RADIATION SAFETY FROM A DIAGNOSTIC PERSPECTIVE

Carly Hansen, MS
April 18, 2021

DISCLOSURES

• None
OBJECTIVES

Understand the Diagnostic Physicist’s responsibilities as RSO

Obtain a better understanding of common regulatory issues encountered in the medical use of radioactive material and x-ray equipment

ABOUT ME

Medical Physicist – Texas Children’s Hospital, Houston, TX

Consulting Medical Physicist – Radcom Associates, Garland, TX

Health Physicist – Texas Radiation Control Program, Austin, TX
WHAT IS A RADIATION SAFETY OFFICER?

According to the Conference of Radiation Control Program Directors’ (CRCPD) Suggested State Regulations (SSR), an RSO is:

• “an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations and has been assigned such responsibility by the licensee or registrant”

RSO RESPONSIBILITIES

10 CFR 35.24(b)

A licensee’s management shall appoint a:

• Radiation Safety Officer who agrees, in writing, to be responsible for implementing the radiation protection program.
• Shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

10 CFR 35.24(g)

A licensee shall provide the RSO sufficient authority, organizational freedom, time, resources, and management prerogative to:

• Identify radiation safety problems;
• Initiate, recommend, or provide corrective actions;
• Stop unsafe operations; and,
• Verify implementation of corrective actions.
HOW DO YOU QUALIFY TO BE AN RSO? (RAM)

**Board Certification**

10 CFR Part 35.50(a)
- Is **certified by a specialty board** whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (d) of this section. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page.

10 CFR Part 35.50(d)
- Has **training in** the radiation safety, regulatory issues, and emergency procedures for the **types of use for which a licensee seeks approval**. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, an Associate Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

**Training & Experience**

**RSO on a previous RAM License**

**Authorized Medical Physicist or Authorized User**
HOW DO YOU QUALIFY TO BE AN RSO? (RAM)

Board Certification

- American Board of Health Physics
- American Board of Science in Nuclear Medicine
- Nuclear Medicine Physics & Instrumentation
- Radiation Protection
- American Board of Radiology
- Diagnostic Radiological Physics
- Diagnostic Medical Physics
- Medical Nuclear Physics
- Nuclear Medical Physics
- American Board of Medical Physics
- Medical Health Physics

Training and Education

- 200 hours of classroom and laboratory training:
  - Radiation physics and instrumentation
  - Radiation protection
  - Mathematics pertaining to the use and measurement of radioactivity
  - Radiation biology
  - Radiation dosimetry

One year of full-time radiation safety experience under the supervision of an RSO. Experience must involve:

- Shipping, receiving, and performing related radiation surveys;
- Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
- Securing and controlling byproduct material;
- Using administrative controls to avoid mistakes in the administration of byproduct material;
- Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
- Using emergency procedures to control byproduct material; and
- Disposing of byproduct material;
- Written attestation, signed by a preceptor Radiation Safety Officer

*Must state that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (d) of this section, and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer*
HOW DO YOU QUALIFY TO BE AN RSO? (RAM)

RSO on a previous RAM license

• If you have been an RSO on a RAM license in the past, you can typically submit a copy of that license that shows you as RSO in lieu of other documentation

To whom it may concern:

I am writing to request the following changes to our Radioactive Materials License:

• Please change the radiation safety officer to Carly Hansen, MS.

• Please see the attached copy of RAM License No. XXXXXX for evidence of qualification.

Sincerely,

Signed by someone in upper management
HOW DO YOU QUALIFY TO BE AN RSO? (RAM)

Authorized User, Authorized Medical Physicist, or Board Certified Medical Physicist

10 CFR Part 35.50(c)
• (1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under § 35.51(a)...
• (2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a Commission or an Agreement State license...

10 CFR Part 35.50(d)
• Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, an Associate Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

PATHWAYS FOR QUALIFYING AS RSO (RAM)

Physicist
• Four pathways outlined above

Technologist (x-ray or nuclear medicine)
• Can qualify under the Training and Education
• May have to take a specific RSO course to complete required training hours
• May be able to show training hours through transcripts and continuing education
• Need “1 year RSO experience”

Physician
• Qualify under Training and Education
• Required hours and topics are completed in radiology residency program
• Need “1 year RSO experience”
• Qualify under Authorized User status
• Still need some “RSO training” signed off by RSO
TEMPORARY RSO

10 CFR 35.24(c)

- For up to 60 days each year, a licensee may permit an individual qualified to be a Radiation Safety Officer, under §§ 35.50 and 35.59, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in paragraph (g) of this section, if the licensee takes the actions required in paragraphs (b), (e), (g), and (h) of this section and notifies the Commission in accordance with § 35.14(b).

RADIATION SAFETY COMMITTEE

When is it required?

