

ACR-AAPM Radiation Safety Officer Resources

2021 Revision



ACR-AAPM Radiation Safety Officer Resources

Essential information for radiation safety officers at medical imaging facilities.

American College of Radiology

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Preface

The following resolution was adopted at the American College of Radiology’s 2012 Annual Meeting and Chapter Leadership Conference. This document is the result of that adoption.

Resolution: Radiation Safety Officer Training

The American College of Radiology, in collaboration with the American Association of Physicists in Medicine and other stakeholders, should provide models and educational materials for medical physicists, radiologists, radiation oncologists, and nuclear medicine physicians who provide radiation safety officer services; adopted 2012 (Res. 43).

Acknowledgements from the Chair

This “ACR-AAPM RSO Resources” revises and updates the previous document that was originally published in 2015. The original report is regularly viewed a few hundred times per month on the ACR website. It has been used in several educational and training programs around the world. This revision was the work of many dedicated individuals under the auspices of the Education Committee of the ACR Commission on Medical Physics. In particular, I wish to thank the members of the revision group with extra special thanks to Dustin Gress for keeping this project going during a worldwide pandemic. Updates to this version include a new section on safety culture with special focus on advancing radiation safety culture and safety awareness campaigns; a framework for starting a new radioactive material use with examples given for Lu-177 therapy; and an overview of emerging technologies radioactive materials use category, 35.1000. We hope you continue to find this tool useful. - *Jessica B. Clements, MS, FAAPM*

The ACR and the AAPM would also like to thank the following individuals for authoring and contributing to prior versions of this resources document:

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Please submit any comments and/or suggestions regarding the ACR-AAPM Radiation Safety Officer Resources for Physicians to the ACR at RSOresources@acr.org.

Description of Revisions

- Updates regarding Part 35 expansion, including information regarding radiation oncology and RAM policy & procedure review
- Updates related to Part 1000
- Information on starting new programs
- Additional resources for X-ray safety programs
- Updates regarding selecting an RSO
- Section on safety culture created, including Image Gently and Image Wisely
- Added hyperlink to NRC's expansive list of FAQs

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Introduction A. Scope and Limitations

This compilation of resources is intended to assist the radiologist in understanding and performing his or her duties as a radiation safety officer (RSO) for unsealed radiopharmaceuticals, sealed sources, and X-ray producing equipment used in medical imaging. Because of the complexity of the subject, the scope has been limited to radiation safety in facilities engaged primarily in medical imaging and some radionuclide therapies, and does not include radiation producing equipment for radiation therapy and/or for research. All links are accurate as of press time.

B. Federal Versus State Regulation

The RSO's role is tied closely to regulations. Regulation of radioactive materials in the United States is under the jurisdiction of the U.S. Nuclear Regulatory Commission (NRC). However, the NRC's authority may be relinquished to a state by an [agreement](#) signed by the state's governor and chair of the NRC.

As of August of 2020, there are 39 such "[Agreement States](#)" (plus the District of Columbia) that take responsibility for regulating radioactive materials within their borders. Each Agreement State must have legally binding requirements that satisfy the [federal legislation](#). State regulations may be more or less stringent than those of the NRC. Agreement State regulations do not apply to federal facilities located in an Agreement State, which are licensed and regulated by the NRC.

It is not possible in this document to address the differences in rules for all states. Therefore, references to regulations and guidance will generally refer to those of the NRC. Most Agreement State regulations mimic the NRC regulations very closely. However, differences may be substantial and the RSO must be aware of them. The NRC's website provides [links to all the Agreement State websites](#).

With the exception of mammographic screening, which is regulated by the U.S. Food and Drug Administration under the [Mammography Quality Standards Act](#) (MQSA), the use of X-ray producing equipment is regulated by individual states. States' X-ray safety rules vary widely. Although it is not possible to address each set of state rules in this resource, the Conference of Radiation Control Program Directors (CRCPD) developed a set of Suggested State Regulations (SSR). These will be referred to rather than specific states' regulations when particular regulatory wording is appropriate. The CRCPD website provides links to [individual state radiation control programs](#). [Section VII](#) also includes more information.

In any case, government rules, regulations, and guidelines are constantly changing. The accuracy of statements in this document is limited to the status at the time of development.

Radiation Safety Officer (RSO) Roles, Responsibilities, and Education

A. Roles and Responsibilities

1. RSO

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.”

The RSO's role in the radiation protection program is outlined in [AAPM Report 160](#), Section 2.4, as follows:

The RSO is responsible for the implementation, coordination, and day-to-day oversight of the radiation protection program. In addition, the RSO has the authority to enforce radiation policies and procedures regarding radiation safety and regulatory compliance of the use of ionizing radiation. The RSO is normally not responsible for the direct supervision of individuals using ionizing radiation in their daily routines. These individuals are supervised (under RSO oversight) by other members of the “radiation safety team” as required by regulation and/or by the radiation protection program.

The responsibilities of the RSO, as outlined in AAPM Report 160, Section 3.2, are as follows:

- Implementing and overseeing the operational aspects of the radiation protection program.
- Ensuring (for the licensee) that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.
- Reviewing and approving (with licensee management) radiation protection program changes before implementation.
- Helping to identify and investigate radiation safety problems.
- Initiating, recommending, or providing corrective actions for identified safety problems.
- Verifying implementation of corrective actions.
- Stopping operations identified as unsafe.
- Notifying management of radiation safety problems, unsafe operations, and corrective actions.
- Serving as a member of the radiation safety committee, if applicable, and attending the meetings.
- Providing a link between the radiation safety committee and the users of ionizing radiation.
- Providing contact between the licensee and the regulatory agencies.

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- Being available for contact by facility staff per regulations and license conditions.
- Signing semiannual sealed-source leak tests and inventories of sealed sources per regulation.

2. Associate RSO

At some institutions the radiation safety officer may need assistance due to availability or the extensiveness of the program. It is not uncommon at institutions where radiologists are the RSOs for them to be assisted in meeting their requirements by a nuclear medicine technologist, a medical physicist, and/or a health physicist. These individuals may assist on an internal basis only or, if state regulations are the same as [10 CFR 35.24](#), the licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer and who are to be identified on the license. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. Appointment of Associate RSOs does not change the RSO's sole authority and responsibility for radiation safety.

3. Temporary RSO

According to [NRC 10 CFR 35.24\(c\)](#), for up to 60 days each year, a licensee may permit an authorized user, an authorized medical physicist or an individual qualified to be a RSO under [NRC 10 CFR 35.50](#) and [NRC 10 CFR 35.59](#) to function as a temporary RSO and to perform the functions of a RSO, as provided in paragraph (g) of [NRC 10 CFR 35.24](#), if the licensee takes the actions required in paragraphs (b), (e), (g), and (h) of [NRC 10 CFR 35.24](#) and notifies the Commission in accordance with [NRC 10 CFR 35.14\(b\)](#).

B. Delegation of Authority

[NRC 10 CFR 35.24\(g\)](#) requires a licensee to provide the RSO sufficient authority, organizational freedom, time, resources, and prerogative of management, to complete the following activities:

- Identify radiation safety problems;
- Initiate, recommend, or provide corrective actions;
- Stop unsafe operations; and
- Verify implementation of corrective actions.

A sample delegation of authority statement can be found in Appendix I of [NUREG-1556, Volume 9, Revision 3](#).

A sample delegation of authority policy for an X-ray facility can be found later in this document, [here](#).

C. RSO Education and Training Requirements

The RSO must meet the training experience requirements of the applicable licensing agency. Training requirements for an RSO are outlined in [NRC 10 CFR 35.50](#).

There are exceptions to the above for certain situations outlined in [NRC 10 CFR 35.57](#).

The NRC posts on their web site the specialty boards that they recognize, [here](#).

Board recognition only applies to individuals who were certified after the date for which the NRC recognized the specialty board. This disallows the board certification pathway for qualification to some experienced individuals who may otherwise be considered for RSO. In addition, presence on the list of approved specialty boards may imply to licensee and its management that the certifications are equal. However, the various certifications are different, and the qualifications indicated by one board certification may be more applicable to an individual licensee's needs than others.

General Radiation Safety Officer (RSO) Duties

A. Radiation Protection Program

[NRC 10 CFR 20.1101](#) states that each licensee must develop, document, and implement a radiation protection program commensurate with the scope of the licensed activity. The program must be sufficient to ensure compliance with the provisions of [NRC 10 CFR Part 20](#) regulations. The licensee is responsible for the conduct of all licensed activities and the acts and omissions of individuals handling licensed material. The radiation protection program should also include all ionizing radiation-producing equipment as well.

1. Radiation Program Audits

Audits are performed on a regular basis to make certain that the radiation safety program is effective and meeting the regulations. [NRC 10 CFR 20.2102](#) discusses maintaining audit records and other reviews of program content and implementation.

2. Radiation Safety Training Program

- Fluoroscopy Safety Training
- See the [AAPM Report 124, A Guide for Establishing a Credentialing and Privileging Program for Users of Fluoroscopic Equipment in Healthcare Organizations](#).
- Radioisotope Handling Techniques for Nuclear Medicine
- See the [Society of Nuclear Medicine and Molecular Imaging \(SNMMI\) Nuclear Medicine Technologist Scope of Practice and Performance Standards](#).
- Radioisotope Training Programs for Nurses
- The use of radioactive materials for therapeutic purposes poses unique problems when the patient is hospitalized. Nurses who provide care for these patients should be trained commensurate with the radiation sources they could encounter. See [Radiation Safety Training for Nurses Who Provide Care for Brachytherapy or Unsealed Radioisotope Therapy Patients](#) for more information.

B. Personnel Monitoring

1. Regulatory requirements for personnel monitoring:

[NRC 10 CFR 20.1502](#)

2. Regulatory limits for occupational exposure:

[NRC 10 CFR Part 20 Subpart C—Occupational Dose Limits](#)

3. Dose equivalent to the embryo/fetus:

[NRC 10 CFR 20.1208](#)

4. Regulatory limits for occupational dose limits for minors:

[NRC 10 CFR 20.1207](#)

5. Personnel Monitoring Frequency

Personnel monitoring frequency can be either monthly or quarterly depending on the employee's radiation usage. Previous dosimetry can be reviewed and the frequency set. In most hospitals, high radiation use is associated with fluoroscopy-guided procedures with cardiology catheterization, cardiac surgery, and interventional radiology.

6. Types of Personnel Monitoring

Under [NRC 10 CFR 20.1501](#), licensees must verify that the processor is accredited by the National Voluntary Laboratory Accreditation Program for the type of radiation for which monitoring will be performed. Consult with the previous radiation safety officer or another facility or Internet source for a National Voluntary Laboratory Accreditation Program (NVLAP)-accredited supplier.

7. Periodic and Annual Reviews

The RSO should review all monitored employees on a regular interval as well as conduct an annual review to make certain the employee maintains his/her exposure below the regulatory limits.

C. Radiation Safety Committee

For specific licenses, the following applies, according to [NRC 10 CFR 35](#):

“Licensees that are authorized for two or more different types of uses of byproduct material under Subparts E (Unsealed Byproduct Material—Written Directive Required), F (Manual Brachytherapy), and H (Photon-Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units) 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 RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO. The committee may include other members the licensee considers appropriate.”

Please note that some states may have regulations that supersede or overlap with NRC radiation safety regulations. In all cases, you should check applicable state regulations for additional requirements.

D. As Low as Reasonably Achievable (ALARA)

What is ALARA? [ALARA](#) is a concept that reminds everyone to keep occupational radiation exposures As Low as Reasonably Achievable. This radiation safety practice minimizes radiation doses and releases of radioactive materials using all reasonable methods available. Using ALARA is a good radiation safety practice and is a regulatory requirement for all radiation safety programs.

1. Setting Facility ALARA Limits

Each RSO should set ALARA limits for employee occupational exposure either through the institution's radiation safety committee, by consulting with other established radiation safety programs, or by consulting with commercial dosimeter companies. The limits are usually a percentage of the allowed limits. For example, you could set an ALARA limit at 10% of the established level.

- ALARA level 1
- This limit is usually a smaller fraction of the exposure limit, such as a 10% limit, which a majority of the institution radiation users can stay under.
- ALARA level 2
- This higher limit that represents a larger fractional exposure than ALARA level 1 such as 30% that few individuals should approach or exceed in your institution.

2. ALARA Level Investigations

If a radiation worker's dosimetry indicates that the ALARA level 1 limit has been exceeded, a notification is sent to the worker to advise him/her that they have exceeded the level 1 dose limit and to provide information on how to reduce occupational radiation exposure.

If a radiation worker's dosimetry indicates that the ALARA level 2 limit has been exceeded, a notification is sent to the worker to advise him/her that they have exceeded the dose limit for level 2 and includes information on how to reduce occupational radiation exposure. The notification also includes a signature page that requires the employee to attest that he/she understands that they have exceeded the level and also requires the employee to specify why the larger-than-expected exposure occurred. Investigation into the exposure can be initiated by the RSO as needed. See [NUREG-1556, Volume 9, Revision 3](#), for more information. Your state may have additional reporting requirements.

E. Safety Culture

1. General

Radiation safety culture is a subset of general safety culture and many of its principles have been formed from nuclear and process safety culture. The [Health Physics Society adopted](#) the [NRC's definition of nuclear safety culture](#), defining radiation safety culture as, "the core values and behaviors resulting from

III. General Radiation Safety Officer (RSO) Duties

a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment.”

