# Compliance Guidance for COMPUTED TOMOGRAPHY QUALITY CONTROL 2<sup>nd</sup> Edition



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## DISCLAIMER

This Compliance Guidance Document is not a substitute for the Department's regulations and compliance is not required with the procedures in this document. The procedures and/or methods described in this document are provided for information only. Performing these procedures does not necessarily constitute Department approval or guarantee compliance.

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# **INTRODUCTION**

On January 16, 2001, the Department of Environmental Protection (Department) and the Commission on Radiation Protection adopted regulations (New Jersey Administrative Code 7:28-22) that require all facilities performing diagnostic x-ray procedures (radiology, fluoroscopy, x-ray bone densitometry or computed tomography) to develop and continually implement a Quality Assurance program. The regulations apply to equipment used on humans in hospital, medical, podiatric, chiropractic, dental, industrial, school, and government facilities.

This document provides guidance for performing QC tests for Computed Tomography (CT). Additional compliance guidance documents are available for the QA Manual, Fluoroscopy and Radiographic quality control. See the section entitled, "Additional Documents Available" for information on receiving these documents.

A Quality Assurance (QA) program, which includes quality control tests, helps to ensure that high quality diagnostic images are consistently produced while minimizing radiation exposure. The QA program covers the entire x-ray system from machine, to producing diagnostic images. This program will enable the facility to recognize when parameters are out of limits, which will result in poor quality images and can increase the radiation exposure to patients. Simply performing the quality control tests is not sufficient. When quality control test results exceed established operating parameters, appropriate corrective action must be taken immediately and documented.

This guide is intended to assist the facility in setting up their QA Program and performing the quality control tests required to maintain high quality images and reduce patient exposure. This guide includes generally accepted procedures that the facility may use to perform the required tests. The procedures in this guide are not the only way to perform the tests. Alternative test procedures may be used without Department approval. However, all procedures being used must be documented in the facility's QA manual and meet the requirements of N.J.A.C. 7:28-22. In some cases, manufacturers' directions may be more appropriate than the generic procedures in this guide.

Product manufacturers, vendors, and service companies all have information available on their website and operator manuals. If the facility finds that they need more instruction than this guide provides, please use these companies and your medical physicist as resources.

The responsibility for the quality control tests should be assigned to a QA program coordinator to ensure consistency in test methodology and interpretation of the data. More than one person may perform the tests but one person should assume overall responsibility for the day to day operation of the program. This leads to better understanding of when to repeat tests, call for service, or consult with the practitioner or medical physicist. The physician, medical physicist, and QC personnel, working together as a team, are the key to providing optimum quality CT images.

Due to the importance of quality control in diagnostic imaging, it is recommended that the appropriate facility personnel review the control tests, data and images quarterly.

The establishment and maintenance of a Quality Assurance program will ensure consistent image quality over the lifetime of the CT system. Quality Assurance begins with baseline performance data acquired during CT system installation including scanning a phantom under a prescribed set of conditions. These baseline images should be saved and used as a visual comparison with the daily and monthly QA checks. The baseline values will provide an objective way to monitor quality by repeating these tests or procedures on a regular frequency to detect changes in image quality values before the problem affects patient images. Early intervention could save time, money and prevent unnecessary patient exposure to radiation.

# **Computed Tomography Quality Control**

Each registrant of diagnostic computed tomography (CT) equipment used in the healing arts must develop and continuously implement a quality assurance program. The required basic elements of the regulations are listed below.

### BASIC ELEMENTS OF CT QUALITY CONTROL

- 1. Quality Assurance Program Manual.
- See Compliance Guidance Document for the Quality Assurance Program Manual.
- 2. Quality control tests, see TABLE 3
- 3. Tests in TABLE 3 (items 1-11) must be performed by licensed radiological technologist, a qualified medical physicist, or a trained service technician.
- 4. Keep records for all tests performed.
- 5. If conventional film processing is used and if any of the test results from item 2 in TABLE 3, Computed Tomography Quality Control Requirements, indicate that the film processing does not meet the standards in TABLE 3, the registrant must immediately initiate steps to bring the processing into compliance. Films may not be processed until the processing meets these standards.
- 6. If laser film imaging is used and if any of the test results from item 5 in TABLE 3, Computed Tomography Quality Control Requirements, indicate that the laser film printer does not meet the standards in TABLE 3, the registrant must immediately initiate steps to repair the laser film printer to meet the standards. Films may not be processed until the processing meets the standards.
- 7. If test results for items 3,4,6,7, and 8 in Table 3 do not meet standards, then immediately initiate steps to repair CT equipment to meet standards. Repairs must be completed within 30 days. Keep records of all corrective actions.
- 8. If test results for items 9, 10, and 11 in Table 3 do not meet standards, then immediately initiate steps to repair CT equipment to meet standards. Repairs must be completed within 15 days. Keep records of all corrective actions.
- 9. Medical Physicist QC Survey, TABLE 3 (item 12), must be performed by a qualified medical physicist for the supervision of quality assurance programs for computed tomography. See TABLE 6.
- 10. If any of the Computed Tomographic QC Survey test results from items 1 through 4 in TABLE 6, Medical Physicist's Computed Tomography QC Survey, indicate that the CT equipment does not meet the standards established in TABLE 6, the registrant must immediately initiate corrective actions to meet the standards. All corrective actions must be completed within 15 days. Keep records of all corrective actions.
- 11. If any of the Computed Tomographic QC Survey test results from items 5 through 11 in TABLE 6, Medical Physicist's Computed Tomography QC Survey, indicate that the CT equipment does not meet the standards established in TABLE 6, the registrant must immediately initiate corrective actions to meet the standards. All corrective actions must be completed within 30 days. Keep records of all corrective actions.
- 12. QA program review, TABLE 3 (item 13), should include the facility's QA team and the qualified medical physicist.

