New York State Department of Health
Bureau of Environmental Radiation Protection

Guide for Radiation/Quality Assurance Program Computed Tomography Equipment

INTRODUCTION

A. Purpose

This guide describes the type and extent of information and standards by which the New York State Department of Health will evaluate Computed Tomography (CT) equipment as part of the Radiation Safety/Quality Assurance Program at a facility. The Department of Health has implemented this program to reduce radiation exposure, optimize diagnostic image quality and foster facility involvement in the responsibility for Quality Assurance (QA). Facilities may substitute quality control tests if the tests are deemed equivalent by the Department prior to their implementation. Written request should be forwarded to the Bureau at 547 River Street, Room 530, Troy, N.Y. 12180-2216.

B. ALARA (As Low As Reasonable Achievable)

The regulations in Part 16 and this guide have been established on the ALARA principle to ensure that the benefits of the use of ionizing radiation exceed the risks to the individual and the public health and safety.

C. Limits and Standards

The control limits and standards used in this guide have been taken from Federal Performance Standard for Diagnostic X-ray Equipment (21CFR1020), Part 16, Report #74 "Quality Control in Diagnostic Radiology " published by the American Association of Physicists in Medicine and from the American College of Radiology's new CT Accreditation Program. Equipment problems should be corrected and documented expeditiously and shall be corrected with appropriate documentation within thirty (30) days of discovery.

D. Authority

The statutory authority for these rules and regulations is found in the New York State Public Health Law, Section 225. The Radiation Safety/Quality Assurance requirements are outlined in Sections 16.5 and 16.23 of Part 16 of Chapter 1 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations. It should be noted that this program is in addition to and does not replace other sections of Part 16, which pertain to each facility operation.

Radiation Safety/Quality Assurance Programs

A. Radiation Safety/Quality Assurance Responsibility

Responsibility for Computed Tomography Quality Assurance is a function of the size of the facility. Large facilities can absorb the responsibilities and structure for CT quality assurance into their existing committee that is responsible for overseeing diagnostic radiography. For the facility that performs 2,500 exams or less per year, CT exams included, radiation safety and quality assurance is the responsibility of the physician who registers the equipment. The responsibility for CT equipment preventative maintenance/testing falls upon several different groups. Medical physicists, radiologic technologists, in-house engineering, and manufacturer service representatives are responsible for various aspects of equipment evaluation or performance. The QA responsibilities for each party shall be defined as a manual item.

B. Records

1. Manual

Each facility will establish a manual that includes the following items:

a) a list of tests to be performed and the frequency of performance;

b) a list identifying which individual or group will be doing each test;

c) a written description of the procedure that will be used for each test;

d) a list of all the variables which comprise CT operating conditions for each test procedure;

e) the acceptability limits for each test;

f) a list of the equipment to be used for testing; and

g) sample records to be used for each test.

2. Equipment Records

Records shall be maintained for each unit currently in operation and include:

a. The initial test results (acceptance testing and radiation safety survey as appropriate);

b. the current year;

c. one set of test results from each intervening year to show changes over time. Records of repairs and other pertinent data shall also be available.

3. Processor and Sensitometer Logs

a) Control charts of sensitometry shall be maintained and used to regulate processing.

b) Processor maintenance logs shall include preventive maintenance, corrective maintenance and cleaning. Each action shall be dated and initialed.

c) Process charting of speed, contrast and base + fog shall be graphed each day of operation and posted as close as possible to the individual processor from which the data is derived. The graphs for each processor shall be kept for review for a period of time equal to at least the facility's inspection interval.

4. QC Records for Test Equipment

Records shall be maintained and available for review for QC test equipment that requires calibration. QC records may be maintained in either a hardcopy or softcopy format, but must be available for review during inspections and whenever else they are needed.

5. Radiation Safety Policies and Procedures

The written policy and procedures must be available on the holding of patients; pregnant patients and operators; and personnel monitoring.

C. Equipment Monitoring

Each facility shall make or have made quality control tests to monitor equipment performance and maintain records of data collected. The tests performed will vary from manufacturer to manufacturer but must include those quality control checks specified by the manufacturer and be modeled after the program below. If, at the time of inspection, significant equipment malfunctions are found, the facility may be required to perform more frequent testing to ensure good diagnostic image quality.

This guide describes a basic Radiation Safety/Quality Assurance Program and represents only a portion of the Quality Control tests your facility may choose to perform as part of an individualized program. Facilities with equipment under warranty or service contract with an Original Equipment Manufacturer (OEM) or an Independent Service Organization (ISO) must follow the testing and preventive maintenance schedule required by the OEM or ISO to keep the warranty or contract valid. The OEM or ISO testing and maintenance schedule must be included in the manual. Facilities with equipment not under warranty or service contract must follow the testing frequency stated in this guide. Facilities must perform all the QC tests which their manufacturer supplied phantom will allow.

Appropriate quality control testing must be conducted whenever major maintenance (X-ray tube replacement) or a change in equipment operation (software change) occurs.

1. Testing frequency - Each day of operation

Equipment functioning: Each day during equipment warm-up, and before scanning the first patient, the operator must check for any malfunction. The operator must also evaluate the mechanical and electrical safety of the CT system. Malfunctions and unsafe conditions shall be corrected promptly.

