

# Texas Regulatory Conference Fluoro & CT Radiation Protocol Committees



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# Objectives:

- Overview of the Texas Regulations for Computed Tomography (CT) Procedures/Fluoroscopically Guided Interventional Procedures(FGI) and Radiation Protocol Committees (RPC).
- Overview of the reasons for regulating CT and FGI procedures.

# Objectives:

- Overview of the development and establishment of an RPC, procedure protocols, maintaining records, and operator training requirements.
- Where we are now
- What to expect with the inspection process

# 25 TAC §289.227

## Proposal & Response

- Started the rule making process in June 2006 - seven years in the making
- 6 separate drafts
- 3 stakeholders meetings
  - One attended by over 100 physicists, physicians & other professionals

# 25 TAC §289.227

## Proposal & Response

- Laborious in-house staff reviews over a period of two years
- Rule became effective May 1, 2013

# Background

- Nationwide Evaluation of X-ray Trends Training (NEXT) in 2009 – Cardiac Catheterization Survey
- Survey training included presentations on fluoro safety which tied severe radiation burns with interventional FGI procedures due in part to a lack of physician safety training.
- Fluoroscopy radiation safety concepts and concerns were brought back to the Department

# Background

- Department developed a White Paper
  - Brief Fluoro History
- Three goals of Fluoro WP:
  - Record of Patient Dose
  - Dose Management Program
  - Safety Awareness Training

# §289.227 – White Paper

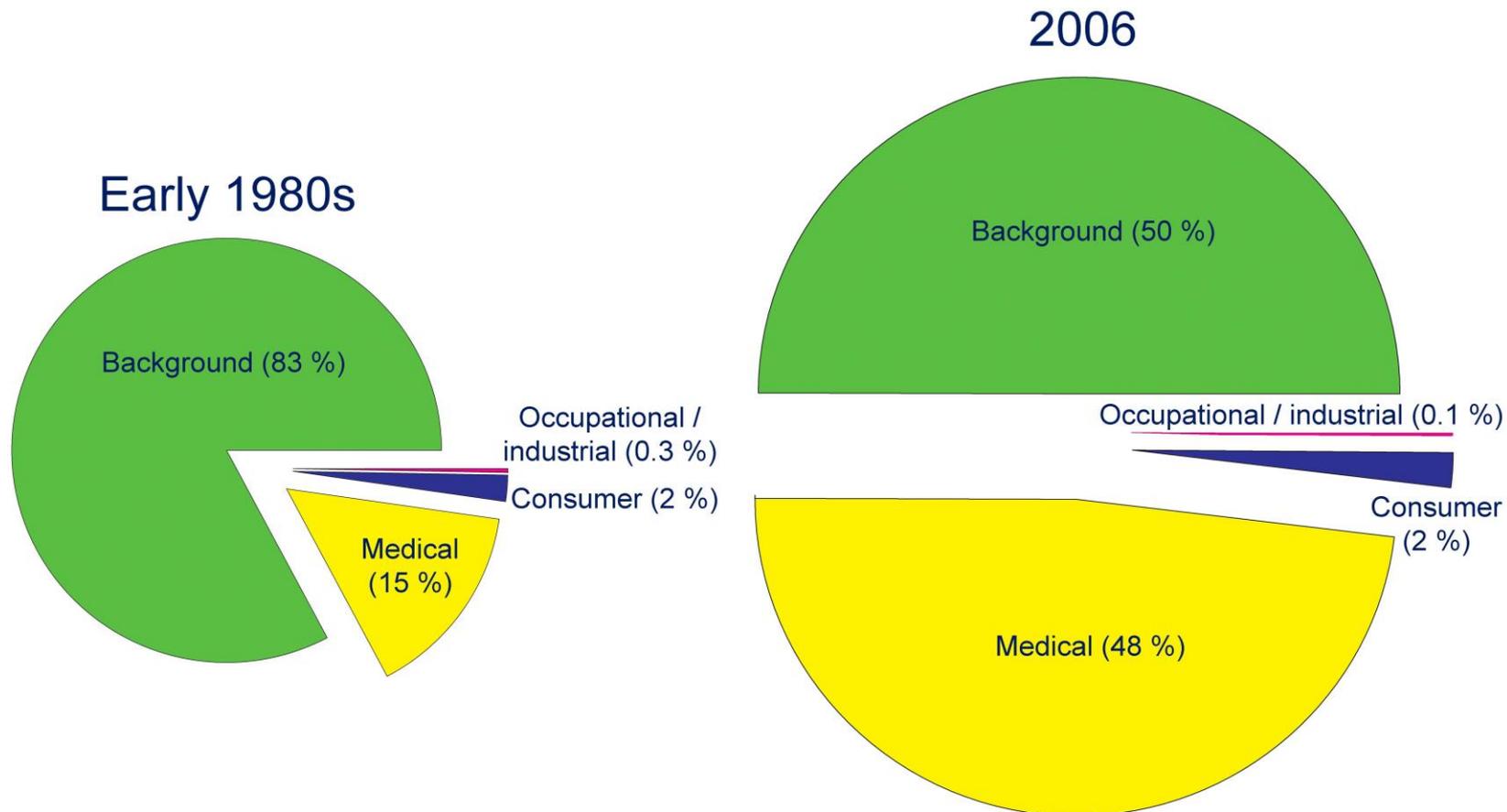
- Why a White Paper?
  - Extra Information to Stakeholders
  - Proposed regulations unprecedented
  - More Detailed than Rule Making Package
  - Gain support from Stakeholders

# §289.227 – Initiatives

- FDA Initiatives:
  - Safe Medical Devices Act (1990)
  - Public Health Advisory (1994)
- FDA Machine Regulations:
  - Max Air Kerma (AK) Rates
  - Display Features
    - Operating AK Rates
    - Accumulated AK



# §289.227 – Background



Report 160, *Ionizing Radiation Exposure of the Population of the United States*, National Council on Radiation Protection and Measurements