The regulation requires that each facility with CT equipment perform, or have performed, the tests in TABLE 3, "Computed Tomography Quality Control Requirements" (page 9), at least at the frequency specified, and maintain records of the test results.

### FREQUENCY

The frequency of tests specified in TABLE 3 is the minimum frequency. The frequency of quality control tests may need to be increased depending on many factors including the age and stability of the x-ray equipment.

Tests may always be performed at a GREATER frequency than required by N.J.A.C. 7:28-22. Tests may NOT be performed at frequencies LESS than required in N.J.A.C. 7:28-22 unless approved by the Department as outlined in N.J.A.C. 7:28-22.3(f). For example, if the facility decides to test Low Contrast Resolution weekly, this new frequency must be documented in the facility's QA manual and the test data needs to be recorded appropriately.

#### **CONSISTENCY IS THE KEY!**

After each link (CT unit, laser film printer, etc.) in the imaging chain is optimized, a working QA program will provide warning flags to the QA program coordinator when something goes awry. If the coordinator finds, during the daily review, that the established tolerances are exceeded, **the test or tests must be repeated to verify the results, then corrective action must be taken.** The coordinator must be capable of identifying problems and willing to resolve them as they occur, or the QA program will not provide the intended benefits.

#### COMPETENCY

The registrant, per N.J.A.C. 7:28-22.5(d), must ensure that all individuals, performing any of the CT quality control tests, have an appropriate level of training to perform the tests competently. The registrant shall ensure that individual performing quality control tests described in TABLE 3, Computed Tomography Quality Control Requirements, is a licensed radiologic technologist, a qualified medical physicist for the supervision of QA programs for CT, or a trained service technician. The facility must ensure that there are sufficient trained personnel so that there is always someone available (i.e. to cover vacation and sick time) to perform the necessary testing.

#### **TRAINING OPTIONS**

The registrant may train their own personnel. This assumes that the registrant is competent in the particular procedure and is able to convey this knowledge adequately to the personnel. Product manufacturers, vendors, and service companies have training aids available on their websites and operator manuals. Companies whose sole purpose is training as well as service and repair companies and the facility's medical physicist can provide seminars and training courses ranging from a few hours to several days or more on the how to of Quality Control tests. Adequate training of personnel will ensure that the tests are performed correctly and consistently.

# Using This Guidance Document

This document is intended to provide guidance for performing Quality Control (QC) tests for CT.

A detailed description of each required test follows in the order listed in TABLE 3. This is the same table that appears in the regulation at N.J.A.C. 7:28-22.7.

Records of QC test results, corrective actions, Medical Physicist's QC Survey, and Quality Assurance Program Review must be maintained for at least the time period specified in N.J.A.C. 7:28-22.7.

#### ADDITIONAL DOCUMENTS AVAILABLE

**Compliance Guidance for QA Manual**: this document provides guidance in setting up a QA program, assignment of QC testing to various individuals, and the information required to be maintained at the facility.

**Compliance Guidance for Radiographic Quality Control:** this document contains detailed descriptions for performing the QC tests required for radiographic machines, film processing and laser film printers.

**Compliance Guidance for Fluoroscopic Quality Control**: this document contains detailed descriptions for performing the QC tests required for fluoroscopic machines.

**Radiation Safety Manual:** this document provides guidance to setting up the radiation safety manual as required by N.J.A.C. 7:28-15.9(a) 8.

**List of Qualified Individuals to Perform Quality Assurance Medical Physicist CT Surveys:** certain tests must be performed by or under the direction of a medical physicist meeting certain educational and experience requirements. This document contains a current list of individuals who meet the requirements of N.J.A.C. 7:29-22.