The [NRC's Safety Culture Policy Statement](#) includes a non-exhaustive list of nine traits characteristic of good safety culture. The traits “describe patterns of thinking, feeling, and behaving that emphasize safety, particularly in goal conflict situations, such as when safety goals conflict with production, schedule or cost goals” and are as follows:

- Leaders demonstrate a commitment to safety in their decisions and behaviors.
- Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance.
- All individuals take personal responsibility for safety.
- The process of planning and controlling work activities is implemented so that safety is maintained.
- Opportunities to learn about ways to ensure safety are sought out and implemented.
- Personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment or discrimination.
- Communications maintain a focus on safety.
- Trust and respect permeate the organization.
- Individuals avoid complacency and continually challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

An International Atomic Energy Association (IAEA) Working Document provides a similar model for safety culture in its pamphlet [A Harmonized Safety Culture Model](#). The IAEA identifies three stages that organizations typically go through in establishing and sustaining a culture of safety. In the first stage, safety is compliance driven; in the second stage, it becomes an organizational goal; and in the third stage, it is seen as a continuing process of improvement to which everyone in the organization is committed. IAEA Safety Standards have extensive guidance on safety culture, creating a system for it, and managing it, particularly these three Safety Guides:

- [Fundamental Safety Principles](#)
- [Leadership and Management for Safety](#)
- [Application of the Management System for Facilities and Activities](#)

2. Methods for Advancing Radiation Safety Culture

The following is a non-exhaustive list of ideas for an RSO to consider in their efforts to advance safety culture in their operation(s):

- Review [ACR Imaging 3.0 case studies](#) that were developed through the Radiology Support and Alignment Network (R-SCAN) to support high-value imaging

- Review the [JACR's patient-friendly summaries](#) of Appropriateness Criteria
- Implement ongoing training and education programs to encourage and operationalize institutional safety (e.g. as described in [NCRP Report No. 168](#), or [ASTRO's Safety is No Accident](#))
- Ensure that radiation protection procedures are written in a clear, concise, and consistent manner and that they align with the guidance from expert professional societies
- Collect occupational exposure data and the number of late-returned and missing badges
- Encourage personnel to report incidents and concerns without fear of retaliation, and note the degree of reporting of such events
- Perform root cause analyses of radiation incidents and close calls
- Perform safety culture self-assessments with quantitative measures by surveying personnel on their radiation protection practices

3. Safety Awareness Campaigns: Image Gently® and Image Wisely®

The goal of the [Image Gently® Alliance](#) is to advocate for the lowering of radiologic exposures to pediatric patients while maintaining diagnostic image quality. The Alliance's ultimate aim is to change practice by providing information for practitioners and families about the benefits of imaging as well as techniques for mitigating risks. The campaign provides role-dependent recommendations for dose reduction and maintenance of quality, protocol recommendations, and online modality-specific education modules.

[Image Wisely®](#) is the corresponding initiative for dose optimization in adult patients. Imaging professionals, referring practitioners, imaging facilities, and associations or educational programs can take the annual Image Wisely Pledge to demonstrate their commitment to safe radiation practices. The annual Image Wisely Pledge Imaging facilities should ensure the following:

- All imaging professionals within the organization have taken the individual pledge
- Those performing exams have an understanding of radiation exposure
- Methodologies for optimization of radiation doses are utilized
- Recommendations for imaging techniques and protocols are reviewed and incorporated into practice
- There is an attempt to prevent duplicate exams
- The radiology practice is consultative in nature
- Dose indices are monitored
- The facility participates in a dose index registry
- The facility has earned accreditation

III. General Radiation Safety Officer (RSO) Duties

Image Wisely® also has an [article on Safety Culture](#), which could be distributed for personnel reference.

4. References

- USNRC [Safety Culture Information for Agreement States](#)
- [P Cole et al. Developing the radiation protection culture in the UK. 2014 J. Radiol. Prot. 34 469 \(pdf\)](#)
- [Key Practical Issues in Strengthening Safety Culture \(IAEA INSAG-15\)](#)

F. Summary of Duties

[AAPM Report 160](#) summarizes the duties of the RSO in the box below:

RSO Duty Topics

(See [AAPM Report 160](#), Appendix I, for detailed information.)

- Action or trigger Levels – overseeing ALARA action and trigger levels
- ALARA – developing and enforcing an ALARA program
- Audits/reports/reviews – auditing or reviewing audits of various aspects of the program
- Contamination/spill response – establishing contamination/spill response procedures and following up on spills
- Facility designation, design, and shielding
- Instruction of workers – ensuring appropriate instructions to workers
- License – maintaining license and procedures
- Machine registration/calibration/performance evaluation
- Medical events – managing medical events
- Ordering/receiving/transporting packages containing radioactive material
- Patient protection – establishing and enforcing patient protection requirements
- Patient release from regulatory control (outpatient)
- Personnel monitoring – establishing and managing personnel monitoring
- Post/reference documents and notices – posting or referencing regulatory documents
- Posting and labeling – signage, labeling, and required emergency procedure posting
- Pregnant workers – managing fetal exposures
- Radiation accidents

III. General Radiation Safety Officer (RSO) Duties

- Radiation safety committee – serving on radiation safety committee
- Radiopharmaceutical therapies (inpatient) – assuring adequate radiation safety for radiopharmaceutical therapies
- Records – overseeing record maintenance (see [AAPM Report 160](#), Appendix III).
- Sealed-source leak test and inventory – assuring testing is performed
- Security – assuring security of radioactive materials
- Surveys and survey instruments – overseeing surveys and calibration instrument maintenance
- Waste disposal – managing disposal of radioactive waste

X-ray Safety Program

A. Scope

A radiation safety officer (RSO) whose sole responsibility is an X-ray safety program will need the following information related to a basic X-ray safety program.

Radiation safety related to X-ray-producing equipment is regulated by state or local radiation safety control agencies in which it is registered. State/local regulations may vary significantly in their details. The regulatory information presented in this section is primarily based on material provided by the Conference of Radiation Control Program Directors (CRCPD) in its [Suggested State Regulations \(SSR\)](#). This information can provide a starting point to understanding the issues, but the RSO must be familiar with the regulations of the state in which the X-ray source is registered.

B. Responsibilities of the RSO in an X-ray Program

The RSO should have a [statement from management](#) delegating authority to perform the following:

- Establishing and overseeing operating and safety procedures that maintain radiation exposures as low as reasonably achievable (ALARA), and to review them regularly to ensure that the procedures are current and conform with regulations;
- 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 regulations;
- Investigating and reporting to the state/local regulatory agency any known or suspected cases of radiation exposure to an individual or radiation level detected in excess of regulatory limits and any theft or loss of source(s) of radiation, determining the cause, and taking steps to prevent its recurrence;
- Having a thorough knowledge of management policies and administrative procedures related to radiation safety and keeping management informed on a periodic basis of the performance of the radiation protection program, if applicable;
- Assuming control and having the authority to institute corrective actions including shut-down of operations when necessary in emergency situations or unsafe conditions;
- Maintaining records required by regulations; and
- Ensuring that personnel are adequately trained and comply with regulations, the conditions of the certificate of registration, and the operating and safety procedures of the X-ray equipment.

C. Qualifications and Training of the RSO

See [Part B of the Suggested State Regulations](#), Appendix C.

D. X-ray Safety Activities

1. Radiation Protection (ALARA) Program

To the extent practical, the RSO should assure that the facility uses procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are in line with ALARA. See the [sample ALARA policy](#).

2. Radiation Dose Limits

Radiation dose limits are specified by individual states but are generally consistent. Dose limits to the general public are specified by the U.S. Environmental Protection Agency, and dose limits to workers are specified by the U.S. Occupational Safety and Health Administration ([OSHA](#)) as well. Although states may only specify annual limits, OSHA limits exposures to one-fourth the typical annual limit in any one calendar quarter as well.

3. Personal Radiation Monitors

a. Who must be monitored?

- Adults likely to receive 10 % of any annual regulatory limit;
- Minors likely to receive in excess of 1 millisievert (mSv) [0.1 rem] per year, a lens dose equivalent in excess of 1.5 mSv (0.15 rem), or a shallow dose equivalent to the skin or to the extremities in excess of 5 mSv (0.5 rem);
- Declared pregnant women likely to receive (during the entire pregnancy) a deep dose equivalent in excess of 1 mSv (0.1 rem);
- Individuals entering a high or very high radiation area; and
- Individuals working with medical fluoroscopic equipment.

b. Where must monitors be worn?

- For the dose to an embryo/fetus of a declared pregnant woman, under the protective apron at the waist.
- For the lens dose, at the neck (collar) or an unshielded location closer to the eye, outside the protective apron.
- When only one individual monitoring device is used to determine the effective dose equivalent, at the neck (collar) outside the protective apron.
- If a second individual monitoring device is used for the same purpose, under the protective apron at the waist.
- The second individual monitoring device is required for a declared pregnant woman.

4. Occupational Dose Limits

a. Adults

- i. Annual limit is the more limiting of the following:
 - The total effective dose equivalent being equal to 0.05 sievert (5 rem); or
 - The sum of the deep dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 sievert (50 rem).
- ii. Some states allow the effective dose equivalent for external radiation to be determined according to Webster's equation¹ as follows:
 - When only one individual monitoring device is used located at the neck (collar) outside the protective apron, effective dose equivalent = reported deep dose equivalent \times 0.3; or
 - When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, effective dose equivalent = deep dose equivalent reported at the waist \times 1.5 + deep dose equivalent reported at the neck \times 0.04.
- iii. Annual limits to tissues/organs include the following:
 - Lens: 0.15 sievert (15 rem);
 - Skin or extremities: 0.5 sievert (50 rem)

b. Minors

The occupational dose limit for minors is 10% of that for adult workers.

c. Dose equivalent to an embryo/fetus

- Fetal limit during gestation from occupational exposure: 5 mSv (0.5 rem)
- Monthly: Some states specify 0.5 mSv / month
- The pregnant individual must declare her pregnancy in writing for this to be in effect.

d. Dose limits for individual members of the public

- Total effective dose equivalent: 1 mSv (0.1 rem) per year (excluding background medical or research exposure),
- 0.02 mSv (0.002 rem) in any one hour; and
- For infrequent exposure 5 mSv (0.5 rem) per year.

These still apply if members of the public are allowed in restricted areas.

¹ Webster EW. EDE for exposure with protective aprons. *Health Phys.* 1989;56: 568-569.

5. General X-ray Safety Policies

[Policies](#) and procedures are required for protection of staff as well as patients, including monitoring of X-ray utilization.

6. Registration of Radiation Machine Facilities

Initial: New X-ray equipment must be registered with the state or local radiation safety control agency (typically within 30 days). The RSO and either a health practitioner (dentist, physician, etc.), user, or for large facilities, an administrator (president, CEO, etc.) must be designated on the application.

Renewal: Registration of an X-ray source is typically good for one year and must be renewed annually at a specified date. Dates are often staggered so that the health department is not inundated with all renewals at the same time each year.

Changes: Changes made to equipment (such as replacement of an X-ray tube) may require notifying the state or local radiation safety control agency. The owner must provide notification if the equipment is moved, sold, leased, or transferred. Lost or stolen X-ray equipment requires more prompt notification, usually within 24 hours of discovery.

7. Equipment Surveys

Registrants must have certain tests of equipment performed and/or allow state/local inspectors to perform tests of X-ray equipment. It is the responsibility of the registrant to ensure that competent and qualified individuals are utilized. For example, only individuals meeting FDA qualifications can perform surveys of mammography equipment.

8. Regulatory Inspections

States generally require X-ray facilities to be inspected on a regular basis. The RSO is responsible for having the appropriate records required for such inspections and being present at inspections.

9. X-ray Room Shielding

New or remodeled facilities or facilities whose use changes in a way that may change radiation exposure levels must have a shielding plan developed by a qualified expert (e.g., qualified medical physicist) and, in some states, submitted to the state or local radiation safety control agency before first use of the equipment. In some states, the individual developing the shielding plan must be registered with the state or local radiation safety control agency before submitting such a plan.

Records related to shielding must be maintained for inspection, including lead-equivalent-thickness of shielding, machine characteristics, and measurements of radiation behind shielding materials. It is important to keep these records to verify current shielding in case a future shielding plan indicates a need to

change the shielding. See Appendix A and Appendix B of [Part B of the SSRs](#). Signage: States have different requirements for signage. X-ray warning signs are typically required at doors to X-ray rooms. Some states require interlocks restricting access to a room or a lighted warning sign whenever X-rays are being produced. Some require posting the lead equivalence of shielding material in the room. Verify what is required with your state regulations.

Surveys must be performed after shielding is installed and as needed thereafter to assure that individual exposures do not exceed regulatory limits.

10. Qualification of Health Physicists and Medical Physicists

New York, Texas, Florida and Hawaii require health physicists or medical physicists to be licensed; Board certification is sometimes required, depending on the equipment being tested, but some individuals may be “grandfathered” into the requirement. The state/local regulations may allow nonlicensed physicists to work under the direction of the licensed physicist. Other states do not require licensure but may require physicists to be approved as service providers.

11. X-ray Equipment Servicing and Services

States typically prohibit individuals from installing, repairing, or testing X-ray equipment unless approved through a state/local process. The RSO has to ensure outside service providers are properly vetted. See specific requirements for your state. A sample [Policy Statement for X-ray Equipment Quality Control](#) can be found in this document.

12. Records

The RSO is responsible for maintaining all records required by the state or local radiation safety control agency regarding the use of radiation. Records of personnel exposure and records verifying exposure levels to the general public must be kept indefinitely. Records of surveys, calibrations, maintenance, and modifications performed on the X-ray systems usually need only to be kept for three years, but states’ requirements differ.

