

Compliance Guidance for
**DENTAL CONE BEAM COMPUTED
TOMOGRAPHY (CBCT)
QUALITY ASSURANCE MANUAL**
(1st 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 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. Additionally, the Food and Drug Administration (FDA) has classified cone beam computed tomography (CBCT) equipment as computed tomography. Due to this classification, dental facilities that have purchased CBCT equipment must comply with the requirements of the Quality Assurance program.

In December 2013 the Commission on Radiation Protection approved an alternate Quality Assurance Program for Dental CBCT equipment and granted an exemption to allow licensed dental radiologic technologists, with additional training, to operate the equipment.

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

In accordance with N.J.A.C. 7:28-22.7 only a licensed radiologic technologist, a qualified medical physicist or a trained service technician can perform the QC tests for computed tomography. As part of the exemption request, granted in December 2013, the dentist may train the licensed dental radiologic technologist to perform the daily testing on the CBCT equipment.

This assumes that the registrant has been trained by the manufacture, is competent in the particular procedure and is able to convey this knowledge adequately to personnel. Product manufacturers, vendors, and service companies have websites for training. 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.

Documents

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, 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 44.

This is the first manual developed specifically for Dental CBCT facilities. 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.

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 shall 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/CR/DR, the x-ray unit, the annual medical physics survey and each quality control test.

2. Quality Control Measure

The facility shall include the following in their manual -

- i. QC Tests that will be performed and the frequency of each test
- ii. A list of equipment to be tested
- iii. Acceptability limits for each test performed
- iv. Description of each QC test procedure
- v. Sample forms for each QC test performed
- vi. Processor and solutions maintenance
- vii. 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, fluoroscopic, and CT 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/digital images
- viii. Policy for labeling films/digital images (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 and relocated x-ray equipment within 60 days. Also a commitment to perform 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 shall 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 shall 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/laser printer/CR/DR imaging systems are determined to need repair or service.

5. Record keeping

The facility shall maintain QC records as follows –

- i. QC test records shall be maintained as specified in N.J.A.C. 7:28-22.5(j), 22.6(i) and 22.7(j)
- ii. Copy of the initial Medical Physicist's QC Survey and copies of the most recent Medical Physicist's QC Surveys for at least two years
- iii. Records of any corrective actions for at least two years
- iv. Personnel monitoring records. Per N.J.A.C. 7:28-8.1(f) records for each employee monitored must be maintained for the length of employment and at least 10 years after termination of employee.

6. Reference manuals (if any) and their location

The facility shall identify the location(s) of all reference and operator manuals associated with the QA program. (ie. processor, acquisition workstation, diagnostic review workstation, x-ray unit, densitometer, etc.)

7. QA Annual Review

The facility shall 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 means the planned and systematic actions that provide adequate confidence that a diagnostic x-ray facility will produce consistently high quality images with minimum exposure of the patients and healing arts personnel.”¹

Quality Control is a series of distinct technical procedures and tests that ensure the production of high-quality diagnostic images. These procedures and tests enable a facility to recognize when established standards have been exceeded. When QC tests are not within established standards it may result in poor quality images and may 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.**

¹ Code of Federal Regulations 21 Part 1000.55

Alternative Quality Assurance Program

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 the Compliance Guidance Documents.

On December 31, 2013, an exemption was granted for CBCT units relating to the QC tests that must be performed; who can perform these tests; and who can perform CBCT procedures. Under this exemption, in addition to a New Jersey licensed dentist, registered dental hygienist, and a licensed diagnostic radiologic technologist, a licensed dental radiologic technologist with additional documented training in CBCT may perform CBCT procedures. Details can be found on pages 46.

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 the approved alternative QA Program. 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/laser printer 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 17-24). 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: <http://www.state.nj.us/dep/rpp/qa/index.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.

Dental CBCT Quality Assurance Manual

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

Facility Name _____

Address _____

Facility ID _____ 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 dental cone beam computed tomography (CBCT), I am required to develop and maintain the alternate Quality Assurance Program that complies with New Jersey Administrative Code N.J.A.C. 7:28-22(g). 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.