**List of Qualified Individuals For The Performance of Radiation Safety Surveys of The Environs:** this document contains the names of individuals who meet the educational and experience requirements in N.J.A.C. 7:28 to perform radiation safety surveys of the environs on x-ray equipment. The individuals on this list are not necessarily the same individuals as on the qualified medical physicists for QC surveys list.

Copies of these documents and other information can be obtained from the Department's website: www.xray.nj.gov

	TABLE 3									
	(To be performed by a licensed radiological technologist, a qualified medical physicist, or a trained service technician)									
ltem	Required Test or Procedure   Frequency   Standard									
1.	Equipment Function: Indicators, Mechanical, and other Safety Checks. Warm-up	Daily, each day x-rays are taken	Must work properly							
2.	For film processing, items 2, 5, 7, and 11 QC tests as specified in Table 1, Radiographic Quality Control Requirements	As specified in Table 1, Radiographic Quality Control Requirements	As specified in TABLE 1, Radiographic Quality Control Requirements							
3.	CT Number for Water	Daily	CT equipment or phantom manufacturers' specifications							
4.	Field Uniformity	Daily	CT equipment or phantom manufacturers' specifications							
5.	Laser Film Printer Quality Control	Weekly	Recommended control limits*OD = optical densitySMPTE Test PatternInverted gray scale0% patch 2.45 $\pm 0.15$ OD*0% patch 2.50 $\pm 0.15$ OD10% patch 2.10 $\pm 0.15$ OD10% patch 2.25 $\pm 0.15$ OD40% patch 1.15 $\pm 0.15$ OD40% patch 1.35 $\pm 0.15$ OD90% patch 0.30 $\pm 0.08$ OD90% patch 0.30 $\pm 0.08$ ODThe 5% patch should just be visible inside of the 0% patchThe 95% patch should be visible inside the 100% patch							
6.	Low Contrast Resolution	Initially and Monthly	CT equipment or phantom manufacturers' specifications							
7.	High Contrast Spatial Resolution	Initially and Monthly	CT equipment or phantom manufacturers' specifications							
8.	Noise	Initially and Monthly	CT equipment or phantom manufacturers' specifications							
9.	Table Position Indicator Accuracy	Initially and Monthly	±2 mm							
10.	Scan Increment Accuracy	Initially and Monthly	±1 mm							
11.	Scan Localization Light Accuracy	Initially and Monthly	± 5 mm							
12.	Medical Physicist's QC Survey	Initially and annually	As required in N.J.A.C. 7:28-22.10							
13.	Quality Assurance Program Review	Initially and annually	As required in N.J.A.C. 7:28-22.4(a)7							

#### ITEM 1 - Equipment Warm-up Procedure

#### **Test Frequency: Each Day of Operation**

#### Standard: Warm up tube; ensure equipment is working properly.

Each day during the CT system warm-up, and before scanning the first patient, check for visual indication of x-ray beam-on, tomographic plane indication (laser or light source), table and gantry mechanical integrity and the electrical safety of the CT system. Malfunctions and unsafe conditions must be corrected promptly.

#### Procedure 1 Equipment Warm-up

Turn on system. Follow the CT manufacturer's recommended warm up procedure.

#### **CORRECTIVE ACTION:**

If an unusual noise, spark or other unusual event is noted, the equipment should not be used until the situation has been corrected and the equipment is operating normally. Contact the CT Service Company to repair. All corrective actions must be completed within 30 days, documented and records of each corrective action, repair and service maintained for at least 2 years.

#### **RECORDS:**

There are no records required of daily equipment warm-up.

## **ITEM 2 - Film Processing**

Hard-copy films of images using a video-base camera and automated chemical processor

Facilities performing hard-copy films of images using a Video-Base Camera and automated chemical processor must also perform the following tests:

Processor Quality Control Processor Maintenance and Chemical Solutions Film and Chemical Shelf Life Analysis of Fixer Retention

Generic procedures for performing these tests can be found in the Compliance Guidance for Radiographic Quality Control document available from the Department's website: <u>www.xray.nj.gov</u>

#### ITEM 3 - CT Number for Water

#### **Test Frequency: Daily**

#### Standard: CT equipment or phantom manufacturer's specifications

The CT number for water test ensures that the relative calibration of CT numbers to water remains within acceptable limits. When you correctly image and analyze the QC phantom, you should measure a CT number for water specified by the CT equipment manufacture or follow the CT phantom specifications. The CT system assigns numbers, also called Hounsfield Units, to the attenuation values of x-ray passing though a variety of material densities. The computer software makes the attenuation visible by assigning shades of gray to the selected groups of numbers. The test for CT Number for Water in the phantom represents the standard against which you can track the system constancy.

#### Procedure 3 CT Number for Water

Equipment Required: CT equipment phantom or other commercially available test phantom.

Follow the CT equipment manufacturer's or phantom manufacturer's procedure to correctly image and analyze the phantom. The CT number for water should be recorded and compared to established specifications.

