The Alphabet Soup of Regulatory Compliance: Being Prepared for Inspections

> Linda Kroger, MS UC Davis Health System

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

Agreement Status

ſ



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	♦SNMMI		
*RHB	*ASTRO		
∻FDA	♦ARRT		
*DOT	♦NMTCB		
*IATA	*ACR		
♦TJC	*AAPM		
*CMS	♦HPS		
*IRB	*NCRP		
*RSC	*ICRP		
*RDRC	*IAEA		

Regulatory Agencies

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

ting People and the Environm

*10CFR19, 10CFR20

C





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

J.S.NR

10CFR35

g People and the Envir

*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.

ſ

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



*35.1000

- *Microspheres (SIRSpheres, Theraspheres)
- *Gliasite
- ***GSR Perfexion**

10CFR35

*****35.10

 License always supersedes the regulations

10CFR35

1

*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 ¹³¹I (Nal) > 30 μCi
 Drug, dosage & route (for all but ¹³¹I)

(

*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

10CFR35

*35.40 *Written Directives

*Radiation Oncology therapies

♦For HDR

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

10CFR35

*35.40

- Written Directives
 - 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.

*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.

1

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 the 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

ple and the Envi

onle and the En

Regulatory Agencies

J.S.NR(

J.S.NR(

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

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

Regulatory Agencies

*FDA



*Drug approval *Equipment approval *Recall *RDRC

IND/NDA/ANDA
 Manufacturing of radiopharmaceuticals

Regulatory Agencies



*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

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.

• Issued Desender 28, 2013 •	Prep Requ	ublication
e Joint Commission has agenve hed in the semiannual updates to d paid substribers can also view an subscription, cal 877-223-6866 Revised Diagnost	d the following reveale o the print manuals (a o them in the monthly or visit http://www.jon Requirement tic Imaging	ons for prepublication. While metred requirements are pub- ss well as in the online E-distion ²⁵ , accredited organizations genotical. The Just Commission Pempectives ⁴⁷ . To begin nc com. ents for g Services
Amuthas Internet and Collect A Effective July 1, 2014 Environment of Care (EC)	KCAM PERMINER	matter, contrats line area line interveloping annotates line archivers in 745 Mill anatorie mann. • Making sure that these restricted areas are antituded in and under the devil succession of Mill barries date.
Standard EC.02.01.01		 Easting surgicity of the orderation to the APE science course that converse that outerthatic descenses.



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

Elements of Performance (EP).
 Leadership (LD)
 Medication Management (MM)
 Environment of Care (EC)
 Medical Staff (MS)

* CMS

*Conditions of Participation (CoP)







- 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

42 CFR 482.53

CFR Number	Medicare Standards	Joint Commission Equivalent Number	Joint Commission Standards
482.53	TAG: A-1026	L0.01.03.01 The governing body is utilimately accountable for the safety and quality and survivas	
§482.53 Condition of Participation: Nuclear Mediane Bankoes If the hospital provides nuclear medicine services, those services must meet the needs of the patients is accordance with acceptable standards of practice.	EP 3 The generating body approves the hospital's writes scope of services (the also PC 01010), EP 7) total PG hospital's that use Joint Commission accorditation for deemed status purposes. If entrygatory services are provided at the hospital the hospital complex with the requestments of 42 CPR 425 St Perform The Moderan Regularismust for Hospital's St Performance in the PC PR 425 St Perform The Moderan Regularisments for Regulari support.		
		EP 5 The governing body provide services. (See also NR 01)	es far the resources needed to maintain safe, quality care, treatment, and .01.01, EP 3)
		LD.04.01.01 The hospital com	plies with law and regulation.
		EP 2 The hospital provides care, rules and regulations.	treatment, and services in accordance with licensure requirements, laws, and
All Joi	nt Commission r	esources r	nust be purchased.





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.