# §289.227 – Recommendations

- Rationale:
- Record of Fluoroscopy Dose Rates
  - More patients, larger patients, multiple procedures
- Dose Management Programs
  - Latency Period of Injury Manifestation
- Radiation Safety Awareness Training
  - Array of physicians performing procedures

# §289.227 – Recommendations

- Record of Patient Dose
  - Record of Dose from Each Procedure
  - Running Accumulated Dose
  - Include Doses from Other Modalities:
    - CT
    - Nuclear Medicine
  - No Limit to Patient Dose
  - **AWARENESS!!**

# §289.227 – Recommendations

- Radiation Safety Training
  - Fluoroscopy “On-Time”
  - Continually Educate Those Using Fluoroscopy
  - **AWARENESS!!**

# §289.227 – Fiscal Impact

## - Department

- Department determined no fiscal impact to state or local governments to administer & enforce new rule

# §289.227 – Fiscal Impact

## - Facilities

- Estimated to range of approximately \$200 to \$3,000 for facilities to comply
  - Depends on
    - Scope of training needed
    - Length of training needed
    - Number of attendees of the training program
- FGI training is one time expense

# §289.227 – Public Benefit

- Enhanced and continued protection from unnecessary exposure to radiation
  - Public
  - Patients
  - Workers
  - The environment

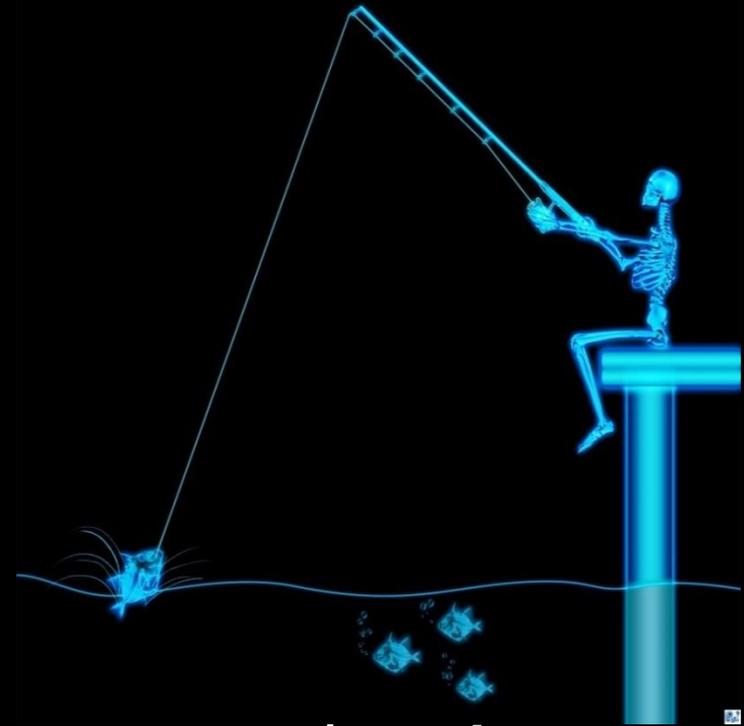
# Who had input?

- Physicists
- Registrants
- Physicians
- Other regulatory agencies
  - Difficult process
    - extensive research
    - input from many professionals



# Input

- Texas Radiation Advisory Board (TRAB)
- TRAB sub-committee response/review
- Professional societies
- State Health Services Council review (members appointed by the Governor)



# TRAB – Texas Radiation Advisory Board

- 18 members appointed by the Governor
  - includes 4 physicians and 2 licensed medical physicists
- All TRAB members discussed, supported and encouraged the Department's promulgation of 227 and especially, the physician's training rule.

# TRAB – Medical Sub-Committee

- The Department presented §289. 227 to the Medical Sub-Committee
  - 6 separate quarterly meetings during 2010 to 2012
- The TRAB Medical Sub-Committee is made up of 8 members
- One member of TRAB summarized the need for training by stating: “doctors don’t tie patient radiation dose to their foot on the pedal.”

# CRCPD –

## Conference of Radiation Control Program Directors

- Established in 1968
- Made up of:
  - State & local government
  - International members
  - Works closely with ACR, AAPM and other professional radiation entities
  - Creates Suggested State Rules as a means to help the states with rule making and promote consistency across the nation

# NEXT –

## Nationwide Evaluation of X-ray Trends

- NEXT: A cooperative effort to document the state of clinical practice of x-ray imaging exams and modalities
- Organization: FDA and CRCPD cooperate to collect data from representative sample of U.S. clinical sites

# NEXT

- NEXT surveys- since 1972- surveys repeated periodically to observe trends
- Support from professional organizations: American College of Radiology (ACR), National Council on Radiation Protection and Measurements (NCRP)

# State Health Services Council

- Study and makes recommendations
  - Executive Commissioner of Health and Human Services Commission
  - Commissioner of the Department of State Health Services (DSHS)

# State Health Services Council

- Recommendations:
  - Management and operation of DSHS
  - Policies and rules
    - Governing the delivery of services to persons who are served by DSHS
    - Rights and duties of persons who are served or regulated by DSHS.

# State Health Services Council

- Takes a lead role
  - Ensuring public review of agency rules
  - Providing a venue for stakeholder input and feedback
- Conducts regular meetings
  - Open to the public
  - Hear from DSHS staff and stakeholders
  - Make recommendations regarding publication of rules in the *Texas Register* for public comment.

# Proposal & Implementation

- Research materials
  - Department reviewed several white papers and documents from national publications
- National organizations also spearheaded an *Image Gently and Step Lightly* campaigns with recommendations for reducing dose in fluoroscopy.