#### **CORRECTIVE ACTION:**

If the measurements indicate the CT number for water exceeds specifications, immediately initiate steps to repair the CT equipment to meet the standards. Perform the CT number for water test again or have the imaging physicist run more detailed tests. If test still does not meet the standard, then contact your service representative. Document steps to repair the CT equipment to meet standards. All corrective actions must be completed within 30 days

#### **RECORDS:**

Ensure records of each corrective action, repair and service are maintained for at least 2 years. Maintain all CT Number for Water test results, written record or digital, for at least one year. Maintain all images (film and/or digital) produce and relied upon in the performance of CT Number for Water testing for at least 30 days.

#### **ITEM 4 - Field Uniformity**

#### **Test Frequency: Daily**

#### Standard: CT equipment or phantom manufacturer's specifications

The Field Uniformity test determines the spatial uniformity of CT numbers in a uniform medium. The uniformity test is a simple and direct approach to determining the accuracy of the image reconstruction process. Scan plane uniformity is evaluated with phantoms constructed of solid acrylic or other water simulating plastic or a phantom filled with distilled water. To evaluate the scan plane uniformity, a phantom with appropriate dimensions and uniform attenuation is scanned under simulated clinical conditions. Example; in an image of the 20-cm diameter phantom filled with a uniformly attenuating medium, the mean CT number of any 100 pixels should not differ by more than 5HU to 7HU from the mean CT number of any other 100 pixels.

#### Procedure 4 Field Uniformity

Equipment Required:

The Manufacturer's uniformity phantom or other commercially available uniformity test phantom of 15-21cm and 30-32cm diameter.

Follow the CT manufacturer's or phantom manufacturer's procedure to correctly image and analyze the phantom. The field uniformity should be recorded and compared to the established specifications.

#### **CORRECTIVE ACTION:**

If the measurements indicate a change in values for uniformity beyond the CT equipment or phantom manufacture's specifications, immediately initiate steps to repair the CT equipment to meet the standards. Perform the field uniformity test again or have the imaging physicist run more detailed tests. If test still does not meet the standard, then contact your service representative. Document steps to repair the CT equipment to meet standards. All corrective actions must be completed within 30 days

#### **RECORDS:**

Ensure records of each corrective action, repair and service are maintained for at least 2 years. Maintain all Field Uniformity test results, written record or digital, for at least one year. Maintain all images (film and/or digital) produce and relied upon in the performance of Field Uniformity testing for at least 30 days.

If the measurements indicate a change in QA values for low contrast resolution and exceeds specifications, then immediately initiate steps to repair the CT equipment to meet the standards. Perform the low contrast resolution test again or have the imaging physicist run more detailed tests. If test still does not meet the standard, then contact your service representative. Document steps taken to repair the CT equipment to meet standards. All corrective actions must be completed within 30 days and documented.

#### ITEM 5 - Laser Film Printer Quality Control

In some clinical settings, the physician makes the diagnosis by reading the images from an image created with a laser film printer. The laser film printer should reproduce the quality and gray scale of the original image displayed on the system monitor. The procedure uses the Society of Motion Picture and Television Engineers (SMPTE) digital test pattern. The SMPTE test pattern is supplied with most laser printers or it can be obtained from accessory vendors.

#### The N.J.A.C. 7:28-22.6 specifies that laser film printer QC MUST be performed weekly.

Generic procedures for performing these tests can be found in the Compliance Guidance for Radiographic Quality Control document available from the Department's website: <a href="https://www.xray.nj.gov">www.xray.nj.gov</a>

Record on Form 1, Laser Film Printer Control Chart

#### **ITEM 6 - Low Contrast Resolution**

#### **Test Frequency: Initially and Monthly**

#### Standard: CT equipment or phantom manufacturer's specifications

The Low Contrast Resolution test determines the capability of the scanner to discriminate low contrast objects. Since soft tissue detail is low contrast in nature; this is perhaps the most clinically important test. The visibility of low contrast objects is constrained mainly by amplitude and frequency characteristics of the image noise. In CT, contrast is defined as the difference in CT numbers values between two structures. Subject contrast in CT is simply the difference in average CT numbers between two adjacent regions of the image.

#### Procedure 6 Low Contrast Resolution

Equipment required:

Manufacturer's low contrast detectable test phantom or other commercially available low contrast detectable test phantom.

Follow the CT manufacturer's test procedure or phantom manufacturer's test procedure for Low Contrast Resolution.

#### **CORRECTIVE ACTION:**

If the measurements indicate a change in QA values for low contrast resolution and exceeds specifications, then immediately initiate steps to repair the CT equipment to meet the standards. Perform the low contrast resolution test again or have the imaging physicist run more detailed tests. If test still does not meet the standard, then contact your service representative. Document steps taken to repair the CT equipment to meet standards. All corrective actions must be completed within 30 days and documented.

