



State of New Jersey

CHRIS CHRISTIE
Governor

DEPARTMENT OF ENVIRONMENTAL PROTECTION
Division of Environmental Safety and Health
Bureau of X-Ray Compliance

BOB MARTIN
Commissioner

KIM GUADAGNO
Lt. Governor

PO Box 420, Mail Code 25-01, Trenton, NJ 08625-0420
Ph: (609) 984-5370 Fax: (609) 984-5811
www.xray.nj.gov

December 31, 2013

Dear Dental Cone Beam Computed Tomography (CBCT) Registrant:

The Bureau of X-ray Compliance (Bureau) received two requests from the New Jersey Dental Association (NJDA). The first request sought Department approval of an alternative quality assurance program for Dental CBCT units (N.J.A.C. 7:28-22.3(g)). The second sought an exemption to permit licensed dental radiologic technologists to perform radiographic procedures involving CBCT units (N.J.A.C. 7:28-19.4(e)). These requests were forwarded to the Commission on Radiation Protection (Commission) for consideration.

The following provides the background that lead to the requests considered by the Commission:

All x-ray equipment marketed for use on humans in the U.S. requires prior classification and approval from the Food and Drug Administration (FDA). Most x-ray equipment used in dental offices is classified by the FDA as dental x-ray equipment and as a result is subject to the Department's requirements under N.J.A.C. 7:28-16 "Dental Radiographic Installations". New equipment known as Dental Cone Beam Computed Tomography (CBCT) has been classified by the FDA as computed tomography (CT) equipment. Due to this classification, CBCT units are subject to the Quality Assurance (QA) regulations as required in N.J.A.C. 7:28-22.7 et seq.

The NJDA requested that the Department approve an alternate QA program for CBCT units based on the unique design compared to traditional Computed Tomography equipment. The alternate QA program seeks to eliminate the need to perform quality control (QC) test Items 9, Table Position Accuracy and 10, Scan Increment Accuracy from the current Table 3 for CBCT units. Due to the design of the dental CBCT unit, these two tests cannot be performed. Additionally, the NJDA requested that the frequency of Items 6 through 8 and Item 11 be changed from "initially and monthly" to "initially and annually." Lastly, NJDA requested that licensed dentists, dental hygienists and dental radiologic technologists be permitted to perform the tests or procedures required by items 1 through 5 in NJDA's Table 3A.

On a separate but related issue, the New Jersey State Board of Dentistry states that a licensed dentist and registered dental hygienist are permitted to operate CBCT units for dental purposes. However, pursuant to N.J.A.C. 7:28-19.4(e), licensed dental radiologic technologists are prohibited from operating any type of fluoroscopy, tomography or computed tomography equipment. Since the FDA classifies dental CBCT units as CT systems under 21CFR 892.1750, a licensed dental radiologic technologist is not permitted to operate a CBCT unit.

As part of its exemption request, NJDA stated that "absent an exemption there will be an unnecessary adverse impact upon the efficient delivery and cost of patient care in dental offices with no corresponding improvement of patient safety."

At its November 20, 2013 meeting, the Commission approved an Alternative QA program for CBCT units and the exemption that allows dental radiologic technologist to perform CBCT procedures with additional training.

The Department concurred with the Commission's recommendations and approved them effective December 3, 2013.

The enclosed letter summarizes the requirements that dental CBCT facilities must adhere to in order to operate dental CBCT units.

If you have any questions, please contact the Bureau at (609)984-5370.

Sincerely,

A handwritten signature in black ink that reads "Ramona V. Chambus". The signature is written in a cursive style with a large initial "R".

Ramona V. Chambus, Acting Chief
Bureau of X-ray Compliance

Enclosure



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BOB MARTIN
Commissioner

December 31, 2013

Dear Dental Cone Beam Computed Tomography (CBCT) Registrant:

This letter is in regards to the following two important decisions made by the Commission on Radiation Protection (Commission) at its November 20, 2013 meeting that affects all registered users of dental CBCT units.

A. The Commission approved a request made by the New Jersey Dental Association (NJDA) for the approval of an alternative quality assurance (QA) program for dental (CBCT) units and to permit dentists, dental hygienists and dental radiologic technologist to perform quality control tests items 1 through 5 in the attached Table 3A. Additionally, the Commission granted registrants of dental CBCT units six months to implement NJDA's alternative QA program. This approval includes all dental CBCT units classified by FDA as computed tomography units.