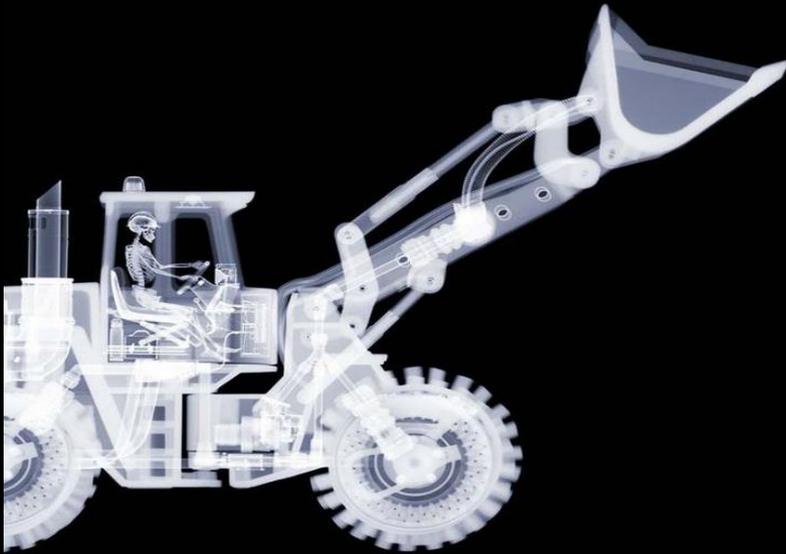
# Resources

- *Federal Performance Standard for Diagnostic X-ray Equipment*  
(21 CFR 1020)
- American Association of Physicists in Medicine (AAPM)
- Conference on Radiation Control Program Directors (CRCPD) H-32 Task Force

# Resources

- *Radiation Dose Management for Fluoroscopically-guided Interventional Medical Procedures*  
National Council on Radiation Protection and Measurements (NCRP) Report No. 168
- American College of Radiology

# Driving Force



- Patient safety
- Texas was determined to avoid the rash of radiation overexposures that shook California a few years ago, due in large part to lack of physician radiation safety awareness and training.

# Why change?

- Overdoses from CT brain perfusion scans have injured more than 400 people across the country.
- The FDA began investigating and issued an alert in 2009.
- Incidents occurred in California, Florida, and Alabama.

# Incidents

## Cedars-Sinai Medical Center in Los Angeles

- CT brain perfusion studies
- administered up to 8x's the normal radiation dose
- 206 patients



# Incidents

## Mad River Community Hospital in Arcata

- 2 ½-year-old boy complaining of neck pain after falling off his bed
- Led to the revocation of the x-ray technician's state license.



# Not in Texas!

- CRCPD H-32 Committee on CT developed safety letter
- Program sent letter to all CT facilities in Texas

# Not in Texas!

## **Computed Tomography (CT) RADIATION CONTROL PROGRAM**

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### Computed Tomography (CT)

As part of our ongoing mission to ensure health and safety, the Texas Department of State Health Services, Radiation Control Program is bringing information regarding excess radiation exposure during brain perfusion Computed Tomography (CT) imaging to your attention.

There is an ongoing investigation by the U.S Food and Drug Administration (FDA), of cases of excess radiation exposure during brain perfusion CT imaging. The investigation has identified over 250 patients who were exposed to excess radiation as much as eight times the expected level during their CT perfusion scans. The FDA has also received reports of possible excess radiation exposure from CT scans in other states. At this time, no cases have been reported in Texas. The reported cases do involve more than one manufacturer of CT scanners.

# CRCPD CT Letter

- Protocol Evaluation
  - CT radiologists
  - CT medical director or lead CT technologist
  - Medical physicist
- Is current protocol appropriate?

# CRCPD CT Letter

- Can the technique be reduced to lower the  $CTDI_{vol}$ ?
  - Take care not to sacrifice image quality
- Record approved techniques & protocols
- Password protect – if available
- Establish investigative thresholds

# Not in Texas!

- Two Requests
  - Asked CT facilities to conduct an internal review of their CT protocols
    - Correct protocol
    - Intended protocol for the exam
  - Implement, as appropriate, recommendations from CRCPD letter

# Not in Texas!



- Proactive approach by implementing what would become 25 TAC §289.227
- Goal - aid in lowering radiation exposure to patients and operators
- Help ensure diagnostic image quality
- Promote facility involvement in the responsibility of quality assurance

§289.227(n)(3)(A)

## Performance of radiation output measurements for CT units

- Within 30 days after initial installation
- At intervals not to exceed 14 months

**Annually is still acceptable!**

- May coordinate with fluoroscopy or mammography output measurements but the interval must not exceed 14 months

# CT output measurements con't:

- Measurements shall be within 30 days of any major maintenance (including tube replacement) that could affect the radiation output
- Within 30 days of any major change in equipment operation as a new software package

# CT Dose Measurements – Tube Changes

- Question: Rule 289.227(n)(3)(A)(iii) does not rule out dose measurements after an x-ray tube exchange, as was the previous rule. **Is x-ray tube replacement now considered a major maintenance, and a new dose measurement is required after each tube replacement?**
  - The rule states:  
289.227(n)(3)(A) Performance of the radiation output measurements shall be:
    - (i) within 30 days after initial installation;
    - (ii) thereafter annually or at intervals not to exceed 14 months from the date of the prior radiation output measurements;
    - (iii) within 30 days of any major maintenance, that could affect radiation output; and
    - (iv) within 30 days of any major change in equipment operation for example, introduction of a new software package.