13. Quality Assurance Program

A quality assurance (QA) program typically includes the following:

- Written standard operating procedures on radiation protection and the practice of radiologic technology reviewed and updated annually by management;
- Employee review and written acknowledgement of standard operating procedures and policies on radiation protection and the practice of radiologic technology;
- Credentialing of practitioners, medical physicists, and X-ray equipment operators;
- Record retention in accordance with state/local statutes and regulations; and

14. Special Requirements for Self-referral Screening Programs

There are special requirements if you wish to provide X-ray screening to patients who self-refer. See Appendix F of [Part B](#) of the CRCPD SSRs for typical requirements. Your state's requirements may differ.

15. Research Involving Radiation

Any research that uses radiation machines on humans must be approved by an institutional review board as required by [HHS CFR 45 Part 46](#) and [FDA CFR 21 Part 56](#). States may have additional requirements.

16. Monitoring of Patient Skin Doses

State/local regulations may require monitoring of patient skin doses from long fluoroscopic procedures, typically those in which skin doses might exceed 2–6 gray (Gy). This may require notifying the patient and/or the state or local radiation safety control agency. Additionally, The Joint Commission (TJC) formerly required analysis of cumulative patient doses for patients who may have received cumulative skin doses in excess of 15 Gy. The RSO should develop a process and [policy](#) to comply with current requirements and adhere to achievable practice guidance for minimizing risk of high patient skin doses.

17. Advanced Imaging Accreditation

Facilities providing CT and PET imaging may have to meet the requirements of one or more accrediting bodies. These include the [ACR](#), [TJC](#), [Intersocietal Accreditation Commission](#) (IAC) and [RadSite](#).

18. Mammography Regulation and Accreditation

Mammography, because it is used in screening, is regulated by the U.S. Food and Drug Administration (FDA) under the [Mammography Quality Standards Act \(MQSA\)](#), which requires the program to be [accredited](#). States often defer to the FDA requirements but may have additional regulations for mammography as well.

E. Sample Policies and Forms for an X-ray Safety Program

1. Sample Policies

- [ALARA Program for X-ray](#)
- [Occupational Dose Limits](#)
- [Delegation of Authority for a Radiation Safety Officer for an X-ray Facility](#)
- [Employee X-Ray Safety Procedures](#)

IV. X-ray Safety Program

- [Monitoring Patients for Potential Skin Damage](#)
- [Personnel Radiation Monitoring](#)
- [Quality Control of X-Ray Equipment](#)
- [Monitoring of X-ray Repeat Exposures](#)

2. Sample Forms

- [Patient Utilization Log](#)
- [Radiation Program Audit](#)

Sample Policy: ALARA Program for X-ray

1. Management Commitment

We, the management of this facility, are committed to the program described herein for keeping individual and collective doses as low as reasonably achievable (ALARA). In accord with this commitment, we will develop the necessary written policies, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee and a Radiation Safety Officer (RSO).

We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., as well as consultations with the RSO and/or outside consultants.

Modifications to operating and maintenance procedures and to equipment and facilities will be made to reduce exposures if the cost, in our judgment, is considered justified. If it is not, we will be prepared to describe the reasons for not implementing the changes.

In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It is not desirable to reduce doses to some individuals to some fraction of the applicable limit if this involves exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Officer Commitment

Annual and Quarterly Review

- The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.
- The RSO will review at least quarterly the external radiation doses of workers to determine that their doses are ALARA in accordance with the provisions of Table 1 below.

Education Responsibilities for ALARA Program

- The RSO will schedule briefing and educational sessions as needed to ensure that users of radiation-producing equipment and ancillary personnel who may be exposed to radiation be instructed in the ALARA philosophy. They will also be made aware that management and the RSO are committed to implementing the ALARA concept.

Cooperative Efforts for Development of ALARA Procedures

- Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.
- The RSO will be in contact with users of X-ray equipment and other workers in order to develop ALARA procedures for working with X-ray equipment.
- The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those programs.
- Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

IV. X-ray Safety Program

Reviewing Instances of Deviation from Good ALARA Practices

- The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes.
- When the cause is known, the RSO will implement changes in the program to maintain ALARA doses.

3. Review of Radiation Doses of Users and Workers

Table 1. Investigational levels for radioactive materials and general radiology (30% of the occupational dose limits set by state/local regulations). *Monitor readings may be modified using Webster's equation² to arrive at the whole-body effective dose for individuals who must wear lead aprons.

| Investigational Levels | mrem Per Calendar Quarter |
|---|---------------------------|
| 1. Total effective dose equivalent* | 375 |
| 2. Lens of eyes | 1125 |
| 3. Sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye, the skin of the whole body, and to the skin of the extremities | 3750 |

2 Webster EW. EDE for exposure with protective aprons. *Health Phys.* 1989;56:568–569.

Sample Policy: Occupational Dose Limits

1. Adults

Annual limit is the more limiting of the following:

- The total effective dose equivalent being equal to 0.05 sievert (5 rem); or
- The sum of the deep dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 sievert (50 rem).
- Some states allow the effective dose equivalent for external radiation to be determined as follows:
 - a. When only one individual monitoring device is used located at the neck (collar) outside the protective apron, effective dose equivalent = reported deep dose equivalent \times 0.3; or
 - b. When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, effective dose equivalent deep dose equivalent reported at the waist \times 1.5 + deep dose equivalent reported at the neck \times 0.04.

Annual limits to tissues/organs include the following:

- Lens: 0.15 sievert (15 rem)
- Skin or extremities: 0.5 sievert (50 rem)

2. Minors

The occupational dose limit for minors is 10 % of that for adult workers.

3. Dose Equivalent to an Embryo/Fetus

- Fetal limit during gestation from occupational exposure: 5 mSv (0.5 rem)
- Monthly: Some states specify 0.5 mSv/month (0.05 rem/month)
- The pregnant individual must declare her pregnancy in writing for this to be in effect.

4. Dose Limits for Individual Members of the Public

- Total effective dose equivalent: 1 mSv (0.1 rem) per year (excluding background medical or research exposure),
- 0.02 mSv (0.002 rem) in any one hour; and
- For infrequent exposure, 5 mSv (0.5 rem) per year.

These still apply if members of the public are allowed in restricted areas.

IV. X-ray Safety Program

Sample Policy: Delegation of Authority for a Radiation Safety Officer for an X-ray Facility

Facility Name:

Facility Registration Number:

_____ is hereby appointed Radiation Safety Officer (RSO) for our X-ray department and is responsible for ensuring the safe use of radiation.

These responsibilities include managing the radiation protection program, identifying X-ray radiation protection problems, ensuring quality control tests are completed and documented, recommending or providing corrective actions, verifying implementation of corrective actions, stopping unsafe activities, and ensuring compliance with state/local regulations.

The RSO is hereby delegated the time and authority necessary to meet those responsibilities, including prohibiting the use of radiation-producing equipment by employees who do not meet the necessary requirements and shutting down operations where radiation safety is compromised. The RSO is required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, the RSO is free to raise issues with the _____ Department of Health at any time. It is estimated that the RSO will spend _____ hours per week conducting radiation protection activities.

The signature below as RSO indicates acceptance of the above responsibilities.

Name of Radiation Safety Officer

Management

Signature of Radiation Safety Officer

Signature of Management Representative

Date

Date

Sample Policy: Employee X-ray Safety Procedures

Policy Owner: Radiation Safety Officer

Information Resource: Radiation Safety Officer

Applicable to:

| Departments, Divisions, Operational Areas | Personnel |
|---|----------------------------------|
| Radiology, surgery, endoscopy, others | X-ray operators, ancillary staff |

POLICY STATEMENT

- A. Except for the patient, only the staff and ancillary personnel required for performance of a procedure may remain in the room during the X-ray exposure. All staff and ancillary personnel who must remain in the room to assist during X-ray procedures must be protected from scatter radiation by protective aprons or a whole-body radiation protective barrier of not less than 0.5-millimeter lead equivalence.
- B. All staff and ancillary personnel required for assistance with X-ray procedures shall be positioned so that no part of the body can be struck by the useful beam unless protected by 0.5 lead-equivalent shielding material.
- C. Mechanical support or restraining devices should be utilized for holding either the patient or image receptor whenever possible.
- D. During any X-ray procedures, any door designed to be part of a protective barrier must be closed.
- E. Prior to putting on a radiation protection garment, personnel will verify that the most recent safety check is within a year. A visual cue (e.g., sticker or color-coded tag) should be apparent to let staff know the check is current.
- F. Personnel who have to stand with their backs to the X-ray source or patient should wear wraparound aprons.
- G. Personnel who do not need to be close to the patient or X-ray source should stand as far away as is practical without compromising patient care.
- H. Personnel whose hands must be very close to the X-ray beam should wear lead-containing gloves. Do not place hands in the direct beam, even with lead gloves, as the lead will only cause a higher level of radiation to be produced.
- I. During angled C-arm or O-arm fluoroscopy, personnel should stand on the image-intensifier side of the patient rather than the side of the X-ray source, provided it is practical and does not compromise patient care.
- J. Personnel radiation monitoring devices must be worn that are appropriate to the individual work environment. (See [Personnel Monitoring Policy](#) for details.)
- K. Additional consideration for protection of the fetus requires the pregnant employee to declare her pregnancy in writing if she opts to accept this added level of protection. (See [Personnel Monitoring Policy](#) for details.)
- L. During use of mobile equipment, the fluoroscope operator or assisting X-ray technologist will notify personnel when X-rays are being used.

IV. X-ray Safety Program

DEFINITIONS

SUPPORTIVE INFORMATION

REFERENCES

RELATED REGULATIONS

Facility's state or local radiation safety control agency rule citation

RELATED DOCUMENTS

[Personnel Monitoring Policy](#)

| | |
|--|-----------------------|
| Approved by: | Approval Date: |
| Radiation Safety Committee or Radiation Safety Officer if no radiation safety committee exists | |

Revised Date:

Sample Policy: Monitoring Patients for Potential Skin Damage

Policy Owner: Radiation Safety Officer (RSO)

Information Resource: Radiation Safety Officer

Applicable to:

| Departments, Divisions, Operational Areas | Personnel |
|---|---|
| Interventional radiology, other | Interventional radiology staff, Radiation Safety Officer |

POLICY STATEMENT

Patients with the potential to receive a radiation skin dose in excess of 5,000 milligray (mGy) must receive information regarding the potential for skin damage and instructions for care.

DEFINITIONS

PROCEDURE

| Responsibility | Action |
|--|---|
| Interventional radiology staff | <ol style="list-style-type: none"> When the air kerma (exposure) for the procedure is in excess of 4000 mGy, let the physician know he or she has exceeded this level and alert the physician at intervals of 500 mGy thereafter. Provide the final exposure in mGy to the physician performing the procedure and record it in the patient record. Fill out the Fluoroscopy Skin Exposure Report for patient(s) whose exposure exceeded 5000 mGy. Include the report in the patient record. Provide the relevant information to the RSO. |
| Physician performing the procedure | <ol style="list-style-type: none"> Notify patient of radiation exposure following the procedure and discuss future care with the patient or arrange to have this done by a designated representative trained to do so. |
| Interventional radiology manager/ RSO | <ol style="list-style-type: none"> Quarterly, query the appropriate patient database (if available) to identify patient studies that exceeded the action threshold. |
| Radiation safety officer | <ol style="list-style-type: none"> Notify the state or local radiation safety control agency (if required by law). Evaluate efficacy of program by comparing database information with procedure notes and individual case reports provided by the cardiovascular/electrophysiology/ interventional radiology staff and report to the radiation safety committee. Review history of high-dose cases to see if any patient received greater than 15,000 mGy within nine months to a single skin location and, if necessary, perform a root-cause analysis for such cases. |
| Radiation safety committee | <ol style="list-style-type: none"> Review the RSO’s report and recommend remedial action if needed. |

SUPPORTIVE INFORMATION

Air kerma: reading of a radiation level provided by the X-ray system equivalent to dose at a specified point in space related, but not equal to, patient skin dose.

REFERENCES

RELATED REGULATIONS AND STANDARDS

- Relevant state or local radiation safety control agency regulations
- The Joint Commission's [Sentinel Event Policy and Procedures](#)
- [ACR–AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures](#)

RELATED POLICIES

Origination Date:

| | |
|---|-----------------------|
| Approved by: | Approval Date: |
| Radiation Safety Committee, if applicable, or Radiation Safety Officer if no radiation safety committee | |

Revised Date:

Sample Policy: Personnel Radiation Monitoring

Policy Owner: Radiation Safety Officer (RSO)

Information Resource: Radiation Safety Officer

Applicable to:

| Departments, Divisions, Operational Areas | Personnel |
|--|--------------------------------|
| Endoscopy, CT, mammography, radiology, radiation oncology, surgery, nuclear medicine | Managers, RSO, RSO's assistant |

POLICY STATEMENT

- Personnel likely to receive a dose in excess of 10% of the annual permissible dose or those working in high radiation areas or very high radiation areas will be supplied with personnel monitors.
- Additional monitors will be supplied to pregnant individuals who declare their pregnancy in writing and are likely to receive a fetal dose in excess of 100 millirem (mrem) during gestation.
- Ring monitors will be provided for individuals who are likely to receive a dose to the hands in excess of 10% of the permissible extremity dose (12,500 mrem per calendar quarter).

