TEXAS DEPARTMENT OF STATE HEALTH SERVICES

Questions and Answers

25 Texas Administrative Code

§289.227

Use of Radiation Machines in the Healing Arts

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(Revised January 13, 2015)

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(Revised January 13, 2015)

I. Rule Implementation Timeline

1. Will there be a grace period from the date the rule is effective and the time to begin implementing the new rule?

The rule is final, *but* the effective date of the rule is May 1, 2013, allowing registrants approximately 2 months to implement the rule (Registrants were emailed notice of the Final rule on March 1, 2013.)

NOTE: The current 25 Texas Administrative Code, §289.227, Use of Radiation Machines in the Healing Arts, with an effective date of September 1, 2004, is still in effect until May 1, 2013.

2. How can I receive notification of final radiation rules?

Subscribe to the FREE DSHS email rule notification system at:

http://www.dshs.state.tx.us/radiation/Sign-up-for-Email-Updates/

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II. Radiation Protocol Committee Requirements for Fluoroscopically-Guided Interventional Procedures *Ref §289.227(m)(9)*

Determining a Fluoroscopically-Guided Interventional Procedure
Ref. §289.227(e)(36) and (m)(9)

1. What is the definition of fluoroscopically-guided interventional procedures?

Fluoroscopically-guided interventional procedures are interventional diagnostic or therapeutic procedures performed via percutaneous or other access routes, usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion, diagnostic site, or treatment site, to monitor the procedure, and to control and document therapy. Fluoroscopically-guided interventional procedures may include but not be limited to:

(A) TIPS creation (transjugular intrahepatic portosystemic shunt);
(B) Embolization (any location, any lesion);
(C) Stroke therapy;
(D) Biliary drainage;
(E) Angioplasty with or without stent placement;
(F) Stent-graft placement;
(G) Chemoembolization;
(H) Angiography and intervention for gastrointestinal hemorrhage;
(I) Carotid stent placement;
(J) RF (radiofrequency) cardiac ablation;
(K) Complex placement of cardiac EP (electrophysiology) devices; and
(L) PCI (percutaneous coronary intervention) (single or multiple vessel).

2. Are pain clinics required to comply with the rule regarding fluoroscopically-guided interventional procedures?

Yes, any facility that performs fluoroscopically-guided interventional procedures, as defined in 289.227(e)(36), shall comply with §289.227. The list of fluoroscopically-guided interventional procedures included in the definition of §289.227(e)(36) is not an all-inclusive list.

3. Will the definition for fluoroscopically-guided interventional procedures be expanded to list additional procedures that could be considered interventional procedures?

No. The list provided in rule is not all-inclusive. Members of the radiation protocol committee shall establish what fluoroscopically-guided interventional procedures are performed based on the definition.

4. Is a fluoroscopically-guided interventional radiation protocol committee required if we perform interventional procedures using only a C-Arm?

Yes.

Development of a Radiation Protocol Committee

Ref. §289.227(m)(9)(A)

1. **What if competition between clinics makes it difficult to form a joint radiation protocol committee?** *Ref. §289.227(m)(9)(A)*

   All registrants performing fluoroscopically-guided interventional procedures are required to establish a radiation protocol committee.

2. **Are there exemptions for rural and critical access facilities regarding the new radiation protocol committee for fluoroscopically-guided interventional procedures rule requirements?** *Ref §289.227(m)(9)(A)*

   No. The rule does not allow any exemptions for compliance of the radiation protocol committee requirements. However, the rule does include a provision that one or more registrants may form a cooperative radiation protocol committee as long as each participating facility has a representative member on the committee.

3. **Can one radiation protocol committee be established if the registrant has multiple sites?** *Ref. §289.227(m)(9)(A)(i)(I)*

   Yes.

4. **What if a pain clinic does not have people that would meet the radiation protocol committee member requirements?** *Ref. §289.227(m)(9)(A)(i)(II)*

   The rule includes a provision that one or more registrants may form a cooperative radiation protocol committee as long as each participating facility has a representative member on the committee.