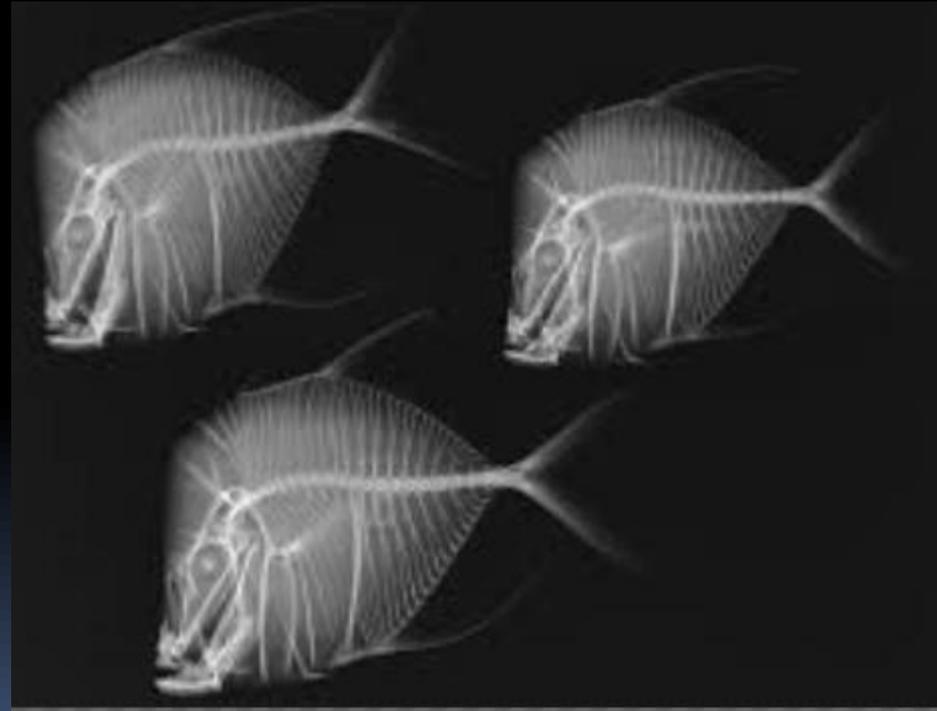
# CT Dose Measurements – Tube Changes

- If the **Licensed Medical Physicist** concludes that the “*major maintenance performed*” **could not have** changed the radiation output, then the **LMP** will need to **make that statement in writing** and send a copy to the Registrant. The **documentation** will then need to be available **during inspection**

§289.227(n)(6)(A)

## Radiation Protocol Committee (RPC)

- May be system-wide if you have more than one site
- May be a cooperative RPC as long as each facility has a representative on the committee



## CT RPC con't:

- Current Radiation Safety Committee may assume the responsibilities if the members meet rule requirements
- Meet **(in person)** as often as necessary but no less than once every 14 months
- **Interim** meetings may be conducted by electronic means

# RPC record requirements

- Record of each RPC meeting
  - Date
  - Names of individuals in attendance
  - Minutes of meeting
  - Actions taken
- Maintain these records for 5 years
- Revised protocols must be maintained for 5 years after the revision

# CT RCP members must include

- a radiologist or radiation oncologist
- a licensed medical physicist
- the RSO
- other individuals as needed.

# CT RCP members

The membership of the RPC is designed such that different subject matter experts can make informed and calculated decisions regarding the safe use of CT equipment.

§289.227(n)(6)(C)

## CT Written Protocol



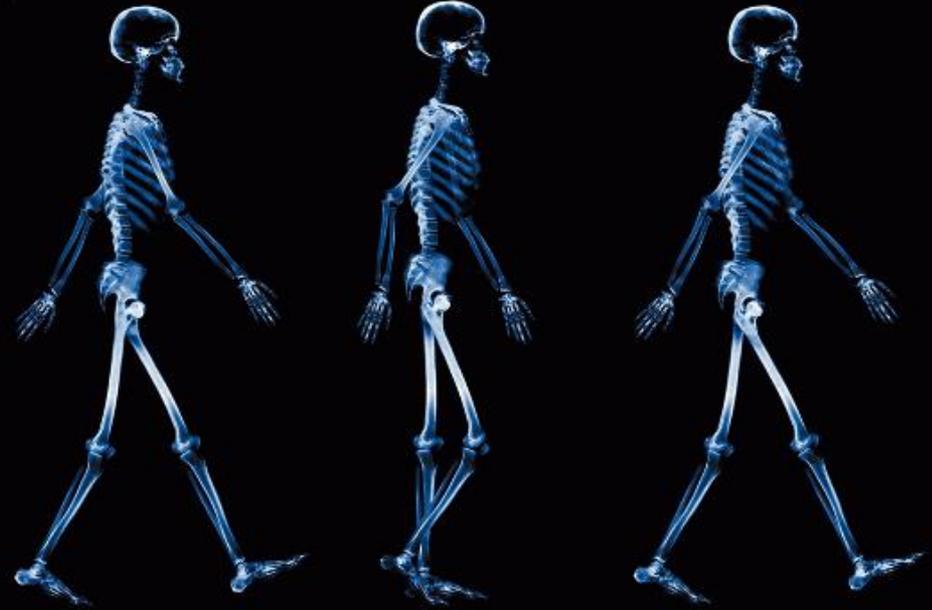
- Method to monitor the radiation output
- Reference level for CT procedures
- Protocols reviewed at an interval not to exceed 14 months
- Actions to be taken if the reference level was exceeded

# CT Protocol Suggestions

- anatomy imaged
- number and timing of the imaging sequences
- contrast or no contrast
- parameters for the image acquisition
- protocols password protected

25 TAC289.227(n)(6)(D)

# Maintenance of records for CT radiation output



- Maintain a record of radiation output so, if necessary, the radiation dose to the skin may be estimated using your established protocols

# Output records

- At a minimum the output record shall include:
  - Patient identification
  - Type and date of examination
  - CT system used
- If possible the  $CTDI_{vol}$ , DLP, or ss identified in Task Group 111 report of American Association of Physicists in Medicine.

