# 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;



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) “CTDIW”, 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. (CTDIW = 2/3 CTDI100 peripheral + 1/3 CTDI100 axial or center). CTDIW represents an average dosein the x and y planes.

(7) “CTDIVOL” represents the integrated dose over the total volume that is irradiated, CTDIVOL = (1/PITCH) x (CTDIW), where “Pitch” is defined as the table travel per rotation divided by the collimation of the x-ray beam. CTDIVOL  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 CTDIvol 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:
6. 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.

1. 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.

1. 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.
2. 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-rays 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.

1. 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 (CTDIvol), 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) Effective one year after the effective date of these regulations, each registrant that performs diagnostic CT scans on human beings shall be accredited by the American College of Radiology (ACR), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the Intersocietal Accreditation Committee (IAC) in CT scanning or an equivalent CT scanning accreditation program as determined by the Department.

(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;

(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;

(iii) the appropriateness of each non-emergent CT scan is reviewed by a radiologist or his or her trained designee prior to the CT scan being performed; and

(iv) if, in the opinion of the reviewing radiologist, the requested CT scan does not appear to be medically necessary, the reviewing radiologist shall notify the referring physician and recommend that the patient be referred for an alternative medical imaging procedure.