PROCESSOR/LASER PRINTER AND X-RAY EQUIPMENT

**PROCESSOR/LASER PRINTER/DIAGNOSTIC WORKSTATION
(if applicable) to be Tested:**

Manufacturer _____ Model #

Serial # _____ Facility Designation _____

Location

Dental CBCT X-RAY Equipment to be Tested:

List the Equipment Registered with State of New Jersey/Bureau of X-ray Compliance:

Manufacturer _____ Model #

Serial # _____ Tube Serial #

NJ Registration # _____ Facility Designation _____

FACILITY'S QA VENDORS

Medical Physicist:

Duties Assigned To: _____

ATTACH BUSINESS CARD

X-ray Equipment Service Company:

Duties Assigned To: _____

ATTACH BUSINESS CARD

**Processor/Laser Printer/Diagnostic
Workstation Service Company:**

Duties Assigned To: _____

ATTACH BUSINESS CARD

SECTION 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 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 image 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 dentist, 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 Table 3A.

SECTION 2: Quality Control Test Procedures

I am committed to performing all QC tests at the frequencies and standards specified in Table 3A on page 16 or appropriate manufacturer Table 3A (download the appropriate manufacture's CBCT Table). 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. All film and chemicals used and stored by my facility will be per manufacturers' specifications.

Guidance: QC Tests - Facilities must be committed to performing the alternate QC tests established pursuant to N.J.A.C. 7:28-22.3(g). Facilities must use the approved manufacture dental CBCT QC procedures. These test procedures must be inserted in the facility's QA manual.

Frequencies - The test frequencies specified in Table 3A or appropriate manufacture's CBCT Table 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/laser printer equipment, as well as the number of problems being encountered. (Extra copies of Table 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/laser printer equipment that will be tested.

Standards for each test performed (See Table 3A or appropriate manufacture's CBCT Table) - 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 back of this QA manuals. Forms other than those that appear in this manual 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.

TABLE 3A

Dental CBCT Alternate QA Program*				
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 QC Testing	Daily	As specified in TABLE 1A, Radiographic Quality Control Requirements	
3.	CT Number for Water	Daily	CBCT equipment or phantom manufacturer's specification*	
4.	Field Uniformity	Daily	CBCT equipment or phantom manufacturer's specification*	
5.	Laser Film Printer Quality Control	Weekly	As specified in TABLE 3, Computed Tomography Quality Control Requirements	
6.	Low Contrast Resolution	Initially & Annually	CBCT equipment or phantom manufacturer's specification*	
7.	High Contrast Spatial Resolution	Initially & Annually	CBCT equipment or phantom manufacturer's specification*	
8.	Noise	Initially & Annually	CBCT equipment or phantom manufacturer's specification*	
9.	Scan Localization Light Accuracy	Initially & Annually	+/- 5 mm	
10.	Medical Physicist's QC Survey	Initially & Annually	As Required in N. J. A. C. 7:28-22.10	
11.	Quality Assurance Program Review	Initially & Annually	As Required in N. J. A. C. 7:28-22.4(a)7	

*Where no performance standard is identified or expressed by the manufacturer, the certified medical physicist shall establish the standard for the facility's CBCT unit with justification. Manufacture specific Tables can be obtained at www.state.nj.us/dep/rpp/cbct_qa/index.htm.

SECTION 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

1. Only a New Jersey licensed dentist, registered dental hygienist, or licensed dental and diagnostic 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 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 or digital receptor during the exposure. **(N.J.A.C. 7:28-16.10(a)3)**
7. No person will order, instruct or otherwise allow a person under the age of 18 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 dental procedure, for training, or for equipment maintenance will be permitted in the x-ray room during an exposure. **(N.J.A.C. 7:28-16.10(a)1)**
3. Individuals who are present in the x-ray room during any exposure will wear protective aprons of at 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).**

1. 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)**.
2. 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

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 (0.50 millisieverts) 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 not behind a protective barrier during x-ray exposures will be 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. Lead shielding must also be used in accordance with NJ Board of Dentistry requirements.

**Policy for Orientation Program for Operators of Dental Cone Beam 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 THE DENTAL CBCT UNIT WILL RECEIVE. ALL NEW AND LICENSED DENTAL RADIOLOGIC TECHNOLOGISTS WHO PERFORM CBCT PROCEDURES WILL RECEIVE THE REQUIRED TRAINING AS OUTLINED ON THE LICENSED DENTAL RADIOLOGIC TECHNOLOGIST CBCT EXEMPTION FORM. A COPY OF THESE FORMS WILL BE PLACED IN THE QA MANUAL.