#### **RECORDS:**

Ensure records of each corrective action, repair and service are maintained for at least 2 years. Maintain all Low Contrast Resolution test results, written record or digital for at least one year. Maintain all images (film and/or digital) produce and relied upon in the performance of Low Contrast Resolution testing for at least one year.

#### **ITEM 7 - High Contrast Spatial Resolution**

#### **Test Frequency: Initially and Monthly**

#### Standard: CT equipment or phantom manufacturer's specifications

This test determines the high contrast spatial resolution limits of the CT scanner under various conditions. In any CT system, the image noise and blurring place upper limits on the spatial resolution of the patient reproduced in the image. The relative importance of noise and blurring is a function of image contrast. For very low contrasts, objective visibility is primarily constrained by image noise, and is independent of blurring effects. At very high contrasts, noise effects are negligible, and object visibility is constrained only by blurring sources. Between these extremes, as contrast increases, the effect of noise on object visibility becomes less important while the influence of blurring source grows. In a patient, visualized tissues span a wide range of contrasts, therefore the evaluation of spatial frequency limits of a scanner should span a similar range.

#### Procedure 7 High Contrast Spatial Resolution

Equipment required:

Manufacturer's high contrast resolution test phantom or other commercially available high contrast resolution test phantom.

Follow the CT manufacturer's test procedure or phantom manufacturer's test procedure for high contrast resolution.

#### **CORRECTIVE ACTION:**

If the measurements indicate a change in QA values for high contrast exceeds specifications, immediately initiate steps to repair the CT equipment to meet the standards. Perform the high contrast resolution test again or have the imaging physicist run more detailed tests. If test still does not meet the standard, then contact your service representative. Document steps to repair the CT equipment to meet standards. All corrective actions must be completed within 30 days.

#### **RECORDS:**

Ensure records of each corrective action, repair and service are maintained for at least 2 years. Maintain all High Contrast Resolution test results, written record or digital for at least one year. Maintain all images (film and/or digital) produce and relied upon in the performance of High Contrast Resolution testing for at least one year.

#### **Test Frequency: Initially and Monthly**

#### Standard: CT equipment or phantom manufacturer's specifications

The Noise test assesses the level of noise under simulated clinical conditions and its variation with different scanning parameters. Noise refers to the fluctuations in CT numbers in a uniform medium around its average value. Image noise is analogous to quantum mottle in conventional radiography and is a part of the signal, which does not add to information. Noise limits the perceptibility of low contrast detail. The lower the noise, the better visibility of low contrast objects. If no manufacturer's procedure is available, then use the procedure below.

Procedure 8NoiseEquipment Required:CT equipment phantom or other commercially available test phantom.

Follow the CT manufacturer's test procedure or phantom manufacturer's test procedure Noise testing.

#### **CORRECTIVE ACTION:**

If the measurements indicate a change in QA values for Noise and exceeds specifications, immediately initiate steps to repair the CT equipment to meet the standards. Perform the Noise test again or have the imaging physicist run more detailed tests. If test still does not meet the standard, then contact your service representative. Document steps to repair the CT equipment to meet standards. All corrective actions must be completed within 30 days.

#### **RECORDS:**

Ensure records of each corrective action, repair and service are maintained for at least 2 years. Maintain all Noise test results, written record or digital, for at least one year. Maintain all images (film and/or digital) produce and relied upon in the performance of Noise testing for at least one year.

## **ITEM 9 - Table Position Indicator Accuracy**

#### **Test Frequency: Initially and Monthly**

#### Standard: ±2 mm

The Table Position Indicator Accuracy test assesses the amount of relative table displacement between successive scans by measuring the actual displacement the table traveled between scans. The CT operator must be able to accurately move patients to the indicated distance between scans from the operator control console. The true position of the bed should agree to within  $\pm$  2.0 mm of the indicated position. If no manufacturer's procedure is available, then use the procedure below.

#### Procedure 9 Table Position Indicator Accuracy

Equipment required: 500 cm ruler Radiochromic film

To perform this procedure, place radiochromic film on top of CT table and set scan width to 2mm. Scan the radiochromic film at a typical starting position. Then from the operator control console increment the tabletop 20mm in a positive direction and scan the radiochromic film. Then repeat incrementing the table top another 20mm and scan the radiochromic film. Repeat incrementing the table top another 20mm and scan the radiochromic film again. View the image and measure the distance between the slices, measuring from the beginning of the first slice to the beginning of the next slice, check the distance between the other consecutive slices. Repeat the same procedure in the negative direction. Test results must be documented.

#### **CORRECTIVE ACTION:**

If the measured distance between consecutive slices exceeds the operator set distance by more than 2 mm, immediately initiate steps to repair the CT equipment to meet the standards. Perform the Table Position Indicator Accuracy test again or have the imaging physicist run more detailed tests. If test still does not meet the standard, then contact your service representative. Document steps to repair the CT equipment to meet standards. All corrective actions must be completed within 15 days.