RESPONSIBILITIES

Radiation Safety Officer (or trained designee where appropriate)

- Maintain program for providing radiation monitors to all workers that require a monitor.
- Designate managers (supervisors) who will be responsible for the program for workers in their areas.
- Establish action limits and provide managers with information regarding exposures exceeding the action limits.
- Review exposure history of declared pregnant workers to determine if a change in duties is required to reduce fetal dose.
- Provide consultation as needed to workers with elevated monitor readings.
- Provide monthly or quarterly exposure reports to manager for posting.
- Provide individual annual reports to manager for distribution to workers.
- Retain records of radiation monitoring as required by law.

Manager/Supervisor

- Supply workers in their area with monitors as required by law.
- Provide RSO with changes in personnel who have or require a monitor.
- Provide new employees with release of monitoring information form if needed to obtain past radiation history.
- Obtain previous occupational exposure records from the employee and forward to the RSO.

IV. X-ray Safety Program

- Advise personnel of excess radiation monitor readings.
- Secure control monitor away from area where radiation is used.
- Inform RSO of employee being terminated, obtain a return address, and send employee a report of exposure while employed at facility.

Monitored Individual

- Exchange monitors either monthly or quarterly as required.
- Advise RSO in writing of need for fetal radiation monitoring.
- Wear monitors as required (at collar level outside of the apron when working in the X-ray procedure rooms). The monitor should be as near the center of the body as possible.
- Protect monitor from damage (such as heat or moisture).

DEFINITIONS

SUPPORTIVE INFORMATION

This policy is intended to help assure personnel radiation exposures are kept as low as reasonably achievable (ALARA) below regulatory limits.

REFERENCES

RELATED REGULATIONS

- Site-specific state/local or U.S. Nuclear Regulatory Commission regulations

RELATED DOCUMENTS

| | |
|--|-----------------------|
| Approved by: | Approval Date: |
| Radiation Safety Committee if applicable or RSO if no radiation safety committee | |

Revised Date:

Sample Policy: Quality Control of X-ray Equipment

Policy Owner: Director of facilities management

Information Resource: Radiation Safety Officer (RSO)

Applicable to:

| Departments, Divisions, Operational Areas | Personnel |
|---|---------------------------------------|
| Biomed, radiology, radiation oncology, radiation safety | Biomed staff, RSO, medical physicists |

POLICY STATEMENT

All X-ray-producing equipment will be tested at regular intervals to assure proper function related to radiation safety of patients and personnel.

RESPONSIBILITIES

Biomed Staff or Medical Physicist

- Biennial/annual performance/safety testing of radiographic and fluoroscopic equipment as required in state/local rules
- Registration of new X-ray equipment with the state or local radiation safety control agency
- Testing of all new X-ray equipment as required by state/local rules prior to first use or assurance that manufacturer’s tests meet health department requirements

Qualified Medical Physicist

- Annual testing of mammography equipment to meet requirements of the Mammography Quality Standards Act and the facility’s accrediting body.
- Annual testing of computed tomography (CT) scanners to meet requirements of state/local rules and the facility’s accrediting body.

Radiation Safety Officer

- Annual registration of all existing X-ray equipment with state or local radiation safety control agency
- Annual audit of the equipment quality control program

REFERENCES

RELATED REGULATIONS

- Site-specific state/local or U.S. Nuclear Regulatory Commission regulation

IV. X-ray Safety Program

RELATED DOCUMENTS

| | |
|--|-----------------------|
| Approved by: | Approval date: |
| Radiation Safety Committee if applicable or RSO if no radiation safety committee | |

Revised Date:

Sample Policy: Monitoring of X-ray Repeat Exposures

Policy Owner: Radiation Safety Officer (RSO)

Information Resource: Radiation Safety Officer

Applicable to:

| Departments, Divisions, Operational Areas | Personnel |
|---|----------------------|
| Radiology, surgery, others | X-ray operators, RSO |

PROCEDURE

| Responsibility | Action |
|----------------------------|--|
| X-ray and CT technologists | 1. Enter repeat data into picture archiving and communications system (PACS) record at the end of an exam when applicable. |
| Manager/supervisor | 2. Provide quarterly report to RSO of repeat analysis data for radiographic and computed tomography (CT) procedures. 3. Advise X-ray personnel of excess levels of repeats and pursue corrective action if needed. 4. Report causes and corrective actions to the RSO as needed. |
| RSO | 5. Review repeat analysis data provided by the radiology manager. Guidelines: –Repeat rate should not exceed 4%. –Action should be taken if repeat rate increases by more than 2% of the norm. 6. Include a review of the repeat process annually in the X-ray safety audit. |

SUPPORTIVE INFORMATION

REFERENCES

RELATED REGULATIONS

- Site-specific state or local radiation safety control agency rules

RELATED DOCUMENTS

- [American College of Radiology Practice Parameters and Technical Standards](#)

| Approved by: | Approval Date: |
|--|----------------|
| Radiation Safety Committee if applicable or RSO if no radiation safety committee | |

Revised Date:

Sample Policy: Patient X-ray Safety

Policy Owner: Radiation Safety Officer (RSO)

Information Resource: Radiation Safety Officer

Applicable to:

| Departments, Divisions, Operational Areas | Personnel |
|---|----------------------|
| Radiology, surgery, others | X-ray operators, RSO |

POLICY STATEMENT

Precautions will be taken to avoid unnecessary radiation exposure to patients. Patient and gonadal shielding is no longer recommended as a standard practice; this facility will adhere to [current consensus of the scientific community](#) within constraints of jurisdictional regulatory requirements.

DEFINITIONS

PROCEDURE

| Responsibility | Action |
|-----------------|--|
| X-ray operators | <ol style="list-style-type: none">1. Question female patients of childbearing age regarding the possibility of pregnancy or perform a pregnancy test if the procedure may involve a higher risk of exposure to the uterus to someone who would have the possibility of being pregnant (such as no period in the last 28 days per guidance from the American College of Radiology). If a woman is pregnant, the continuation of a radiation procedure will be at the discretion of the referring physician in consultation with the procedure physician and the informed consent of the patient.3. Demonstrate collimation on all images and limit to the area of interest.4. Select the imaging X-ray technique factors to achieve adequate image quality at a minimum patient radiation dose. Use automatic exposure systems (e.g., automatic exposure control (AEC), automatic brightness systems (ABS), auto-mA) where feasible.5. Document fluoroscopic exposure indices in the patient record. |
| RSO | <ol style="list-style-type: none">6. Respond to requests for patient radiation dose estimates as needed. |

SUPPORTIVE INFORMATION

All procedures must be performed under the direction of a physician.

REFERENCES

RELATED REGULATIONS

- Your specific state or local radiation safety control agency rules

RELATED DOCUMENTS

- [American College of Radiology Practice Parameters and Technical Standards](#)

Origination Date:

| | |
|---|-----------------------|
| Approved by: | Approval Date: |
| Radiation Safety Committee if applicable or RSO | |

Revised Date:

Sample Form: Radiation Program Audit

| Item | Status |
|--|--------|
| Printed name and title of person performing audit | |
| Signature of person performing audit | |
| Date of audit | |
| Deficiencies identified and listed | |
| Radiation safety officer (RSO) designated | |
| RSO delegation agreement in place | |
| RSO established and reviewed retake and reject analysis | |
| Shielding plans submitted for remodel or new construction | |
| All equipment registered with state or local radiation safety control agency | |
| State or local radiation safety control agency notified of new/removed equipment | |
| Personnel | |
| Equipment operators authorized per state/local regulations to expose humans to X-rays | |
| Equipment operators trained in radiation safety program | |
| Equipment operators trained in operating procedures | |
| Equipment operators trained in emergency procedures | |
| Documentation of training in new modalities (computed tomography (CT), fluoroscopy, digital, etc.) | |
| Individual Monitoring Devices | |
| Facility use of individual monitoring devices | |
| Monitors worn correctly | |
| New employee individual monitor (dosimeter records) history collected | |
| Employees annually notified of accumulated dose | |
| Employees notified of total dose upon termination | |
| Monitoring records maintained for the period required by regulations | |
| Policies | |
| Radiation safety policies and procedures in place | |
| Written holding policy in place | |
| Quality assurance manual up-to-date | |
| Repeat/reject analysis policies/procedures in place | |
| Technique charts complete and maintained near the X-ray control | |
| Patient utilization logs maintained and complete | |
| Quality Control | |
| Equipment performance evaluations and calibrations conducted at the proper frequency | |
| Service provider recommendations evaluated | |
| Processor quality control performed at the proper frequency | |
| Darkroom quality control (fog test) performed at the proper frequency | |
| Digital manufacturer quality control protocols followed | |
| Repeat rate calculated quarterly and reasons for rejections reviewed | |

IV. X-ray Safety Program

| Item | Status |
|---|--------|
| Lead aprons, gloves, and thyroid shield integrity checked every 24 months or annually if required by some state/local regulations | |
| Screen speed and contact tests checked every 24 months | |
| Additional Comments | |
| | |

F. Additional Resources

The following is a non-exhaustive list of additional resources that may be helpful for an X-ray facility RSO.

- [RadiologyInfo.org Patient Safety page](#)
- [US FDA Medical X-ray Imaging information page](#)
- [AAPM/RSNA Physics Tutorial for Residents](#)
- [California Radiologic Health Branch of the Department of Public Health X-ray Radiation Safety and Protection Program Requirement Guidance](#)
- [Colorado Department of Public Health and Environment Radiation Protection Program \(RPP\) Guidance](#)
- [Rocky Mountain Fluoro Training](#) from the Rocky Mountain Chapter of the AAPM
- [Iowa State University Environmental Health and Safety X-ray Safety Manual](#)
- [Image Wisely®](#)
- [Image Gently®](#)

Radioactive Material Specific Policies and Procedures

A. Spill or Contamination Response

1. Spill/Contamination Procedure Requirements

- All types and forms of licensed material used should be addressed.
- Spill procedures should be posted in restricted areas where licensed materials are used or stored.
- Instructions should specifically state the names and telephone numbers of persons to be notified such as the radiation safety officer (RSO), staff, state and local authorities, and the U.S. Nuclear Regulatory Commission (NRC) when applicable.
- Include procedures for evacuation of the area and containment of spills and other releases as well as appropriate methods for reentering and decontamination facilities when necessary.

2. Model Emergency Procedures

a. Minor spills of liquids and solids

- Notify persons in the area that a spill has occurred.
- Prevent the spread of contamination by covering the spill with absorbent paper.
- Wear gloves and protective clothing such as a lab coat and booties, and clean up the spill using absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a bag labeled “caution radioactive material” for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
- Survey the area with a low-range radiation detection survey instrument sufficiently sensitive to detect the radionuclide. Check for removable contamination to ensure contamination levels are below trigger levels. Check the area around the spill. Also check hands, clothing, and shoes for contamination.
- Report the incident to the RSO.

b. Major spills of liquids and solids

- Clear the area. Notify all persons not involved in the spill to vacate the room.
- Prevent the spread of contamination by covering the spill with absorbent paper labeled “Caution Radioactive Material,” but do not attempt to clean it up. To prevent the spread of contamination, clearly indicate the boundaries of the spill and limit the movement of all personnel who may be contaminated.
- Shield the source if possible. Do this only if it can be done without further contamination or a significant increase in radiation exposure.

V. Radioactive Material Specific Policies and Procedures

- Close the room and lock or otherwise secure the area to prevent entry.
- Notify the RSO immediately.
- Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with mild soap. If contamination remains, the RSO may consider inducing perspiration. Then wash the affected area again to remove any contamination that was released by the perspiration.

c. Estimating the amount of radioactivity spilled

Based on your estimate and the following information, initiate a major or minor spill/contamination procedure. Spills above the millicurie (mCi) amounts listed in Table 2 are considered major, and spills below these levels are considered minor. Spills involving curie quantities of positron emission tomography (PET) radionuclides should initially be considered major spills; either downgrade to a minor spill after decay or restrict access pending complete decay.

The decision to implement a major spill/contamination procedure instead of a minor spill/contamination procedure depends on many incident-specific variables, such as the number of individuals affected, other hazards present, likelihood of contamination spread, types of surfaces contaminated, and radiotoxicity of the spilled material. For some spills of radionuclides with half-lives shorter than 24 hours and in amounts less than five times the lowest ALI, an alternative spill/contamination procedure may be to restrict access pending complete decay. Note: A report to the NRC may be required pursuant to [NRC 10 CFR 30.50](#).

General guidance to determine whether a major spill/contamination procedure or a minor spill/contamination procedure will be implemented is available (Table 2). All spills/contaminations of radium-226 will be considered major spills.

