permitted by established written instructions of the licensed medical physicist or radiologist. Upon completion of corrective action, the QC testing shall be repeated to verify that the system is back within tolerance.

(5) Commencing one (1) year after the effective date of these regulations, each registrant performing CT scans on human beings shall ensure that for each scan, the radiation dose delivered by the scanner to a reference phantom or the dose received by the patient is saved and recorded. The dose delivered shall be recorded as Computed Tomography Dose Index volume ($CTDI_{vol}$), dose length product (DLP) or other dosimetry metric published in the peer reviewed scientific literature and acceptable to the Department. The dose received by a patient shall be

recorded as organ dose or other dosimetry metric published in the peer reviewed scientific literature and acceptable to the Department.

(6) The displayed dose shall be verified on an annual basis by or under the supervision of a licensed medical physicist to ensure that the equipment manufacturer's displayed dose is within 20% of the measured dose.

(7) Eighteen months after the effective date of these regulations, each current registrant that performs diagnostic CT scans on human beings shall be accredited by a nationally recognized accreditation program that is acceptable to the Department. A facility performing CT that loses their existing accreditation or a registrant or licensee that fails to obtain accreditation must report this fact within 30 days to the Department. After the effective date of these regulations new licensees or registrants will have 18 months to become accredited, but must demonstrate that they have initiated the accreditation process within 90 days of the start of operations.

(8) Each registrant that performs CT scans on human beings shall establish and implement a policy and a procedure to ensure that:

(i) a request for a CT scan originates from a physician or other authorized health care practitioner familiar with the patient's clinical condition; and

(ii) the request includes sufficient information to demonstrate the medical indication for the CT examination and allow for the proper performance and interpretation of the CT scan.

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) & (q) and 201(1)(r) authorize SSC regulations to protect the public from the adverse effects of ionizing radiation. These statutory provisions authorize the Department, pursuant to 10 NYCRR Part 16, to license or register health care providers to use radioactive materials or ionizing radiation emitting equipment on patients.

The federal Atomic Energy Act of 1954, (the Act), (codified at 42 USC §§ 2021 et. seq.) authorizes the U.S. 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 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 Sections 225(5)(p) & (q) and 201(1)(r) is to protect the public from the adverse effects of ionizing radiation. Establishing regulations to ensure safe and effective clinical uses of radiation producing equipment is consistent with this legislative objective.

Needs and Benefits:

DOH's regulations are designed to require the delivery of quality care while protecting people and the environment from the harmful effects of radiation. In recent years, technology and equipment used for diagnostic medical imaging has become significantly more complex. Computed Tomography delivers high quality imaging that is of significant benefit to patients and for this reason it represents the dominant imaging modality. However, it also represents the largest contributor to an increase in population radiation exposure based on reports from the National Council on Radiation Protection and Measurements. The usage of CT scans has more than tripled in the past decade and currently there are about 80 million CT scans in the US each year.

The problems that have been documented with CT scans in the past several years reflect a lack of quality assurance and/or a lack of administrative controls which these regulations seek to implement. These regulations seek to ensure high quality CT imaging that is appropriate with respect to professional bodies such as the American College of Radiology's (ACR) recommendations on appropriateness criteria. These regulations will implement Quality Assurance (QA) requirements that are already being voluntarily implemented by a majority of facilities in New York State.

Currently the only provisions in the State Sanitary Code that apply are general quality assurance regulations that do not adequately describe the operations or quality assurance requirements for the use of CT equipment.

Costs:

The Department estimates that many regulated parties that use Computed Tomography will not incur any additional costs to comply with the proposed addition of 10 NYCRR § 16.59. There are approximately 440 facilities that are registered with the DOH that operate one or more CT scanners for diagnostic purposes on human beings. Approximately 75% of these sites already have been accredited by bodies currently accepted by Centers for Medicare and Medicaid Services (CMS), (American College of Radiology, Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and IAC). The initial costs of this accreditation vary based on which of the three organizations are used, however the ACR is the most popular and in general the least expensive for a facility that only has a single CT scanner. The costs of a three year accreditation from the ACR will average \$7550, which includes: (i) the typical fees for a consulting physicist (average of \$1750); (ii) a \$2500 accreditation fee from the ACR; and (iii) \$3300 for the purchase of an ACR phantom if the facility does not already have one. Facilities that already have the ACR phantom (or for reaccreditation) will not need to purchase another phantom.

