

Compliance Guidance for
QUALITY ASSURANCE MANUAL
(2nd Edition)

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DEDICATION

This Guidance Document is dedicated to the memory of Joyce Zeisler. Her efforts to improve Quality Assurance Programs in New Jersey were instrumental in bringing about this program.

ACKNOWLEDGEMENTS

This Guidance Document was prepared through the efforts, advice and input of many people. We offer our thanks to all of the contributors. In particular, we thank the principal author; Mark S. Sciranka, Radiation Physicist I.

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 any facility performing diagnostic x-ray procedures (radiography, fluoroscopy, x-ray bone densitometry or computed tomography) to develop and continuously implement a Quality Assurance program. The regulations apply to x-ray equipment used on humans in hospital, medical, podiatric, chiropractic, industrial, school, and government facilities.

The requirements of N.J.A.C. 7:28-22 do NOT apply to mammography equipment that must comply with Federal Mammography Quality Standards Act, 42 U.S.C.A. §263(b) or N.J.A.C. 7:28-15.4. Facilities with bone densitometers only (no other x-ray equipment) are NOT required to have a Quality Assurance Manual.

The average person in the United States receives approximately 12% of their radiation exposure from medical x-ray procedures. This is the highest man-made source of exposure. Since exposure to radiation has the potential to increase the risk of cancer, minimizing exposure to x-rays while optimizing image quality is necessary to protect public health.

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 processor, to view box. This program will enable the facility to recognize when parameters are out of limits, which could 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.

Implementation of the QA program is accomplished through the work of several people. The QA Manual is the unifying element bringing together information about what the QC tests are, how the tests are performed, who performs them, and what records must be kept. The regulatory requirements for the manual are specified in N.J.A.C. 7:28-22.4. A Model QA Manual has been provided beginning on page 10. It can be “personalized” by the individual facility by simply filling in the blanks.

Training

The registrant, in accordance with N.J.A.C. 7:28-22.5(d) and 22.6(c), must ensure that all individuals performing any of the quality control tests have an appropriate level of training to perform the tests competently. The regulations do not specify that a physician, a radiologic technologist or a physicist must perform the tests (The only exception is the Medical Physicist’s QC Survey which must be performed by a Medical Physicist meeting the requirements of N.J.A.C. 7:28-22). Anyone with adequate training can perform quality control tests for radiographic and fluoroscopic equipment. The level of training required depends on the test being assigned. Some procedures such as darkroom cleaning require minimal training. Performing the Processor Quality Control test requires more training. 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. N.J.A.C. 7:28-22.7 requires that a licensed radiologic technologist, a qualified medical physicist or a trained service technician perform the Q.C. tests for computed tomography.

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 personnel. Product manufacturers, vendors, and service companies have training aids available in the form of leaflets, and videos. 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" perform Quality Control tests. Adequate training of personnel will ensure that the tests are performed correctly and consistently.

Guidance Documents

The Department has prepared four Compliance Guidance Documents. The Compliance Guidance Documents are **not** regulatory standards. They have been developed as tools to assist the facility to develop and implement their QA program as required by N.J.A.C. 7:28-22.

Product manufacturers, vendors, and service companies all have information available in the form of leaflets, videos and hands-on help. If the facility finds that more instruction is needed than is covered by the Compliance Guidance Documents, the facility should use these companies and the medical physicist as resources. A bibliography that includes some of the available books on quality assurance is on page 53. This is the first of the four Compliance Guidance Documents developed by the Department. It provides guidance on establishing a QA Manual, setting up a QA program, assigning QC tests to various individuals, and maintaining records at the facility. The Quality Assurance Manual must fully describe the facility's quality assurance program.

The other three Compliance Guidance Documents are the Compliance Guidance Document for Radiographic Quality Control, the Compliance Guidance Document for Fluoroscopic Quality Control, and the Compliance Guidance Document for Computed Tomography Quality Control. These documents are intended to assist the facility in setting up their Quality Assurance Program and performing the quality control tests required to maintain high quality images and reduce patient exposure. These guides include generally accepted procedures and forms that the facility may use to perform the required tests, specified in N.J.A.C. 7:28-22.5, 6, and 7.

The procedures described in the Guidance Documents are not the only way to perform the QC tests. The registrant may use procedures and forms which differ from those contained in the Compliance Guidance Documents; however, the actual procedures, which will be used by the registrant to perform the QC tests, must be described in the facility's QA manual.

Elements that the Quality Assurance Manual Must Contain

The regulations require that the facility's QA Manual must contain the following seven elements:

1. Quality Control Personnel

The facility must identify the individual who will have the overall responsibility of the QA program. The facility must also specify which individuals will be responsible for the processor, the x-ray unit, the annual physics survey and each quality control test.

2. Quality Control Measure

The facility must include the following in their manual -

- i. A list of the QC Tests that will be performed and the frequency of each test
- ii. A list of x-ray equipment and processor to be tested
- iii. Acceptability limits for each test performed
- iv. A description of each QC test procedure
- v. Sample forms that the facility will use for each QC test performed
- vi. The facility's plan for processor and solutions maintenance

- vii. A copy of the initial and the two most recent annual Medical Physicist's QC Survey.

3. Policies and Procedures

The facility is required to develop and implement policies and procedures for the following -

- i. Policy for holding patients and for presence of individuals in room during radiation exposure
- ii. Policy for pregnant patients and employees
- iii. Policy for the use of gonadal shielding
- iv. A description of the orientation program for operators of radiographic equipment including the duration and content of that program
- v. Procedures for proper use and maintenance of equipment
- vi. Policies and employee responsibilities concerning personnel radiation monitoring
- vii. Policy for releasing films
- viii. Policy for labeling films (i.e., patient's statistics, facility information)
- ix. A commitment to perform a Radiation Safety Survey of the Environs in accordance with N.J.A.C. 7:28-15.10 on newly installed x-ray equipment within 60 days of installation and the initial and annual Medical Physicist's QC Survey as required by N.J.A.C. 7:28-22.8(a), 22.9(a), and 22.10(a).
- x. Policy for using technique charts
- xi. Policy and rules on Radiation Safety as required by N.J.A.C. 7:28-15.9(a) 8.

4. Corrective Actions

The facility must describe their plan for taking corrective action(s) when quality control tests indicate the need for repair, service or calibration. The plan for taking corrective actions must include -

- i. Measures to be taken when the x-ray equipment is determined to need repair, service or calibration and,
- ii. Measures to be taken when the processor is determined to need repair or service.

5. Record keeping

The facility must maintain QC records as follows -

- i. Records for the most recent one year of the QC tests performed by the registrant
- ii. Records of the initial Medical Physicist's QC Survey plus the two most recent QC Surveys
- iii. Records of any corrective actions for the most recent two years
- iv. Personnel monitoring records. Per New Jersey Administrative Code 7:28-8.1(f) records for each employee monitored must be maintained for the length of employment plus 10 years.

6. Reference manuals (if any) and their location

The facility must identify the location(s) of all reference and operator manuals associated with the QA program. (ie. Processor, x-ray unit, densitometer, etc..)

7. QA Annual Review

The facility must identify its plan describing how the registrant and the qualified medical physicist will review the QA program annually.

Definitions of QA and QC

Quality Assurance is a plan that involves continuous monitoring to ensure consistent film processing, regular testing to detect equipment malfunction, regularly scheduled equipment maintenance, and an ongoing assessment of variables that could affect image quality and diagnosis. The quality assurance program includes many facets, including quality control, as well as preventive maintenance and calibration of equipment.