CT Number Accuracy of Water, Image Noise, Image Uniformity, and Artifact evaluation shall be performed daily using a common technique setting with a head sized phantom. The average CT number and standard deviation of noise must be performed using a region of interest that is standardized for the QA tests. Image uniformity and artifact evaluation must be done using an appropriate and consistent window level and width.

2. Frequency - Monthly

a. Imaged Slice Thickness or Slice Sensitivity Profile
Performed at each available slice thickness, using an appropriate phantom for both the axial and helical modes of operation.

b. Slice Positioning Accuracy
Evaluate the accuracy of slice localization lights, the accuracy of slice positioning and the accuracy of table motion with incrementation.

c. CT Number Scale Accuracy
CT numbers must be evaluated using a phantom containing a variety of materials to evaluate a wide range of CT numbers. The measured values must remain within manufacturer's specifications.

d. Hard Copy Devices
Hard copy devices and dry image processors must be monitored for consistency in accordance with the manufacturers published recommendations. Many of these devices utilize a SMPTE test pattern, which can be readily used and printed for review.

2. Test frequency - Semi annually

a. Dose Profile Width

This test must be performed at each available slice thickness. This test can readily be performed using packaged film, which is placed around the surface of the phantom. Alternative methods of evaluation can also be used. Multiple slice units need to be evaluated for over-beaming and adjusted to manufacturer's specifications.

b. Spatial Resolution

Must be evaluated in the x-y plane using a phantom with suitable objects. The objects will be of different sizes and shapes. In-plane resolution must be evaluated in the axial mode, for a single slice thickness using both standard and high-resolution algorithms. If an appropriate phantom is available, the system must also be evaluated in the helical mode to test for longitudinal resolution with different combinations of collimation and pitch.

c. Low-Contrast Detectability

Must be performed using a phantom with test objects that will evaluate the system for less than 1% contrast sensitivity.

3. <u>Test frequency - Annually</u>

Patient dose

Each facility shall have available dose measurements based on the most common conditions of operation of their CT units. Since the advent of $CTDI_{FDA,}$ the International Electrotechnical Commission (IEC) has defined a new standard for dose index. This standard is called the $CTDI_{100}$. $CTDI_{100}$ utilizes measurements 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).

$CTDI_{W,}$ the weighted or blended dose, is calculated by adding together two-thirds of the $CTDI_{100}$ peripheral dose with one-third of the $CTDI_{100}$ axial or center dose. ($CTDI_{W}$ = 2/3 $CTDI_{100}$ peripheral + 1/3 $CTDI_{100\ axial}$ or center

It is important to remember that $CTDI_{W}$ represents an average dose in the x and y planes. With multiple slice helical scanning, the dose is better represented by $CTDI_{VOL}$ which takes into account the effect of pitch and averages over the x, y, and z planes. $CTDI_{VOL}$ represents the integrated dose over the total volume that is irradiated.

$$CTDI_{VOL} = 1 \div PITCH \times CTDI_{W}$$

The resultant measurements should not exceed the following:

<u>Examination</u>	**<u>$CTDI_{VOL}$ (mGy)</u>**
Adult Head	**75**
Adult Abdomen	**25**
Pediatric Abdomen (5 yr. Old)	**20**

And the measurements shall not exceed:

Examination	**$CTDI_{VOL}$ (mGy)**
Adult Head	**80**
Adult Abdomen	**30**
Pediatric Abdomen (5yr. Old)	**25**

4. On Installation of New Tube

All daily and monthly tests must be completed before patient examinations commence. All semi-annual and annual tests must be completed within thirty days of tube replacement.

5. On Installation of New Unit

All daily and monthly tests must be completed before patient examinations commence. All semi-annual and annual tests must be completed within thirty days of a new installation.

A. Half-Value Layer

The manufacturer's procedure to evaluate HVL shall be followed and the manufacturer's published specifications shall be met.

B. Radiation Protection Survey

A radiation protection survey must be completed before operation to ensure that the structural shielding is adequate to meet the requirements of Sections 16.6 and 16.7.

C. Scan protocols

Each CT unit shall have posted scan protocols available for reference by the operator. As a minimum, these protocols shall be include the following scan factors: use of oral contrast; use of intravenous contrast; slice thickness; slice spacing; anatomical description of the extent of the field for scanogram; and the technical factors selected for the examination. Technical factors must differentiate between pediatric and adult sized patients as well as anatomical areas that are to be imaged.

The radiologist, CT technologist and medical physicist should work together on establishing the technique (kV and mAs) used on each projection, so that patient dose is minimized. The technique used should always be sufficient, so as to avoid the appearance of clinically unacceptable quantum mottle.

D. Log Book

Each facility shall maintain a logbook or equivalent record system containing the patient's name, date and type of examination, contrast media administered, and any other patient identification deemed necessary by the facility.

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Bibliography

1. **Regulations for the Administration and Enforcement of the Radiation Control for Health and Safety Act of 1968. USDHHS, April 2006.**

2 **Title 10 NY Code of Rules and Regulations, Chapter I, Part 16 "Ionizing Radiation" February 2004.**

2. **The American College of Radiology Accreditation Program for Computed Tomography ACR 8/6/07 Revision 1/1/08**