5. **May several different facilities form one committee?** *Ref. §289.227(m)(9)(A)(i)(II)*

   Yes. A radiation protocol committee may be coordinated with members from various facilities. The cooperative radiation protocol committee could function for several different hospitals or clinics as long as each participating facility has a representative member on the committee.

6. **If we form a cooperative committee with other rural facilities in our area, how do we decide which licensed medical physicist and licensed physician to place on this committee? Each of the potential facilities for this cooperative committee use different physicist groups and physicians.** *Ref §289.227(m)(9)(A)(i)(II)*

   The cooperative facilities determine the membership of the radiation protocol committee and therefore determine which licensed medical physicist and licensed physician will serve on the committee. Each facility shall have a representative member on the committee.

7. **If there is a radiation safety committee already established at the facility, is it necessary to form another committee?** *Ref. §289.227(m)(9)(A)(i)(III)*

   No. The current committee may assume the additional responsibilities as long as the minimum member requirement is achieved.

8. Does the radiation protocol committee's first meeting have to be held by 05/01/2013 or just the committee established by 05/01/2013? *§289.227(m)(9)(A)(i)(IV)*

The radiation protocol committee should be established by May 1, 2013. Although, the rule allows up to 14 months for the committee to officially meet and conduct business, the initial meeting can occur earlier. The date of the initial meeting will then establish the timeframe for the subsequent 14 month meeting.

9. Do the radiation protocol committee meetings have to be face-to-face (in person) or may they be conducted by teleconference? *§289.227(m)(9)(A)(i)(IV)*

The intent of the rule is that the required members of the radiation protocol committee meet together in person, ideally when the licensed medical physicist is on site to perform the required radiation machine testing, not to exceed 14 months. However, circumstances may dictate that meetings be held by video-conferencing or teleconferencing. Communication by facsimile only or email only does not satisfy the meeting requirements of this rule.

10. My equipment undergoes annual checks by a medical physicist; can my radiation protocol committee meeting correspond with this check? *Ref. §289.227(m)(9)(A)(i)(IV)*

Yes. The radiation protocol committee should be established by May 1, 2013. Although, the rule allows up to 14 months for the committee to officially meet and conduct business; the initial meeting can occur earlier. The date of the initial meeting will then establish the timeframe for the subsequent 14 month meeting.

11. Can the interim meetings of the radiation protocol committee be held by electronic means? *Ref. §289.227(m)(9)(A)(i)(V)*

Yes. Interim meetings may occur as needed with communication permitted by facsimile, email, or teleconference. A record of the meetings shall be maintained that includes the date, names of individuals in attendance, minutes of the meeting and any actions taken.

12. Is documentation of the radiation protocol committee meetings required to be submitted to the Radiation Control Program (Agency)? *Ref. §289.227(m)(9)(A)(ii)*

No. Section 289.227(m)(9)(A)(ii), requires a record to be made of each radiation protocol committee meeting to include the date, names of individuals in attendance, minutes of the meeting, and any action taken. The registrant keeps the records of the meetings for 5 years for inspection by the Agency.

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Members Required for the Radiation Protocol Committee

Ref §289.227(m)(9)(B)

1. Who is required to be on a radiation protocol committee for fluoroscopically-guided interventional procedures?

Required members of the radiation protocol committee for fluoroscopically-guided interventional procedures:

- a licensed physician that meets the training requirements identified in §289.227(m)(9)(E);
- a licensed medical physicist;
- the radiation safety officer; and
- other individuals as deemed necessary by the registrant.

2. Can one individual serve as multiple members on the radiation protocol committee?

Yes.

