

# REGULATORY CONFERENCE SEPTEMBER 3, 2010



Radiation Control

Texas Department of State Health Services

# OUR OBJECTIVES ARE TO:

- **Facilitate understanding of the regulations**
- **Review suggested rule changes**
- **Go over tri-fold showing possible changes concerning CT and fluoroscopic excessive exposures**
- **Explain what we are looking for on the Report of Assembly FDA 2579 Form**

# 25 Texas Administrative Code

❖ The regulations may be downloaded at the following internet address:

❖ <http://www.dshs.state.tx.us/radiation/rules.shtm>

# UNDERSTANDING THE REGULATIONS

❖ *Refer to your set of regulations*

*25 Texas Administrative Code §289.227*

The format is as follows:

- Table of Contents
- Texas Register Format §289 is the chapter
- 25 TAC §289.227 is the section

# 25 TAC §289.227

## Texas Register Format

- .227 is the section

- (a) subsection

- (1) paragraph

- (A) subparagraph

- (i) clause

- (I) subclause

- (-a-) item

- (-1-) subitem



# *How it looks in writing*

25 TAC (Texas Administrative Code)

25 TAC §289 (289 is the chapter)

25 TAC §289.226 (226 is the section or the title.)

25 TAC §289.226(a) (a is the subsection)

25 TAC §289.226(a)(2) (2 is the paragraph number)

25 TAC §289.226(a)(2)(A) (A is the subparagraph)

25 TAC §289.226(a)(2)(A)(i) (i is the clause)

25 TAC §289.226(a)(2)(A)(i)(I) (I is the subclause)

25 TAC §289.226(a)(2)(A)(i)(I)(-a-) (-a- is the item)

25 TAC §289.226(a)(2)(A)(i)(I)(-a-)(-1-) (-1- is the

subitem)

# A Couple Examples

- The rule stating the requirements for verifying timer accuracy during an equipment performance evaluation is:

**25 TAC §289.227(o)(5)(A)**

**§289.227 Use of Radiation Machines in the Healing Arts**

**(o) Equipment Performance Evaluation**

**(5) Radiographic Equipment Performance Evaluation**

**(A) Timer**

- Requirements for a special purpose x-ray system center alignment is: 25 TAC §289.227(1)(1)(D)(i)(II)

## §289.227 Use of Radiation Machines in the Healing Arts

(1) Additional machine requirements for radiographic systems

(1) Beam limitation

(D) Special purpose systems

(i) When the x-ray beam is perpendicular to the plane of the image receptor, a means shall be provided to do the following:

(II) align the center of the x-ray field with the center of the image receptor to within plus or minus 2.0% of the SID

# *Report of Assembly (FDA 2579 Form)*



25 TAC §289.226(n)(2)(A); (B); (C)

Common errors on the Report of Assembly  
Federal Form

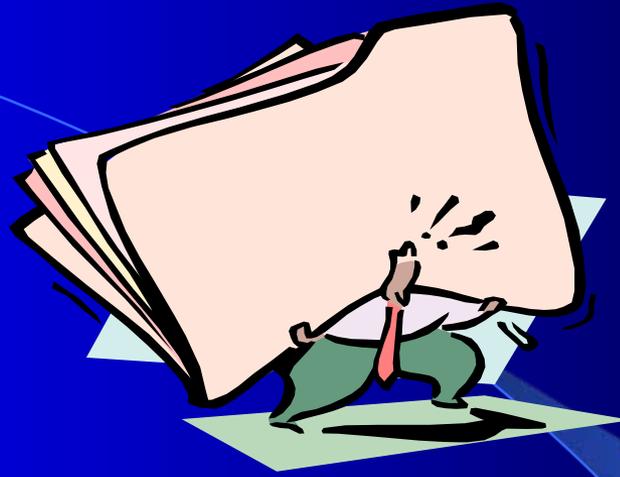


- Registration number missing - document the registration number in the comment section Box #6 or on top of the form.
- Registration number not assigned - if a new registration application has been submitted but the registration number has not been assigned, note this in the comment section of the FDA 2579
- The company's name is missing - the doctor's name is documented rather than the actual business name that is on the Certificate of Registration

## FDA 2579 Continued:

- Sometime the address is wrong. Always double check.
- Some sections are omitted/not filled out
- The serial number is taken from an area other than the control panel
- The installation date recorded on the FDA 2579 form exceeds the 30 day requirement when submitted to the Agency

# RECOMMENDED REVISIONS IN §289.226



- Some of the recommended changes in §289.226 were initially written as a condition on your Certificate of Registration.
- If the revisions are approved, they will appear as rule and no longer be noted on the Certificate of Registration.
- It will be especially necessary for you to read/review the rules carefully at that time.