# CT Reference level

- Indicates when your facility should review the procedures again
- Will notify its time to evaluate if acceptable image quality can be achieved at a lower radiation output as compared with measurements taken from a selected phantom
- Provide a benchmark for comparison of imaging equipment performance under prescribed conditions

# CT Reference level

- It is NOT intended to define a maximum or minimum exposure limit for any patient
- DSHS does NOT recommend reference levels or agencies that have recommended or established reference levels
- The reference levels are determined by your RPC
- The inspector will only verify they are documented in the RPC records





## §289.227 Fluoro Rules

- Many stakeholders sent in their suggestions for a definition of Fluoroscopically-guided Interventional Procedures. (FGI)
- TRAB asked their medical sub-committee to help finalize the definition

§289.227(e)(36)

## **FGI – was finally defined as**

An interventional diagnostic or therapeutic procedure 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. FGI procedures may include but not be limited to:

**§289.227(e)(36)**

## **Lets review the definition again**

- FGI is an interventional diagnostic or therapeutic procedure;
- It is performed via percutaneous or other access routes;
- It is usually performed with local anesthesia or intravenous sedation;

§289.227(e)(36)

## Lets review the definition again

- FGI uses external ionizing radiation in the form of fluoroscopy to:
  - localize or characterize a lesion
  - localize a diagnostic site
  - localize a treatment site
  - monitor the procedure
  - and control and document therapy

§289.227(e)(36)

## **FGI definition**

FGI procedures may include but not be limited to:

- TIPS creation (transjugular intrahepatic portosystemic shunt)
- Embolization (any location, any lesion)
- Stroke therapy
- Biliary drainage

§289.227(e)(36)

## **FGI definition**

- Angioplasty with or without stent placement
- Stent-graft placement
- Chemoembolization
- Angiography and intervention for gastrointestinal hemorrhage

§289.227(e)(36)

## **FGI definition**

- Carotid stent placement
- RF (radiofrequency) cardiac ablation
- Complex placement of cardiac EP (electrophysiology) devices
- PCI (percutaneous coronary intervention) (single or multiple vessel)

# Is my procedure FGI ?

- **Most fluoro procedures are FGI**
- Example of what is not considered FGI:
  - Upper GI
  - Hysterosalpingiogram
  - Closed finger reduction
- Why aren't they?

# Is my procedure FGI ?

- So, if your procedure isn't on the list are you exempt?
- How have you handled this in your facilities?
- Members of the RCP are responsible for establishing what procedures qualify as FGI.

# Hospital Privileges

- Can the hospital tie this to my privileges?
  - **Yes, the hospital can handle fluoro credentialing as they see best**
- Can the hospital declare all procedures are FGI?
  - **Yes, the Radiation Protocol Committee can declare that all procedures are FGI**

# Why does it matter?



Deep ulceration with exposure of the humerus at 6 1/2 months after the cardiac catheter ablation, tissue necrosis occurred. Within 6.5 months, deep ulceration exposed the humerus.

# Erythema from Fluoroscopy



**Erythema &**

**Desquamation from Fluoroscopy**



# Transluminal coronal angioplasty

- Eleven months after the procedure a percutaneous painful ulcer developed
- Surgical debridement was performed and the adjacent skin flap was raised
- Eight months after the reconstructive surgery, there was no complaint of pain



# **Skin injury is dependent on variables**

- Rate of radiation delivery
- The fractionation of the absorbed dose
- The age of the person
- Characteristics of the skin exposed
- The site/area of the skin exposure

# **Radiation injuries can be difficult to diagnose**

- The medical community has found fluoroscopically-induced injuries especially difficult to diagnose.
- One reason is because the result of the injuries may occur at various times (days/weeks) after the procedure.

# Radiation injuries ... what are you doing?



- Do your established benchmarks / thresholds have any real meaning?
- Are you following up?
- Have you had any radiation injuries?



§289.227(m)(9)

## Fluoro Radiation Protocol Committee

- May be system-wide if you have more than one site
- May be a cooperative RPC as long as each facility has a representative on the committee

# Fluoro RPC con't:

- Current Radiation Safety Committee may assume the responsibilities if the members meet rule requirements
- Meet **(in person)** as often as necessary but no less than once every 14 months
- **Interim** meetings may be conducted by electronic means

**§289.227(m)(9)(B)**

**The RPC members shall include:**

- Licensed physician
- Licensed medical physicist
- Radiation safety officer
- Any other individual deemed necessary by the RPC.

§289.227(m)(9)(B)

## The RPC members

The membership of the RPC is designed such that different subject matter experts can make informed and calculated decisions regarding the safe use of Fluoroscopic equipment.



# Fluoroscopy Radiation Safety

- What is required?
  - Specific radiation safety awareness training regarding these machines before using them
- Who is exempt?
  - Radiation oncologists
  - Board-certified radiologists
  - Board Certified Radiological Technologists

§289.227(m)(9)(E)

## Radiation Safety Awareness Training

- Physicians, **or individuals delegated by the physician**, have two years to complete the training from the time the rule became effective. (May 2015)
- After May 2015 individuals performing FGI procedures must complete the radiation safety awareness training **prior** to performing FGI procedures

**§289.227(m)(9)(E)(1))**

**The basic radiation safety awareness training includes:**

- Principles of radiation protection
- Biological effects of x-ray radiation
- Principles of fluoroscopic systems
- Operation of fluoroscopic systems used for interventional purposes

# Radiation safety training

- Fluoroscopic exposure outputs
- High level control options
- Dose reduction techniques
- Procedures for recording pertinent data
- The records for radiation safety awareness training for physicians must be retained as long as they perform FGI procedures

# Fluoroscopy Radiation Safety

- Question: If the tech steps on the pedal instead of the M.D., does the doctor have to get the CEU's and training?
- RESPONSE: **Yes**, if fluoroscopically-guided interventional procedures, as defined in §289.227(e)(36), are performed, the radiation safety awareness training for physicians is required.
- The **list of FGI pocedures included in the definition of §289.227(e)(36) is not an all-inclusive list.**

# Fluoroscopy Radiation Safety

- Question: If the tech steps on the pedal instead of the M.D., does the doctor have to get the CEU's and training?
- The **physician must complete the training** as required by rule. The physician **has responsibility for and control of quality, radiation safety, and the technical aspects of the application of ionizing radiation** to human beings. The **tech, RN or PA that "assists" the physician is under their supervision**; therefore the physician must be knowledgeable of the equipment and radiation safety aspects of dose reduction.