Fluoroscopy Protocols

Ref §289.227(m)(9)(C)

What are examples of protocols for fluoroscopically-guided interventional procedures?
Ref. §289.227(m)(9)(C)(i)

Protocols for fluoroscopically-guided interventional procedures shall include, but are not limited to:

- A restriction of the use of fluoroscopic systems for interventional purposes to radiologists, radiation oncologist, physicians, and individuals to whom a physician has delegated authority pursuant to the Occupations Code, Chapter 601, and the applicable rules of the Texas Medical Board, who have completed the radiation safety awareness training required by this rule.
- A method to be used to monitor radiation exposure.
- A recommended reference level for fluoroscopically-guided interventional procedures performed.
- Actions to be taken for cases when the reference level is exceeded which may include patient follow-up.
- A review of established protocols at intervals not to exceed 14 months.

If the radiation protocol committee revises a protocol, the registrant shall maintain the previous documentation for inspection by the Agency for 5 years. *Ref §289.227(m)(9)(C)(ii)*

Reference Levels for Fluoroscopically-Guided Interventional Procedures

Ref 289.227(m)(9)(C)(i)(II)

1. Will the Agency establish dose limits or reference levels?

No.

2. Is the purpose of reference levels to establish maximum or minimum dose limits?
Ref. §289.227(e)(76)

The purpose of the reference level is to provide a benchmark for comparison of imaging equipment performance under prescribed conditions and is not intended to define a maximum or minimum exposure limit for any patient or procedure. It should also be used to determine what actions should be taken for cases when the reference level is exceeded, which may include patient follow-up.

3. Are there established reference levels to use as a guide?

No. Establishing dose limits or reference levels for fluoroscopically-guided interventional procedures is the responsibility of the members of the radiation protocol committee. In addition to consulting the licensed medical physicist on your radiation protocol committee, there are several resources via the internet that can be used to assist in determining a reference level. The Agency does not recommend one over another.

Procedures for Maintaining Records

Ref. §289.227(m)(9)(D)

1. What records are to be maintained for fluoroscopically-guided interventional procedures?

The registrant shall make and maintain a record of the radiation output information so the radiation dose to the skin may be estimated in accordance with established protocols. The record shall include the following:

- patient identification;
- type and date of examination;
- identification of the fluoroscopic system used; and
- cumulative air kerma or dose area product used if the information is available on the fluoroscopic system.

If the cumulative air kerma or dose area product is not displayed on the fluoroscopic system, records shall include other information necessary to estimate the radiation dose to the skin in accordance with established protocol or the following as necessary:

- fluoroscopic mode, such as, high-level or pulsed mode of operation;
- cumulative fluoroscopic exposure time; and
- number of films or recorded exposures.

The registrant shall maintain records in accordance with the record retention policies of the facility. *Ref §289.227(m)(9)(D)(iii)*

2. Who should establish procedures for recording the radiation output/air kerma?

The radiation protocol committee shall develop procedures for maintaining records. The procedure shall establish a method to make and maintain a record of the radiation output information so the radiation dose to the skin may be estimated in accordance with the established protocols.

Procedures for Maintaining Records (Contd)

Ref. §289.227(m)(9)(D)

3. Is it necessary to estimate the radiation dose to the patient for each fluoroscopically-guided interventional or computed tomography procedure?

No. The actual dose to the patient does not need to be calculated for each procedure. However, the registrant shall make and maintain a record of the radiation output information and use the data to estimate the radiation dose to the skin if necessary.

Radiation Safety Awareness Training

Ref §289.227(m)(9)(E)

The Texas Department of State Health Services will delay the implementation of the radiation safety awareness training indefinitely. The department is considering additional information relating to this requirement that may impact the department's enforcement of the rule. During this time period, registrants and users of fluoroscopy equipment will not be required to meet the state training requirements set forth in the rule (25 Texas Administrative Code, Section 289.227(m)(9)(E)). In addition to delaying the implementation, the department will evaluate modification of the training requirements particularly as they relate to physicians.

