The Alphabet Soup of Regulatory Compliance: Being Prepared for Inspections

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Objectives
- Recognize the various regulatory bodies and organizations with oversight or impact in Nuclear Medicine, Radiation Oncology and Radiology.
- Examine 10CFR35 requirements.
- Discuss available guidance documents
- Look at TJC and CMS requirements

Inspections are often unannounced, so BE PREPARED

DOCUMENTATION
Who has Oversight or Impact?

- Regulatory Bodies
  - NRC or State (RHB)
- Institutional Committees
  - RCS
- Professional Organizations
  - SNMMI, ACR, ASTRO, HPS, AAPM
- Guidance Organizations
  - NCRP, ICRP, ICRU

Regulatory Bodies

- NRC

Agreement Status

Currently, there are 37 Agreement States.
Regulatory Bodies
- NRC
- State Radiologic Health Branch
- FDA
- DOT/IATA
- CMS
- TJC (JCAHO)

Institutional Oversight
- Radiation Safety Committee (RSC)
- Quality of Care (CQI)
- Institutional Review Board (IRB)
- Radioactive Drug Research Committee (RDRC)
- Pharmacy (Nuc Med)

Professional Organizations
- ARRT
- NMTCB
- SNMMI
- ACR
- ASTRO
- AAPM
- Health Physics Society (HPS)
Alphabet Soup

- NRC
- RHB
- FDA
- DOT
- IATA
- TJC
- CMS
- IRB
- RSC
- RDRC
- SNMMI
- ASTRO
- ARRT
- NMTCB
- ACR
- AAPM
- HPS
- NCRP
- ICRP
- IAEA

Regulatory Agencies

- NRC
  - 10CFR35
    - NRC States follow it directly
    - Agreement States adopt Part 35
      - Some adopt it in its entirety
      - Others recognizes selected sections
    - Read Part 35 and your state regulations carefully
  - 10CFR19, 10CFR20

NRC Guidance

Revision 2
10CFR35

- Covers the medical uses of radioactive materials
- Defines authorization
- Written Directive
- Medical Events
- Recordkeeping

10CFR35

- 35.2
  - Authorized User – A physician, dentist or podiatrist who meets the requirements in 35.59 and 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.590 or 36.690 or is identified as an AU on a recognized license.

10CFR35

- 35.190, 290, 390, 392, 394, 396, 490, 690
  - Defines the training requirements for physicians to be an AU on a license
  - Board certified and Attestation or
  - Physician who meets the training requirements and Attestation or
  - Already identified as an AU on a state or NRC license

NRC 313A Form
10CFR35

35.1000
• Microspheres (SIRSpheres, Theraspheres)
• Gliasite
• GSR - Perfexion

10CFR35

35.10
• License always supersedes the regulations

10CFR35

35.40
• Written Directives
  • Required for all therapies
  • AU signature and date (Electronic signatures are allowed - have a formal procedure)
• Nuclear Medicine
  • Any dose of $^{131}$I (NaI) > 30 µCi
• Drug, dosage & route (for all but $^{131}$I)
10CFR35

35.40

- Written Directives
  - Radiation Oncology therapies
    - For GSR (GK)
      - Total dose, treatment site, coordinate (and sector) settings for each site
    - For Teletherapy
      - Total dose, dose/fraction, # fractions, treatment site

- For HDR
  - The radionuclide, treatment site, dose/fraction, # fractions, and total dose

- For All Other Brachytherapy (e.g. seeds)
  - Before implantation - Treatment site, radionuclide and dose
  - After implantation – Radionuclide, treatment site, # of sources, total source strength and exposure time OR the total dose.

NOTE: There will be new regulations by the end of 2015 for WD and seeds.
10CFR35

35.40 & 35.41
- Written Directives
  - Most common violations:
    - Failure to follow written procedures
    - Failure to have a signed and dated WD prior to administration

10CFR35

35.75
- Defines the ability to release patients
  - < 5 mSv to the public
- NUREG 1556, vol 9, Appendix U
- Information Notice from NRC
  - Licensees to provide consequences if directions are not followed
  - Precautions around children, pregnant women or staying at hotels

10CFR35

35.92
- Decay in Storage
  - Despite the language in 35.92,
  - Some states mandate that licensees must hold waste for a minimum of 10 half lives
  - Stipulate 90 days as the maximum half life of radionuclides to be held for decay.
Correct Administration

- Record of the prescribed dose
- Record of what dose was administered
  - Radiopharmaceutical
  - Quantity (mCi)
  - Patient ID
  - Date and time of dose determination
  - Name of the person who determined the dose
  - Check to assure the dose matches the prescription.