Table 2. Relative Hazards of Common Radionuclides. For PET radionuclides, see section c above.

| Radionuclide | mCi | Radionuclide | mCi |
|--------------|-----|--------------|-----|
| P-32 | 1 | Tc-99m | 100 |
| Cr-51 | 100 | In-111 | 10 |
| Co-57 | 10 | I-123 | 10 |
| Co-58 | 10 | I-125 | 1 |
| Fe-59 | 1 | I-131 | 1 |
| Co-60 | 1 | Sm-153 | 10 |
| Ga-67 | 10 | Yb-169 | 10 |
| Se-75 | 1 | Hg-197 | 10 |
| Sr-85 | 10 | Au-198 | 10 |
| Sr-89 | 1 | Tl-201 | 100 |

3. Spill/Contamination Kit Contents

- Disposable gloves and housekeeping gloves
- Disposable lab coats
- Disposable head coverings
- Disposable shoe covers
- Roll of absorbent paper with plastic backing
- Masking tape
- Plastic trash bags with twist ties
- Radioactive material labeling tape
- Marking pen
- “Caution Radioactive Material” signs
- Detergent produced for cleaning contamination (e.g., Radiacwash™)
- Prestrung “Radioactive Material” labeling tags
- Contamination wipes
- Instructions for emergency procedures
- Clipboard with copy of Radioactive Spill Report Form
- Pencil
- Appropriate survey instruments, including batteries

4. References

- Spill Contamination Procedures. In: Consolidated Guidance About Materials Licenses. [NUREG-1556, Vol. 9, Rev. 3](#). Published September 2019; 8-73.
- [NRC 10 CFR 19.11\(a\)\(3\)](#): Posting of Notices to Workers.
- [NRC 10 CFR 20.1101](#): Subpart B--Radiation Protection Programs
- [NRC 10 CFR 20.1406](#): Minimization of Contamination
- [NRC 10 CFR 20.2202](#): Notification of Incidents
- [NRC 10 CFR 20.2203](#): Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits
- [NRC 10 CFR 30.32](#): Application for Specific Licenses
- [NRC 10 CFR 30.35\(g\)](#): Financial Assurance and Recordkeeping for Decommissioning
- [NRC 10 CFR 30.50](#): Reporting Requirements
- [NRC 10 CFR 30.51](#): Records
- [NRC 10 CFR 35.27](#): Supervision

B. Unintended Administrations of Radioactive Materials

1. Medical Events

a. Definition

The NRC defines a medical event in [NRC 10 CFR 35.3045\(a\)](#). 35.3045(a)(1) defines medical events for non-permanent implant brachytherapy, which includes the administration of radioactive material or the use of radiation from radioactive material. 35.3045(a)(2) defines medical events for permanent implant brachytherapy.

It is important to note that the term “[prescribed dose](#),” as used by the NRC, refers to the radiation dose to tissue from some source of radioactive material, whereas “[prescribed dosage](#)” refers to the activity of radioactive material administered to a patient, for example by IV injection, inhalation, or oral ingestion. Evaluating a medical event related to the use of radiation from sealed radioactive material (e.g. brachytherapy or teletherapy) requires consideration of dose and/or source strength. On the other hand, evaluating a medical event related to the administration of unsealed-source radioactive material (e.g. I-131 sodium iodide or Lu-177 Lutathera) requires consideration of both dosage and dose.

The potential for exceeding the threshold for a medical event is higher with the use of radioactive material where a written directive is required, i.e. therapeutic procedures. However, medical events may still occur for applications where a written directive is not required, particularly when the generator eluate that is used for an administered radiopharmaceutical exceeds the breakthrough limits.

b. Risks associated with medical events

The NRC states in their factsheet, [Risks Associated with Medical Events](#), that a “medical event” indicates potential problems in a medical facility’s use of radioactive materials. It does not necessarily result in harm to a patient.

c. Reporting requirements

Medical events must be reported. The NRC in [NRC 10 CFR 35.3045\(c-g\)](#) requires that the licensee shall notify by telephone the NRC Operations Center no later than the next calendar day after discovery of the medical event. The referring physician and patient must be notified no later than 24 hours after its discovery. In addition, a written report is required to be submitted to the appropriate NRC Regional Office within 15 days after discovery of the medical event. In Agreement States, there may be differing requirements for reporting. See your individual state regulations for reporting requirements.

d. Patient dose calculations

Patient dose resulting from many common radiopharmaceutical administrations may be determined using tables provided by the NRC in [NUREG-CR 6345](#),

which list organ dose equivalent and effective dose equivalent as dose per unit administered activity. Each radioactive drug has a corresponding package insert that lists organ-dose equivalent and effective-dose equivalent as dose-per-unit administered activity. These are available from the radiopharmacy from which the material was purchased.

2. References

- [NRC 10 CFR 35.3045](#): Reporting Requirements for Medical Events
- [U.S. Nuclear Regulatory Commission Fact Sheet](#): Risks Associated with Medical Events
- [NUREG/CR-6345](#): Radiation Dose Estimates for Radiopharmaceuticals
- [NRC 10 CFR 35.2](#): Definitions: Prescribed Dose and Prescribed Dosage

3. Dose to an Embryo, Fetus, or Nursing Child

a. Definition

[NRC 10 CFR 35.3047\(a\) and \(b\)](#) requires the reporting of certain events that are not medical events, as defined in [NRC 10 CFR 35.3045\(a\)](#). These reportable events include the following:

- Dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.
- Dose to a nursing child that is a result of an administration of byproduct material to a breastfeeding individual that 1) is greater than 50 millisieverts (mSv) [5 rem] total effective dose equivalent; or 2) has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

b. Reporting requirements

These unintended doses must be reported. [NRC 10 CFR 35.3047 \(c-f\)](#) requires that the licensee shall notify by telephone the U.S. Nuclear Regulatory Commission Operations Center no later than the next calendar day after discovery of the dose. The referring physician and patient must be notified no later than 24 hours after discovery. In addition, a written report is required to be submitted to the appropriate NRC Regional Office within 15 days after discovery of the dose. In Agreement States, there may be differing requirements for reporting. See your individual state regulations for reporting requirements.

c. Patient dose calculations

Tables for estimating the dose to an embryo/fetus or nursing child have not been provided by the NRC. Although there are some references in the literature (Wagner, 1997), it is recommended that a radiation safety

professional/medical physicist be contacted to perform patient dose calculations in these cases. Additional guidance may be found in the [ACR-SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation](#).

d. References

- [NRC 10 CFR 35.3045](#): Reporting Requirements for Medical Events
- [NRC 10 CFR 35.3047](#): Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child
- Wagner LK, Lester RG, Saldana LR. *Exposure of the Pregnant Patient to Diagnostic Radiations: A Guide to Medical Management*. Madison, WI: Medical Physics Publishing; 1997.
- American College of Radiology. [ACR-SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation](#).

C. Routine Surveys

1. General Requirements

As stated in NRC NUREG-1556, Volume 9, Section 8.24, the Radiation Protection Program that licensees are required to develop, document, and implement in accordance with [NRC 10 CFR 20.1101](#) must include provisions for area surveys. Surveys are evaluations of radiological conditions and potential hazards. These evaluations may be measurements (e.g., radiation levels measured with survey instruments or results of wipe tests for contamination), calculations, or a combination of measurements and calculations. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess radiological conditions.

The two types of routine surveys considered in this section are surveys of ambient radiation exposure rate and surveys for removable contamination. Other surveys may be required to comply with [NRC 10 CFR Part 20](#), including surveys of air and water effluent, bioassays, and air concentrations and package surveys and surveys required for decommissioning.

2. Ambient Radiation Exposure Rate

The NRC in [NRC 10 CFR 35.70](#) requires that a licensee shall survey with a radiation detection survey instrument at the end of each day of use. A licensee shall survey all areas where unsealed byproduct material requiring a written directive was prepared for use or administered. Survey records must be retained for three years and must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey ([NRC 10 CFR 35.2070](#)). Appendix R of [NUREG-1556, Volume 9, Revision 3](#), provides guidance in the form of a model procedure for area surveys, including areas to be surveyed and appropriate trigger levels.

3. Removable Contamination

In order to comply with the requirements of [NRC 10 CFR 20.1101](#) and [NRC 10 CFR 20.1501](#), the NRC recommends in [Appendix R of NUREG-1556, Volume 9, Revision 3](#), that the following areas and frequencies should be followed for surveys of removable contamination:

- Removable contamination surveys weekly for radiopharmaceutical elution, preparation, assay, and administration areas. If diagnostic administrations are occasionally made in patients' rooms (e.g., bone scan injections, technetium-99m (Tc-99m) heart agents), with special care taken to remove all paraphernalia, those rooms need not be surveyed.
- Removable contamination surveys monthly of laboratory areas where only small quantities of photon-emitting radioactive material are used (<200 microcuries (μCi) at a time).
- Removable contamination surveys weekly for radionuclide storage and radionuclide waste storage areas.

Additional information is provided in the guidance, including appropriate trigger levels and follow up.

[NRC 10 CFR 20.2103](#) requires a licensee to maintain records showing the results of surveys and calibrations required by [NRC 10 CFR 20.1501](#) and [20.1906\(b\)](#). The licensee shall retain these records for three years after the record is made. In Agreement States, there may be differing requirements.

4. References

- [NRC 10 CFR 35.2070](#): Records of Surveys for Ambient Radiation Exposure Rate
- [NRC 10 CFR 35.70](#): Surveys of Ambient Radiation Exposure Rate
- [NRC 10 CFR 20.2103](#): Records of Surveys
- [NUREG-1556, Volume 9, Revision 3](#). Appendix R: Model Procedure for Area Surveys
- [NUREG-1556, Volume 9, Revision 3](#). Section 8.10.12: Area Surveys
- [NRC 10 CFR 20.1101](#): Radiation Protection Programs
- [NRC 10 CFR 20.1501](#): Subpart F: Surveys and Monitoring
- [NRC 10 CFR 20.1906](#): Procedures for Receiving and Opening Packages

D. Handling Radioactive Materials

1. Receiving (Opening Packages)

Appendix P of [NUREG-1556, Volume 9, Revision 3](#) provides a model procedure for opening packages containing radioactive material to meet the requirements of [NRC 10 CFR 20.1906](#). In particular it is important to note that these

requirements include both surveys for contamination on the external surfaces of labeled packages (White I, Yellow II, Yellow III), as well as surveys for radiation levels, depending on package contents and condition upon arrival. Generally, wipe samples from surveys for contamination are counted in a sodium iodide activated with thallium [NaI(Tl)] well counter. The guidance points out that a dose calibrator is not sufficiently sensitive for this measurement. A Geiger-Mueller (GM) survey instrument is typically used for surveys of radiation levels from packages. Records of surveys must be retained for three years after the record is made in compliance with [NRC 10 CFR 20.2103 \(a\)](#). Receipt of packages containing radioactive material is solely under the jurisdiction of the NRC or respective Agreement State.

2. Shipping

Appendix W of [NUREG-1556, Volume 9, Revision 3](#) recommends the following model procedure for return of licensed material to authorized recipients (pharmacy or sealed sources to vendor):

- In accordance with [NRC 10 CFR 30.41\(a\)\(5\)](#), confirm that persons are authorized to receive byproduct material prior to transfer (e.g., obtain a copy of the transferee's NRC license or Agreement State license that authorizes the byproduct material).
- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container.
- Assemble the package in accordance with the manufacturer's instructions.
- Perform the dose-rate and removable-contamination measurements.
- Label the package and complete the shipping papers in accordance with the manufacturer's instructions.
- Retain records of receipts and transfers in accordance with [NRC 10 CFR 30.51](#).

When returning sources of radioactive material to the vendor, such as a partially decayed Co-57 flood source or a partially decayed high dose rate remote afterloader brachytherapy source, an acknowledgment of receipt should be obtained from the vendor and kept on file. Shipment of radioactive materials, including empty containers (UN 2908), is generally under the jurisdiction of the DOT or must comply with DOT requirements found in [DOT 49 CFR](#).

3. Department of Transportation (DOT) Training

Any individual who prepares a package containing radioactive materials or which has contained radioactive materials is classified as a shipper and must receive training prescribed by the DOT in [DOT 49 CFR 172.704](#) at least every three years. DOT hazardous materials training requirements listed below can be found in more detail on the [DOT Training Requirements](#) webpage:

- General awareness/familiarization
- Function-specific, training

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- Safety
- Security awareness
- In-depth security training, if a security plan is required (typically not required for medical radioactive materials users)
- Driver training (for each hazmat employee who will operate a motor vehicle)

A new employee, or an employee who changes job functions, may perform hazmat job functions before completing training, provided the following:

- The employee does so under the direct supervision of a properly trained and knowledgeable hazmat employee; and
- The hazmat training is completed within 90 days of employment or change in job function.

Recurrent training is required at least once every three years. The three year period begins on the actual date of training. Relevant training received from a previous employer or other source may be used to satisfy the requirements, provided a current record of training is obtained from the previous employer or source. Training must address components specified in [CFR 172.704\(a\) of the Hazardous Materials Regulations](#) to be considered applicable.

Training records must include the following:

- Hazmat employee's name
- Completion date of most recent training
- Training materials (copy, description, or location)
- Name and address of hazmat trainer
- Certification that the hazmat employee has been trained and tested

4. Transportation

[NRC 10 CFR 71.5\(a\)](#) states that each licensee who transports licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the DOT regulations in [DOT 49 CFR](#) parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport. Medical use licensees do not typically need to transport radioactive materials. It is recommended that licensees consult with a radiation safety professional/medical physicist prior to attempting to transport licensed materials.