## ***Draft Rule §289.226 -***

### ***Recommended Revisions:***

- a) 30 day notification will be required when the registrant adds an additional use location (sub-site).
- b) Training records will be maintained until termination of registration or 5 years after the individual terminates employment.
- c) Other than the initial installation of the first machine(s), no person shall provide radiation machine services for a person who cannot produce evidence of application for registration or a valid certificate of registration.

## §289.226 Continued:

- d) Those authorized for demonstration and sales of a radiation machine shall: ensure all machines used on humans meet the requirements of §289.227, keep a log that includes the date radiation machine was provided, name of customer and customer's certificate of registration number.
- e) Demonstration of radiation machines on humans shall be performed by or under the direction of a practitioner of the healing arts. Demonstration by the service provider must be on phantoms only.
- f) Equipment performance evaluations will be required on all dental, veterinary, medical, chiropractic or podiatric radiation machines.

# *Draft §289.227*

## *Recommended Revisions:*

- The requirement to perform EPEs:
  - a) within 30 days after initial installation of a radiation machine;
  - a) within 30 days after reinstallation of a radiation machine;
  - b) within 30 days after repair of a machine component that would effect the radiation output that includes but is not limited to the timer, tube, and power supply; or
  - c) at the time of installation.

## §289.227 Continued:

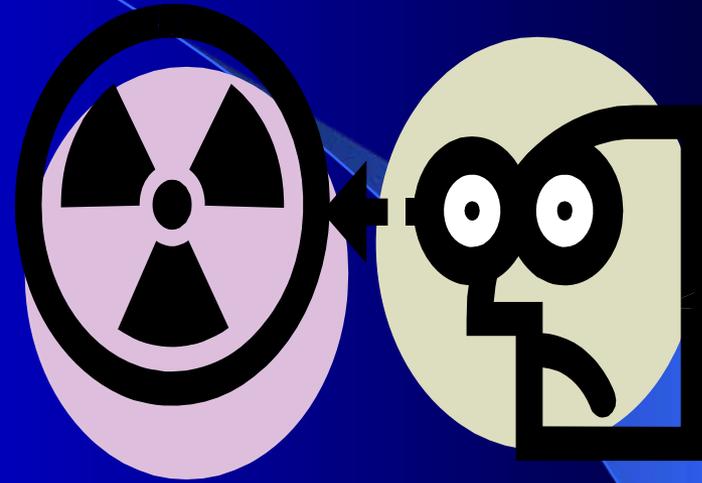
- d) measurements stated in mGy/min rather than only R/min
- e) if approved, output measurements for CT and fluoroscopy units will be extended from time of installation to 14 months rather than 12 months
- f) establishment of a dose management committee for fluoroscopy and computed tomography

# ***Remember:***

- **The doctor is registered for a particular number of radiation machines.**
- **It is not necessary for them to notify the Agency unless the number of units listed on their Certificate has increased or if the radiation machine type category has changed.**
- **However, they must keep record in their office of the deletion, disposition and addition of all units by performing an annual inventory.**

# The inventory is to include:

- Manufacturer
- Serial number
- Model number
- Location of the unit (room number or room name - not the physical mailing address)
- Date of inventory



# REMEMBER:

- Do not tell the registrant that you will notify DSHS about the new x-ray unit added to their inventory.
- The FDA 2579 form, being submitted to the Agency within 30 days, meets compliance only for the installer of the unit.
- The doctor must request, in writing, that the Certificate of Registration is to be updated to include the newly installed unit.

# Excessive Exposure Concerns

Regarding:

-  Interventional Fluoroscopy  
*and*
-  Computed Tomography

(Review Tri-Fold Handout)

# QUESTIONS



Call us, we are here to help.

# For Assistance Contact Us:



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