#### **RECORDS:**

Ensure records of each corrective action, repair and service are maintained for at least 2 years. Maintain all Table Position Indicator Accuracy test results, written record or digital, for at least one year.

# **ITEM 10 - Scan Increment Accuracy**

#### **Test Frequency: Initially and Monthly**

#### Standard: ±1 mm

This test determines the deviation of indicated versus actual scan increment. Under computer control from operator's console the patient table must be able to accurately and reproducibly move the patient to any indicated position in the scan field. Accuracy is critical since it influences the multi-scan dose and determines relative locations of image sections. If no manufacturer's procedure is available, then use the procedure below.

Procedure 10Scan Increment AccuracyEquipment:500 mm rulerBent paper clip for a pointerAdhesive tape

To perform this procedure, tape a ruler along the tabletop edge, near the foot end of the table. Tape the end of the paper clip onto the table frame opposite the middle of the ruler with the pointer directed at ruler midpoint. Zero table position. Place on the table 70-100kg, or have an assistant lie on the table. This gives the table the weight it needs to simulate a patient. From control console, note the table position. Under computer control, move the tabletop 300mm in one direction, and then back to the original position. The table top should go back to the original position. At this point, measure the difference, if any indicated by the pointer and the ruler. Repeat this measurement again in the opposite direction to be sure that the measurements are consistent. Test results must be documented.

Additional information on Scan Increment Accuracy is in The Code of Federal Regulation 21 CFR 1020.33(i).

#### **CORRECTIVE ACTION:**

If the measured deviation between the starting position and the incremented position measures greater than  $\pm 1$  mm, then perform the Scan Increment Accuracy test again or have the imaging physicist run more detailed tests. If test still does not meet the standard, then contact your service representative. Document steps to repair the CT equipment to meet standards. All corrective actions must be completed within 15 days.

#### **RECORDS:**

Ensure records of each corrective action, repair and service are maintained for at least 2 years. Maintain all Scan Increment Accuracy test results, written record or digital, for at least one year.

# Item 11 - Scan Localization Light Accuracy

#### **Test Frequency: Initially and Monthly**

#### Standard: ±5 mm

The Scan Localization Light Accuracy test verifies the congruence of scan localization light/laser and x-ray field scan plane. Patient anatomy to be scanned is often defined by scan alignment lights/lasers. Alignment lights/lasers may be located within the gantry at the slice plane, outside the gantry at a reference distance from the scan plane, or both. If both internal and external alignment lights are supplied, and are independently aligned, both should be tested. If no manufacturer's procedure is available, then use the procedure below.

#### Procedure 11 Scan Localization Light Accuracy

Equipment: A phantom with external visible radiopaque markers.

Using the alignment lights/lasers, position the phantom to the radiopaque markers within the gantry at the slice plane. Zero the table location indication. Scan the phantom using a scan width of less then or close to 2 mm. View the image and verify the radiopaque markers are visible. Error should not exceed  $\pm 5.0$ mm. Test results must be documented

#### **CORRECTIVE ACTION:**

If the measured alignment measures greater than  $\pm 5.0$ mm, then immediately initiate steps to repair the CT equipment to meet the standards. Perform the Scan Localization Light Accuracy test again or have the imaging physicist run more detailed tests. If test still does not meet the standard, then contact your service representative. Document steps to repair the CT equipment to meet standards. All corrective actions must be completed within 15 days.

#### **RECORDS:**

Ensure records of each corrective action, repair and service are maintained for at least 2 years. Maintain all Scan Localization Light Accuracy test results, written record or digital, for at least one year.

# Item 12 - Medical Physicist's Computed Tomography QC Survey

#### **Test Frequency: Initially and Annually**

#### Standard: As required in N.J.A.C. 7:28-22.7(1)

The QC Survey is a series of measurements performed by a qualified medical physicist for the supervision of quality assurance programs for computed tomography equipment and to verify that a CT system conforms to manufacturer's specifications and state regulations. The physicist's primary concerns are image quality, radiation dose and radiation protection. The QC Survey will test performance characteristics that can be quantified by a medical physicist using widely available instruments and phantoms.

#### Procedure 12 MEDICAL PHYSICIST'S COMPUTED TOMOGRAPHY QC SURVEY

The registrant must ensure that a qualified medical physicist for the supervision of quality assurance programs for computed tomography equipment has performed and documented all the tests in Table 6. The Medical Physicist's Computed Tomography QC Survey must include the tests identified in the TABLE 6, Medical Physicist's Computed Tomography QC Survey. If the standard for any test in TABLE 6 refers to a manufacturer's specification and no such specification exists, then that standard does not apply. The physicist will still perform the QC test with no manufacturer's specification and develop a reasonable standard for the QC test.