A 19. © For Icritical access! hospitals that provide diagnostic computed tomography (CT) services: At least annually, a diagnostic medical physicist conducts a performance evaluation of all CT imagine equipment. The evaluation results, along with recommendations for correcting any problems identified, are documented. The evaluation includes the use of obstitutes to assess the following imaging metrics:

- Image uniformity
- Slice thickness accuracy
- Slice position accuracy (when prescribed from a scout image) <u>Alignment light accuracy</u>
- <u>Table travel accuracy</u>
- Radiation beam width
- High-contrast resolution
- Low-contrast resolution Geometric or distance accuracy
- CT number accuracy and uniformity
- <u>Artifact evaluation</u>

REPERTY + DAVE + DVINE + LONANCEUR + MERCID + DVERSER	I SAN THEO I NOT TRANSPORT OF THE OWNER & SANTALCING
ARREST FORM FROM FROM FROM FROM FROM	
A ANTHONY SERVICE (N.D. PROFILINGE OF RADIACION DA STREET, SALES AND SACIAMENTO, CALIFORNIA 19817	Telephone: (Mrs / Ne 000 Incomain: (Mrs / Ne 000 Incomit, productifications)
May 31, 2015	
NY, A	I DE CERTE DE LORSE DE
RE: Annual C1 inspection, Somens Definition Ca	ntiovascular C.1 Scanner, Room 1925 D1
On May 26, 2015, 1 performed an annual inspectio scanner located in the Main Hospital, room 1925 E	n on the Siemens candiovascular-dual energy CT tavis Tower. The following tests were performed:
Test	Result
Image Uniformity	PASS
Since Huckness Accuracy	16
Alignment Light Accuracy (presented	u iron scour) PASS
Table Tread & courses	PASS
Rediation Bram Width	PASS
High Contrast Resolution	PASS
Low Contrast Resolution	PASS
Geometric or Distance Accuracy	PASS
CT Number Accuracy and Uniform	nity PASS
Artifact Evaluation	PASS
Radiation Dosimetry	PASS
Gray Level Performance of CT Ac	quisition Display PASS
Evaluation of Technologist Contin	aous QC Program PASS
In summary, the system is performing within expo- uniformity, demonstrates expected spatial resoluti. For head and body imaging protocols. Since imple- software, the system is consistently providing high attached report has detailed measurements. Daily Quality Control data acquired by the technol the CT extreme demonstrative merchanisk median	eted limits, provides accurate CT numbers, has good in and indicates CTOLa, values within +-6 five percent neutration of the "SAFIRE" herative reconstruction quality, low dose images for most protocols. The uights and evaluated by software programs resident on anon survive.
evaluation of the console monitor used for displayi	and enterties, the nominary inclusion includes and CT images in addition to general verification of second in this mouth element contact me directly.

est	Result
mage Uniformity	PASS
Slice Thickness Accuracy	PASS
Slice Position Accuracy (prescribed from scout)	PASS
Alignment Light Accuracy	PASS
Table Travel Accuracy	PASS
Radiation Beam Width	PASS
High Contrast Resolution	PASS
Low Contrast Resolution	PASS
Geometric or Distance Accuracy	PASS
CT Number Accuracy and Uniformity	PASS
Artifact Evaluation	PASS
Radiation Dosimetry	PASS
Gray Level Performance of CT Acquisition Display	PASS
Evaluation of Technologist Continuous QC Program	PASS

(



Because the testing is annual, TJC says that they will not cite facilities until July 1, 2016.