10 CFR 35.24(f)

- Licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H of this part, or two or more types of units under Subpart H of this part, shall establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.
RADIATION SAFETY COMMITTEE - WHEN IS IT REQUIRED?

2 or more of these:

<table>
<thead>
<tr>
<th>Subpart</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subpart E</td>
<td>Unsealed Byproduct Material – Written Directive Required</td>
</tr>
<tr>
<td>Subpart F</td>
<td>Manual Brachytherapy</td>
</tr>
<tr>
<td>Subpart H</td>
<td>Photon Emitting Remote afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units</td>
</tr>
</tbody>
</table>

--- Or ---

2 or more of these:

| Subpart H | Photon Emitting Remote afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units |

RSO RESPONSIBILITIES X-RAY

State Specific

Example: Texas

- Establishing and overseeing operating and safety procedures that maintain radiation exposures as low as reasonably achievable (ALARA)
- Review operating procedures them at intervals not to exceed 12 months;
- Ensuring that individual monitoring devices are properly used by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by §289.203 of this title;
- Investigating and reporting to the agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this chapter
- Assuming control and having the authority to institute corrective actions including shut-down of operations when necessary in emergency situations or unsafe conditions; and
- Maintaining records as required by this chapter
HOW DO YOU QUALIFY TO BE AN RSO?  X-RAY

State Specific Requirements
Typically More Pathways
Less Strict T&E requirements
State specific
- knowledge of potential radiation hazards and emergency precautions; and
- completed educational courses related to ionizing radiation safety or a radiation safety officer course; or
- experience in the use and familiarity of the type of equipment used.

EXAMPLE X-RAY RSO PATHWAYS

Example: Texas

Physician
- Practitioner with documentation of licensing board number

Physicist
- Texas medical physics license

Technologist
- ARRT & 2 years experience
- MRT & 2 years experience
- LMRT & 4 years experience

Other
- Associate degree in radiologic technology, health physics, or nuclear technology, and at least 2 years experience
- Nurse & 2 years experience with radiation machinery
- PA & 2 years experience
- Bachelor’s or higher in radiologic technology, health physics, or nuclear technology and at least 2 years of supervised experience
HOW DO YOU QUALIFY TO BE AN RSO?  X-RAY

Example: Minnesota

The individual designated as a radiation safety officer must be either a licensed practitioner of the healing arts;
or an individual who has completed training in the following items:

• fundamentals of radiation safety;
• familiarization with facility’s radiation-producing equipment;
• film processing, if applicable;
• quality assurance program;
• audits of the quality assurance program;
• emergency procedures for radiation-producing equipment failures;
• proper use of personal dosimetry, if applicable;
• requirements of pertinent state rules; and
• the registrant’s written operating and emergency procedures
The hospital designates an individual to serve as the radiation safety officer who is responsible for making certain that radiologic services are provided in accordance with law, regulation, and organizational policy. This individual has the necessary authority and leadership support to do the following:

- Monitor and verify compliance with established radiation safety practices (including oversight of dosimetry monitoring)
- Provide recommendations for improved radiation safety
- Intervene as needed to stop unsafe practices
- Implement corrective actions

For CT, PET, NM, or Fluoro

- The results of staff dosimetry monitoring are reviewed at least quarterly
- To assess whether staff radiation exposure levels are ALARA
- Reviewed by:
  - RSO
  - Diagnostic medical physicist
  - Health physicist
TJC - SHIELDING DESIGNS

EC.02.06.05 EP 4

For CT, PET, or NM services:
- A structural radiation shielding design assessment is conducted
  - Prior to:
    - Installation of new imaging equipment
    - Replacement of existing imaging equipment
    - Modification to rooms
  - For:
    - Rooms where ionizing radiation will be emitted
    - Rooms where radioactive materials will be stored (scan rooms or hot labs)
  - Conducted by:
    - Medical physicist
    - Health physicist

TJC - SHIELDING INTEGRITY TESTING

EC.02.06.05 EP 6

For CT, PET, or NM services:
- Radiation protection survey to verify the adequacy of installed shielding
  - Prior to:
    - Clinical Use of Room
  - For:
    - Installation of imaging equipment
    - Construction in rooms where ionizing radiation will be emitted
    - Construction in rooms where radioactive materials will be stored (scan rooms or hot labs)
  - Conducted by:
    - Medical physicist
    - Health physicist
TJC – FLUOROSCOPY DOSE TRACKING AND REFERENCE LEVELS

- Document Fluoroscopy Doses in Retrievable Format
- Set Dose Threshold Levels
- Is Threshold Exceeded?
  - Yes: Review and analyze case
  - No: Keep calm and fluoro on

TJC – FLUOROSCOPY DOSE DOCUMENTATION

PC.01.02.15 EP 13

For hospitals that provide fluoroscopic services:

- The cumulative-air kerma or kerma-area product is documented in a retrievable format.
- For fluoroscopy equipment that cannot display or provide cumulative-air kerma or kerma-area product, fluoroscopy time and number of images acquired are documented in a retrievable format, such as a picture archiving and communication system.
- Note: This element of performance does not apply to fluoroscopy equipment used for therapeutic radiation treatment planning or delivery or fluoroscopy equipment classified as a mini C-arm.
TJC – FLUOROSCOPY DOSE THRESHOLD LEVELS

PC.02.01.01 EP 30

For hospitals that provide fluoroscopic services:

- The hospital identifies radiation exposure and skin dose threshold levels that, if exceeded, trigger further review and/or patient evaluation to assess for adverse radiation effects.
- Note 1: Information on radiation exposure thresholds can be found in the National Council on Radiation Protection’s (NCRP) report number 168 and on the US FDA’s CDRH website.
- Note 2: Radiation exposure thresholds may be established based on metrics such as reference-air kerma, cumulative-air kerma, kerma-area product, or fluoroscopy time.

TJC – FLUOROSCOPY DOSE REVIEW

PC.02.01.01 EP 20

For hospitals that provide fluoroscopic services:

- The hospital reviews and analyzes instances where the radiation exposure and skin dose threshold levels identified by the organization are exceeded.
AMERICAN COLLEGE OF RADIOLOGY (ACR)

ACR Toolkit

• Updated from time-to-time
• Make sure you are using the most up-to-date Toolkit
• Will make ACR surveys go smoother!

https://www.acraccreditation.org/resources/validation-site-survey

ACR - ULTRASOUND

2/11/2021

Ultrasound/Breast Ultrasound Equipment Annual Survey Summary
• All facilities applying for accreditation or renewal must demonstrate compliance with the ACR ultrasound QC requirements by completing and submitting the ACR's Ultrasound/Breast Ultrasound Equipment Annual Survey Summary for each unit.
• Strongly recommend submitting the ACR Ultrasound/Breast Ultrasound Equipment Annual Survey Summary page,
• May provide own summary as long as it itemizes the pass/fail results for each required test.
• The original comprehensive annual survey report must be retained by the facility and will be requested during validation site surveys.
## ACR - NUCLEAR MEDICINE

### Quality Control: Nuclear Medicine

#### Phantom Scan

- **Required Semiannually**
- **Recommended Quarterly**

### Continuous Quality Control

#### Quality Control: Nuclear Medicine Tests

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<tbody>
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<td>Intrinsic or System Spatial Resolution</td>
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</tr>
<tr>
<td>Center of Rotation</td>
<td>Monthly</td>
</tr>
<tr>
<td>High-Count Flood for Uniformity Correction</td>
<td>Semiannually (quarterly recommended)</td>
</tr>
<tr>
<td>Overall System Performance for SPECT Systems</td>
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<tr>
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<tr>
<td>Thyroid Uptake and Counting Systems</td>
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### ACR - NUCLEAR PET

### Quality Control: PET

#### Phantom Scan

- **Required Semiannually**
- **Recommended Quarterly**

## Nuclear Medicine Technologist’s Quality Control Tests

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COMMON RECOMMENDATIONS / VIOLATIONS

HAZMAT TRAINING FREQUENCY

DOT
- All employees involved with the packaging, marking, labeling, measuring, loading, transporting, and storage of packages containing radioactive material are classified as “Hazmat Employees” and must have DOT training within 90 days of employment and every 3 years thereafter. (49 CFR 172.704)

IATA (International Air Transport Association)
- 2 years
- Ex: rubidium generators are shipped by air
RAM RECEIPT LOGS

10 CFR Part 20.1906

Procedures for Receiving and Opening Packages
- The licensee shall perform the monitoring required by paragraph (b) of this section as soon as practical after receipt of the package, but not later than 3 hours after the package is received at the licensee’s facility if it is received during the licensee’s normal working hours, or not later than if it is received after 3 hours from the beginning of the next working day working hours.

Do you know what time are your packages delivered?

How do you ensure they are checked in within 3 hours?

• Some solutions:
  - Delivery person writes time on box with dry erase marker
  - Log sheet left in hot lab that driver fills out
LABELS FOR RAM SOURCES AND SOURCE HOLDERS

10 CFR 20.1904 Subpart J – Precautionary Procedures

Labeling Containers
- The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL” or “DANGER, RADIOACTIVE MATERIAL.” The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation in the vicinity of the containers, to take precautions to avoid or minimize exposures, levels, kinds of materials, and mass enrichment) to permit individuals handling or using the containers, or working...