If you have any questions about this information, please contact Chuck Flynn at 512-834-6770, ext. 2821 or chuck.flynn@dshs.state.tx.us

View the DSHS letter sent to Registrants and other interested parties at:
www.dshs.state.tx.us/radiation

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III. Radiation Protocol Committee Requirements for Computed Tomography Procedures *Ref §289.227(n)(6)*

Determining if a Computed Tomography Radiation Protocol Committee is Required
Ref. §289.227(n)(6)

1. Is a radiation protocol committee for computed tomography systems required for the computed tomography (CT) machine on a PET/CT? *Ref §289.227(n)(6)(A)*

Yes, a radiation protocol committee is required for a PET/CT, since the computed tomography machine delivers a dose to the patient while producing a diagnostic image.

2. Is a computed tomography radiation protocol committee required if we perform interventional procedures using computed tomography fluoroscopy?
Ref §289.227(n)(6)(A)

Yes. Computed tomography fluoroscopy has become a useful tool for physicians performing interventional procedures. The anomaly in the patient is located with conventional computed tomography imaging, and then the physician uses computed tomography fluoroscopy to track the position of a biopsy needle. Simple biopsies require only a few seconds of computed tomography fluoroscopy on-time, but during more complicated procedures, the physician and patient may be exposed to five minutes or more of radiation exposure.

3. Are oncology facilities using computed tomography for simulation only required to establish a computed tomography radiation protocol committee? *Ref: §289.229(h)(4)(D)*

No. If the computed tomography system is used for simulation of radiation therapy procedures only, the facility shall meet the requirements of §289.229(h)(4)(D) for radiation therapy simulators utilizing computed tomography capabilities.

Development of a Radiation Protocol Committee
Ref §289.227(n)(6)(A)

1. What if competition between clinics makes it difficult to form a joint radiation protocol committee? *Ref. §289.227(n)(6)(A)*

All registrants performing computed tomography are required to establish a radiation protocol committee.

2. Are there exemptions for rural and critical access facilities regarding the new computed tomography radiation protocol committee rule requirements?
Ref §289.227(n)(6)(A)

No. The rule does not allow any exemptions for compliance of the radiation protocol committee requirements. However, the rule does include a provision that one or more registrants may form a cooperative radiation protocol committee as long as each facility has a representative member on the committee.

3. Can one radiation protocol committee be established if the registrant has multiple sites? *Ref. §289.227(n)(6)(A)(i)(I)*

Yes. If the facility has multiple sites, a system-wide radiation protocol committee may be established.

4. What if a computed tomography facility does not have people that would meet the radiation protocol committee member requirements? *Ref. §289.227(n)(6)(A)(i)(II)*

The rule includes a provision that one or more registrants may form a cooperative radiation protocol committee as long as each participating facility has a representative member on the committee.

5. May several different facilities form one committee? *Ref. §289.227(n)(6)(A)(i)(II)*

Yes. A radiation protocol committee may be coordinated with members from various facilities. The cooperative radiation protocol committee could function for several different hospitals or clinics as long as each participating facility has a representative member on the committee.

6. If we form a cooperative committee with other rural facilities in our area, how do we decide which licensed medical physicist and radiologist to place on this committee? Each of the potential facilities for this cooperative committee use different physicist groups and radiologist groups. *Ref §289.227(n)(6)(A)(i)(II)*

The cooperative facilities determine the membership of the radiation protocol committee and therefore determine which licensed medical physicist and radiologist will serve on the committee. Each facility shall have a representative member on the committee.

7. If there is a radiation safety committee already established at the facility, is it necessary to form another committee? *Ref. §289.227(n)(6)(A)(i)(III)*

No. The current committee may assume the additional responsibilities as long as the minimum member requirement is achieved.

8. Does the computed tomography radiation protocol committee's first meeting have to be held by 05/01/2013 or just the committee established by 05/01/2013?
§289.227(n)(6)(A)(i)(IV)

The radiation protocol committee should be established by May 1, 2013. Although, the rule allows up to 14 months for the committee to officially meet and conduct business, the initial meeting can occur earlier. The date of the initial meeting will then establish the timeframe for the subsequent 14 month meeting.