ENVIRONMENT of CARE LEADER	May 11, 2015
For an isster of interaction for any end of a subject of to magnetic Any end of the subject of the subject of the any end of the subject of the subject of the subject of the end of the subject of the subject of the subject of the end of the subject of the subject of the subject of the end of the subject of the subject of the subject of the subject of the subject of the subject of the end of the subject of the subject of the subject of the subject of the subject of the subject of the end of the subject of the subject of the subject of the end of the subject of the subject of the subject of the end of the subject of the subject of the subject of the subject of the end of the subject of the subject of the subject of the subject of the end of the subject of the subject of the subject of the subject of the end of the subject of the subject of the subject of the subject of the end of the subject of the subject of the subject of the subject of the end of the subject of the subject of the subject of the subject of the end of the subject of the subject of the subject of the subject of the end of the subject of the subject of the subject of the subject of the end of the subject	Set of the
zere adjusto della conclusión de la publicaria advoyage anes/ reconcentra advoyage anes/	Source and the second preparation review
Entermonet Activ 20 Cardines networks are deal Composed and an antipation of the antipation Composed and antipation of the antipation of the antipation and antipation of the antipation of the antipation of the antipation and antipation of the antipation of th	i clock from balance (March Conners 16) is clock to March Conners (March Conners) is clock to March Conners is clock to March Conners
Survey readiness	Each patient room:
Use quick reminder list to help staff concentrate on common survey problems When system expecting a sarvey, create a quick enriched tak two and the help them toerty is and comme core mon problems source by surveyors. This inverters of possible HIS toers within the enri- noment of core had bees modified time a checklin- used help them the Medical Chene is thome Robers Co.	Norsecond made Norsecond made Norsecond made Norse size and conserve medicize drawer to ensure that also const. Some to sear and taby Comparison on wheels Norsecond made. Ormative more made to paid an aplication performance Informative more more than the up and no paid an appendix

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 equiment
- 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 <u>inspector</u>.
- > 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

 - Total Source Strength (SS) to deliver the
 - 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

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 <u>outside</u> Treatment Area compared to the total SS in post-implantation WD
 - Absorbed Dose to the maximally exposed 5 contiguous cc of normal tissue <u>outside</u> 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 <u>outside</u> 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 <u>outside</u> 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 (CTDIvol, 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
- Implementation of dose calculation software engin
- 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

EXAM: CT ABDOMEN + CT PELVIS, WITH CONTRAST DATE OF STUDY: 10/9/2012 11 29 AM

JATE OF STUDY: 10/9/2012 11 29 AM CLINICAL INFORMATION: Pain(acute), location: Pelvis: Left Othe specify: left hemia Bowel Comments:

TECHNIQUE: Helically acquired centrast enhanced multidetector CT of the abdomen and pelvis acquired in the portal venous phase, extending from the lung bases through the grains. Uneventful administration of 125 mi of Ommipaque 350 mjected at a rate of 2.5 milder. Images are reconstructed in the axial pane with subsequent reformatting in coronal and savital chances.

No P.O. contrast was ad

DOSE REPORT: This study involved (1) CT acquisition(s). The CTDW and DLP values are included below as required by state law. 1; Series: 3; Abdomen; 32 cm; CTDIvol=17.7 mGy; DLP=856.7 mGy

or further information on CT radiation dose, see http://www.ucdmc.ucdavis.edu/radiology/RadiationDose.html

COMPARISON: None.

FINDINGS:

EXAM TYPE: CT ANGIO CHEST WITH / WITHOUT CO COMPARISON: 8/12/2011

DATE: 10/9/2012 11:42 AM

1

INDICATION: History of 4-cm ectatic aota. Follow-up CT. TECHNQUE: Helical scanning from the thraceic lieft through the demands was performed following the unwentful administration of 100 mL of Ommogaes 350 at a rate of 4.0-mL's through a 29-pauge left interclubit wire. Reconstruction of 5-mm and 1.0 mm contiguous urages was performed. 5-mm contiguous coronal and sagital images 10 mm contiguous MIP axail images were reformated.

RADIATION DOSE: This study impleid () CT acquisition(s). The CTUhel and DLP values are included below as required by state law: 1. Series 2; Desk1; 22 cm; CTUhel2 9 Moy; DLP-3 mGy-cm 2. Series 3; Dhest; 32 cm; CTUhel2 4 Moy; DLP-26 mGy-cm Series 5; Dhest; 32 cm; CTUhel3 5 Moy; DLP-26 mGy-cm Fer further information on CT radiation dose, see http://www.odcm.ucdesis.edu/vad/adogn/FadatationDose.html

FINDINGS:

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

ſ

Radiologists request for minimal content (dose report often longer than anything else)