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 dental CBCT 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/laser printer/diagnostic workstation.

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. 7:28-16.10(a)6**.

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.
 - c. 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.

_____ I do not provide personnel monitoring equipment. The estimated workload is below the regulatory limits in **N.J.A.C. 7:28-16.10(a)6** 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/Digital images)

I will retain medical records for a period of 7 years for 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.

Additionally, the recording media will be stored in conditions that will ensure that deterioration does not occur for the record retention period. 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 or digital images. The above policy may be modified by the facility but the facility must ensure compliance with the appropriate regulations. Patient records must be maintained in accordance with NJ Board of Dentistry requirements.

Policy for Releasing Films/Digital Images

Upon request by, or on behalf of the patient, I will permanently or temporarily transfer the original films/digital images 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 a release form prepared by this office.

Guidance: The facility should develop a policy for the release of patient films/digital images 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 or if the films/digital images are to be returned.

Policy for Availability of Patient Films/Digital Images, 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. Closure of facility must comply with the New Jersey Board of Dentistry requirements.

Policy for Labeling Films/Digital Images

Each x-ray film/digital image 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/digital images. 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. 7:28-16.8 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 7:28-22.10(a) as appropriate for the type of x-ray equipment.

As with other types of dental 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 dental radiographic or CBCT equipment.

A certified medical physicist will perform a Medical Physicist QC Survey within 60 days of the installation of each newly installed CBCT equipment.

Guidance: The facility must develop a policy for the performance of a Radiation Survey of the Environs as required by N.J.A.C. 7:28-16.8.

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**). A Radiation Safety Manual can be found in the Forms section of this manual.

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 has been received. A Radiation Safety Manual can be found in the Forms Section of this manual. Employees should read and sign. The above policy is based on regulatory standards which is identified in **BOLD** print.

SECTION 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.

SECTION 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.	Records of QC Test Performed Table 3A – Items 2 – 11	Most Recent 1 year	
ii.	All images (film or digital) for Items 2, 3, 4 and 5	30 days	
iii.	All images (film or digital) for Items 6, 7 and 8	1 year	
iv.	Medical Physicists QC Survey Initial Current	Permanently Most Recent 2 years	
v.	Corrective Action Records	Most Recent 2 years	
vi.	Personnel Monitoring Records	10 years past the last date of employment for each employee	
vii.	QA Program Review	Most Recent 2 years	

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 Dentistry.

SECTION 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.

SECTION 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.

Quality Assurance Program Review Checklist

Has any of the following items in the manual changed during the past year?	√ if Updated	Date Manual Revised
Did the facility and physicist review the latest version of the Quality Assurance Manual?		
Is the list of clearly identified individuals and assigned responsibilities for maintaining the quality assurance program and for performing the quality control tests current?		
<p>Quality Control (QC) Measures</p> <p>Are QC Tests being performed at the frequency stated?</p> <p>Is the list of equipment to be tested current?</p> <p>Have the acceptability limits for each test changed?</p> <p>Are the descriptions for each QC test procedure current?</p> <p>Are the sample forms for each QC test current?</p> <p>Is this the most recent Annual Medical Physicist's QC Survey?</p>		
<p>Policies and Procedures</p> <p>Policy for holding patients and for presence of individuals in room during radiation exposure</p> <p>Policy for pregnant patients and employees</p> <p>Policy for gonadal shielding</p> <p>A description of the orientation program for operators of radiographic equipment including the duration and content of that program</p> <p>Procedures for proper use and maintenance of equipment</p> <p>Policies and employee responsibilities concerning personnel radiation monitoring</p> <p>Policy for releasing films/digital images</p> <p>Policy for labeling films/digital images (i.e., patient's statistics, facility information)</p> <p>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)</p> <p>Policy for using technique charts</p> <p>Policy and rules on Radiation Safety as required by N.J.A.C. 7:28-15.9(a)8</p>		
<p>Corrective actions</p> <p>A plan for repairing or calibrating the x-ray equipment</p> <p>A plan for repairing or servicing the processor/laser/printer/diagnostic workstation</p>		
<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>		

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 X-ray Compliance 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 X-ray Compliance 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 X-ray Compliance be notified in writing within 30 days of a change of any of the information on the Registration form.</p>		
<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 verify the license status of any individual by visiting our website at www.xray.nj.gov. Only a New Jersey licensed dentist, dentist, registered dental hygienist, or licensed dental or diagnostic radiologic technologist is permitted to operate any x-ray equipment and position patients for radiological procedures. For CBCT procedures, a licensed dental radiologic technologist must also meet the requirements in the December 2013 exemption.</p>		

Annual Medical Physicist's QC Survey

The following Medical Physicist's QC Survey Requirement Tables (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. 7:29-22.10. (See Table 6 in the rule). The facility must describe how the registrant and certified medical physicist will review the QA program annually.