Quality Control is an integral part of quality assurance. It is a series of distinct technical procedures and tests that ensure the production of a satisfactory product, e.g., high-quality diagnostic images. These tests will enable the facility to recognize when parameters are out of limits. Out of limits parameters result in poor quality images and can increase the radiation exposure to patients. **Simply performing the quality control tests will not result in any useful information if the data is not evaluated. Whenever quality control test results exceed established operating parameters, corrective action is required immediately.**

Alternative Quality Assurance Program

The Department recognizes that although great effort was expended to establish quality assurance standards that reflect the most current and appropriate quality assurance standards available, some specific provisions of the quality assurance program specified in the regulations may not apply to all diagnostic x-ray practices. Therefore, the Department has established a procedure in N.J.A.C. 7:28-22.3(f, g, h, i, j, k) by which the registrant, or an organization representing a group of registrants, may apply for approval of an alternative quality assurance program from the Department. To be approved, an alternative quality assurance program must be shown to be equally effective in achieving consistent high quality imaging while reducing unnecessary radiation to patients and workers. Persons wishing to apply for approval for an Alternative Quality Assurance Program must write to the Department and submit a request for approval for the Alternative Quality Assurance Program. No Alternative Program may be implemented until the Department has granted approval. Please see N.J.A.C. 7:28-22.3(f) for the details of the Alternative Quality Assurance Program approval process. If approved, the facility must include the alternative procedures and forms in their manual.

Test procedures and forms that differ from those that appear in the Compliance Guidance Documents may be used without approval from the Department, as long as the procedures and forms are sufficient to demonstrate compliance with the provisions contained in the rules. However, all procedures and forms 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.

How to use the Model QA Manual

The next section of this document is a Model QA Manual that the facility may complete and use to describe their QA program. The model manual is organized to parallel the regulations and provisions of N.J.A.C. 7:28-22.4. The registrant may use the procedures and forms provided in the Compliance Guidance Documents, or the registrant may develop their own and include them in their Manual. To satisfy the regulation that requires the facility have a QA manual, the Model QA manual must be signed and all blanks completed.

For Example:

On page 10, the manual cover page, the facility should write its name, address, the date the manual was completed, the date reviewed with the medical physicist, and sign the QA commitment statement.

On page 13, Facility's QA Vendors, the facility should insert the name or attach the business card of their medical physicist, x-ray equipment service company and processor service company.

On page 14, Quality Control Personnel Responsibilities, the facility should enter the name of the person who is assigned the overall responsibility for the QA program.

The manual includes radiation safety policies and procedures (pages 19-26). Many of the policies/procedures that are shown are required by the State Radiation Protection Regulations. If the policy is established in a regulation, the rule cite is listed in bold type for ease of identification. The facility can adopt these policies and procedures in the Model QA Manual or they can develop their own policies and procedures and include them in the manual. Please note that if a facility chooses to modify any policy/procedure, they must ensure that the modified policy/procedure complies with the regulations that are noted in bold type.

Please note: Items in gray boxes are guidance only and are included to help the facility to understand the manual and to come into compliance with the regulations.

The Model QA Manual provides blank copies of ALL necessary forms in the back of the manual and the forms are available for download at the Department's website: www.state.us.nj/dep/rpp/download.htm.

The following Model QA Manual is provided as guidance and may be modified to meet the facility's needs. The facility must fill in all applicable information for each section. Any modifications or additions to the facility's QA program must be identified in its manual.

Quality Assurance Manual

**THIS MANUAL DESCRIBES THE QUALITY ASSURANCE PROGRAM
that will be continuously implemented by:**

Facility Name _____

Address _____

Date Completed by Facility _____

Date(s) reviewed/updated with Medical Physicist _____

I _____(registrant) will carryout the QA Program, set the goals and direction, determine the policies, and assess the effectiveness of the QA program. The medical physicist and I will review the QA program annually. The review will consist of the certified medical physicist and I reviewing the QA Manual, all tests, test results and corrective action taken and any recommendations offered by the medical physicist or other staff.

QUALITY ASSURANCE MANUAL

Since I use diagnostic medical x-ray equipment, I am required to develop and maintain a Quality Assurance Program that complies with New Jersey Administrative Code N.J.A.C. 7:28-22. This QA manual describes the Quality Assurance Program and the Quality Control tests that will be performed as part of my QA program. The procedures that I will use are identified in this QA Manual.

I understand that due to the importance of quality control in diagnostic imaging, I am required to ensure that the Quality Assurance Program, including the quality control tests, data and images, are reviewed at least annually, to ensure consistency of the program.

Guidance: The manual specifies the Quality Assurance Program standards and procedures being used to perform QC tests. The generally accepted procedures can be found in the Compliance Guidance Document for Radiographic Quality Control, the Compliance Guidance Document for Fluoroscopic Quality Control, and the Compliance Guidance Document for Computed Tomography Quality Control. These may be used by the facility or the facility may develop their own procedures.

PROCESSOR AND X-RAY EQUIPMENT

PROCESSOR to be Tested:

Manufacturer _____ Model # _____

Serial # _____ Facility Designation _____

Location _____

X-RAY Equipment to be Tested:

List the Equipment Registered with State of New Jersey/Bureau of Radiological Health:

Manufacturer _____ Model # _____

Serial # _____ Tube Serial # _____

NJ Registration # _____ Facility Designation _____

Circle Type: Radiographic Fluoroscopic CT

X-RAY Equipment to be Tested:

List the Equipment Registered with State of New Jersey/Bureau of Radiological Health:

Manufacturer _____ Model # _____

Serial # _____ Tube Serial # _____

NJ Registration # _____ Facility Designation _____

Circle Type: Radiographic Fluoroscopic CT

FACILITY'S QA VENDORS

Medical Physicist:

Duties Assigned To: _____

ATTACH BUSINESS CARD

X-ray Equipment Service Company:

Duties Assigned To: _____

ATTACH BUSINESS CARD

Processor Service Company:

Duties Assigned To: _____

ATTACH BUSINESS CARD

1. Quality Control Personnel Responsibilities

The overall quality control program responsibilities are assigned to: _____(name).

These duties are as follows:

1. To ensure that quality control personnel have adequate training, continuing education and continuing experience in QA/QC.
2. To provide an orientation program for QA/QC personnel.
3. To provide motivation, oversight, and direction in all aspects of the quality assurance program to ensure that an effective quality assurance program exists for the facility's diagnostic imaging practice.
4. To select and assign a qualified individual to perform the prescribed quality control tests.
5. To assign appropriate personnel to perform corrective action and retest equipment after corrective action is completed.
6. To ensure that the test equipment (eg. Sensitometer and densitometer) is calibrated and working properly and materials are available to perform the QC tests.
7. To arrange staffing and scheduling so that adequate time is available to carry out the quality control tests and to record and interpret the results.
8. To provide frequent and consistent feedback to QA/QC personnel about clinical film quality and quality control procedures.
9. To select a medical physicist who will assist with the QC program and perform the Medical Physicist's Quality Control Survey.
10. To review the QC test results at least every 3 months or more frequently if consistency has not yet been achieved; to review the physicist's test results annually, or more frequently when needed.
11. To oversee, or designate a qualified individual to oversee, the radiation protection program for employees, patients, and other individuals in the surrounding area.
12. To ensure that records concerning employee qualifications, radiographic techniques and procedures, quality control, safety, and protection are properly maintained and updated in the Quality Assurance Program Manual.
13. To ensure that each employee reviews the policy and procedure manual upon employment and at least annually.
14. To perform or assign a qualified individual to record results of the required quality control tests.

Guidance: 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 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 radiographic images. The individual assigned to perform each QC test must be listed in Tables 1A, 2A or 3A.

2. Quality Control Test Procedures

I am committed to performing all QC tests at the frequencies and standards specified in Table 1A, 2A, or 3A on pages 16, 17, and 18. Any changes in the test frequencies and/or acceptability limits will be documented in my manual. I have identified all equipment that will be tested on page 12. Additionally, I have inserted in this manual a copy of the QC test procedures and sample forms that will be used by my facility. Film and chemicals used and stored by my facility will be per manufacturers' specifications.