Development of a Radiation Protocol Committee (Contd)

Ref §289.227(n)(6)(A)

9. Do the radiation protocol committee meetings have to be face-to-face (in person) or may they be conducted by teleconference? *§289.227(n)(6)(A)(i)(IV)*

The intent of the rule is that the required members of the radiation protocol committee meet together in person, ideally when the licensed medical physicist is on site to perform the required radiation machine testing, not to exceed 14 months. However, circumstances may dictate that meetings be held by video-conferencing or teleconferencing. Communication by facsimile only or email only does not satisfy the meeting requirements of this rule.

10. My equipment undergoes annual checks by a medical physicist; can my radiation protocol committee meeting correspond with this check? *Ref. §289.227(n)(6)(A)(i)(IV)*

Yes. The radiation protocol committee should be established by May 1, 2013. Although, the rule allows up to 14 months for the committee to officially meet and conduct business; the initial meeting can occur earlier. The date of the initial meeting will then establish the timeframe for the subsequent 14 month meeting.

11. Can the interim meetings of the radiation protocol committee be held by electronic means? *Ref. §289.227(n)(6)(A)(i)(IV-V)*

Yes. Interim meetings may occur as needed with communication permitted by facsimile, email, or teleconference. A record of the meetings shall be maintained that includes the date, names of individuals in attendance, minutes of the meeting and any actions taken.

12. Is documentation of the radiation protocol committee meetings required to be submitted to the Radiation Control Program (Agency)? *Ref. §289.227(n)(6)(A)(ii)*

No. Section 289.227(n)(6)(A)(ii), requires a record to be made of each radiation protocol committee meeting to include the date, names of individuals in attendance, minutes of the meeting, and any action taken. The registrant keeps the records of the meetings for 5 years for inspection by the Agency.

Members Required for the Radiation Protocol Committee

Ref §289.227(n)(6)(B)

1. Who is required to be on a radiation protocol committee for computed tomography procedures? *Ref. §289.227(n)(6)(B)*

Required members of the radiation protocol committee for computed tomography procedures:

- radiologist or radiation oncologist;
- a licensed medical physicist;
- the radiation safety officer; and
- other individuals as deemed necessary by the registrant.

Members Required for the Radiation Protocol Committee (Contd)

Ref §289.227(n)(6)(B)

2. Does the radiologist on the computed tomography committee have to be an interpreting radiologist at our facility? Or, can an independent radiologist be acquired for this committee? *Ref. §289.227(n)(6)(B)(i)*

No. The radiologist on the computed tomography radiation protocol committee may be either an interpreting radiologist at your facility or an independent radiologist who is not associated with your facility.

3. If the RSO is a physician, can this individual serve as two of the members of the computed tomography radiation protocol committee? *Ref §289.227(n)(6)(B)*

No. Other than the radiologist or radiation oncologist, the computed tomography radiation protocol committee is not required to include a licensed physician. Therefore, the licensed physician can only serve as the RSO or other individual as deemed necessary by the registrant.

4. Can the x-ray tech serve as the "other individual" member of the radiation protocol committee? *Ref §289.227(n)(6)(B)(iv)*

It is up to the registrant to determine who the "other individuals" will be to meet the radiation protocol committee member requirement.

5. I represent the RSO and report directly to him. Is my ARRT, (R)(CT) certification sufficient to meet the requirement to serve as the RSO on the radiation protocol committee? *Ref §289.227(n)(6)(B)(iv)*

No. You may not serve as the RSO on the radiation protocol committee since you have not been authorized as the RSO on the facility's certificate of registration, per 25 TAC §289.226(e)(2). However, you could serve on the radiation protocol committee as "other individuals as deemed necessary by the registrant."