#### **CORRECTIVE ACTION:**

Document steps to repair the CT equipment to meet standards. If any test results from items 1 through 4 in Table 6, indicate that the CT equipment does not meet the standards, you must immediately initiate corrective actions to meet the standards. All corrective actions must be completed within 15 days.

If any test results from items 5 through 11 in Table 6, indicate that the CT equipment does not meet the standards established in Table 6, you must immediately initiate corrective actions to meet the standards. All corrective actions must be completed within 30 days.

For item 12 in Table 6, the medical physicist must ensure that both the adult and pediatric scan protocols are separate and unique.

#### **Records:**

Ensure records of each corrective action, repair and service are maintained for at least 2 years. The registrant must ensure that the initial Medical Physicist's Computed Tomography QC Survey is permanently maintained and the records of the annual Medical Physicist's Computed Tomography QC Survey are maintained for at least two years. Permanently maintain a written and/or digital copy of initial Medical Physicist's Computed Tomography QC Survey. Maintain for at least two years a written and/or digital copy of Annual Medical Physicist's Computed Tomography QC Survey.

	TABLE 6   MEDICAL PHYSICIST'S COMPUTED TOMOGRAPHY QC SURVEY							
Item	Test	Standard						
1.	Scan Increment Accuracy	±1mm						
2.	Scan Localization Light Accuracy	±5mm						
3.	Patient Dose (Multiple Scan Average Dose-MSAD or Computed Tomography Dose Index-CTDI)	CT equipment manufacturers' specifications and scan protocol or phantom manufacturers' specifications						
4.	Pre-Patient Collimation Accuracy	Manufacturers' specifications						
5.	Contrast Scale	CT equipment or phantom manufacturers' specifications						
6.	CT Number for Water	CT equipment or phantom manufacturers' specifications						
7.	Slice Thickness	CT equipment or phantom manufacturers' specifications						
8.	Field Uniformity	CT equipment or phantom manufacturers' specifications						
9.	Low Contrast Resolution	CT equipment or phantom manufacturers' specifications						
10.	High Contrast Resolution	CT equipment or phantom manufacturers' specifications						
11.	Noise	CT equipment or phantom manufacturers' specifications						
12.	Scan Protocol Review	Ensure that both the adult and pediatric scan protocols are separate and unique						
13.	Review of Facility and Technologist QC Tests	Review QC tests for proper procedure and corrective action						
14.	Physicist Report and Recommendations	Communicate results and recommendations to registrant						

# Item 13 - Quality Assurance Program Review

#### Test frequency - Initially and annually thereafter

#### Standard - As required in N.J.A.C. 7:28-22.4(a)7

The Quality Assurance Program must be reviewed in its entirety to ensure that all information is current and accurate. The review must occur annually or after any equipment or personnel change. If personnel or operating procedures change frequently, reviews should be conducted more frequently to ensure that facility's Quality Assurance Program is maintained.

**Physician should review the QA program when it is initially established, after each change in personnel, equipment or policy and annually.** A good time for the review is right after the Medical Physicist performs the annual QC Survey. Any changes can be reviewed with the Medical Physicist.

Record on Form 2 Quality Control Log - Annual Tests (page 43).

NOTE: Most of the following list is taken form the requirements in N.J.A.C. 7:28-22.4 and are contained in the facility's QA Program Manual. There are additional item listed that should be reviewed at least annually to ensure that the facility is in compliance with all applicable sections of N.J.A.C.7:28.

# **Quality Assurance Program Review Checklist**

Has a	ny of the following items in the manual changed during the past	$\sqrt{\mathbf{if}}$ Updated	Date Manual Revised				
year :			Reviseu				
Did th	e facility and physicist review the latest version of the Quality						
Is the	list of clearly identified individuals and assigned responsibilities for						
	maintaining the quarty assurance program and for performing the						
	quality control tests current?						
Quali	ty Control (QC) Measures						
a)	Are QC Tests being performed at the frequency stated?						
D)	Is the list of equipment to be tested current?						
() ()	Have the acceptability limits for each test changed?						
(a)	Are the descriptions for each QC test procedure current?						
e)	Are the sample forms for each QC test current?						
I)	Processor and solutions maintenance up-to-date?						
g)	Is this the most recent Annual Medical Physicist's QC Survey?						
Polici	es and Procedures						
a)	Poncy for notating patients and for presence of individuals in room						
1-)	during radiation exposure						
D)	Policy for pregnant patients and employees						
c)	Policy for gonadal shielding						
a)	A description of the orientation program for operators of radiographic						
	equipment including the duration and content of that program						
e)	Procedures for proper use and maintenance of equipment						
I)	Policies and employee responsibilities concerning personnel radiation						
	monitoring						
g)	Policy for Medical Record Retention (Films/Digital Images)						
h)	Policy for releasing films/digital images						
1)	Policy for labeling films/digital images (i.e., patient's statistics,						
	facility information)						
J)	j) A commitment to perform a Radiation Safety Survey of the Environs						
	in accordance with N.J.A.C. /:28-15.10 on newly installed x-ray						
	equipment within 60 days of installation and an initial Medical						
1 \	Physicist's QC Survey as required by N.J.A.C. 7:28-22.8(a)						
k)	Policy for using technique charts						
1)	Policy and rules on Radiation Safety as required by N.J.A.C. 7:28-						
Corro	15.9(a) 8						
Cone	A plan for repairing or calibrating the y ray againment						
a) b)	A plan for repairing or servicing the processor						
Reco	<b>'ds keeping:</b> See specific Guidance Compliance Document for the						
requir	ed record retention of QC tests and QC test images.						
a)	Records of the initial Medical Physicist's QC Survey plus the two						
/	most recent QC Surveys						
b)	Records of corrective actions for the most recent two years						
c)	Personnel monitoring records. Per New Jersev Administrative Code						
	7:28-8.1(f) records for each employee monitored must be maintained						
	for the length of employment plus 10 years.						