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 3A

Dental CBCT Alternate QA Program*				
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 QC Testing	Daily	As specified in TABLE 1A, Radiographic Quality Control Requirements	
3.	CT Number for Water	Daily	CBCT equipment or phantom manufacturer's specification*	
4.	Field Uniformity	Daily	CBCT equipment or phantom manufacturer's specification*	
5.	Laser Film Printer Quality Control	Weekly	As specified in TABLE 3, Computed Tomography Quality Control Requirements	
6.	Low Contrast Resolution	Initially & Annually	CBCT equipment or phantom manufacturer's specification*	
7.	High Contrast Spatial Resolution	Initially & Annually	CBCT equipment or phantom manufacturer's specification*	
8.	Noise	Initially & Annually	CBCT equipment or phantom manufacturer's specification*	
9.	Scan Localization Light Accuracy	Initially & Annually	+/- 5 mm	
10.	Medical Physicist's QC Survey	Initially & Annually	As Required in N. J. A. C. 7:28-22.10	
11.	Quality Assurance Program Review	Initially & Annually	As Required in N. J. A. C. 7:28-22.4(a)7	

*Where no performance standard is identified or expressed by the manufacturer, the certified medical physicist shall establish the standard for the facility's CBCT unit with justification. Manufacture specific Tables can be obtained at www.state.nj.us/dep/rpp/cbct_qa/index.htm.

PROCESSOR/LASER PRINTER AND X-RAY EQUIPMENT

PROCESSOR/LASER PRINTER/DIAGNOSTIC WORKSTATION to be Tested:

Manufacturer _____ Model # _____

Serial # _____ Facility Designation _____

Location: _____

Dental CBCT X-RAY Equipment to be Tested:

Type of Equipment Registered with State of New Jersey/Bureau of X-ray Compliance:

Manufacturer _____ Model # _____

Serial # _____ Tube Serial # _____

NJ Registration # _____ Facility Designation _____

Dental CBCT X-RAY Equipment to be Tested:

Type of Equipment Registered with State of New Jersey/Bureau of X-ray Compliance:

Manufacturer _____ Model # _____

Serial # _____ Tube Serial # _____

NJ Registration # _____ Facility Designation _____

**Licensed Dental Radiologic Technologist
CBCT Exemption Form**

Licensed Dental Radiologic Technologist Information:

Name	
NJ X-ray License Number	

CBCT Unit Information:

Manufacturer	
Model	
NJDEP Registration Number	

Documentation of Completion of Initial training:

Option A: Training Provided by the CBCT Manufacturer

I, _____ certify that I provided manufacturer CBCT training that included scan protocol and equipment operation to technologist named above.

Manufacturer Trainer – Sign

Date

OR

Option B: Training Provided by a Licensed Dentist, Registered Dental Hygienist, or a Licensed Dental Radiologic Technologist

I, _____ certify that I provided manufacturer CBCT training that included scan protocol and equipment operation to the technologist named above. Proof of my CBCT training is attached.

I, _____ attest that the technologist named above has competently performed at least five CBCT procedures while under my direct supervision. Proof of my CBCT training is attached.

Signature of Supervisor

Date

The technologist named above is permitted to perform CBCT procedures provided that a licensed dentist who has been trained by the CBCT manufacturer in CBCT scan protocol and its operation is present and is immediately available to assist the licensed dental radiologic technologist, if needed.

Signature of Dentist

Date

Signature of Licensed Technologist

Date

Technique Chart

Position	Body part Thickness (cm)	mA(mAs)	kVp	Time	SID	Film Size	Film Screen Speed	Grid	Other

**ORIENTATION PROGRAM FOR OPERATORS OF DENTAL CONE BEAM 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 dental x-ray exams on human beings, other than a New Jersey licensed dentist or registered dental hygienist, will provide proof of current New Jersey State License Pursuant to N.J.A.C. 7:28-19. Verification of a license is recommended and can be made on-line at www.xray.nj.gov (Contact the Technologist Education and Licensing Section of the Bureau of X-ray Compliance for questions or licensing information, (609)984-5890).