Computed Tomography Protocols

Ref §289.227(n)(6)(C)

1. What are examples of protocols for computed tomography procedures? *Ref. §289.227(n)(6)(C)(i)*

The protocols for computed tomography procedures shall include, but are not limited to:

- A method to be used to monitor the radiation output.
- A recommended reference level for computed tomography procedures performed.
- Actions to be taken for cases when the reference level is exceeded which may include patient follow-up.
- A review of established protocols at an interval not to exceed 14 months.

If the radiation protocol committee revises a protocol, the registrant shall maintain the previous documentation for inspection by the Agency for 5 years. *Ref §289.227(n)(6)(C)(ii)*

Computed Tomography Protocols (Contd)

Ref §289.227(n)(6)(C)

2. Do protocols have to be established for all computed tomography protocols or just the most common protocols? *Ref. §289.227(n)(6)(C)(i)*

Yes. All computed tomography exams performed shall have a protocol established.

3. If we have a cooperative radiation protocol committee, do we design uniform protocols when each of us use different size computed tomography scanners ranging from single-slice to 64-slice technology? *Ref §289.227(n)(6)(C)(i)*

The cooperative radiation protocol committee is required to develop protocols unique to each computed tomography machine and the procedures performed. The actions taken when a reference level is exceeded and a review process could easily be identical for each machine included in the cooperative. But the method of monitoring radiation output and the reference level is greatly influenced by the machine. The radiation protocol committee is expected to use the knowledge base of the committee members to establish a means of monitoring radiation output for each computed tomography machine and set the reference level for each procedure, based on the capabilities and features of the machine.

Reference Levels for Computed Tomography Procedures

Ref §289.227(n)(6)(C)(i)(II)

1. Will the Agency establish dose limits or reference levels? *Ref §289.227(n)(6)(C)(i)(II)*

No.

2. Is the purpose of reference levels to establish maximum or minimum dose limits? *Ref. §289.227(e)(76)*

The purpose of the reference level is to provide a benchmark for comparison of imaging equipment performance under prescribed conditions and is not intended to define a maximum or minimum exposure limit for any patient or procedure. It should also be used to determine what actions should be taken for cases when the reference level is exceeded, which may include patient follow-up.

3. Are there established reference levels to use as a guide?

No. Establishing dose limits or reference levels for computed tomography procedures is the responsibility of the members of the radiation protocol committee. In addition to consulting the licensed medical physicist on your radiation protocol committee, there are several resources via the internet that can be used to assist in determining a reference level. The Agency does not recommend one over another.

Reference Levels for Computed Tomography Procedures (Contd)

Ref §289.227(n)(6)(C)(i)(II)

4. How do we establish a reference level for computed tomography units that do not have a method of determining dose during a patient exam? *Ref. §289.227(n)(6)(D)*

If the system is not capable of displaying output information during the patient exam, document the parameters that are available. In addition to consulting the licensed medical physicist on your radiation protocol committee, there are several resources via the internet that can be used to assist in determining a reference level.

5. We can create reference levels based on comparison techniques, but our computed tomography unit operates in an "Automatic" or "Automatic Brightness Control" mode. The system automatically adjusts the dose based on the size of the patient. How can we determine if the reference levels are exceeded without additional dose information per patient? *Ref. §289.227(n)(6)(D)*

The licensed medical physicist on your radiation protocol committee should be consulted in determining what additional factors can be utilized to determine a reference level.