Guidance: QC Tests - Facilities must be committed to performing the QC tests established pursuant to N.J.A.C. 7:28-22.5, 6, or 7, (See Tables 1, 2, or 3 in the rule). Generally accepted Quality Control (QC) procedures are found in the Compliance Guidance Documents for Radiographic, Fluoroscopic, and Computed Tomography Quality Control. If the registrant is going to use the procedures developed by the Department, he should insert the appropriate Compliance Guidance Document in the manual. If the registrant is using other procedures, these must be inserted in the manual. Forms and procedures other than those that appear in the Compliance Guidance Documents are permitted without approval provided they are sufficient to demonstrate compliance with the rule provisions. The actual procedures, which will be used by the facility, must be described in the facility's QA Manual.

Frequencies - The test frequencies specified in Tables 1A, 2A, and 3A are the minimum frequencies. The frequencies of quality control tests may need to be increased depending on many factors including the age and stability of the x-ray equipment and film processing equipment, as well as the number of problems being encountered. (Extra copies of Tables 1A, 2A, and 3A are also provided in the Forms section.)

List of equipment to be tested (See page 12) – Facilities must identify the x-ray and processor equipment that will be tested.

Standards for each test performed (See Tables 1A, 2A, and 3A) - Facilities must be committed to ensuring that all QC tests performed meet the minimum standards set forth in the rules. A facility may choose to use standards that are more stringent than the required minimum standards and must document the changes.

Sample forms for each QC test performed - Facilities must be committed to recording all QC Test results. Examples of forms are provided in the Compliance Guidance Documents. Forms other than those that appear in the Compliance Guidance Documents are permitted provided they are sufficient to demonstrate compliance with the provisions contained in the rule. Copies of the forms must be included in the QA Manual.

Processor and solutions maintenance - Facilities must be committed to following manufacturers' specifications for preventative maintenance and service of the processor. The facility must be committed to using, storing and maintaining solutions according to manufacturers' specifications. At a minimum, processor maintenance must be performed every 2 months.

TABLE 1A

Radiographic Quality Control Tests, Frequencies, Standards, and Assignments				
Item	Required Test or Procedure	Minimum Frequency	Minimum Standards	Duties Assigned to:
1.	Equipment Warm-up Procedure	Daily, each day x-rays are taken	Warm up tube; ensure equipment is working properly	
2.	Processor Quality Control (Sensitometry/Densitometry)	Daily, each day x-rays are taken	Medium Density ± 0.15 Optical Density (OD), Density Difference ± 0.15 OD, Base + Fog + 0.03 OD of operating levels	
3.	Laser Film Printer Quality Control	Weekly	As specified in Table 2a., Fluoroscopic Quality Control Requirements	
4.	Darkroom Cleanliness	Weekly	Free from dust and dirt	
5.	Processor Maintenance and Chemical Solutions	Initially and every 2 months (more frequently if needed)	Manufacturer's specifications	
6.	Facility's Equipment Visual Checklist	Initially and quarterly	All tests passed	
7.	Film and Chemical Shelf Life	Initially and quarterly	Use film and chemicals with earliest expiration date first	
8.	Light Field/X-ray Field Alignment	Initially, quarterly and after service	Not to exceed 2% of Source to Image Distance (SID)	
9.	Repeat Analysis	Semiannually (review rejected films immediately for corrective action)	No standard, but goal should be < 5%	
10.	Artifact Evaluation	Examine every film for artifacts, in-depth evaluation semiannually	No significant artifacts	
11.	Analysis of Fixer Retention	Initially and semiannually	≤ 5 micrograms/sq. centimeter or ≤ 0.05 grams/sq. meter	
12.	Darkroom Fog	Initially, semiannually and after service	≤ 0.05 Optical Density Difference	
13.	Screen-Film Contact/Cassette Integrity/Screen Cleanliness	Initially and annually or as needed	No areas of poor contact > 2cm. in diameter	
14.	Lead Aprons, Gloves, Gonadal and Thyroid Shield Integrity Check	Initially and annually	No breaks in protective garments	
15.	Medical Physicist's QC Survey	Initially and annually	As required in N.J.A.C. 7:28-22.8	
16.	Quality Assurance Program Review	Initially and annually	As required in N.J.A.C. 7:28-22.4(a)7	

TABLE 2A

Fluoroscopic Quality Control Tests, Frequencies, Standards, and Assignments														
Item	Required Test or Procedure	Minimum Frequency	Standards	Duties Assigned to:										
1.	Equipment Warm-up Procedure	Daily, each day fluoroscopy is performed	Tube warm-up and ensure equipment is working properly Fluoro phantom image is comparable to facility standard											
2.	Laser Film Printer Quality Control	Weekly	<p>Recommended control limits</p> <table border="0"> <tr> <td align="center">SMPTE Test Pattern</td> <td align="center">Inverted gray scale</td> </tr> <tr> <td>0% patch 2.45± 0.15 OD*</td> <td>0% patch 2.50± 0.15</td> </tr> <tr> <td>10% patch 2.10± 0.15 OD</td> <td>10% patch 2.25± 0.15</td> </tr> <tr> <td>40% patch 1.15± 0.15 OD</td> <td>40% patch 1.35± 0.15</td> </tr> <tr> <td>90% patch 0.30± 0.08 OD</td> <td>90% patch 0.30± 0.08</td> </tr> </table> <p>*OD = Optical Density The 5% patch should just be visible inside of the 0% patch The 95% patch should be visible inside the 100% patch</p>	SMPTE Test Pattern	Inverted gray scale	0% patch 2.45± 0.15 OD*	0% patch 2.50± 0.15	10% patch 2.10± 0.15 OD	10% patch 2.25± 0.15	40% patch 1.15± 0.15 OD	40% patch 1.35± 0.15	90% patch 0.30± 0.08 OD	90% patch 0.30± 0.08	
SMPTE Test Pattern	Inverted gray scale													
0% patch 2.45± 0.15 OD*	0% patch 2.50± 0.15													
10% patch 2.10± 0.15 OD	10% patch 2.25± 0.15													
40% patch 1.15± 0.15 OD	40% patch 1.35± 0.15													
90% patch 0.30± 0.08 OD	90% patch 0.30± 0.08													
3.	For spot film and radiography, items 2, 4, 5, 7, 9 and 11 QC tests as specified in Table 1, Radiographic Quality Control Requirements	As specified in Table 1A, Radiographic Quality Control Requirements	As specified in Table 1A, Radiographic Quality Control Requirements											
4.	Phantom Images (Fluoro Video Monitor)	Monthly	kVp ± 5%, MA±10% , high & low contrast depends on phantom used											
5.	Equipment Visual Checklist	Initially and quarterly	All tests passed											
6.	Lead Aprons, Gloves, Gonadal and Thyroid Shield Integrity Check	Initially and annually	No breaks in protective garments											
7.	Medical Physicist's QC Survey	Initially and annually	As required in N.J.A.C. 7:28-22.9											
8.	Quality Assurance Program Review	Initially and annually	As required in N.J.A.C. 7:28-22.4(a)7											

TABLE 3A

Computed Tomography Quality Control Tests, Frequencies, Standards, and Assignments				
Item	Required Test or Procedure	Minimum Frequency	Minimum Standards	Duties Assigned to:
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 1A, 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	As specified in TABLE 2A, Fluoroscopic Quality Control Requirements	
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.	Medical Physicist QA Program Review	Initially and annually	As Required in N. J. A. C. 7:28-22.4(a)7	

3. Policies and Procedures

The following policies and procedures have been adopted by my facility. My facility will adhere to all of the following policies and procedures. I understand that any modifications to the policies or procedures must be documented in my manual.