5. References

- [NUREG-1556, Volume 9, Revision 3](#). Appendix P: Model Procedure for Safely Opening Packages Containing Radioactive Material
- [NUREG-1556, Volume 9, Revision 3](#). Appendix Z. Summary of DOT Requirements for Transportation of Type A or B Quantities of Licensed Material

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- [NRC 10 CFR 20.1906](#): Procedures for Receiving and Opening Packages
- [NRC 10 CFR 20.2103](#): Records of Surveys
- [NRC 10 CFR 20.2203](#): Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits
- [NUREG-1556, Volume 9, Revision 3](#). Appendix O. Model Procedures for Ordering and Receiving Packages
- [NRC 10 CFR 30.41](#): Transfer of Byproduct Material
- [NUREG-1556, Volume 9, Revision 3](#). Appendix T. Model Procedures for Safe Use of Unsealed Licensed Material
- [DOT CFR Title 49](#). Subpart H. Hazardous Materials Training Requirements
- [NRC 10 CFR 71.5](#): Transportation of Licensed Materials
- [NRC 10 CFR 71.0](#): Subpart A—General Provisions
- [NRC 10 CFR 30.51](#): Records

E. Patient Consults (Therapeutic, Breastfeeding)

1. Requirement

Licensees may authorize the release from its control any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

Licensees shall provide the released individual, or the individual's parent or guardian, with instructions to include written instructions, on actions recommended to maintain doses to other individuals as low as reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem), assuming there was no interruption of breastfeeding, the instructions must also include the following:

- Guidance on the interruption or discontinuation of breastfeeding; and
- Information on the potential consequences, if any, of failure to follow the guidance.
- Licensees must maintain a record of the following:
 - o Basis for authorizing the release of an individual in accordance with [NRC 10 CFR 35.2075\(a\)](#)
 - o Instructions provided to a breastfeeding woman in accordance with [NRC 10 CFR 35.2075\(b\)](#)

If a patient does not qualify for release and must be treated as an inpatient, several requirements must be met. First, occupational and public dose requirements must be satisfied during the stay, including providing education to the nursing staff who will care for the patient. Special preparation of the patient room is required

V. Radioactive Material Specific Policies and Procedures

and includes posting of instructions and regulatory signage. Finally, once the patient is eligible for release, the patient must be provided with instructions, and the room must be decontaminated and released.

Note that the current revision of [NUREG-1556, Volume 9, Revision 3](#), describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

2. References

- U.S. Nuclear Regulatory Commission. Press release. “[NRC Issues New Guidance on Release of Patients Following Iodine Treatment for Thyroid Conditions](#).” Available at <http://pbadupws.nrc.gov/docs/ML1104/ML110450729.pdf>. Published February 14, 2011.
- [U.S. Nuclear Regulatory Commission Regulatory Guide 8.39](#). Available at <http://pbadupws.nrc.gov/docs/ML0833/ML083300045.pdf>. Published April 1997.
- [NRC 10 CFR 35.75](#): Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material.
- Sisson JC, Freitas J, Ross McDougall I, et al. [Radiation safety in the treatment of patients with thyroid diseases by radioiodine I-131: practice recommendations by the American Thyroid Association](#). *Thyroid*. 2011;21(4):335–46.
- Beasley CW, Moore WH, Wagner LK. Release Instructions for Hyperthyroid Patients Treated with I-131. *Thyroid*. 2011;21(10):1163–1164.

Sample Policy: Screening and Criteria for Patient Release after I-131 Sodium Iodide (NaI) Administration

Objectives

- Screen patients and evaluate criteria to determine if a patient is releasable after administration of I-131
- Instruct patients receiving I-131 with precautions appropriate for administered activity

Indications

- I-131 for treatment of hyperthyroidism (diffuse toxic goiter/Graves’ disease, toxic nodular goiter, and solitary toxic nodule): administered activity generally ≤ 33 mCi.

| Basis for Release | Criteria for Release | Instructions Needed? | Release Records Required? |
|-----------------------|-------------------------------------|--|---------------------------|
| Administered Activity | Administered Activity ≤ 33 mCi | Yes, if activity administered > 7 mCi ¹ | No |

¹Refer to precautions for patients administered an activity of I-131 between 7 and 33 mCi when customizing patient instructions.

- I-131 for ablation of postoperative thyroid remnant and for therapy of iodine-avid thyroid cancer: administered activity generally ≥ 33 mCi.

| Basis for Release | Criteria for Release | Instructions Needed? | Release Records Required? |
|-------------------------------|--|---|---------------------------|
| Patient-Specific Calculations | Calculated dose ≤ 5 mSv (500 mrem) ² | Yes, if calculated dose > 1 mSv (100 mrem) ³ | Yes |

²Refer to calculated method for determining patient release.

³Refer to precautions for patients administered an activity of I-131 above 33 mCi when customizing patient instructions.

Contraindications

- Pregnancy
- Breastfeeding
- Recent medical imaging using contrast
- Consumption of large amounts of iodine
- Certain concurrent medical conditions

Screening

The treatment of all patients with an administered activity of I-131 must first be approved by an authorized physician user before scheduling. Absence of pregnancy and breastfeeding must be well established prior to treatment.

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Patient Consult

Patients administered an activity of I-131 ≥ 33 mCi must also be interviewed about their living conditions and ability to follow safety guidelines after proposed release. This information, along with patient-specific calculations, will be used to determine if the patient may be released following administration. Individualized patient-specific precautions may also be developed as needed with the assistance of the radiation safety officer (RSO). A decision for patient treatment plan is made, either outpatient or inpatient.

Consider inpatient I-131 therapy in the following situations:

1. When the proposed I-131 dose is ≥ 200 mCi or total effective dose equivalent (TEDE), and patient, despite written instructions, is likely to exceed 0.5 rem to an adult family member or caregiver or exceed 0.1 rem to a pregnant woman, child, or a member of the general public.
2. When the patient is unable to comply with oral and written instructions and therefore will require special planning because of:
 - Incontinence issues;
 - Requires help with devices such as Foley catheters, peritoneal dialysis equipment, feeding tubes, etc.;
 - Cognitive/psychiatric limitations;
 - Travel/housing limitations; or
 - Other limitations.

Eligibility Assessment Questionnaire

Absolute contraindications to I-131 therapy include pregnancy and breastfeeding. Documentation and/or testing to determine absence of pregnancy is required prior to treatment. An answer of “Yes” to any of the following questions indicates the patient may not be eligible for release.

| Question | Yes/No | Notes |
|--|--------|---|
| Will the patient travel home with others or use public transportation on the day of treatment or subsequently? | | If the patient will not be traveling alone and instead will be traveling with others or using public transportation, the patient can sit alone in the back seat >3 feet from the driver and no children or pregnant women will be present. If the patient can only travel by public transportation, this option requires a calculation of TEDE for other individuals and approval by the RSO. |
| What are the relationship, age and gender of each household member? | | For all household members, patient must be able to stay >6 feet away most of the time (caregivers may approach 3 feet up to 25% of the time). |
| Is a household member pregnant? | | If the patient cannot stay at least 6 feet away at all time, provide appropriate information and make an alternate arrangement. |
| Are any household members under the age of 16? | | If the patient cannot stay at least 6 feet away at all time, provide appropriate information and make an alternate arrangement. |

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| Question | Yes/No | Notes |
|---|--------|---|
| Is the patient responsible for the care of an infant or young child? | | If so, provide information and make an alternate arrangement. |
| Is there sufficient space to maintain at least a 6-foot distance from others? | | If not, provide information and make an alternate arrangement. |
| Is the patient unable to sleep alone at night during the restricted period? | | If so, consult RSO and/or consider admission. |
| Must the patient share a bathroom with others? | | If so, provide information and make an alternate arrangement. |
| What is the work/school status? | N/A | From all co-workers or classmates patient must be able to maintain at least 6 feet distance at all times except for momentary encounters. |
| In a work/school situation, is the patient associated with children under age 16? | | If patient cannot stay at least 6 feet from others, delay return to work/school. |
| In a work/school situation, is the patient associated with pregnant women? | | If patient cannot stay at least 6 feet from others, delay return to work/school. |
| Is the patient involved in food preparation for others? | | If so, get special instructions from RSO/radioiodine treatment team. |
| In commuting to work or school, does the patient carpool or use public transportation during the restricted period? | | If so, make an alternate arrangement or obtain special instructions from the RSO. |

F. Patient Release

1. Precautions for Patients Administered an Activity of I-131 NaI Between 7 and 33 mCi

For examples of precaution requirements and recommendations after treatments with I-131, refer to Tables 2A-1 and 2B-1 found in [Radiation Safety in the Treatment of Patients with Thyroid Diseases by Radioiodine I-131: Practice Recommendations of the American Thyroid Association](#).

2. Precautions for Patients Administered an Activity of I-131 NaI Above 33 mCi

For examples of precaution requirements and recommendations after treatments with I-131, refer to Tables 2A-2 and 2B-2 found in [Radiation Safety in the Treatment of Patients with Thyroid Diseases by Radioiodine I-131: Practice Recommendations of the American Thyroid Association](#).

3. Calculated Method for Determining Patient Release After Administration of I-131 NaI

Patients receiving quantities of I-131 greater than 33 mCi may be released if the TEDE to any other individual from exposure to the released individual is not likely to exceed 5 mSv (500 mrem). Written instructions are required when the TEDE to any other individual is likely to exceed 1 mSv (100 mrem). To demonstrate release criteria are met, a calculation based on patient-specific factors is completed. The TEDE from a patient administered I-131 may be calculated to account for the time for the I-131 to be absorbed from the stomach to the blood and the holdup of iodine in the urine while in the bladder.

For uptake assumptions, refer to Table B-1 found in [Regulatory Guide 8.39, Release of Patients Administered Radioactive Materials](#).

a. Calculate external dose

$$D(\infty) = \frac{34.6\Gamma Q_0}{(100cm)^2} \left\{ E_1 T_p (0.8) \left(1 - e^{-0.693(0.33)/T_p} \right) + e^{-0.693(0.33)/T_p} E_2 F_1 T_{1eff} + e^{-0.693(0.33)T_p} E_2 F_2 T_{2eff} \right\} \quad (\text{Equation B - 5})$$

F_1 = Extrathyroidal uptake fraction

F_2 = Thyroidal uptake fraction

E_1 = Occupancy factor for the first 8 hours

E_2 = Occupancy factor from 8 hours to total decay

V. Radioactive Material Specific Policies and Procedures

where $D(t)$ = Accumulated dose to time t , in rems

34.6 = Conversion factor of 24 hrs per day times the total integration of decay (1.44)

G = Exposure rate constant for a point source, $\frac{R}{\text{mCi}} \times \text{hr at 1 cm}$

Q_0 = Initial activity at the start of the time interval

T_p = physical half – life in days

r = Distance in centimeters. This value is typically 100 cm.

$r = 2.2 \frac{R}{\text{mCi}}$ per hour at 1 cm for I – 131

t = Exposure time in days

b. Calculate internal dose

$$D_i = Q(10^{-5})(DCF)$$

where D_i = Maximum likely interval committed effective dose equivalent to the individual exposed to the patient in rems, Q = Activity administered to the patient in millicuries, 10^{-5} = Assumed fraction intake, DCF = Dose conversion factor to convert an intake in millicuries to an internal committed effective dose equivalent

DCF for ingestion of I – 131 = $1.44 \times 10^{-8} \frac{\text{Sv}}{\text{Bq}}$, which is equal to $53,000 \frac{\text{mrem}}{\text{mCi}}$.

Maximum activity that can be administered for the dose to an individual member of the public to receive a total exposure < 500 mrem accounts for both internal and external exposure.

| Purpose of Administration | Occupancy Factor (E1 and E2) | Average Distance | Maximum Activity Administered mCi |
|--|------------------------------|------------------|-----------------------------------|
| After thyroidectomy for thyroid cancer | 0.25 | 1 meter | 200 |
| Hyperthyroidism | 0.25 | 1 meter | 50 |

V. Radioactive Material Specific Policies and Procedures

Sample Procedure: Instructions to Iodine-131 (I-131) Sodium Iodide (NaI) Patients

To be given verbally and in writing and edited as appropriate for the patient. (Instructions should be given in the native language of the patient whenever possible to increase understanding.)

Patient name: _____ Date: _____

With regard to your radioiodine therapy, please consider the following steps.

Step 1: Talk with your doctor or a member of the radioiodine treatment team about the following:

- Why treated women must 1) avoid pregnancy for a period of time and 2) not breastfeed
- When treated men can consider fathering a child
- Who will give you the radioiodine therapy and where and when this will happen

Step 2: Make preparations before treatment and talk with your doctor or a member of the radioiodine treatment team about the following specific items:

Obtaining the following:

- Wipes and/or toilet paper that can be flushed down the toilet
- Disposable gloves if others will be helping to take care of you
- Heavy-duty (doubled if possible), leak proof, specific plastic trash bags for tissues, paper towels, and other things that may be contaminated and trashed

When traveling:

- If you are well enough, it is best to drive yourself
- If you ride with someone else, confirm she is not pregnant and maintain a distance of >3 feet (use the back seat on opposite side of the driver)
- When and where you can take necessary trips
- When it is safe to use public transportation

At home:

- Living or working with a pregnant woman
- Associations with children
- Inability to control your urine or bowels
- Using special medical equipment, such as catheters, ostomy bags, or anything that could be contaminated by your body fluids
- Getting sick easily (vomit or get woozy)
- If you are not able to go directly home after your treatment, please consult your treatment team about your options. Hotel, motel, or other short-term rental property stays are strongly discouraged.

Step 3: Your doctor or member of the radioiodine treatment team will discuss with you the following items and fill in the number of days related to each.

- _____ Days that you need to stay >3 feet away from your adult family members and caregivers for at least 18 hours a day, and at least 6 feet away as much as possible
- _____ Days that you need to stay >6 feet away from babies, children younger than age 16, and pregnant women
- _____ Days that you need to stay away from work and close contact with others in public places (movies, shopping, etc.)
- _____ Days that you need to stay away from school or daycare (includes both teachers and students)

Step 4: Review the following recommendations for after therapy

Home

Specific recommendations; ask your doctor for the number of days you'll need to:

- Sleep alone in a bed that is >6 feet away from another person and, if possible, use a separate bedroom or sleeping room all by yourself.
- Not kiss anyone.
- Not have sexual activity.
- Move your bowels every day and use a laxative if you need help
- Empty your bladder (urinate) every hour or so during the day of, and day after your radioiodine treatment; follow your doctor's advice on how much to drink. Men should sit down to urinate to reduce possible splashing.
- Use wipes (preferably flushable) to clean the toilet seat after use; men should sit down to urinate and use wipes to remove splatter of urine; wipe yourself dry after urinating so that you do not drip.
- For a phone you share with others, wipe off the mouthpiece after use or, while using, cover the phone with a plastic bag that, after use, is placed in specified plastic trash bag.