Procedures for Maintaining Records

Ref §289.227(n)(6)(D)

1. What radiation output records are to be included for computed tomography systems? *Ref. §289.227(n)(6)(D)*

The registrant shall make and maintain a record of the radiation output information so the radiation dose to the skin may be estimated in accordance with established protocols. The record shall include the following:

- patient identification;
- type and date of examination;
- identification of the computed tomography system used; and
- if the computed tomography system is capable of calculating and displaying these values
  - CTDI $_{vol,}$;
  - DLP; or
  - recommendations as identified in "Comprehensive Methodology for the Evaluation of Radiation Dose in X-ray Computed Tomography. Report of American Association of Physicists in Medicine, Task Group 111; The Future of CT Dosimetry, February 2010," may be used to meet compliance actions as identified in “Comprehensive methodology for the Evaluation of Radiation Dose in x-Ray Computed Tomography. Report of the American Association of Physicists in Medicine, Task Group111; The Future of CT Dosimetry, February 2010,” may be used to meet compliance.

2. Who should establish procedures for recording the radiation output/air kerma? *Ref. §289.227(n)(6)(D)*

The radiation protocol committee shall develop procedures for maintaining records. The procedure shall establish a method to make and maintain a record of the radiation output information so the radiation dose to the skin may be estimated in accordance with the established protocols.

3. Is it necessary to estimate the radiation dose to the patient for each computed tomography procedure? *Ref. §289.227(n)(6)(D)*

No. The actual dose to the patient does not need to be calculated for each procedure. However, the registrant shall make and maintain a record of the radiation output information and use the data to estimate the radiation dose to the skin if necessary.

4. Does any kind of procedure, diagnostic or invasive, performed under computed tomography need to have a record of the amount of radiation output by patient? *Ref. §289.227(n)(6)(D)*

Yes, specifically §289.227(n)(6)(D) outlines the patient record information.

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IV. General/Miscellaneous

MRT Credentialing

1. What is the rule for who can operate a C-arm for interventional type procedures as long as the physician is controlling the fluoroscopic machine pedal? Can a scrub tech just manipulate and maneuver the C-arm? What about a registered nurse?

For credentialing requirements and interpretation of the rules for Medical Radiologic Technologists (25 Texas Administrative Code, Chapter 140. Health Professions Regulation), please contact Ann Hammer, Program Director, with the Dept. of State Health Services, Professional Licensing and Certification Unit, at Ann.Hammer@dshs.state.tx.us or (512) 834-6730.

2. Are registered nurses, physician assistants, nurse practitioners, or registered radiologic technologists permitted to perform fluoroscopically-guided interventional procedures? *Ref. §289.227(m)(9)(C)(i)(I)*

The rule restricts the use of fluoroscopic systems for fluoroscopically-guided interventional procedures to the radiologist, radiation oncologist, or physicians that have completed the required radiation safety awareness training, as well as individuals delegated by the physician in accordance with Occupations Code, Chapter 601, and the applicable rules of the Texas Medical Board who have completed the radiation safety awareness training.

Equipment Performance Evaluations

1. Do the new §289.227 equipment performance evaluation requirements also apply to dental computed tomography radiation machines? *Ref §289.227(o)*

No. Cone beam computed tomography equipment used in a dental practice is held to the dental rules of 25 TAC §289.232. Since the equipment is registered for dental use, the equipment performance evaluation for dental cone beam computed tomography shall be performed every 4 years.

To clarify, if a cone beam computed tomography unit is registered to a medical facility other than a dental office then the equipment performance evaluation shall be performed in accordance with §289.227(o).

2. When do we have to begin complying with the rule that requires the equipment performance evaluation testing within 30 days from installation of radiation machines? *Ref §289.227(o)(2)*

This requirement applies to radiation machines installed on or after May 1, 2013. Previously, the Agency accepted the FDA Form 2579 report of assembly form in lieu of the initial equipment performance evaluation report. However, these forms (which provide the date of radiation machine installation) will no longer satisfy the rule requirement to demonstrate that the initial equipment performance evaluation was performed within 30 days of installation.

Notification of Radiation Machine Installation

Will the FDA Form 2579 report of assembly form still be accepted by the Agency as notification of radiation machine installation?

Yes, if the certificate of registration number is added to the FDA Form 2579. However, the FDA Form 2579 is no longer acceptable documentation of the initial equipment performance evaluation.