Policy for holding patients and for presence of individuals in the room during radiation exposure:

Policy for Holding Patients

1. Only a licensed practitioner (chiropractor, dentist, medical doctor, podiatrist, or a New Jersey licensed radiologic technologist) will be permitted to operate x-ray equipment and position a patient for a radiographic procedure. **(N.J.A.C. 7:28-19.3).**
2. A person who is licensed pursuant **N.J.S.A. 26:2D and N.J.A.C. 7:28-19**, will not hold a patient during a radiation exposure, except in a life-threatening situation.
3. No licensed practitioner will order or otherwise cause an individual who is licensed pursuant to **N.J.S.A. 26:2D and N.J.A.C. 7:28-19** to hold a patient during a radiation exposure, except in a life-threatening situation. **(N.J.A.C. 7:28-15.9(a)2iii).**
4. No person will be employed, routinely assigned, or required to hold a patient during radiographic and fluoroscopic procedures. **(N.J.A.C. 7:28-15.9(a)2iv).**
5. If a patient must be held during the x-ray exposure, non-radiation workers such as aides, orderlies, nurses, or members of the patient's family may be asked to perform this duty. **(N.J.A.C. 7:28-15.9(a)2v).**
6. No person other than the patient will hold the film during the exposure. **(N.J.A.C. 7:28-15.9(a)vi).**
7. No person will order, instruct or otherwise allow a person under the age of 19 to hold a patient during any radiographic, fluoroscopic or therapy simulation procedure.
8. The person holding the patient will be protected with a lead apron of at least 0.25 mm lead equivalent. **(N.J.A.C. 7:28-15.9(a)2i)**
9. The person holding the patient will be protected with lead gloves of at least 0.25 mm lead equivalent when hands are in the radiation beam. **(N.J.A.C. 7:28-15.9(a)2ii)**

Policy for presence of individuals in the room during radiation exposure

1. No person will permit or arrange for the intentional irradiation of a human being except for the purpose of medical diagnosis or treatment. **(N.J.A.C. 7:28-15.9(a)9)**
2. Only individuals required for the medical procedure, for training, or for equipment maintenance will be permitted in the radiographic, fluoroscopic or computed tomography rooms during an exposure. **(N.J.A.C. 7:28-15.9(a)1)**
3. Individuals who are present in the radiographic, fluoroscopic, or computed tomography room during any exposure will wear protective aprons of a least 0.25 mm lead equivalent during every exposure. **(N.J.A.C. 7:28-15.9(a)1i).**
4. Individuals whose hands may be in the primary beam will be required to wear protective gloves of at least 0.25 mm lead equivalent. **(N.J.A.C. 7:28-15.9(a)1ii).**

5. I have provided a method to observe the patient during the x-ray exposure for all x-ray units. Observation of the patient will be made from behind the protective barrier. **(N.J.A.C. 7:28-15.9(a)6).**
6. No person will be permitted to operate an x-ray producing machine unless he/she understands and uses radiation safety procedures necessary to keep radiation exposure as low as reasonably achievable (ALARA) **(N.J.A.C. 7:28-15.9(a)11).**

Guidance: The facility must develop a policy for holding patients as required by N.J.A.C. 7:28-22.4. The above policy is based on regulatory standards that are identified in **BOLD** print. The above policy may be modified by the facility but the facility must ensure compliance with the appropriate regulations.

Policy for pregnant patients and employees:

Policy for Pregnant Patients

1. Before an x-ray examination to the torso, the x-ray operator(s) will ask female patients of child bearing age about the possibility of pregnancy. If the patient is unsure, the x-ray procedure will be delayed until the pregnancy status is confirmed.
2. Pregnancy is to be determined by:
 - a. A pregnancy test performed by this office to determine status.
 - b. Patient referred to primary care provider to obtain a pregnancy test.
3. For a confirmed pregnancy, the patient's referring physician will be called to determine if the x-ray exam can be postponed until after the patient is no longer pregnant. If the consultation determines that the x-ray exam is immediately necessary for the mother's health, then every precaution will be taken to protect the fetus. We will contact the medical physicist prior to the exam to determine the best way to keep the dose to the fetus as low as possible and to determine the dose that is delivered to the fetus during the x-ray procedure.
4. Signs are posted in the waiting room and the x-ray room reminding the patient to inform the doctor (technologist, if applicable) if they are or suspect that they are pregnant.

Policy for Pregnant Employees

Although risks to the unborn child are small under normal working conditions, I have instituted a policy to limit the radiation dose from occupational exposure to no more than 50 millirems per month during the term of pregnancy. (NCRP #116)

The policy is as follows when the x-ray operator has declared that she is pregnant.

1. When a radiation worker declares a pregnancy, she will be provided with at least one personal radiation-monitoring device to be worn near the abdominal area for the duration of the pregnancy to ensure that allowable limits to the fetus are not exceeded.
2. Pregnant workers assigned to fluoroscopy will provided with two personnel monitoring devices. She has been instructed to wear one personnel monitoring device marked "abdomen" at or near her abdominal area, under the protective apron. The other personnel monitoring device marked "collar" should be worn at her neck or collar area, outside the protective apron.

3. The staff and the pregnant employee will work together to try to limit the radiation exposure to the unborn child. Methods that we will use are as follows:
 - a. Reduce the time spent in the radiation area, if possible, by working out a schedule to take fewer x-rays or modify the duties during the time of the pregnancy.
 - b. Stand in a shielded area during all radiographs.
 - c. Keep an extra distance from the radiation source whenever possible.

Guidance: The facility must develop a policy for pregnant patients and pregnant employees. The above policy may be modified by the facility but the facility must ensure compliance with the appropriate regulations.

Policy for the Use of Gonadal Shielding

The use of gonadal shielding is as follows:

1. Gonadal shielding of not less than 0.5 mm lead equivalent is available and is to be used on a patient during a radiographic or fluoroscopic procedure, except in a case when the shielding would interfere with the diagnostic procedure. If the patient is sterile, the use of gonadal shielding may be omitted (**N.J.A.C. 7:28-15.9(a)3**).
2. Specific area gonadal shielding, that is gonadal shielding that covers and is slightly larger than the region of the gonads, is used when the gonads will lie within the primary x-ray field, or within close proximity (about 5 centimeters), despite proper collimation of the x-ray beam.
3. Specific area ovarian shielding is used on female patients after having determined that she is not pregnant.
4. Specific area gonadal shielding will not be used as a substitute for careful patient positioning, the use of correct technique factors and film processing, or proper beam limitation (confinement of the x-ray field to the area of diagnostic interest).

Guidance: The facility must develop a policy for the use of gonadal shielding as required by 7:28-22.4. The above policy is based on regulatory standards which are identified in **BOLD** print. The above policy may be modified by the facility but the facility must ensure compliance with the appropriate regulations.

Policy for Orientation Program for Operators of Radiographic/Fluoroscopic/Computed Tomography Equipment (Insert the contents of facility's orientation program)

ATTACHED IS A COPY OF MY FACILITY'S ORIENTATION PROGRAM THAT ALL NEW OPERATORS OF RADIOGRAPHIC/FLUOROSCOPIC/COMPUTED TOMOGRAPHY WILL RECEIVE. ALL NEW OPERATORS WILL RECEIVE TRAINING ON THE EQUIPMENT AND THE ROUTINE PROCEDURE OF EACH EXAM THAT ARE PERFORMED (IE: PA & LATERAL FOR ROUTINE CHEST EXAMINATION, ETC.).

THE INDIVIDUAL LISTED BELOW WILL BE RESPONSIBLE FOR CONDUCTING THE ORIENTATION PROGRAM. (SEE FORMS SECTION FOR NECESSARY DOCUMENTATION FOR PERSONNEL FILE.)

