TEXAS DEPARTMENT OF STATE HEALTH SERVICES

Questions and Answers
Radiation Protocol Committee Requirements for
Fluoroscopically-Guided Interventional and Computed Tomography Procedures
in 25 Texas Administrative Code, §289.227
(relating to Use of Radiation Machines in the Healing Arts)
March 1, 2013

Will there be a grace period from the date the rule is effective and the time to begin radiation output tracking for fluoroscopically-guided interventional procedures?

The rule is final, *but* the effective date of the rule is May 1, 2013, allowing registrants approximately 2 months to implement the rule.

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.

Who is required to be on a radiation protocol committee?
Ref. §289.227(m)(9)(B) and (n)(6)(B)

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.

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.

NOTE: For private office facilities, the licensed physician and the RSO may be the same individual.

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) and (n)(6)(A)(i)(III)

The current committee may assume the additional responsibilities as long as the minimum member requirement is achieved.

Can one radiation protocol committee be established if the registrant has multiple sites?
Ref. §289.227(m)(9)(A)(i)(I) and (n)(6)(A)(i)(I)

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

May several different facilities form one committee?
Ref. §289.227(m)(9)(A)(i)(II) and (n)(6)(A)(i)(II)

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 member on the committee.

Can the interim meetings of the radiation protocol committee be held by electronic means?
Ref. §289.227(m)(9)(A)(i)(IV-V) and (n)(6)(A)(IV-V)

The radiation protocol committee shall meet in person, at an interval not to exceed 14 months. 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.

What is the definition of fluoroscopically-guided interventional procedures?
Ref. §289.227(e)(36)

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).

Will the definition for fluoroscopically-guided interventional procedures be expanded to list additional procedures that could be considered interventional procedures?
Ref. §289.227(e)(36)(A-L)

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.

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

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 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.

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

If the computed tomography system is used for simulation of radiation therapy procedures, the facility shall meet the requirements of §289.229(h)(4)(D) for radiation therapy simulators utilizing computed tomography capabilities.

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

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.

Who should establish procedures for recording the radiation output/air kerma?
Ref. §289.227(m)(9)(D) and (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.

Is it necessary to estimate the radiation dose to the patient for each fluoroscopically-guided interventional or computed tomography procedure?
Ref. §289.227(m)(9)(D) and (n)(6)(D)

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.

What records are to be maintained for fluoroscopically-guided interventional procedures?
Ref. §289.227(m)(9)(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 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 for in accordance with the record retention policies of the facility.

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.

Will the Agency establish dose limits or reference levels?

Establishing dose limits or reference levels for fluoroscopically-guided interventional and computed tomography procedures is the responsibility of the members of the radiation protocol committee.

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.

Are there established reference levels to use as a guide?

There are several resources that can be used and the radiation protocol committee should determine the guidance to use. The Agency does not recommend one over another.

Are pain clinics required to comply with the rule regarding fluoroscopically-guided interventional procedures?
Ref. §289.227(m)(9)

If fluoroscopically-guided interventional procedures are performed, a radiation protocol committee for fluoroscopically-guided interventional procedures is required.

Are pain clinics that perform fluoroscopically-guided interventional procedures required to comply with the physician radiation safety awareness training?
Ref. §289.227(m)(9)(E)

If fluoroscopically-guided interventional procedures are performed, the radiation safety awareness training for physicians is required.

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 facility has a representative on the committee.

What if competition between clinics makes it difficult to form a joint radiation protocol committee?
Ref. §289.227(m)(9) and (n)(6)

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

Can the radiation protocol committee limit privileges to individuals performing fluoroscopically-guided interventional procedures?

Privileges should be limited to those individuals who have completed the training required in §289.227(m)(9)(E)(iii-iv). Physicians other than radiologists and radiation oncologists, as well as individuals to whom a physician has delegated authority pursuant to the Occupations Code, Chapter 601, and applicable rules of the Texas Medical Board, will be required to complete the radiation safety awareness training.

Who is qualified to provide the required continuing medical education training?

Any organization, individual or group can provide the training if the curriculum has been reviewed and certified as Category 1 Continuing Medical Education. The Category 1 designation may be obtained from the Accreditation Council for Continuing Medical Education, the American Osteopathic Association, a state medical society, or an equivalent organization.

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.