All dental CBCT facilities must implement the NJDA's alternative QA program by June 30, 2014 and adhere to the following conditions:

1. Ensure that the dental CBCT unit complies with all radiation protection regulations (registration, surveys and quality assurance).
2. Ensure that all tests listed in Table 3A are properly performed at the required frequencies.
3. Ensure that a New Jersey certified medical physicist is hired to perform the initial and annual Medical Physicist Computed Tomography QC survey.
4. Ensure that only appropriately credentialed and properly trained staff perform quality control test items 1 through 5 in Table 3A. All remaining items must be performed by the certified medical physicist during the initial and annual Medical Physicist Computed Tomography QC survey.
5. Ensure that all CBCT procedures performed on patients follow the established scan protocol (i.e., patient age, mA, kVp, field of view, etc.) as evaluated by a New Jersey certified medical physicist as part of the initial and on-going annual Medical Physicist Computed Tomography QC Survey.

B. The Commission also approved NJDA's request for an exemption from New Jersey Administrative Code (N.J.A.C.) 7:28-19.4(e) to allow licensed dental radiologic technologists to operate CBCT units provided that specific training and radiation safety precautions are followed. Dental CBCT units covered under this exemption include those designed similar to dental panoramic units. This exemption does NOT cover CBCT units that function similar to conventional head CT scanners, such as, the New Tom 5G, or fluoroscopic c-arm

units, such as, the MyRay SkyView unit.

Each Registrant that permits a licensed dental radiologic technologist to operate CBCT equipment and the licensed dental radiologic technologist shall:

1. Ensure that, prior to the first use of the CBCT unit by a licensed dental radiologic technologist, the technologist has been initially trained by the CBCT manufacturer in scan protocol and in the operation of the CBCT unit or trained by a licensed dentist, registered dental hygienist or licensed dental radiologic technologist who has been trained by the manufacturer in CBCT scan protocol and its operation. Training must be documented on the attached form, maintained in the facility file and made available upon the request of the Department.
2. Ensure that after initial training is completed, the licensed dental radiologic technologist competently performs a minimum of five (5) CBCT procedures under the direct supervision of a licensed dentist, registered dental hygienist or license dental radiologic technologist who has been trained in CBCT scan protocol and its operation. Direct Supervision requires the supervisor to be in the room with the operator to observe and supervise the procedure and post- procedure processing. Attestation of competency must be documented on the attached form, maintained in the facility file and made available upon the request of the Department.
3. Ensure that a licensed dentist who has been trained by the CBCT manufacturer in CBCT scan protocol and its operation is present in the office or department to provide supervision and assistance to the trained licensed dental radiologic technologist, if needed.
4. Ensure that if a trained licensed dental radiologic technologist should take a leave of absence for more than six months, prior to performing CBCT procedures, the technologist must repeat the competency training described in 2. above. Retraining should be documented using similar forms as above.
5. The exemption is not transferrable to another facility or to other CBCT dental units. If a licensed dental radiologic technologist should seek employment with a new employer, they must receive training and competency testing at the new facility. If the facility purchases a new CBCT unit of a different model, the dental radiologic technologist must receive training in the new device.

The Alternative QA Program Table 3A and the Licensed Dental Radiologic Technologist CBCT Exemption Form follows this letter. If you have any further questions regarding this matter, please contact our office at (609) 984-5370.

Sincerely,



Ramona V. Chambus, Acting Chief
Bureau of X-ray Compliance

TABLE 3 A - QC Requirements for Dental CBCT

Item	Required Test or Procedure	Frequency	Standard	Notes
1	Equipment Function: Indicators, Mechanical, & other Safety Checks	Daily	Must work properly	
2	Film Processing QC Testing	Daily	As specified in Table 1 Radiographic Quality Control Requirements	If Present
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 QC	Weekly	As specified in Table 3 Computed Tomography Quality Control Requirements	If Present
6	Low Contrast Resolution	Initial & Annually	CBCT Equipment or Phantom manufacturer's specification*	
7	High Contrast Resolution	Initial & Annually	CBCT Equipment or Phantom manufacturer's specification*	
8	Noise	Initial & Annually	CBCT Equipment or Phantom manufacturer's specification*	
9	Scan Localization Light Accuracy	Initial & Annually	(+/-5MM)	
10	Medical Physicist's QC Survey	Initial & Annually	As required in NJAC 7:28-22.10	
11	Quality Assurance Program Review	Initial & Annually	As required in NJAC 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.

**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.

Trainer – Sign

Date

Documentation of Completion – Competency Training in CBCT under Direct Supervision:

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

Supervision Policy:

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