Insert name of person doing the training

Duration of Training (hours)

Guidance: The facility must develop an orientation program that ensures all new operators of the x-ray equipment are familiar with the facility's protocol, procedures and technique factors for each examination. In addition, the new employee should be familiarized with any additional information needed to perform their duties according to all appropriate Federal, State, and local regulations concerning the use of x-ray equipment.

Procedures for proper use and maintenance of equipment

My staff and I will follow the manufacturer's recommendation for the safe use, maintenance and service of the x-ray equipment and processor.

Preventive maintenance on both the processor and chemicals is performed initially and at least every 2 months or according to manufacturers' specifications and more frequently if needed.

Photographic materials will be stored at temperatures less than 24°C (75°F), preferably in the range of 15°C to 21°C (60°F to 70°F) as recommended in NCRP Report #99. Open packages of photographic film are stored in an area with humidity ranging between 40% and 60%. Photographic materials will not be stored in areas where they can be exposed to direct sunlight, chemical fumes or radiation. Processor chemistry shall not be used after the expiration date.

The emulsion batch of film that will expire first will be used first. Film will not be allowed to remain in the film bin past the expiration date. New shipments of film will be checked and will not be accepted from the vendor unless they can be used before the expiration date

If expired film is used to clean processor, the box will be clearly marked "NOT FOR PATIENTS."

Guidance: Facilities can not use either film or processor chemicals beyond their expiration dates.

Policy and Employee Responsibilities for Personnel Radiation Monitoring

Personnel monitoring devices are provided to and are worn by each individual who is likely to exceed the limits in **N.J.A.C. 7:28-7**.

1. Each personnel monitoring device is assigned to and worn by only one individual.
2. Records of the radiation exposure derived from each personnel-monitoring device are kept in accordance with the requirements of **N.J.A.C. 7:28-8**.
3. The personnel monitoring records are maintained for each individual badge. The records are reviewed monthly/quarterly by the qualified individual responsible for quality control and/or certified medical physicist.
4. The personnel monitoring devices are processed in accordance with manufacturer's specifications. The results of the personnel-monitoring device are made available to each assigned employee.
5. Radiation exposure shall be ALARA (As Low As Reasonably Achievable) and at no time shall exceed the limits specified in N.J.A.C. 7:28-6.1. Any incidence of excessive exposure as indicated on the personnel monitoring device report is investigated in consultation with the certified medical physicist, is discussed with the employee and is reported to the Department in accordance with N.J.A.C. 7:28-13. Corrective action is documented and kept with the personnel monitoring device records.
6. Personnel monitoring device records are maintained for each employee for 10 years past the last date of employment. (**N.J.A.C. 7:28-8.1(f)**).
7. When an individual is provided with a personnel-monitoring device, the individual is instructed to only wear the device assigned to him/her.
 - a. If one whole body personnel monitoring device is provided to each individual, the device is to be worn at the collar outside of any protective clothing.
 - b. If two whole body personnel monitoring devices have been assigned to an individual, he/she has been instructed to wear one device at the collar outside of any protective clothing and the second device is to be worn at the waist level inside any protective clothing. I will ensure that the reports obtained from these personnel monitoring devices are clearly labeled as to their placement.
8. Intentional exposure of a personnel-monitoring device to deceptively indicate a dose delivered to an individual is prohibited and will result in disciplinary action.

_____ I provide personnel monitoring equipment to each individual licensed pursuant to **N.J.S.A. 26:2D-26 and N.J.A.C. 7:28-19** and each individual working in the controlled area.
(See Section 5, page 31, of this manual)

_____ I do not provide personnel monitoring equipment. The estimated workload is below the regulatory limits in N.J.A.C. 7:28-7.4 as determined by _____.

Guidance: The facility must develop a policy and employee responsibilities for personnel monitoring devices as required by N.J.A.C. 7:28-22.4 (a)3. The above policy is based on regulatory standards that are identified in **BOLD** print. The above policy may be modified by the facility but the facility must ensure compliance with the appropriate regulations.

Policy for Medical Record Retention (Films)

I will retain medical records for a period of 7 years for of adults and for 7 years after the age of adulthood for minors in order to support treatment, and to provide a record of treatment and diagnosis. Below, I have indicated the media used by my facility below.

___ My facility uses hard copy film to store images.

___ My facility uses both computer media and hard copy film to store images.

___ My facility uses computer media to store study information for which a report is generated. The recording media will be stored in conditions that will ensure that deterioration does not occur for the record retention period.

Additionally, if a patient's medical images are identified as being involved in a legal case, the records will immediately be coded appropriately, and maintained for the record retention period.

Guidance: The facility must develop a policy for medical record retention of films. The above policy may be modified by the facility but the facility must ensure compliance with the appropriate regulations.

Policy for Releasing Films (see Forms Section)

Upon request by, or on behalf of the patient, I will permanently or temporarily transfer the original films to a medical institution, the patient's health care provider, or the patient directly within 7 days of receiving a valid request. The patient or the patient's representative is required to sign the release form prepared by this office.

The release form (located in Forms Section) will contain appropriate information relating to location, date of release, and individual(s) having custody of the records.

Guidance: The facility should develop a policy for the release of patient films to any health care provider and should require the patient, or the patient's representative, to sign a release form identifying the person(s) when the films are to be released. In addition, the facility should have a policy notifying the patient how the films are to be returned.

Policy for availability of patient films, in the event a facility closes

In the event our facility discontinues services, patient records will be made available. Our facility has a responsibility to its patients to ensure that all medical records are properly handled. If my facility ceases operations I will either transfer my medical records to another facility, or provide the medical records to my patients. A certified letter as to the location, or disposition, of the records will be sent to notify the patients of the transferal.

Guidance: This policy is not required by 7:28-22.4(a)3. It is highly recommended that facilities develop a method to notify patients in the event the facility closes.

Policy for Labeling Films

Each x-ray film taken on a patient will be clearly and permanently labeled with the following information:

- patient's name
- date of exam
- patient ID number (if applicable)
- name of this facility
- the technologist/operator's initials

Logbook

A logbook or an equivalent record system will be maintained. The logbook will contain the patient's name, date of exam, type of examination, the initials of the person performing the exam, number of views taken, and when applicable, the reason for holding the patient.

Guidance: This policy should identify the items that identify pertinent patient information on all films. A logbook is not required but it is recommended that it contain patient identifiers and examination information.

Policy to commit to perform a Radiation Safety Survey of the Environs in accordance with N.J.A.C. 7:28-15.10 on newly installed x-ray equipment within 60 days of installation and an Initial Medical Physicist's QC Survey as required by N.J.A.C 7:28-22.8(a), 22.9(a), or 22.10(a) as appropriate for the type of x-ray equipment.

A qualified individual for the performance of radiation safety surveys of the environs, will perform a radiation safety survey of the environs within 60 days of the installation, relocation, or change to the shielding of the room of each radiographic, fluoroscopic, computed tomography or bone densitometer equipment.

A certified medical physicist will perform a Medical Physicist QC Survey within 60 days of the installation of each newly installed x-ray machine.

Guidance: The facility must develop a policy for the performance of a Radiation Survey of the Environs as required by N.J.A.C. 7:28-15.10.

Policy for using technique charts

Each x-ray unit will have an appropriate technique chart located in a conspicuous location for reference by the operators. At a minimum, this chart will include patient size versus technique factors, source to image distance (SID), grid data, film/screen combination, gonad or breast shielding as appropriate. These charts will be updated when different film/screen combinations are purchased and when new x-ray tubes or calibrations change the baseline data from which the charts were developed. (See Forms Section for a sample Technique Chart.)

Guidance: The facility must develop a technique chart that includes patient size versus technique factors, source to image distance, grid data, film/screen combinations, gonad, ovary or breast shielding as appropriate for each study done at the facility.