Have a	my of the following items in the manual changed during the past year?	$\sqrt{\mathbf{if} \mathbf{Updated}}$	Date Manual
	· · · · · · · · · · · · · · · · · · ·		Revised
a)	A provision describing how the registrant and the qualified medical		
	physicist will review the QA program annually.		
Have y	you purchased new x-ray equipment either as a replacement or an		
	additional unit? If so, did you:		
a)	Register it with the Bureau of X-ray Compliance within 30 days of		
	installation? And		
b)	Have a qualified individual perform a Radiation Safety Survey of the		
	Environs and submit a copy to the Bureau of X-ray Compliance within		
	60 days of installation?		
c)	Have an initial Medical Physicist QC Radiographic Survey performed		
	within 60 days of installation?		
Review	w of each <b>Registration of a Radiation Producing Machine</b> form to be		
	sure the information is current. Questions to ask yourself:		
a)	Have you moved?		
b)	Are you the owner of record?		
c)	Has the facility contact person changed?		
d)	Is the x-ray machine on the Registration form the one you are currently		
	using?		
e)	New Jersey Administrative Code 7:28-3 requires that the Bureau of X-		
	ray Compliance be notified <b>in writing</b> within 30 days of a change of		
	any of the information on the Registration form.		
a)	Are your registration fees paid for the current and previous year?		
a)	Are all persons licensed to take x-rays licensed as required by N.J.S.A.		
	26:2D-24 and N.J.A.C. 7: 28-19? You may verify the license status of		
	any individual by visiting our website at <u>www.xray.nj.gov</u> . Only a		
	New Jersey licensed physician, podiatrist, or chiropractor provided		
	he/she is practicing within the scope of the license, or a New Jersey		
	licensed diagnostic radiologic technologist is permitted to operate any		
	type of medical x-ray equipment and position patients for radiological		
	procedures.		



(Also can be downloaded at: www.xray.nj.gov)

## Laser Film Printer Control Chart Weekly Frequency

Ye	ar:		 L	aser F	ilm P	rinter	:			-				
Month														
Dav														
Initials														
		I										1		
<b>0%</b> 2	.60		 											
	15													
2	.43													
	2.3													
		<b>,</b> ,					1	1	I	1	I	1		
10% 2	.25													
		+	 +										 	
2	.10													
1	.95		 										 	
400/ 1.2	20	г												
40% 1	50	+	 +										 	
1.	15													
1	.00		 										 	
0	38		 										 	
90%	.50													
0.	30													
0	.22		 										 	
<u> </u>		<u> </u>	 -											
5% visible in 0%		$\left  - \right $												
95% visible in 100%														

Date	Remarks/Action Taken

#### Form 2 Quality Control Log - Annual Tests

Each time a listed procedure is completed, person performing it must fill in date, their name/initials and note if equipment passed or failed. If equipment failed, the appropriate person(s) must be notified and corrective action taken. Procedure should be repeated after correction to ensure that equipment now passes.

	Date (MM/DD/YY)				
Lead aprons, gloves, gonadal and thyroid shielding integrity Refer to Compliance Guidance Document for Radiographic OC	Performed by				
	PASS/FAIL (If failed, note corrective actions taken.)				
Modical Physicist's	Date (MM/DD/YY)				
QC Survey Refer to Page 21	Performed by				
	PASS/FAIL (If failed, note corrective actions taken.)				
Quality Assurance	Date (MM/DD/YY)				
Program Review Refer to Page 23	Performed by				
	PASS/FAIL (If failed, note corrective actions taken.)				

 $\sqrt{1}$  = Pass X = Fail

Comments and corrective actions taken can be recorded on reverse of form.

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