Radiation Safety Manual

New Jersey Administrative Code (N.J.A.C.) 7:28-15 requires the registrant of x-ray equipment to develop written radiation safety rules and to ensure that these rules are read and followed by all operators of x-ray equipment. To assist facilities in complying with this radiation protection regulation, the Department of Environmental Protection has developed this sample Radiation Safety Manual

These guidelines have been developed to assist your office in the preparation of safety measures specific to your practice. You should include additional safety rules which are unique to your situation, equipment and office design.

RADIATION PERSONNEL SHALL OBSERVE THE FOLLOWING AT ALL TIMES:

- Only individuals required for the medical procedure, for training, or for equipment maintenance shall be in the x-ray room during an exposure.
- Only a New Jersey licensed dentist, registered hygienist or licensed dental or diagnostic radiologic technologist is permitted to operate x-ray equipment and position a patient for a dental radiographic procedure.
- Individuals who are present in the x-ray room during any exposure shall wear protective aprons of at least 0.25 mm lead equivalent during every exposure.
- When a patient must be provided with auxiliary support during a radiation exposure and mechanical holding devices are insufficient, the following procedures shall be followed:
 1. The person holding the patient shall be protected with a lead apron of at least 0.25 mm lead equivalent.
 2. The person holding the patient shall be protected with lead gloves of at least 0.25 mm lead equivalent if the hands must be placed in the useful beam.
 3. No licensed practitioner shall order or otherwise cause an individual who is licensed pursuant to N.J.S.A. 26:2D and this N.J.A.C. 7:28-19 to hold a patient during a radiation exposure, except in a life-threatening situation.
 4. No person shall be employed, routinely assigned, or required to hold a patient during x-ray procedures.
 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.
 6. No person other than the patient shall hold the image receptor during the exposure.
- Gonadal shielding of not less than 0.5 mm lead equivalent shall be used on a patient during radiographic procedures, except for cases in which this would interfere with the diagnostic procedure. If the patient is

sterile, the use of gonadal shielding may be omitted. Lead shielding must also comply with New Jersey Board of Dentistry requirements.

- The radiographic field shall be restricted to the area of clinical interest as far as practical.
- A method to observe the patient during the x-ray exposure shall be provided for all units.
- Observation of the patient shall be made from the shielded area.
- During radiographic exposures, the operator shall stand behind the protective barrier or shall wear protective apron as described above.
- No person shall permit or arrange for the intentional irradiation of a human being except for the purpose of diagnosis or treatment.
- Before an x-ray examination, operators shall ask female patients of child bearing age about the possibility of pregnancy. If the patient is unsure, the procedure should be delayed until the pregnancy status is confirmed.
- Signs should be placed in the waiting room and x-ray room reminding the patient to inform the doctor/technologist if they are pregnant.
- Pregnant radiation workers shall be provided with a personnel radiation monitoring device to assure the allowable limits to the fetus are not exceeded. There should be written policies regarding pregnant radiation workers.
- No person shall operate an ionizing-radiation-producing machine unless that person understands and uses the principles of radiation safety to keep radiation exposure **AS LOW AS REASONABLY ACHIEVABLE**.

The undersigned operator(s) acknowledge they have read the above safety manual:

Operator's Signature

Date

Operator's Signature

Date

Operator's Signature

Date

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?		
<p>Quality Control (QC) Measures</p> <p>Are QC Tests being performed at the frequency stated?</p> <p>Is the list of equipment to be tested current?</p> <p>Have the acceptability limits for each test changed?</p> <p>Are the descriptions for each QC test procedure current?</p> <p>Are the sample forms for each QC test current?</p> <p>Is this the most recent Annual Medical Physicist's QC Survey?</p>		
<p>Policies and Procedures</p> <p>Policy for holding patients and for presence of individuals in room during radiation exposure</p> <p>Policy for pregnant patients and employees</p> <p>Policy for gonadal shielding</p> <p>A description of the orientation program for operators of radiographic equipment including the duration and content of that program</p> <p>Procedures for proper use and maintenance of equipment</p> <p>Policies and employee responsibilities concerning personnel radiation monitoring</p> <p>Policy for releasing films/digital images</p> <p>Policy for labeling films/digital images (i.e., patient's statistics, facility information)</p> <p>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)</p> <p>Policy for using technique charts</p> <p>Policy and rules on Radiation Safety as required by N.J.A.C. 7:28-15.9(a) 8</p>		
<p>Corrective actions</p> <p>A plan for repairing or calibrating the x-ray equipment</p> <p>A plan for repairing or servicing the processor/laser/printer/diagnostic workstation</p>		
<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>		