Policy and Rules on Radiation Safety

I will provide written safety rules to each individual operating x-ray equipment including any restrictions as to the operating technique require for the safe operation of the particular x-ray apparatus, and require that the operator sign a form acknowledging that the safety manual was read (**N.J.A.C. 7:28-15.9(a)8**).

Guidance: The facility must develop a policy on rules of radiation safety as required by N.J.A.C 7:28-15.9(a)8 and have each employee sign a form acknowledging that the safety manual as been received. The above policy is based on regulatory standards which is identified in **BOLD** print.

4. Plan for taking corrective actions

If the test indicates that the x-ray equipment is not functioning within specified standards, I will contact _____ (x-ray equipment service company) to ensure that the equipment is repaired as soon as possible.

If the test indicates that the film processor is not functioning within specified standards, I will contact _____ (the film processor repair company) to ensure that the equipment is repaired before radiographs are taken.

If other image quality is not satisfactory, I will contact _____ (the medical physicist) to evaluate the system and correct the problem as soon as possible.

All corrective actions will be carried out as soon as possible (within regulatory limits).

Guidance: The registrant must specify their plan for taking corrective action and be committed to ensure that all QC Test Standards are met. If the results of the QC tests indicate that the standard has not been met, the plan must identify what immediate steps will be taken to ensure the test results demonstrate compliance with the provisions contained in the rule.

5. Record Keeping (QC Tests)

I will retain QC tests records as required. I have specified their locations in the following chart.

	Test/Record	Minimum Records Retention	Where Records are Located
i.	QC Tests Performed	Most Recent One Year	
ii	Medical Physicists QC Survey Initial Current	Permanently Most Recent 2 years	
iii.	Corrective Action Records	Most Recent 2 years	
iv.	Personnel Monitoring Records	10 years past the last date of employment for each employee	
v.	QA Program Review	Most Recent	

Guidance: Registrants must also comply with the procedures for record reporting, record keeping, record retention and patient report requests in accordance with rules set forth by the State Board of Examiners for Medical/Chiropractic disciplines.

6. Reference Manuals

I maintain the following reference and operator's manuals for each x-ray machine, processor, sensitometer, densitometer, and thermometer.

Manual Title/ Description	Location

Guidance: The facility must develop a policy identifying the location of all reference manuals in the event system errors occur or corrective action is required.

7. Quality Assurance Program Review

– Test frequency - initially and annually thereafter

I will review and update my QA program when any changes occur at my facility. Additionally, the medical physicist and I will review the entire QA program annually and discuss any changes that have occurred during the past year.

Guidance: The Quality Assurance Program must be reviewed in its entirety to ensure that all information is current and accurate. The review must occur annually. If personnel or operating procedures change frequently, reviews should be conducted more frequently to ensure that facility's Quality Assurance Program is maintained. The following form may be used to assist the facility with its review.

Physician (registrant) 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.

<p>Records keeping:</p> <p>Records for the most recent one year of the QC tests performed by the registrant</p> <p>Records of the initial Medical Physicist’s QC Survey plus the two most recent QC Surveys</p> <p>Records of corrective actions for the most recent two years</p> <p>Personnel monitoring records. Per New Jersey Administrative Code 7:28-8.1(f) records for each employee monitored must be maintained for the length of employment plus 10 years.</p>	<hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/>
<p>Have any of the following items in the manual changed during the past year?</p>	<p>√ if Updated</p>	<p>Date Manual Revised</p>
<p>A provision describing how the registrant and the qualified medical physicist will review the QA program annually.</p>	<hr/> <hr/>	<hr/> <hr/>
<p>Have you purchased new x-ray equipment either as a replacement or an additional unit? If so, did you:</p> <p>Register it with the Bureau of Radiological Health within 30 days of installation? And</p> <p>Have a qualified individual perform a Radiation Safety Survey of the Environs and submit a copy to the Bureau of Radiological Health within 60 days of installation?</p> <p>Have an initial Medical Physicist QC Radiographic Survey performed within 60 days of installation?</p>	<hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/>
<p>Review of each Registration of a Radiation Producing Machine form to be sure the information is current. Questions to ask yourself:</p> <p>Have you moved?</p> <p>Are you the owner of record?</p> <p>Has the facility contact person changed?</p> <p>Is the x-ray machine on the Registration form the one you are currently using?</p> <p>New Jersey Administrative Code 7:28-3 requires that the Bureau of Radiological Health be notified in writing within 30 days of a change of any of the information on the Registration form.</p>	<hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/>
<p>Are your registration fees paid for the current and previous year?</p>	<hr/> <hr/>	<hr/> <hr/>
<p>If any person other than a licensed practitioner takes x-rays, is each such person licensed as required by N.J.S.A. 26:2D-24 and N.J.A.C. 7: 28-19? You may call 609-984-5890 to check the license status of any individual. Only a New Jersey licensed physician, podiatrist, or chiropractor, 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. “Operate” means the use or manipulation of x-ray equipment in any way that leads to or causes the emission of radiation or affects the amount or quality of radiation that is received by a patient. Examples of “operate” include, activating or terminating the x-ray exposure, setting or adjusting technical factors, setting the mode of imaging, setting the camera rate, and setting or</p>	<hr/> <hr/>	<hr/> <hr/>

<p>adjusting the collimator. Tasks associated with turning on the x-ray equipment at the beginning of the day without a patient on the table, resetting the five minute timer, adjusting the imaging monitor, and post exposure data processing are not considered operating x-ray equipment. Please note that the activation of the x-ray exposure for fluoroscopic procedures by a licensed diagnostic radiologic technologist is only permitted if a licensed physician is in the room and directing the fluoroscopic procedure. "Position patients" means the alignment of the x-ray tube, image receptor and the area of the patient intended for exposure to radiation.</p>		
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Annual Medical Physicist's QC Survey

The following Medical Physicist's QC Survey Requirement Tables (4A, 5A, 6A) are supplied to remind the facility what the required QC tests are that the physicist must perform on your equipment.

Guidance: The facility must commit to have performed, by a certified medical physicist, those QC tests pursuant to N.J.A.C. 7:29-22.8, 9, or 10. (See Table 4, 5, 6 in the rule). The facility must describe how the registrant and certified medical physicist will review the QA program annually.

TABLE 4A

Physicist Radiographic Quality Control Survey Requirements		
Item	Test	Standard
1.	Radiographic Unit Assembly Evaluation	As Required at N. J. A. C. 7:28-15.3
2.	Collimation Assessment	As Required at N. J. A. C. 7:28-15.3
3.	Collimator Illumination	As Required at N. J. A. C. 7:28-15.3
4.	Half Value Layer	As Required at N. J. A. C. 7:28-15.3
5.	mA Exposure Linearity	As Required at N. J. A. C. 7:28-15.3
6.	kVp Accuracy/Reproducibility	As Required at N. J. A. C. 7:28-15.3
7.	Timer Accuracy/Reproducibility	As Required at N. J. A. C. 7:28-15.3
8.	Automatic Exposure Control, Reproducibility, Tracking, Density Control	As Required at N. J. A. C. 7:28-15.3
9.	Entrance Skin Exposure (ESE) Measurement	Determine ESE for common exam and compare with National Evaluation of X-ray Trends (NEXT) data available in the Compliance Guidance Documents referenced at NJAC 7:28-22.3(c)2
10.	Image Quality Evaluation (Recommendation)	Establish standard for phantom test tool used
11.	Review Facility QC Test Records	Review QC tests for proper procedure and corrective action
12.	Medical Physicist Report and Recommendations	Communicate results and recommendations to registrant
13.	Medical Physicist QA Program Review Date Performed _____.	Date to call for next year's survey _____.