Are registered nurses, physician assistants, nurse practitioners and medical radiologic technologist that perform interventional procedures under the supervision of a physician required to complete the 8 hours continuing medical education radiation safety awareness and the 1 hour fluoroscopic machine training?
Ref. §289.227(m)(9)(E)(i)

Physician assistants and registered nurses will be required to complete the 8 hours of Category 1 continuing medical education radiation safety awareness training and the 1 hour fluoroscopic machine training.

An individual who is registered with the American Registry of Radiologic Technologists has completed extensive radiation safety training that meets the requirement in §289.227(m)(9)(E)(i). A medical radiologic technologist who has passed the American Registry of Radiologic Technologists registry and holds a certified medical radiologic technologist license with the Medical Radiologic Technologist Certification Program is not required to complete radiation safety awareness training.

Is a test required to complete the required radiation safety awareness training?

The providers of the training are required to have a method for evaluating the level of competence of the student's performance. This may include a written test.

When does the radiation safety awareness training need to be completed?
Ref. §289.227(m)(9)(E)(iii-iv)

Physicians, or individuals delegated by the physician, currently have two years to complete the training from the time rule becomes effective May 1, 2013. After May 1, 2015, physicians, or individuals delegated by the physician, who intend to perform fluoroscopically-guided interventional procedures shall complete the radiation safety awareness training prior to performing fluoroscopically-guided interventional procedures.

Will it be necessary for the individuals to complete periodic refresher courses in fluoroscopically-guided interventional procedures?

Refresher training is not required by rule. However, criteria for maintaining clinical privileges and completion of periodic refresher training can be determined by the facility's radiation protocol committee.

Is the radiation safety awareness training required to be provided at approved locations?
Ref. §289.227(m)(9)(E)(iv)

No, the Department will not approve training curriculum or training sites. The radiation protocol committee must evaluate the training to determine that it meets the needs of the facility and the regulatory requirements.

If an individual has completed the radiation safety awareness training at one hospital, and works at another hospital, do they have to complete training for each location?
Ref. §289.227(m)(9)(E)(vi)

After the 8 hours of Category 1 continuing medical education in radiation safety awareness training and 1 hour of fluoroscopic machine training has been completed, the physician, or individual delegated by the physician, may perform fluoroscopically-guided interventional procedures at other facilities. It is at the discretion of each facility to either accept the training previously received or require additional training. Either way, documentation of the completed training shall be maintained at each location the physician, or individual delegated by the physician, performs fluoroscopically-guided interventional procedures.

If an individual from another state, such as California, has a license for perform fluoroscopy from that state, will that be accepted in Texas?

The license alone would not be enough to meet the requirements. The radiation protocol committee would need to evaluate the training completed by the individual and determine whether it meets the requirements described in §289.227(m)(9)(E)(i).

Is the 1 hour fluoroscopic radiation machine training for interventional fluoroscopy procedures required for each manufacturer of the units?
Ref. §289.227(m)(9)(E)(ii)

It is not necessary to train on every fluoroscopy system used at a facility. The facility's radiation protocol committee may extend the requirements to meet their particular needs. The intent of rule is for the individual to demonstrate and apply the principles of radiation protection, be aware of fluoroscopic exposure outputs, use high level control options available on the system, and to implement dose reduction techniques provided during the required radiation safety awareness training.

Who may perform the 1 hour fluoroscopic machine training?
Ref. §289.227(m)(9)(E)(ii)(II)

A radiologist, licensed medical physicist, or a physician that has successfully completed the 8 hours of Category 1 continuing medical education in radiation safety awareness training and has completed the 1 hour fluoroscopic machine training may perform the training.

Can the 1 hour fluoroscopic machine training for fluoroscopically-guided interventional procedures be provided by video?
Ref. §289.227(m)(9)(E)(ii)(I)

The rule requires that the radiation safety awareness training include the demonstration of the proper operation of a fluoroscopic radiation machine used for interventional purposes. This cannot be accomplished by the use of a video.

Are cardiologists exempt from the requirements concerning fluoroscopically-guided interventional procedures and the radiation safety awareness training?
Ref. §289.227(m)(9)(E)

If the cardiologist performs fluoroscopically-guided interventional procedures, they are required to complete the 8 hours of Category 1 continuing medical education radiation safety awareness training and 1 hour fluoroscopy machine training.

Will there be separate training requirements listed in the rule for the various fluoroscopically-guided interventional procedures?
Ref. §289.227(m)(9)(E)(i)

Any training requirements, beyond what is stated in the rule, are at the discretion of the registrant.