# What about radiation dose limits for FGI?

- DSHS has **NOT** set dose limits for FGI procedures
- The term “reference level” was selected as the most appropriate term to be used in rule

# FGI Reference Levels

- Do I have to set a reference level for all FGI Procedures?
  - Yes, the RPC needs to establish reference levels for all FGI procedures.
- Can it be based on fluoro time only?
  - It should be based on the dose estimating parameters available on your fluoro unit

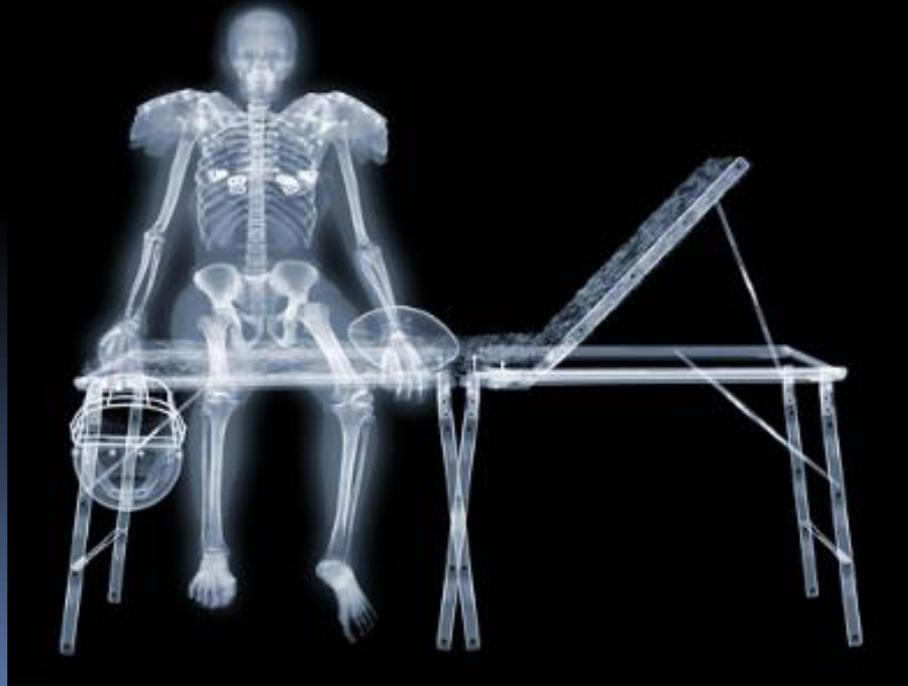
# Texas Radiation Control Act

- Texas Health and Safety Code, Chapter 401, the Department is the lead agency for the State of Texas in regulating the possession and use of radioactive material and radiation producing devices



# Texas Radiation Control Act

- No person is allowed to use a radiation producing device such as a fluoroscopic unit in Texas without meeting the Department's regulations.



# Texas Radiation Control Act

- Consistent with the health and safety requirements of the Department's rules
- Includes authority over the use of x-ray at:
  - Veterinarian
  - Physicians
  - Dentists
  - Chiropractors
  - Etc.

# Texas Radiation Control Act

- Texas radiation rules have required physician training for use of:
  - mammography 25 TAC §289.230(r)(1)
  - radioactive materials for decades 25 TAC §289.256(jj)
    - Each mammography interpreting physician is required to obtain 60 hours initially, and 15 hours of CME every three years in mammography interpretation.

# Texas Radiation Control Act

- Department does not regulate the practice of medicine
- Charged by the Legislature with ensuring the safe use of a radiation producing device by anyone, including physicians



# Impact of Physician Training

- Does not affect the ability of a physician to keep his or her Texas medical license
- Rule regulates the facilities that permit physicians to use their fluoroscopic units
- Texas Medical License does not supersede the Department's obligation to set safety rules under which any professional can use a radiation producing device.



# Impact of Physician Training

- By **May 1, 2015**, each facility that has a fluoroscopic unit must confirm that each physician on its staff who performs FGI procedures at the facility has the required radiation safety training.



# FGI Dose

- The “reference level” must be determined by your RPC
- The reference level is **NOT** designed to set a maximum or minimum exposure limit

# Operator training is vital

- Insufficient experience leads to prolonged use of radiation and possible injuries
- Some injuries have been associated with procedures for which the physician was inexperienced in the components of radiation safety.
- The technical aspects of a medical intervention are of utmost importance especially concerning radiation safety and management.

# Impact of Physician Training

- Texas Medical License does not supersede the Department's obligation to set safety rules under which any professional can use a radiation producing device.



# Impact of Physician Training

- 8 hours of Category 1 CMEU's
  - One time basis with no further continuing education requirements.
  - Can be used once as part of the 24 hours of Category 1 CMEU's that are required each year for a physician to maintain licensure with Texas Medical Board

# Impact of Physician Training

- Training Cost

- Online search:

- “Texas radiation safety training”
    - Courses available
    - Under \$200

- By comparison to other areas not under radiation rule requirements:

- 8 CMEU hours – Vascular Ultrasound
    - 8 CMEU hours – musculoskeletal \$635
    - Over \$600



# Fluoro Training Exemptions

- Board Certified Radiologists
- Board Certified Radiation Oncologists
- Board Certified Radiological Technologists
- Exempted because they receive radiation safety training as part of their credentialing for certification in either radiology or radiation oncology.