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 X-ray Compliance 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 X-ray Compliance 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 X-ray Compliance be notified in writing within 30 days of a change of any of the information on the Registration form.</p>		
<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 verify the license status of any individual by visiting our website at www.xray.nj.gov. Only a New Jersey licensed dentist, dentist, registered dental hygienist, or licensed dental or diagnostic radiologic technologist is permitted to operate any x-ray equipment and position patients for radiological procedures. For CBCT procedures, a licensed dental radiologic technologist must also meet the requirements in the December 2013 exemption. “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, setting the technical factor, setting the x-ray tube distance to the image receptor, setting the size of the exposure field and making the x-ray exposure. “Position patients” means the movement or placement of the x-ray tube, or patient, or the image receptor to achieve an image of human anatomy.</p>		

**DAILY
DENTAL CBCT EQUIPMENT TESTS (Insert Results)**

DATE	PERSON RESPONSIBLE FOR TEST	EQUIPMENT FUNCTION (Pass/Fail)	CT NUMBER FOR WATER	FIELD UNIFORMITY	NOISE		

BIBLIOGRAPHY

- American Association of Physicists in Medicine, Report Number 39 Specification and Acceptance Testing of Computed Tomography Scanners, 1993
- American College of Radiology, *ACR Standard for Performance of Adult Dual Absorptometry*, 1998
- American College of Radiology, Committee on Quality Assurance in Mammography, *Mammography Quality Control Manual*, Revised, Edition, 1994 and 1998
- American College of Radiology, Committee on Barium Enema Quality Control, *Barium Enema Quality Control Manual*, 1998
- American College of Radiology, ACR Standard for Diagnostic Medical Physics Performance Monitoring of Radiographic and Fluoroscopic Equipment, 1997
- American Society of Radiologic Technologists; Processor Quality Control for Radiographers, Home Study Reference NM 904; Albuquerque; 1994
- Conference of Radiation Control Program Directors (CRCPD), Committee on Quality Assurance in Diagnostic X-ray (H-7). *Minimum Quality Control Recommendations for Diagnostic X-Ray Facilities (Draft)*, 1999
- Fitterman, Alan, Brayer, Franklin, and Cumbo, Peter, *Processing Chemistry for Medical Imaging*, Kodak Health Sciences Division, 1994
- Food and Drug Administration, Code of Federal Register, Food and Drugs 21, Parts 800 to 1299, April 1, 1999*
- Gray, Joel, et. al., *Quality Control in Diagnostic Imaging*, University Park Press, Baltimore, 1983.
- Haus, Arthur, *Screen-Film Image Receptors and Film Processing*, Kodak Health Sciences Division, 1994
- Haus, A., and Jaskulski, S, *Film Processing in Medical Imaging*, Medical Physics Publishing, Madison, 1997
- Konn, Terry, Program Director Radiologic Technology, Brookdale Community College, *Lecture given at NJSRT Conference*, 11/4/00
- National Conference on Radiation Protection and Measurements (NCRP), Report Number 99, *Quality Assurance for Diagnostic Imaging Equipment*, 1988
- National Conference on Radiation Protection and Measurements (NCRP), Report Number 105, *Radiation Protection for Medical and Allied Health Personnel*, 1989
- New York State Department of Health, *Guide for Radiation Safety/Quality Assurance Program*, 1991
- Widmer, John H., Lillie, Ronald F., Jaskulski, Susan M., and Haus Arthur G., *Identifying and Correcting Processing Artifacts*, Kodak Health Sciences Division, 1994
- Wilson, Russell L.; *Chiropractic Radiography and Quality Assurance Handbook*; CRC Press; New York; 2000

¹ Code of Federal Regulations 21 Part 1000.55