General recommendations (especially for patients sharing a bathroom):

- Flush the toilet after each use; flush toilet paper and wipes.
- Always wash your hands well after using the toilet.
- Rinse the sink and wash your hands after brushing your teeth to wash away the saliva (spit).
- Do not share your toothbrush, razor, face cloth, towel, food or drinks, spoons, forks, glasses and dishes.
- Shower every day for at least the first two days after your treatment.
- Do not cook for other people. If cooking is necessary, use plastic gloves and dispose of the gloves in the specified plastic trash bag.
- Wash your dishes in a dishwasher or by hand; it is better not to use disposable (throw away) dishes, which must be put into a specified plastic trash bag.

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- Wash your hands after using the toilet. Using warm water, wash hands hourly the first few days after treatment and use a barrier such as food-grade plastic wrap or gloves between fingers and what is touched. These barriers can be used around bathroom handles, personal electronic devices, and other frequently used hand-held items.
- Try to flush any tissues or any other items that contain anything from your body, such as blood, down the toilet; items that cannot be flushed, such as menstrual pads, bandages, paper/plastic dishes, spoons and forks and paper towels should be put in the specified plastic trash bag.
- Wash your underwear, pajamas, sheets, towels, washcloths, and any clothes that contain sweat, blood, or urine by themselves; use a standard washing machine; you do not need to use bleach and do not need extra rinses, although extra rinses demonstrate compliance with the as low as reasonably achievable (ALARA) philosophy. Be sure to use hot water.
- Have anyone who helps you clean up vomit, blood, urine, or stool wear plastic gloves; the gloves should then be put in the specified trash plastic bag.
- Disposable eating utensils, plates, and napkins may be used.
- Disposing of your toothbrush will minimize contamination later.

Trash

- Keep the specified plastic trash bags separate from other trash; keep the bags away from children and animals.
- A member of your radioiodine treatment team will tell you how and when to get rid of the specified plastic trash bag; you may be asked to bring the bag back to your treatment facility or, after 80 days, the bag may be removed as other trash bags. (If trash is not held for at least 80 days, it may set off radiation detectors at the local landfill and you could be fined.)

Pets

- Usually pets will not receive enough radiation to harm them. But do not sleep with pets (ask your doctor for how long) since your saliva, perspiration, or other secretions may be carried away by the pet.

Outside the Home

Ask your doctor or a member of the radioiodine treatment team when:

- It will be safe to eat out, go shopping, and attend events such as religious services, parties, and movies.
- You will be able to return to work and to care for or teach others.
- It would be safe to donate blood.
- Special or longer distance travel is possible. Note that for up to three months or more following radioiodine treatment you may set off radiation detectors at national borders, airports, bus and train stations, tunnels, bridges, trash collection sites, and even your place of employment; a member of your radioiodine treatment team will issue you a letter or card describing the therapy and the phone number of a person knowledgeable about your treatment (usually at the treating facility) in case local law enforcement agents need to check on this information; you should keep the letter or card containing the information with you whenever you are traveling for at least three months.

Emergency Care

- You will receive an information card or letter at the time of your treatment that will show the date, type, and amount of radioiodine that you were treated with; carry this card with you at all times for at least three months following your treatment.
- If you are in a traffic accident or any other medical emergency during the first week after your treatment, you should show this card to medical personnel to let them know about the date and dose of your radioiodine treatment.

Risks of Radiation: Important Information for Patients

Radiation exposure to others should always be as low as reasonably achievable. If you follow the above advice, the radiation from you to others is likely to be less than what they receive from radiation in nature over a year's time.

Please call us if:

- You have any questions.
- Any of the above instructions cannot be followed.
- You see anything that may have accidentally or unavoidably increased exposure of others to radiation.

We welcome your input on how we can improve our methods and advice to patients.

References

- U.S. Nuclear Regulatory Commission. [Regulatory Guide 8.39](#). Published April 1997.
- [NUREG-1556, Volume 9, Revision 3](#). Appendix U: Release of Patients or Human Research Subjects Administered Radioactive Materials
- American College of Radiology. [ACR-ASTRO Practice Parameter for the Performance of Therapy With Unsealed Radiopharmaceutical Sources](#). Revised 2015.
- Sisson JC, Freitas J, McDougall IR, et al. [Radiation safety in the treatment of patients with thyroid diseases by radioiodine I-131: practice recommendations by the American Thyroid Association](#). *Thyroid*. 2011;21(4):335–346.
- Environmental Protection Agency. [Federal Guidance Report No. 11: Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion](#). Published September 1988.

Sample Procedure: Radiation Safety During Inpatient Iodine-131 (I-131) Therapy

The following procedure will be used to reduce worker and public dose during radiopharmaceutical therapy:

1. The patient's room will be as far away from the nursing station and heavily trafficked hallways as is consistent with good medical care. It will be a private room with private sanitary facilities and should be without carpet.
2. Prepare the room for the procedure as follows:
 - a. Use leak-proof absorbent paper to cover large surfaces (bed, pillow, chairs, night stand, bedside table, and entire floor of the room and restroom) that are likely to be contaminated. Small items (telephone, door knobs, bed remote control, television control, and nurse call cord) may be covered with absorbent paper or plastic bags. Plastic protector sheets will be placed under the absorbent paper beside the bed and around the toilet in the bathroom.
 - b. Prepare two separate plastic bags; one should be used for disposable contaminated items and the other should be used for nondisposable contaminated items.
 - c. Stock additional gloves, shoe covers, absorbent paper, and radioactive waste labels in the room for use as necessary by nursing, nuclear medicine, and radiation safety personnel. Gloves and shoe covers are used when entering the room.
3. Order disposable table service for the duration of the patient's stay. Inform environmental services that their personnel should stay out of the room until otherwise notified.
4. Supply nursing personnel with personnel dosimeters.
5. Prior to the administration of I-131 nursing personnel will be briefed on radiation safety precautions. Document education of nursing personnel on relevant iodine therapy checklists.
6. Leave a written copy of the radiation safety precautions at the nurses' station. It is also advised to post nursing instructions on the patient's door.
7. Administering personnel will brief patient on radiation safety procedures for the dosage administration, visitor control, radioactive waste, and other items as applicable.
8. Only those persons needed for medical, safety, or training purposes should be present during the administration.
9. Following administration of the dosage, measure and record the exposure rate in millirem/hour (mrem/hr) at the bedside, at 1 meter from the patient and in adjacent rooms. Establish a safe distance line at 2 mrem/hr and mark with tape on the floor. Post the measurements at the door to the room.
10. Calculate nursing time at bedside and record this and exposure rates on a form of "Room Survey Instructions for Patients Treated with Iodine" and post form on door to the patient's room.
11. Quarterly, calculate thyroid burden of all nuclear medicine technologists who are involved with inpatient I-131 therapies.
12. As the therapy proceeds, pick up waste daily for transfer to a decay-in-storage area.
13. Do not release any patient until either the exposure rate from the patient is less than 7 mrem/hr at 1 meter or the retained radioactivity is less than 33 millicuries. (Note that state or local requirements may have stricter limits.) If the exposure rate standard is used as the release criterion, then measure at a distance of 1

V. Radioactive Material Specific Policies and Procedures

meter from the umbilicus while the patient is standing or, if the patient is not ambulatory, 1 meter from the bedside with the patient supine.

14. Before using the room for general occupancy, it must be decontaminated and released to the ward.

Complete the steps outlined below:

1. Remove all absorbent paper and place it in the appropriate container.
2. Transfer all containers to a decay-in-storage or decontamination area.
3. Use a radiation detection survey meter to check for room contamination. Clean contaminated areas until removable contamination is less than 200 disintegrations per minute (dpm)/100 centimeters squared (cm²).
4. When decontamination is complete (removable contamination below 200 dpm), the Room Release Survey Form must be completed, signed, and dated to release the room for general occupancy. Remove radioactive labels and notify housekeeping to clean the room.

G. Sealed Source Inventory

1. Sealed Source Inventory

The NRC requires that the licensee in possession of a sealed source or brachytherapy source conduct a semiannual physical inventory of all such sources in its possession.

2. References

- [NUREG-1556, Volume 9, Revision 2](#): Consolidated Guidance About Materials Licenses
- [NRC 10 CFR 20.1801](#): Storage and Control of Licensed Material
- [NRC 10 CFR 20.1802](#): Control of Material Not in Storage
- [NRC 10 CFR 30.51](#): Records
- [NRC 10 CFR 35.67](#): Requirements for Possession of Sealed Sources and Brachytherapy Sources
- [NRC 10 CFR 35.406](#): Brachytherapy Sources Accountability
- [NRC 10 CFR 35.2067](#): Records of Leaks Test and Inventory of Sealed Sources and Brachytherapy Sources
- [NRC 10 CFR 35.2406](#): Records of Brachytherapy Source Accountability

Sample Procedure: Sealed Source Inventory

Sample Inventory

1. On a semiannual basis, a physical inventory of sealed sources must be conducted.
2. A report documenting inventory validation must be complete with each source model number, serial number, identity of each source by radionuclide and its estimated activity, date of the inventory, name of the person performing the inventory, and the location of each source.
3. Records must be maintained for at least three years.

The following is a sample inventory entry:

| Model # | Serial # | Radionuclide | Est. Activity | Date | Location | Found by |
|---------|----------|--------------|---------------|--------|-----------------|----------|
| 1234 | ABC12 | Cs-137 | 0.500 mCi | 1/1/14 | Hot lab cabinet | JC |
| 8094 | OQ123 | Co-57 | 0.345 mCi | 1/1/14 | Hot lab cabinet | JC |

H. Leak Testing

1. Requirement

Sealed sources containing $>10 \mu\text{Ci}$ of an alpha emitting material or $>100 \mu\text{Ci}$ of a beta or gamma emitting material must be tested for leakage at least every six months. The wipe of a sealed source must be performed using a leak test kit or method approved by the NRC or an Agreement State. Records of leak tests must be maintained in accordance with federal or local regulations or as specified in the facility operating procedures (typically three years).

2. References

- [NUREG-1556, Volume 9, Revision 3](#): Appendix Q: Model Leak Testing Program
- [NRC 10 CFR 39.35](#): Leak Testing of Sealed Sources
- [NRC 10 CFR 35.67](#): Requirements for Possession of Sealed Sources and Brachytherapy Sources
- [NRC 10 CFR 35.2067](#): Records of Leaks Tests and Inventory of Sealed Sources and Brachytherapy Sources
- [NRC 10 CFR 35.3067](#): Report of a Leaking Source
- [NRC 10 CFR 20.1501 \(F\)](#): Surveys and Monitoring
- [NRC 10 CFR 20.2103](#): Records of Surveys

Sample Procedure: Leak Testing

1. Choose a low-background area for leak test sample analysis and consider using a NaI(Tl) well counter with a single or multichannel analyzer.
2. The instrumentation must be able to detect 185 Bq or 0.005 µCi of radioactivity. The minimum detectable activity (MDA) of the system will tell you if the system is sensitive enough to be used. The following formula should be used to calculate the MDA:

$$MDA = \frac{3 + 4.65 \left(\frac{bkg}{t} \right)^{1/2}}{E}$$

Where:

MDA = minimum detectable activity in disintegrations per minute (dpm)

bkg = background count rate in counts per minute (cpm)

t = background counting time in minutes

E = detector efficiency in counts per disintegration

For example, where:

bkg = 200 cpm

E = 10% or 0.1

t = 2 minutes

$$MDA = \frac{3 + 4.65 \left(\frac{200 \text{ cpm}}{2 \text{ minutes}} \right)^{1/2}}{(0.1)}$$

= 495 dpm

3. The efficiency of the counting system must be known and can be checked using a standard source with the same or similar energy characteristics. The following formula should be used to check the efficiency of the counting system:

$$Eff = \frac{[(cpm \text{ from } std) - (cpm \text{ from } bkg)]}{(\text{activity of } std \text{ in microcuries})}$$

Where:

Eff = efficiency, in cpm per microcurie

cpm = counts per minute

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std = standard

bkg = background

4. The wipe sample must be taken from the nearest accessible point to the sealed source where contamination might accumulate and must be performed by a person approved by the NRC or an Agreement State to perform the analysis.
5. Measure the background count rate and record.
6. Analyze each wipe sample to determine net count rate.
7. For each sample, calculate the activity in microcuries and record. The activity on the wipe is given by the following formula:

$$\frac{[(cpm \text{ from wipe sample}) - (cpm \text{ from bkg})]}{\left(\text{Eff in } \frac{cpm}{\text{microcuries}} \right)} = \text{activity on wipe sample in microcuries}$$

8. Make a record of the leak test and include model number and serial number of each source tested, identity of each source radionuclide and its estimated activity, measured activity of each test sample expressed in microcuries, a description of the method used to measure each test sample, the date of the test, and the name of the individual who performed the test.
9. If the test fails, follow appropriate procedures.