TABLE 5A

Medical Physicist's Fluoroscopic QC Survey		
Item	Test	Standard
1.	Fluoroscopic Unit Assembly Evaluation	As Required at N. J. A. C. 7:28-15.5
2.	Entrance Exposure Rate to Image Intensifier	Fluoroscopic equipment manufacturer's specifications
3.	Patient Entrance Exposure Rate	Fluoroscopic equipment manufacturer's specifications
4.	Maximum Exposure Rate	As Required at N. J. A. C. 7:28-15.5
5.	High Contrast Resolution/Low Contrast for Fluoroscopy Video Monitor	Fluoroscopic equipment manufacturer's specifications
6.	Spot Film Automatic Exposure Control (AEC) System Performance	Fluoroscopic equipment manufacturer's specifications
7.	High Contrast Resolution/Low Contrast for Fluoroscopy Image Recording System	Fluoroscopic equipment manufacturer's specifications
8.	Half-Value Layer	Fluoroscopic equipment manufacturer's specifications
9.	Kilovoltage	Fluoroscopic equipment manufacturer's specifications
10.	Fluoroscopic and Spot Film Collimation Assessment	As required at N.J.A.C. 7:28-15.5
11.	Review Facility QC Test Records	Review QC tests for proper procedure and corrective action
12.	Medical Physicist Report and Recommendations	Communicate results and recommendations to registrant
	Medical Physicist QA Program Review Date Performed _____.	Date to call for next year's survey _____.

TABLE 6A

Medical Physicist's Computed Tomography QC Survey		
Item	Test	Standard
1.	Scan Increment Accuracy	±1 mm
2.	Scan Localization Light Accuracy	± 5 mm
3.	Patient Dose (Multiple Scan Average Dose – MSAD or Computed Tomography Dose Index-CTDI)	CT equipment manufacturer's specifications and scan protocol or phantom manufacturer's specifications
4.	Pre-Patient Collimation Accuracy	Manufacturer's specifications
5.	Contrast Scale	CT equipment or phantom manufacturer's specifications
6.	CT Number for Water	CT equipment or phantom manufacturer's specifications
7.	Slice Thickness	CT equipment or phantom manufacturer's specifications
8.	Field Uniformity	CT equipment or phantom manufacturer's specifications
9.	Low Contrast Resolution	CT equipment or phantom manufacturer's specifications
10.	High Contrast Resolution	CT equipment or phantom manufacturer's specifications
11.	Noise	CT equipment or phantom manufacturer's specifications
12.	Scan Protocol Review	As required at N.J.A.C. 7:28-15.5
13.	Review of Facility and technologist's QC Test	Review QC tests for proper procedure and corrective action
14.	Medical Physicist Report and Recommendations	Communicate results and recommendations to registrant
	Medical Physicist QA Program Review Date Performed _____.	Date to call for next year's survey _____.

FORMS

(Also can be downloaded at www.state.nj.us/dep/rpp/downloads.htm)

TABLE 1A**Radiographic Quality Control Tests, Frequencies, Standards, and Assignments**

Item	Required Test or Procedure	Minimum Frequency	Minimum Standards	Duties Assigned to:
1.	Equipment Warm-up Procedure	Daily, each day x-rays are taken	Warm up tube; ensure equipment is working properly	
2.	Processor Quality Control (Sensitometry/Densitometry)	Daily, each day x-rays are taken	Medium Density ± 0.15 Optical Density (OD), Density Difference ± 0.15 OD, Base + Fog + 0.03 OD of operating levels	
3.	Laser Film Printer Quality Control	Weekly	As specified in Table 2a., Fluoroscopic Quality Control Requirements	
4.	Darkroom Cleanliness	Weekly	Free from dust and dirt	
5.	Processor Maintenance and Chemical Solutions	Initially and every 2 months (more frequently if needed)	Manufacturer's specifications	
6.	Facility's Equipment Visual Checklist	Initially and quarterly	All tests passed	
7.	Film and Chemical Shelf Life	Initially and quarterly	Use film and chemicals with earliest expiration date first	
8.	Light Field/X-ray Field Alignment	Initially, quarterly and after service	Not to exceed 2% of Source to Image Distance (SID)	
9.	Repeat Analysis	Semiannually (review rejected films immediately for corrective action)	No standard, but goal should be < 5%	
10.	Artifact Evaluation	Examine every film for artifacts, in-depth evaluation semiannually	No significant artifacts	
11.	Analysis of Fixer Retention	Initially and semiannually	≤ 5 micrograms/sq. centimeter or ≤ 0.05 grams/sq. meter	
12.	Darkroom Fog	Initially, semiannually and after service	≤ 0.05 Optical Density Difference	
13.	Screen-Film Contact/Cassette Integrity/Screen Cleanliness	Initially and annually or as needed	No areas of poor contact > 2cm. in diameter	
14.	Lead Aprons, Gloves, Gonadal and Thyroid Shield Integrity Check	Initially and annually	No breaks in protective garments	
15.	Medical Physicist's QC Survey	Initially and annually	As required in N.J.A.C. 7:28-22.8	
16.	Quality Assurance Program Review	Initially and annually	As required in N.J.A.C. 7:28-22.4(a)7	

TABLE 2A

Fluoroscopic Quality Control Tests, Frequencies, Standards, and Assignments				
Item	Required Test or Procedure	Minimum Frequency	Standards	Duties Assigned to:
1.	Equipment Warm-up Procedure	Daily, each day fluoroscopy is performed	Tube warm-up and ensure equipment is working properly Fluoro phantom image is comparable to facility standard	
2.	Laser Film Printer Quality Control	Weekly	Recommended control limits SMPTE Test Pattern Inverted gray scale 0% patch 2.45 ± 0.15 OD* 0% patch 2.50 ± 0.15 OD 10% patch 2.10 ± 0.15 OD 10% patch 2.25 ± 0.15 OD 40% patch 1.15 ± 0.15 OD 40% patch 1.35 ± 0.15 OD 90% patch 0.30 ± 0.08 OD 90% patch 0.30 ± 0.08 OD *OD = Optical Density The 5% patch should just be visible inside of the 0% patch The 95% patch should be visible inside the 100% patch	
3.	For spot film and radiography, items 2, 4, 5, 7, 9 and 11 QC tests as specified in Table 1, Radiographic Quality Control Requirements	As specified in Table 1A, Radiographic Quality Control Requirements	As specified in Table 1A, Radiographic Quality Control Requirements	
4.	Phantom Images (Fluoro Video Monitor)	Monthly	kVp ± 5%, MA ± 10% , high & low contrast depends on phantom used	
5.	Equipment Visual Checklist	Initially and quarterly	All tests passed	
6.	Lead Aprons, Gloves, Gonadal and Thyroid Shield Integrity Check	Initially and annually	No breaks in protective garments	
7.	Medical Physicist's QC Survey	Initially and annually	As required in N.J.A.C. 7:28-22.9	
8.	Quality Assurance Program Review	Initially and annually	As required in N.J.A.C. 7:28-22.4(a)7	

TABLE 3A

Computed Tomography Quality Control Tests, Frequencies, Standards, and Assignments				
Item	Required Test or Procedure	Minimum Frequency	Minimum Standards	Duties Assigned to:
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 1A, 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	As specified in TABLE 2A, Fluoroscopic Quality Control Requirements	
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.	Medical Physicist QA Program Review	Initially and annually	As Required in N. J. A. C. 7:28-22.4(a)7	

X-ray Film Release Form

This film(s) is Permanent Record of _____ *please return when finished.*

Patient's Name _____

X-Ray ID # _____

Released to: _____

Date Released: _____

Date Returned: _____

Patient (Representative) Signature _____ Date _____

PROCESSOR AND X-RAY EQUIPMENT

PROCESSOR to be Tested:

Manufacturer _____ Model # _____

Serial # _____ Facility Designation _____

Location: _____

X-RAY Equipment to be Tested:

Type of Equipment Registered with State of New Jersey/Bureau of Radiological Health:

Manufacturer _____ Model # _____

Serial # _____ Tube Serial # _____

NJ Registration # _____ Facility Designation _____

Circle Type: Radiographic Fluoroscopic CT

X-RAY Equipment to be Tested:

Type of Equipment Registered with State of New Jersey/Bureau of Radiological Health:

Manufacturer _____ Model # _____

Serial # _____ Tube Serial # _____

NJ Registration # _____ Facility Designation _____

Circle Type: Radiographic Fluoroscopic CT

**ORIENTATION PROGRAM FOR OPERATORS OF RADIOGRAPHIC/FLUOROSCOPIC/COMPUTED
TOMOGRAPHY EQUIPMENT**

On _____(date of training) the operator(s) listed below received an orientation program conducted at this facility by _____ .