The other proposed additions in 10 NYCRR §16.59 will impose little or no cost to regulated parties because existing facility staff can comply with the new quality assurance requirements.

Local Government Mandates:

There are fourteen hospitals that fall under this category, including three State University hospitals, a Department operated hospital and ten hospitals operated by public benefit corporations. Of these fourteen hospitals, ten are already accredited in CT scanning. The remaining four hospitals would incur additional costs to comply with the new regulatory

requirement to be certified in CT (approximately \$9,500 for each three year period). 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.

Paperwork:

DOH 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 CT accreditation. 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 registration documents issued by the Department to current registrants. The Department plans to provide updated QA guidance when these regulations are adopted.

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:

One alternative to adopting these regulations is to take no action and maintain the existing structure that relies on DOH guidance and voluntary compliance. However, while rapid advances in CT technology have produced better healthcare outcomes in many cases, there has been a downside to this increased use – particularly, patients experiencing radiation burns as a result of the improper use of CT scans. The New York Times and the Los Angeles Times have both reported on CT-related medical problems that were caused by the failures of both regulators and medical personnel. The scientific press also has numerous articles documenting overutilization of CT and quality assurance failures. The general population and the scientific community are aware that New York State currently lacks adequate quality assurance regulations and monitoring. The development of these proposed regulations, after consultation with radiologists, physicists and several professional organizations including the Hospital Association of New York State and the New York State Radiological Society, is intended to minimize future CT-related medical events in New York State. New York is not the only state to strengthen its regulation of this area: Texas and California have adopted regulations governing CT quality assurance (California) and reporting of events and monitoring of patient dose (Texas).

As a result, there are no suitable alternatives to the proposed addition of 10 NYCRR §16.59. There are no alternative requirements that would meet the objectives of implementing appropriate Quality Assurance on CT scanners.

Federal Standards:

These proposed revisions to 10 NYCRR §16.59 do not conflict with any federal regulations. Existing federal regulations relate only to the manufacture and distribution of radiation producing equipment and not to its operations.

Compliance Schedule:

The proposed regulatory amendments will be effective upon publication of the Notice of Adoption in the State Register, except for the requirements in proposed 10 NYCRR §16.59(f)(5) relating to accreditation in computed tomography. Proposed 10 NYCRR §16.59(f)(5) requires that registrants apply for accreditation by one of the previously mentioned organizations and that such accreditation becomes effective within one year of the effective date of the proposed regulation.

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.ny.gov

Regulatory Flexibility Analysis for Small Businesses and Local Governments

Effect on Small Business:

The Department has issued registrations to approximately 440 facilities for the use of Computed Tomography equipment of which an estimated 230 are small business. Specifically these are private practice or group practice physicians who own and operate their own CT scanner. Some of these registrants would be affected by the proposed revisions to 10 NYCRR §16.59, in particular the requirement for accreditation may affect some businesses. However, as of January 1, 2012, the Centers for Medicare and Medicaid Services (CMS) required that all non-hospital providers of the technical component of CT imaging must meet the accreditation requirements in Section 135 (a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Therefore the majority of small business, private practice physicians have or are in the process of obtaining accreditation for CT.

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 12 months of the effective date of the rule.

Professional Services:

The majority of large facilities have in-house staff who will conduct the required QA and small facilities either contract with the manufacturer of the equipment or professional medical physicists that perform quality assurance testing for CT. The average cost for professional service for the accreditation component of these regulations ranges from \$1550 to \$1950 per CT, depending on location. This service would be required every three years.

Capital Costs and Annual Costs of Compliance:

The amortized annual cost is estimated to be approximately \$2500 per year for accreditation (based on a three-year accreditation cost of \$7550). However, approximately 75% of the facilities are currently accredited; therefore this regulation will not impose an additional cost. There are no capital costs mandated by this regulation directly, however, one of the three accrediting bodies requires the use of their own phantom at a cost of \$3300.

Economic and Technology Feasibility:

There are no capital costs or new technology required to comply with the proposed rule. Facilities that use the ACR as the accrediting body must have or purchase an ACR CT phantom. The use of some type of phantom is the industry standard for CT testing and evaluation.

Minimizing Adverse Impact:

Facilities will have 12 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.