# National Trends

- Several national organizations have established recommended guidelines for managing the radiation dose during FGI procedures, including physician training
  - Conference of Radiation Control Program Directors (CRCPD)
  - American Association of Physicists in Medicine (AAPM)
  - American College of Cardiology; American Heart Association; the Heart Rhythm Society
  - Society for Cardiovascular Angiography
  - National Council on Radiation Protection (NCRP #168)

# National Trends

- Other states with fluoro training requirements:

Arkansas	24 hrs every 2 years
Rhode Island	Topics required, but no time limit – plan to correct in 2015
Alaska	10 hours
Massachusetts	2 to 4 hours annually – depends on type of operator
California	10.5 hours
Oregon	8 hours for non-radiologist operators
Louisiana	State physician license requirement
Wisconsin	Similar to TX – based on operator

# National Trends

- States that plan on implementing new fluoro training requirement within the next 12 months:

- Tennessee
- North Carolina
- Alabama



# National Trends

- CRCPD has drafted physician training requirements based on the language from the Texas 227(m) rule, for adoption by other states
- Proposed draft has additional physician training requirements that the Texas rule did not include
  - 2 hours of recurring continuing radiation safety training every 2 years.

# National Trends

- The Joint Commission Requirements
  - Effective 7/1/2012

## The Joint Committee CT Requirements

**Standard EC.02.02.01 A17** CT has the new requirement for the monitoring of staff occupational exposure with quarterly-reviewed dosimetry results by RSO or diagnostic medical physicist

## DSHS Rules

Our rules establish occupational dose limits in 231 (m). The registrant is required to record the exposure data for the current year on RC Form 231-3 or equivalent 231(r)(3). The RSO is responsible ensuring that records are kept of monitoring results 226(n)(1)

# National Trends

- The Joint Commission Requirements
  - Effective 7/1/2012

**Standard EC.02.04.03 A17** A requirement for a medical physicist review of dose produced by each CT system for four protocols (Adult Brain, Adult Abdomen, Pediatric Brain, Pediatric Abdomen or other protocol if above are not used.) These reviews are to verify that the displayed dose is within 20% of the delivered dose. These tests are to occur at least annually.

Our rules require the Radiation Protocol Committee (RPC) to establish and implement written protocols that include monitoring of the radiation output, recommended reference level, actions to be taken if reference level is exceeded and to review the protocols at an interval not to exceed 14 months. 227(n)(6)(C)

# National Trends

## ■ The Joint Commission Requirements

**Standard EC.02.04.03 A19** CT gets its own list of specific QC checks that must be executed at least annually by the medical physicist. These required tests include:

Image uniformity

Slice thickness accuracy

Slice position accuracy

Alignment light accuracy

Table travel accuracy

Radiation beam width

High-contrast resolution

Low-contrast resolution

Geometric or distance accuracy

CT number accuracy and uniformity

Artifact evaluation

Our rules require an EPE to be conducted on CT units at an interval not to exceed 14 months and to be performed by or under the supervision of a licensed medical physicist 227(o). Additionally, measurements of CT systems are to be performed with calibrated dosimetry systems as required in 227(i)(14) and CT systems containing a gantry manufactured after 9/3/1985 shall meet the requirements of 227(n)(1)(H)(i through iii).

# National Trends

- The Joint Commission Requirements

**Standard EC.02.04.03 A23** annual tests of the scanner, the console display must also be checked for luminance (maximum, minimum, and uniformity), resolution, and spatial accuracy.

Our rule requires the acquisition of images for quality control purposes using protocols and intervals recommended by the manufacturer or the licensed MP 227(n)(4)(C).

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# National Trends

- The Joint Commission Requirements

**Standard EC.02.06.05 A4 & A6** CT requirement for shield designs to be provided by medical physicists (for any new or replacement equipment, or modifications to either equipment or shielded enclosure), and that shield construction be tested for integrity / attenuation prior to being put into service.

Our rule regulates the dose to individual members of the public 231(o) and (p). Dose to public shall not exceed 0.5 rem per year 231(o)(1)(A) from radiation machines. Dose to public at facilities utilizing both radiation machines and radioactive materials shall not exceed 0.1 rem/year 231(o)(B)(4).

# National Trends

- The Joint Commission Requirements

CT standards have very specific qualification requirements for the operator (technologist), the minimum requirements are:

Our rule on operator credentialing on CT refers to the MRT Certification Act 227(if) which allows MRTs and Physicians to operate CTs 140.516(b)(1)(4).

# National Trends

- The Joint Commission Requirements

CT standards have very specific qualification requirements for the operator (technologist), the minimum requirements are:

Our rule on operator credentialing on CT refers to the MRT Certification Act 227(if) which allows MRTs and Physicians to operate CTs 140.516(b)(1)(4).

# National Trends

- The Joint Commission Requirements

Standard HR.01.02.05 C19 Registered and certified by ARRT, or certified by the Nuclear Medicine Technology Board (NMTCB).

Trained and experienced in the operation of CT equipment.

The standard does not specifically state that the certification should be at the sub-specialty level (such as RT[CT] for sub-specialized CT technologists), so we are currently operating under the presumption that RT [R] is all that would be required.

MRT rules allows both ARRT and NMTCB certified individuals to be MRTs 140.507(d).

# National Trends

## ■ The Joint Commission Requirements

**Standard HR.01.02.05 C19** qualifications for the medical physicist performing the system checks on CT scanners. Yes, within this standard revision there are no specific requirements for education or certification for physicists verifying Nuclear Medicine or MRI equipment operation

The MP Board has various requirements for MP licensure including ABR, ABMP, CCPM and others 601.8(d)

Board certified in Diagnostic Radiologic Physics, or Radiologic Physics, by the ABR, or,  
Board certified in Diagnostic Imaging Physics, by the ABMP, or,  
Board certified in Diagnostic Radiologic Physics, by the CCPM.

In the absence of one of the above board certifications, the physicist must possess *all* of the following:

A graduate degree in physics (or closely related science or engineering degree) from an accredited university, and,

Formal, graduate-level coursework in the biological sciences (with specific course requirements), and,

# National Trends

- The Joint Commission Requirements

**Standard HR.01.05.03 A14** CT technologists are required to receive ongoing training with annual training on radiation dose reduction techniques, Image Gently and Image Wisely.