10 CFR 20.1905

Exemptions to labeling requirements
- A licensee is not required to label:
  - Containers holding licensed material in quantities less than the quantities listed in appendix C to part 20...
  - Co-57: 100 uCi
  - Cs-137: 10 uCi

COMMON RAM LABELING ISSUES

New flood sources
- Update the label on the existing case
- FYI, an extra label is included in the source envelope kit for this purpose!

Watch vial sources (especially older ones)
- Labels can peel off
- Sometimes the label stays in place, but printing comes off
CONTAMINATION WIPES / WELL COUNTER

BACKGROUND

10 CFR 20.1101 & NRC 10 CFR 20.1501

Appendix R of NUREG-1556, Volume 9, Revision 3, recommends:

• Removable contamination surveys weekly for radiopharmaceutical elution, preparation, assay, and administration areas.

Where is the well counter located?

When is the background performed?

When are the wipe tests performed?

Is background recounted before the wipe tests are counted?
Provide Exposure in Writing

NRC Form 3 (or state equivalent)

“Notice to Employees”

...your employer is required to provide you with an annual report of the dose you received in that monitoring year if the dose exceeds 100 millirem, or if you request an annual report.
PERSONNEL MONITORING – RECORD KEEPING

Dosimetry Records

How long do I have to keep them?

10 CFR Part 20.2106

Records of Individual Monitoring Results

• The licensee shall retain the required form or record until the Commission terminates each pertinent license requiring this record.

PERSONNEL MONITORING – RECORD KEEPING

10 CFR Part 20.2106

Records of Individual Monitoring Results

(a) Recordkeeping Requirement

• Each licensee shall maintain records of doses received by all individuals for whom monitoring was required...

(b) Recordkeeping Frequency

• The licensee shall make entries of the records at least annually

(c) Recordkeeping Format

• The licensee shall maintain the records specified in paragraph (a) of this section on NRC Form 5, or in clear and legible records containing all the information required by NRC Form 5
PERSONNEL MONITORING – EDE CORRECTIONS

EDE 1
- Two dosimeters
- Waist level under lead apron
- Collar level outside lead apron
- $1.5 \text{ (waist DDE)} + 0.04 \text{ (Collar DDE)} = \text{Assigned deep dose equivalent}$

EDE 2
- One dosimeter
- Collar level outside lead apron
- $0.3 \text{ (Collar DDE)} = \text{Assigned deep dose equivalent}$

Determine if your state accepts this correction method
Determine which corrections are applicable to what employees

TECHNIQUE CHARTS

Example: Texas

Technique Chart Use
- A technique chart relevant to the particular radiation machine shall be provided or electronically displayed in the vicinity of the control panel and used by all operators.

Technique chart definition
- A chart that provides technical factors, anatomical examination, patient thickness for examination being performed, and source-to-image distance needed to make clinical radiographs when the radiographic system is in manual mode.
TECHNIQUE CHARTS

Example: Minnesota

Radiographic Technique Chart

- A radiographic technique chart must be provided in the vicinity of the x-ray system’s control panel.
  - The technique chart must specify the following information for all examinations:
    - the technique factors to be used for anatomical parts and patient size;
    - the type of screen, type of film, and speed combination to be used;
    - the source-to-image distance to be used;
    - for automatic exposure control (AEC) or phototimed units, the percent differences between the AEC increments.
  - For computed tomography systems, a current technique chart for each routine examination and the computed tomography conditions of operation must be provided.
  - For filmless radiography, including computed radiography, digital radiography, computed tomography systems, and photostimulable storage phosphor imaging, the technique chart must reflect the adult and pediatric technique parameters for the individual system. This includes the manufacturer’s requirements for technique parameters.

Exceptions.

- Diagnostic radiation-producing equipment manufactured with anatomical programming and industrial facilities with radiation-producing equipment are exempt from subpart 2.

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TECHNIQUE CHARTS

Be familiar with your state’s regulations regarding technique charts

Develop a strategy for discussing with technologists

- Ask how/if techs use the technique chart
- Explain what an inspector may be looking for during an inspection
- Explain some physics measurements and how they impact the technique chart

Demonstration

Have 3 or 4 technologists write down what technique they would use on an abdominal x-ray of yourself.

Compare answers – may be surprised at differences!
CAUTION SIGNS FOR DIAGNOSTIC X-RAY & CT ROOMS

So many options......

10 CFR 20.1902(a) - Subpart J

Posting of radiation areas.

- The licensee shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words “CAUTION, RADIATION AREA.”

Definitions

- Radiation area means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates. 10 CFR §20.1003

Definitions
CAUTION SIGNS FOR DIAGNOSTIC X-RAY & CT ROOMS

10 C.F.R. § 20.1901

Caution Signs

• Sign must include standard radiation symbol

• Radiation symbol shall be magenta, purple, or black on yellow background

RSO RESOURCES

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Medical Use Licenses
THANK YOU FOR LISTENING