Small Business Input:

A copy of the draft proposed rule was sent via email to individuals representing the Healthcare Association of New York State (HANYYS), the New York state chapter of the ACR, physicists throughout the state, the NYS Society of Radiological Sciences and other interested parties including private practice physicians. The majority of the comments were technical clarifications that have been incorporated in the currently proposed regulations. The Department is developing guidance to assist the affected facilities in implementing and complying with the new requirements.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

There are 106 affected facilities with approximately 120 CT units located in 40 of the 43 rural counties in New York State. Including the total from 11 other counties that have a population of 200,000 or greater, and towns with population densities of 150 persons or fewer per square mile, brings the total to 309 registrants and 426 CT scanners. The statewide totals were 436 registrants and 596 CT scanners for facilities outside of New York City.

Reporting, Recordkeeping and Other Compliance Requirements and Professional Services:

A misadministration involving a CT-scan must be reported to the Department in writing within 15 days of occurrence. CT misadministrations are distinguished from events involving other diagnostic imaging modalities because of the greater risk associated with the radiation dose and contrast agents used in CTs. No additional professional service costs are anticipated for already accredited facilities. 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 an initial \$7550 every three years. This will be a new cost to approximately 25% of the facilities that will be subject to the proposed 10 NYCRR §16.59, because 75% 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 for a number of reasons. However the main reason facilities have pursued accreditation is to meet the 2012 CMS requirements for Medicare Part B payments.

Minimizing Adverse Impact:

Facilities will have 12 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.

Rural Area Participation:

A copy of the proposed regulations was sent via e-mail to members of the New York State chapter of the American College of Radiology and to members of the American Association of Physicists in Medicine for review. The only comments received back were of a technical nature requiring clarification of the proposal. No comments were received objecting to the cost of accreditation.

Job Impact Statement

Nature of Impact:

It is anticipated that no jobs will be adversely affected by this rule. Diagnostic imaging providers in New York will need to become familiar with, and implement the new regulatory requirements set forth in the proposed 10 NYCRR §16.59. The Department does not expect that the new regulatory requirements would significantly change the training or experience requirements of radiological technologists or physicians. The Department anticipates that few if any persons will be adversely affected. Facility staff, specifically those designated as the radiation safety officer, medical physicist, radiological technologist especially CT technologists will need to become familiar with the new requirements.

Categories and Numbers Affected:

There are approximately 440 facilities with a total of about 600 CT units that would be subject to the rule. The registered facilities include 150 hospitals or their satellite facilities with approximately 300 of the CT units. The other 300 registrants (typically with only 1 CT at each site) represent individual or group practice physicians.

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

Public comments were submitted to the NYS Department of Health (DOH) in response to the regulation. The public comment period for this regulation ended on June 22, 2015. The Department received a total of 6 comments from 5 different individuals representing the medical physics community as well as comments from the Public Health and Health Planning Council members during the May 21, 2015 meeting.

The majority of the comments were from licensed medical physicists requesting clarification on specific wording or expressions used in the regulations.

COMMENT: A licensed medical physicist asked what types of CT equipment (diagnostic, simulator, dental cone beam, etc.) are covered by the annual audit requirement and what type of equipment is included in the accreditation requirement.

RESPONSE: The accreditation requirement applies to medical equipment used for diagnostic imaging. Therapy simulator, biopsy only and attenuation correction computed tomography units would not be covered by the accreditation requirement. Most of the other provisions would apply to all medical use equipment, but dental CBCT would not be required to meet the provisions of these regulations.

COMMENT: Several physicists asked where they could find the written definition of “under the direction of” used in section 16.59(d)(1).

RESPONSE: There is no formal definition for this term. The Department will issue updated guidance on CT QA requirements and will include additional clarifications at that time.

COMMENT: A licensed medical physicist asked if personnel who fit the ACR's criteria (but who are not licensed as a medical physicist in NYS) would be able to test the CT unit during annual evaluations.

RESPONSE: New York State has licensed the practice of medical physics for about 15 years and has determined that certain activities described in these regulations must be performed by a licensed medical physicist. Where the regulations state that an activity must be performed "by a licensed medical physicist", the individual performing the activity must actually be a licensed medical physicist. Other sections use the phrase "by or under the supervision of", which allows non-licensed medical physicist to perform functions.