Medical Events (10CFR35.3045)

- Dose or Dosage that differs from what was prescribed by more than 0.05 Sv EDE or 0.5 Sv to an organ, tissue or SDE to the skin and
  - The total dose differs that prescribed by 20% or more or
  - Is outside the prescribed dosage range by 20% or more or
  - The fractionated dose delivered for a single fraction differs from the dose prescribed by 50% or more

Medical Events (10CFR35.3045)

- Dose exceeds 0.05 Sv EDE or 0.5 Sv to an organ, tissue or SDE to the skin from:
  - Wrong patient.
  - Wrong radiopharmaceutical.
  - Wrong route.
  - Wrong mode.
  - A leaking sealed source
- Dose to skin or an organ other than the treatment site that exceeds 0.5 Sv or is 50% more than expected in the WD
- Reports must be made within 24 hours.
Regulatory Agencies

- NRC
  - 10CFR19
    - Notices, Instructions and Reports
    - Notice to Employees
    - Annual dosimetry reporting

U.S. NRC

Regulatory Agencies

- NRC
  - 10CFR20
    - Standards for Protection
      - Occupational and Public Dose Limits
      - Surveys and monitoring
      - Storage and Posting requirements
      - Waste disposal

U.S. NRC

Regulatory Agencies

- California - RHB
  - Title 17
    - Public Health
      - Subchapter 4 – Radiation
        - §30195 – Part 35
  - Title 22
    - Social Security
      - Division 5 – Licensing of facilities
        - §70507 – Nuc Med Requirements

U.S. NRC

Regulatory Agencies

- FDA
  - Drug approval
  - Equipment approval
  - Recall
  - RDRG
  - IND/NDA/ANDA
  - Manufacturing of radiopharmaceuticals

Regulatory Agencies

- DOT / IATA
  - Receiving
  - Shipping
  - DOT (ground) – 49CFR
  - IATA (air)
    - Staff must be certified to ship spent Rb generators
    - Return of Ir-192 HDR sources

The Joint Commission (TJC)

- Formerly known as JCAHO.
- They are not a regulatory body.
- Accreditation of hospitals/healthcare facilities
- Publish standards / guidelines
- TJC strives for compatibility with CMS
- They are aware of NRC/State oversight.
On December 20, 2013 TJC published “Revised Requirements for Diagnostic Imaging Services” effective July 1, 2014.

On May 19, 2014, they delayed implementation

Cited the “significant feedback from key stakeholders”… that “shed light on issues” not identified or sufficiently evaluated.

On January 9, 2015 TJC published “Revised Requirements for Diagnostic Imaging Services” effective July 1, 2015.
TJC & CMS

- TJC
  - Leadership (LD)
  - Medication Management (MM)
  - Environment of Care (EC)
  - Medical Staff (MS)
- CMS
  - Conditions of Participation (CoP)

Title 42

§482.53

EPs in 2009 were expanded to cover 42CFR482.53 (Nuclear Medicine).

Areas addressed include:
- Radiopharmaceutical management
- QA/QC
- Physician oversight
- Staff training
- Records retention
- Waste management
All Joint Commission resources must be purchased.

The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.

482.52(c)(2) Nuclear Medicine equipment must be inspected, tested and calibrated annually.

EP14 (EC) Qualified hospital staff inspect, test, and calibrate nuclear medicine equipment annually. The dates of these activities are documented.
Testing of image acquisition systems is greatly expanded in the new 2015 TJC Standards.

- Image uniformity
- Slice thickness accuracy
- Slice position accuracy when prescribed from a scout image
- Alignment accuracy
- Table travel accuracy
- High contrast resolution
- Low contrast resolution
- CT number accuracy and uniformity
- Artifact evaluation
- Radiation dosimetry
- Gray level performance of CT acquisition display
- Evaluation of technologist continuous QC program
Because the testing is annual, TJC says that they will not cite facilities until July 1, 2016.