Technologist's Name	New Jersey License Number

Personnel employed to perform x-ray exams on human beings, other than a licensed practitioner, will provide proof of current New Jersey State License Pursuant to N.J.A.C. 7:28-19. (Contact the Technologist Certification Section of the Bureau of Radiological Health for questions or licensing information, (609)984-5890).

Quality Assurance Program Review Checklist

Has any of the following items in the manual changed during the past year?	✓ if Updated	Date Manual Revised
Is the list of clearly identified individuals and assigned responsibilities for maintaining the quality assurance program and for performing the quality control tests current?		
Quality Control (QC) Measures Are QC Tests being performed at the frequency stated? Is the list of equipment to be tested current? Have the acceptability limits for each test changed? Are the descriptions for each QC test procedure current? Are the sample forms for each QC test current? Processor and solutions maintenance up-to-date? Is this the most recent Annual Medical Physicist's QC Survey?	_____ _____ _____ _____ _____ _____ _____	_____ _____ _____ _____ _____ _____ _____
Policies and Procedures Policy for holding patients and for presence of individuals in room during radiation exposure Policy for pregnant patients and employees Policy for gonadal shielding A description of the orientation program for operators of radiographic equipment including the duration and content of that program Procedures for proper use and maintenance of equipment Policies and employee responsibilities concerning personnel radiation monitoring Policy for releasing films Policy for labeling films (i.e., patient's statistics, facility information) A commitment to perform a Radiation Safety Survey of the Environs in accordance with N.J.A.C. 7:28-15.10 on newly installed x-ray equipment within 60 days of installation and an initial Medical Physicist's QC Survey as required by N.J.A.C. 7:28-22.8(a) Policy for using technique charts Policy and rules on Radiation Safety as required by N.J.A.C. 7:28-15.9(a) 8	_____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____	_____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____
Corrective Actions: A plan for repairing or calibrating the x-ray equipment A plan for repairing or servicing the processor	_____ _____	_____ _____
Record keeping: Records for the most recent one year of the QC tests performed by the registrant Records of the initial Medical Physicist's QC Survey plus the two most recent QC Surveys Records of corrective actions for the most recent two years Personnel monitoring records. Per New Jersey Administrative Code 7:28-8.1(f) records for each employee monitored must be maintained for the length of employment plus 10 years.	_____ _____ _____ _____	_____ _____ _____ _____

Have any of the following items in the manual changed during the past year?	✓ if Updated	Date Manual Revised
A provision describing how the registrant and the qualified medical physicist will review the QA program annually.		
<p>Have you purchased new x-ray equipment either as a replacement or an additional unit? If so, did you:</p> <p>Register it with the Bureau of Radiological Health within 30 days of installation? And</p> <p>Have a qualified individual perform a Radiation Safety Survey of the Environs and submit a copy to the Bureau of Radiological Health within 60 days of installation?</p> <p>Have an initial Medical Physicist QC Radiographic Survey performed within 60 days of installation?</p>		
<p>Review of each Registration of a Radiation Producing Machine form to be sure the information is current. Questions to ask yourself:</p> <p>Have you moved?</p> <p>Are you the owner of record?</p> <p>Has the facility contact person changed?</p> <p>Is the x-ray machine on the Registration form the one you are currently using?</p> <p>New Jersey Administrative Code 7:28-3 requires that the Bureau of Radiological Health be notified in writing within 30 days of a change of any of the information on the Registration form.</p>		
Are your registration fees paid for the current and previous year?		
<p>If any person other than a licensed practitioner takes x-rays, is each such person licensed as required by N.J.S.A. 26:2D-24 and N.J.A.C. 7: 28-19? You may call 609-984-5890 to check the license status of any individual. Only a New Jersey licensed physician, podiatrist, or chiropractor, 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. "Operate" means the use or manipulation of x-ray equipment in any way that leads to or causes the emission of radiation or affects the amount or quality of radiation that is received by a patient. Examples of "operate" include, activating or terminating the x-ray exposure, setting or adjusting technical factors, setting the mode of imaging, setting the camera rate, and setting or adjusting the collimator. Tasks associated with turning on the x-ray equipment at the beginning of the day without a patient on the table, resetting the five minute timer, adjusting the imaging monitor, and post exposure data processing are not considered operating x-ray equipment. Please note that the activation of the x-ray exposure for fluoroscopic procedures by a licensed diagnostic radiologic technologist is only permitted if a licensed physician is in the room and directing the fluoroscopic procedure. "Position patients" means the alignment of the x-ray tube, image receptor and the area of the patient intended for exposure to radiation.</p>		

DAILY CT EQUIPMENT TESTS (Insert Results)

DATE	PERSON RESPONSIBLE FOR TEST	EQUIPMENT FUNCTION	CT NUMBER FOR WATER	FIELD UNIFORMITY

RADIOGRAPHIC: Equipment Warm-up (DAILY)

MONTH/DATE	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
January																															
February																															
March																															
April																															
May																															
June																															
July																															
August																															
September																															
October																															
November																															
December																															

FLUOROSCOPIC: Equipment Warm-up/Video Image Evaluation (DAILY)

MONTH/DATE	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
January																															
February																															
March																															
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June																															
July																															
August																															
September																															
October																															
November																															
December																															

Radiographic Quality Control Monthly, Quarterly, Semi-Annual, and Annual Schedule

Year	Month	Initial*	1	2	3	4	5	6	7	8	9	10	11	12
	Date													
	Person Responsible for test													
	Processor Maintenance and Chemical Solutions													
	Facility's Equipment Visual Checklist													
	Film and Chemical Shelf Life													
	Light Field/X-ray Field Alignment													
	Repeat Analysis													
	Artifact Evaluation													
	Analysis of Fixer Retention													
	Darkroom Fog													
	Screen-Film Contact/Cassette Integrity/Screen Cleanliness													
	Lead Apron, Glove, Gonadal Thyroid Shield Integrity													
	Medical Physicist's QC Survey													
	Quality Assurance Program Review													

**Fluoroscopic Quality Control
Monthly, Quarterly, Semi-Annual, and Annual Schedule**

Year	Month	Initial*	1	2	3	4	5	6	7	8	9	10	11	12
	Date													
	Person Responsible for test													
	Phantom Images (Fluoro Video Monitor)													
	Equipment Visual Checklist													
	Lead Apron, Glove, Gonadal Thyroid Shield Integrity													
	Medical Physicist's QC Survey													
	Quality Assurance Program Review													

* All of the tests must be performed initially, when the QA program is first started. This column on the form can also be used to document the previous year's last annual set of tests.

Computed Tomography Quality Control Monthly, and Annual Schedule

Year		Month	Initial*	1	2	3	4	5	6	7	8	9	10	11	12
	Performed	Date													
		Person Responsible for test													
		Low Contrast Resolution													
		High Contrast Resolution													
		Noise													
		Table Position Indicator Accuracy													
		Scan Increment Accuracy													
		Scan Localization Light Accuracy													
		Medical Physicist's QC Survey													
		Quality Assurance Program Review													

* All of the tests must be performed initially, when the QA program is first started. This column on the form can also be used to document the previous year's last annual set of tests.

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