COMMENT: A licensed medical physicist asked if every misadministration (CT of a wrong patient, CT of a wrong body part) must be reported to the Department in writing. For those facilities other than Article 28 locations that are required to report to NYPORTS, the physicist further suggested that the regulations require that the facility record misadministrations and demonstrate corrective action, but that the facility need only report the misadministration if there is a high dose to the recipient (such as 5 rem whole body) or adverse effects are observed (such as hair loss or erythema).

RESPONSE: With respect to the reporting of all CT errors, this is required to ensure that the Department can improve its understanding of the frequency and nature of such errors. Article 28

facilities report all events in NYPORTS, while other facilities can make direct reports to BERP by fax, email, or letter.

COMMENT: A licensed medical physicist (LMP) asked what the term “evaluated” meant in section 16.59(e)(2)—specifically, whether it means performed or something else. The LMP also asked whether the section should state “only a licensed and qualified Medical Physicist (ACR) should be allowed to perform these annual QA tests and dose calibrations.”

RESPONSE: An LMP must evaluate the QA testing to determine if it is acceptable, but another individual may have actually made the measurements. The regulations do not reference specific accrediting body requirements since these vary and may change over time. NYS Education Law (Article 166) defines the requirements to practice as a physicist in NYS. Any questions of scope of practice should be directed to the State Education Department.

COMMENT: A licensed medical physicist asked if the NY State CT QA Guidelines should be an acceptable method for establishing a CT QA program. The commenter asked whether this rule now obviates the need to adhere to the Department of Health’s CT QA Guidelines.

RESPONSE: The requirements of 16.23(a) are still in place as referenced in 16.59(e)(1). The CT QA Guidelines will be updated to reflect changes that are in regulations, but the quality assurance program described in that guidelines are still required. These regulations are in addition to the requirements of 16.23.

COMMENT: A licensed medical physicist asked whether a radiologist is competent to write a quality assurance program.

RESPONSE: The radiologist has the final responsibility for patient imaging and is allowed to develop the quality assurance program if they are competent to do so.

COMMENT: A licensed medical physicist commented on 16.59(f)(5): “The dose received by a patient shall be recorded as organ dose.” The commenter asked how patient doses will be recorded because no scanners to date record patient dose, and because patient dose can only be estimated from dose to a phantom and utilization of very broad scaling factors.

RESPONSE: The wording of that section indicates that “reference dose delivered to a phantom or the dose received by a patient” must be recorded. The “dose delivered” that is being referred to in the following sentence can be either reference dose or actual dose.

COMMENT: A licensed medical physicist commented that with regards to the requirement of CT accreditation, that general hospital accreditation by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) does not meet the amendment’s requirement that the accrediting organization perform a review that includes the physical layout of the facility, policy and procedures, quality assurance and image assessment as it is related to CT. The commenter stated that there is a specific JCAHO accreditation that would mimic, for example, the American College of Radiology’s criteria.

RESPONSE: This is reflected in the language of the regulation 16.59(f)(7), which states that the accreditation must be in CT scanning or an equivalent as determined by the Department.

COMMENT: A licensed medical physicist commented that the proposed regulation states that CT specific misadministration does not use a dose threshold for CT errors, which is inconsistent with other diagnostic imaging error reporting.

RESPONSE: With respect to the reporting of CT errors without regard to patient dose, this is required to ensure that the Department can make a determination as to the frequency and nature of CT errors. Article 28 facilities report all events in NYPORTS, while other facilities can make direct reports to BERP either by fax, email, or letter.

COMMENT: A member of the Public Health and Health Planning Council commented that there have been discussions in the past about how difficult it is to come up with a cumulative radiation exposure dose because all the CT scans operate in slightly different ways. The member asked whether it would be possible within the context of these regulations to use the SHIN-NY or some other mechanism to keep track of patient dose.

RESPONSE: Currently CT scanners are not capable of tracking patient dose but rather use a reference dose. Reference dose can vary significantly from the actual patient dose due to patient size/weight. It is our understanding that the CT manufacturers are developing scanners that can input these variables to derive a patient dose. We plan to look at this issue when this capability becomes available.

COMMENT: A commenter asked if dose information is accessible to the ordering clinician or patient when they receive the results.

RESPONSE: The reference dose will be accessible, but a patient specific dose is not available. The actual dose can vary significantly from the reference dose.