**Institutional Oversight**

- **RSC**
  - Radiation Safety Committee
  - License compliance
  - Serves as oversight and review of amendments

**Institutional Oversight**

- **IRB**
  - Institutional Review Board
  - Experimental drugs in clinical trials
  - Under IND, NDA, HUD
  - Experimental uses of new imaging equipment
  - Experimental radiotherapy
  - Standard of Care imaging or radiotherapy associated with a clinical trial
Institutional Oversight

- RDRC
  - Radioactive Drug Research Committee
  - Chartered by the FDA (21CFR361.1)
  - Use of radiotracers for basic research

Professional Organizations

- Well respected
- Provide guidance documents
- Provide continuing education
- Credentialing
- Accreditation

Key Elements in Preparedness

- Know what is required based on the regulations, your license conditions, and your procedures.
- Make tables or lists of what needs to be done and their frequency.
- The Radiation Safety & Compliance Program should be on an annual review cycle. (10 CFR 20.1101)
- DOCUMENT! DOCUMENT! DOCUMENT!
**Documentation**

- Must be readily accessible.
- Filed in a logical manner.
- Forms must be legible (in INK) and rational to both staff and the inspector.
- The documentation should clearly state:
  - Who
  - What
  - Where
  - When

**Corrective Actions**

**Summary**

- Model your program after NUREG 1556, vol 9 and/or other guidance documents.
- Radiation safety elements (package receipt, QA, waste management, training, credentialing) will come up in inspections.
- Be sure the staff at your facility know who you are (Radiation Safety Officer) and how they can get in touch with you.
- Compliance with TJC will likely cover a facility in terms of CMS.

**Thank You for your Attention**
Possible New Written Directive Requirements

- Pre-Implantation:
  - Radionuclide
  - Treatment site
  - Dose
  - Intended absorbed dose to treatment site
  - Total Source Strength (SS) to deliver the dose
  - Expected dose to normal issues within treatment site (i.e., urethra)

Written Directive Requirements

- Post-Implantation but before procedure end:
  - Radionuclide
  - Treatment Site
  - # of Sources implanted
  - Total Source Strength
  - Exposure time
  - AU signature and date
Written Directive Procedures
Proposed New Procedures

• 10 CFR 35.41(b)
  - Determine if Medical Event has occurred
  - Source position verification within 60 Days:
    • Total SS outside Treatment Area compared to the total SS in post-implantation WD
    • Absorbed Dose to the maximally exposed 5 contiguous cc of normal tissue outside of Treatment Site
    • Absorbed Dose to maximally exposed 5 contiguous cc of normal tissue inside Treatment Site

Medical Event Criteria
Permanent Implant Only

• Total SS administered differs by 20% or more from the documented SS in Post-implant WD.
• Total SS administered outside of Treatment site exceeds 20% of the documented SS in the post-implant portion of WD.
• Absorbed dose to 5 contiguous cc of normal tissue outside of Treatment site exceeds 50% of the absorbed dose prescribed to the Treatment site in Pre-implant WD.

Medical Event Criteria
Permanent Implant Only (cont.)

• Absorbed dose to 5 contiguous cc of normal tissue located within the treatment site exceeds by 50% or more the dose to that tissue based on the pre-implant distribution approved by the AU.
Medical Event Criteria
Permanent Implant Only (cont.)

- An administration that includes any of the following:
  - Wrong radionuclide
  - Wrong person
  - Sealed source delivered to wrong treatment site
  - A leaking source resulting in 0.5 Sv to an organ or tissue
  - A 20% or more error in calculating the SS documented in the pre-implant WD

How to get the dose information (CTDvol, DLP or SSDE) into the interpretive report?

- Dictate
- Tedious
- Prone to error
- Hard to search in the future
- Import the data
University of California - UC DOSE

- Electronically send CT dose page to PACS
- Automated import of CTDIvol and DLP to report
  - Implementation of dose calculation software engine
  - Extraction of series by series CT dose metrics
  - Inclusion of user defined message in speech engine
  - Creation of final report in RIS with dose metrics
  - Provide brief explanatory text in report

Example Reports

Implementation Considerations

- Radiologist speech templates must have a field to accept data for dose metric values
- Time for dose extraction step is needed (~10 minutes), before dose metrics are populated
- Exam splitting often results in different accession numbers with same dose metrics
- Radiologists request for minimal content (dose report often longer than anything else)