An MRT must complete 24 hours of continuing education acceptable to the department during each biennial renewal period 140.511(a)(1)

# National Trends

- The Joint Commission Requirements

**STANDARD PC.01.02.15 C5 & C6** For nearly all CT exams, the calculated radiation dose is to be recorded with the images in the patient's medical record and is in the radiologist's report and/or the protocol page accompanying the image. This requirement only applies to exams using CT equipment that calculate and display the dose.

Our rules require The radiation dose to skin shall be recorded, if a CT system is capable of calculating and displaying the values 227(n)(6)(D)

# National Trends

- The Joint Commission Requirements

**STANDARD PC.01.02.15 A10 & A12** CT is also required to verify patient identity, imaging site, and proper positioning, as well as consider the modality's appropriateness for the exam and patient. In addition to these shared criteria, CT also is to verify the correct imaging protocol and scanner settings, prior to the exam.

Our rules require a record to be maintained that includes patient identification, type and date of examination and identification of the CT system used 227(n)(6)(D)

# National Trends

- The Joint Commission Requirements

**STANDARD PC.01.03.01 A26** TJC will now require that hospitals specifically develop their CT scanning protocols (including appropriateness, clinical indications, contrast, age, size, and projected dose) to reflect the industry standards of practice. Once developed, the provider needs to make a regular effort to update these protocols to maintain compliance with the evolving standards of practice.

Our rules require a Radiation Protocol Committee for CT to be established and to implement written CT protocols 227(n)(6)(C).

# National Trends

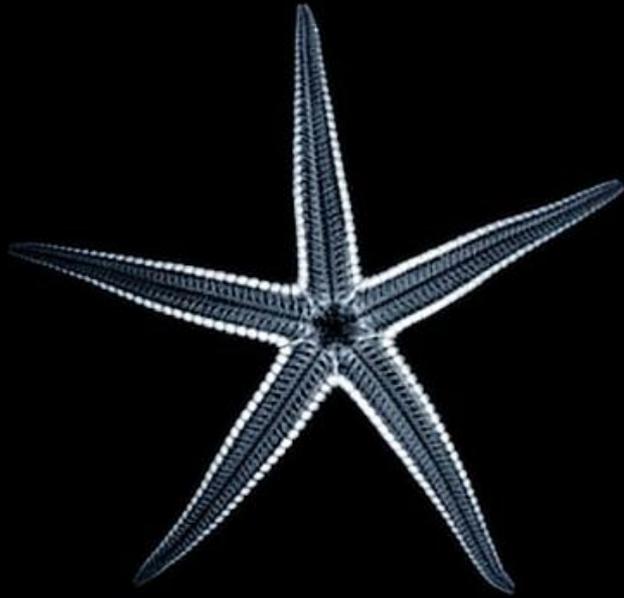
- The Joint Commission Requirements

**STANDARD PI.02.01.01 A6** CT providers must track information on patient radiation dose, and compare this internal data against industry benchmarks.

Our rules require the RCP to monitor the radiation output, recommended reference levels for CT procedures performed, actions to be taken when reference leveled are exceeded and to review protocols at an interval not to exceed 14 months 227(n)(6)(C)

# FGI Reference Levels

- Sets an initial standard for comparing current data
- Triggers an internal review if the reference level is exceeded
- May reveal times when procedural methods should be reviewed
- Helps to determine if image quality can be achieved at a lower radiation dose



# Are you ready for your inspection?

- Has your committee met?
- Do you have the records?
- Have you made improvements or did you just do the bare minimum to satisfy the rule requirement?

# Are you ready for your inspection?

- Does the facility have an RPC?

- Did the facility meet in person once every 14 months?

- Did the facility make a record of each RPC meeting and include all required items?

# Are you ready for your inspection?

- Does the RPC include all required members?

- Did the RPC establish and/or implement written protocols for the CT system?

- Did the registrant make and/or maintain a record of radiation output information in order to estimate skin dose?

# Are you ready for your inspection?

■ Does the facility have an RPC?

■ Did the facility meet in person once every 14 months?

■ Did the facility make a record of each RPC meeting and include all required items?

■ Does the RPC include all required members?

# Are you ready for your inspection?

- Did the RPC establish and/or implement written protocols for the FGI procedures?

- Did the registrant make and/or maintain a record of radiation output information in order to estimate skin dose?

- Do individuals performing FGI procedures have the required training?

# A few more things...



# Service Companies & LMP's

- §289.227(m)(5) No Registrant shall engage any person for services described in subsection (b)(11) of this section until the person provides to the registrant evidence of registration with the agency
- So – **confirm the service company and/or the physicist have a Certificate of Registration**
- **Read your** physics **reports** when you receive them, look for **passes** and **fails**

# EPE's within 30 days of install

- §289.226(0)(5) **requires the assembler/installer** of medical, dental & veterinary equipment **to perform an EPE within 30 days** of assembly or reinstallation.
- If a facility refuses, the assembler/installer may require them to sign a statement to that effect.
- **If the facility refuses**, and doesn't have an EPE done, **they will be issued a violation**. However, if the assembler/installer has documentation of the refusal, they will not receive a secondary violation.

# New Inspection methods

- Department began using new software that links the inspection reports to our database on 8/12/2014.
- Changes:
  - **Inspectors will spend more time onsite**
  - **No more CI-37** - the “yellow sheet”
    - You will receive an **email instead**
  - During the inspection, Registrants will **sign the inspector’s computer tablet.**

# Acknowledgements

[www.crcpd.org](http://www.crcpd.org)

[www.acr.org](http://www.acr.org)

[www.aapm.org](http://www.aapm.org)

[www.jointcommission.org](http://www.jointcommission.org)

[www.dshs.state.tx.us/radiation](http://www.dshs.state.tx.us/radiation)

[www.dshs.state.tx.us/trab](http://www.dshs.state.tx.us/trab)

[www.dshs.state.tx.us/council](http://www.dshs.state.tx.us/council)

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