Sample Report: Leak Test Analysis

Facility: Your Hospital

Date: 5/28/2013

Location: Nuclear Medicine

Performed by: John Smith

1. Counting System

Nuclear Medicine Hot Lab

Capintec Caprac R SN 1234

Authorized to perform leak test analysis on Radioactive Materials License 12345

2. Minimum Detectable Activity (MDA)

Performed: 7/19/2012 by John Smith

| Isotope | Model/SN | Date | Activity (µCi) | Half-life (days) | Energy (keV) | Efficiency | MDA (µCi) | Result |
|---------|--------------|-----------|----------------|------------------|--------------|------------|-----------|--------|
| Eu-152 | AB / 123 | 11/1/2006 | 0.5 | 4933.34 | 122 | 0.825 | 0.000039 | Pass |
| Ba-133 | 12A / 14893 | 2/25/1994 | 8.3 | 3854 | 80 & 342 | 0.669 | 0.000049 | Pass |
| Cs-137 | 34B / 65761 | 10/1/2006 | 100 | 11018 | 659 | 0.380 | 0.000086 | Pass |
| Co-57 | 56C / 354734 | 7/1/2005 | 100 | 272 | 100000 | 0.988 | 0.000033 | Pass |
| I-129 | 78D / 467341 | 12/5/1995 | 10 | 5.7305E+10 | 78 | 0.612 | 0.000053 | Pass |

3. Efficiency of Counting System

Performed: 7/19/2012 by John Smith

Background counts:

Counts: 223

Duration: 60 sec

CPM: 223

| Isotope | Half-life (days) | Orig. Act. (mCi) | Date | Current Act. (mCi) | Count Time (s) | Net Counts | Expected Counts | Efficiency |
|---------|------------------|------------------|-----------|--------------------|----------------|------------|-----------------|------------|
| Eu-152 | 4933.34 | 500 | 11/1/2006 | 372.93 | 60 | 683300 | 827895 | 0.825 |
| Ba-133 | 3854 | 8300 | 2/25/1994 | 2478.95 | 60 | 3682000 | 5503264 | 0.669 |
| Cs-137 | 11018 | 500 | 10/1/2006 | 437.63 | 60 | 369500 | 971529 | 0.380 |
| Co-57 | 272 | 100000 | 7/1/2005 | 141.31 | 60 | 309800 | 313710 | 0.988 |
| I-129 | 57305000000 | 78 | 12/5/1995 | 78.00 | 60 | 105900 | 173160 | 0.612 |

V. Radioactive Material Specific Policies and Procedures

4. Wipe Count/Leak Test Using Capintec Caprac-R

Performed: 5/28/2013 by John Smith

Background counts:

Counts: 220

Duration: 60 sec

CPM: 220

| Source Description | Efficiency | Count | Net | Activity | Result |
|--------------------|------------|-------|-----|----------|--------|
| Eu-152 | 0.612 | 60 | 39 | 0.000029 | Pass |
| Ba-133 | 0.612 | 60 | 10 | 0.000007 | Pass |

All measured activity on wipe samples is <0.005 μ Ci and passes leak test analysis.

I. Survey Instrument Calibration

1. General Requirements

Survey instruments, for example GM survey meters, ionization chambers and NaI(Tl) scintillator probes, are required for performing various surveys (see [Routine Surveys](#)). [NUREG-1556, Volume 9](#), Section 8.17, states that the “instruments should be available for use at all times when byproduct material is in use. The licensee should possess survey instruments sufficiently sensitive to measure the type and energy of radiation used, including survey instruments used to locate low-energy or low-activity seeds [e.g., iodine-125 (I-125), palladium-103 (Pd-103)] if they become dislodged in the operating room or patient’s room. The Radiation Protection Program that licensees are required to develop, document, and implement in accordance with [NRC 10 CFR 20.1101](#) must include provisions for survey instrument calibration. Instruments used for quantitative radiation measurements must be calibrated for the radiation measured.” The NRC in [NRC 10 CFR 35.61](#) requires the “calibration of survey instruments used to show compliance with [NRC 10 CFR 35](#) and [NRC 10 CFR 20](#) before first use, annually, and following a repair that affects the calibration.” (Battery changes are not considered “servicing.”)

2. Calibrating Survey Instruments

It is possible for a licensee to perform calibration of their own survey instruments, e.g., GM survey meters as discussed by [Pat Zanzonico in a 2008 Journal of Nuclear Medicine](#) review article. Smaller licensees typically rely on services provided by calibration laboratories, a survey instrument vendor or a consultant. As pointed out in [NUREG-1556, Volume 9](#), Section 8.17, “one method a licensee may use to determine if the service is qualified to perform these activities is to determine that it has an NRC (or an equivalent Agreement State) license.” [NUREG-1556, Volume 9, Appendix K](#), provides a model procedure for calibration of survey instruments should the licensee choose to calibrate their own survey instruments. According to that appendix, “Licensees typically commit to having survey instruments calibrated by a person qualified to perform survey meter calibrations.” Note that the NRC states that, as an operational check, each day before use perform a check (with a dedicated check source) as well as a battery check. A record of each survey instrument calibration must be retained for three years in accordance with [NRC 10 CFR 35.2061](#).

3. References

- [NRC 10 CFR 35.2061](#): Records of Radiation Survey Instrument Calibrations
- [NRC 10 CFR 35.61](#): Calibration of Survey Instruments
- [NUREG-1556, Volume 9, Revision 2](#): Appendix K: General Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program
- [NRC 10 CFR 20.1101](#): General Requirements for Radiation Protection Programs

- Zanzonico P. [Routine Quality Control of Clinical Nuclear Medicine Instrumentation: A Brief Review](#). *J Nucl Med*. 2008;49(7):1114–1131.
- [NUREG-1556, Volume 9, Revision 2](#): Radiation Monitoring Instruments

J. Waste Disposal/Decay-in-Storage

1. Decay-in-Storage

- a. Criteria for decay-in-storage and disposal after decay

A licensee may hold product material in storage for decay if it has a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if it:

- Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
- Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

A licensee shall retain a record of each disposal permitted under [NRC 10 CFR 35.92](#) in accordance with [NRC 10 CFR 35.2092](#).

- b. Model procedures for decay-in-storage

[NRC 10 CFR 35.92](#) describes the requirements for decay-in-storage. Storage should be designed to allow for segregation of wastes with different half-lives (e.g., multiple shielded containers). Containers should have shielded covers to maintain occupational exposure at ALARA levels. Storage areas must be in a secure location.

- i. If possible, use separate containers for different types of waste (e.g., needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container). Because the waste will be surveyed with all shielding removed, the containers in which the waste will be placed must not provide any radiation shielding for the material.
- ii. When the container is full, seal it and attach an identification tag that includes the date sealed and the longest-lived radionuclide in the container. The container may then be transferred to the decay-in-storage area.
- iii. Prior to disposal as in-house waste, monitor and record the results of monitoring of each container as follows:
 - Use a survey instrument that is appropriate for the type and energy of the radiation being measured.

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- Check the radiation detection survey meter for proper operation and current calibration status.
- Monitor in a low-level radiation (<0.05 mrem/hr) area away from all sources of radioactive material, if possible.
- Remove any shielding from around the container or generator column.
- Monitor, at contact, all surfaces of each individual container.
- Remove or deface any radioactive material labels (unless the containers will be managed as biomedical waste after they have been released from the licensee as described in [NRC 10 CFR 35.92](#)).
- Discard as in-house waste only those containers that cannot be distinguished from background radiation. Containers may include trash bags full of waste, generator columns, and biohazard (needle) boxes. Record the disposal date, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred to an authorized byproduct material recipient.

2. References

- [NRC Regulatory Issue Summary 2004-17: Revised Decay-In-Storage Provisions for the Storage of Radioactive Waste Containing Byproduct Material](#)
- [NRC 10 CFR 35.92](#): Decay-in-Storage
- [NUREG-1556, Volume 9, Revision 2](#): Appendix W. Model Procedure for Waste Disposal by Decay-In-Storage, Generator Return, and Licensed Material Return

K. Written Directives

1. Requirement

Similar to a prescription, a written directive must be dated and signed by an authorized user before the administration of:

- I-131 sodium iodide greater than 1.11 megabecquerel (MBq) or 30 μ Ci;
- any therapeutic dosage of unsealed byproduct material; or
- any therapeutic dose of radiation from byproduct material.

It is relevant to note that [lutetium-177 \(Lu-177\) radiopharmaceuticals](#) and [radium-223 \(Ra-223\) dichloride](#) are licensed under [NRC 10 CFR 35.300](#), while [yttrium-90 \(Y-90\) microspheres](#) are licensed under [10 CFR 35.1000](#).

V. Radioactive Material Specific Policies and Procedures

As described in [NRC 10 CFR 35.40](#), the written directive must contain the patient or human research subject's name and the following information:

- For administrations of I-131 sodium iodide (NaI) greater than 1.11 megabecquerel (MBq) or 30 μ Ci, the dosage;
- For administration of a therapeutic dosage of unsealed byproduct material other than I-131 NaI: radiopharmaceutical, dosage, and route of administration;
- For permanent implant brachytherapy:
 - o Before implantation: treatment site, radionuclide, and total source strength; and
 - o After implantation but before the patient leaves the post-treatment recovery area: treatment site, number of sources implanted, total source strength implanted, and date;
- For all other brachytherapy including low, medium, and pulsed dose rate remote afterloaders such as eye-plaque brachytherapy (but excluding high dose rate remote afterloading brachytherapy):
 - o Before implantation: treatment site, radionuclide, dose; and
 - o After implantation but before completion of the procedure: radionuclide, treatment site, number of sources, total source strength, and exposure time (or total dose), and date;
- For high dose rate remote afterloading brachytherapy: radionuclide, treatment site, dose per fraction, number of fractions, and total dose.

Requirements for other treatment modalities can be found in [10 CFR 35.40](#).

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

The licensee shall retain a copy of the written directive in accordance with [NRC 10 CFR 35.2040](#).

2. References

- [NUREG-1556, Volume 9, Revision 2](#): Written Directive Procedures
- [NRC 10 CFR 35.40](#): Written Directives
- [NRC 10 CFR 35.27](#): Supervision
- [NRC 10 CFR 35.41](#): Procedures for Administrations Requiring a Written Directive
- [NRC 10 CFR 35.2040](#): Records of Written Directives
- [NRC 10 CFR 35.2041](#): Records for Procedures for Administrations Requiring a Written Directive
- American College of Radiology. [ACR-ASTRO Practice Parameter for the Performance of Therapy With Unsealed Radiopharmaceutical Sources](#). Published 1996. Amended 2014.
- Sisson JC, Freitas J, Ross McDougall I, et al. [Radiation safety in the treatment of patients with thyroid diseases by radioiodine I-131: practice recommendations by the American Thyroid Association](#). *Thyroid*. 2011;21(4):335–46.
- [United States Environmental Protection Agency Report 11: Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion](#). Published September 1988.

Sample Procedure: Written Directives/Managing and Releasing Restricted Areas

A written directive must be prepared for any administration of I-131 sodium iodide greater than 1.11 MBq (30 μ Ci), any therapeutic dosage of a radiopharmaceutical, and any therapeutic dose of radiation from byproduct material. The WD must contain the information described in [NRC 10 CFR 35.40](#) and be retained in accordance with [NRC 10 CFR 35.2040](#).

Follow the steps below for such a procedure:

1. Have an authorized user date and sign a WD prior to the administration that includes the information in [NRC 10 CFR 35.40\(b\)](#), including the name of the patient or human research subject;
2. Verify the identity of the patient or human research subject prior to each administration;
3. Verify that the administration is in accordance with the treatment plan, if applicable, and the WD;
4. Check both manual and computer-generated dose calculations;
5. Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices; and
6. Determine and record the activity of the radiopharmaceutical dosage or radiation dose before medical use.

Sample Form: Written Directive

For I-131 doses greater than 30 μ Ci and other therapeutic compounds

Patient name: _____ Medical Record #: _____ Date: _____

Radiopharmaceutical and dose prescribed

- I-131 for hyperthyroidism
- I-131 for thyroid cancer
- I-131 for thyroid cancer mets
- Lu-177 DOTATATE
- Y-90 TheraSphere
- Ra-223 Xofigo
- Sr-89 colloidal therapy
- P-32 therapy
- Sm-153 therapy (Quadramet)
- Y-90 Zevalin
- Y-90 SIR-Spheres
- Other _____

Is dialysis required? If yes, notify radiation safety officer (RSO) before dosing.

Is the patient breastfeeding? If yes, notify RSO before dosing?

Is anyone in the house pregnant? If yes, provide extra instructions.

Prescription: radiopharmaceutical, dose, form, route (e.g., I-131, 35 mCi, gel capsule, oral administration): _____

Authorized user signature to order radiopharmaceutical: _____

Date: _____

Two patient ID confirmations prior to administration:

- Home address
- Driver's license
- Full name
- Date of birth
- ID band

Has the patient been provided with written instructions?

Dose preparation and administration.

Lot #: _____ Calibration date/time: _____

Measured activity: _____ mCi - Residual activity: _____ mCi = administered activity: _____ mCi

V. Radioactive Material Specific Policies and Procedures

Technologist administering dose: _____

Second check of dose calibrator measurement: _____

Authorized user signature to administer radiopharmaceutical:

Date: _____

L. Managing and Releasing Restricted Areas

1. Definition of Restricted Areas

Definition of a restricted area: any area to which access is controlled for the protection of individuals from exposure to radiation and radioactive materials.

Table 3. Surface Contamination Levels in Restricted Areas (dpm/100 cm²)

| | | | |
|---|----------------|--|---|
| Area, clothing | alpha emitters | P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, Y-90, In-111, I-123, I-125, I-131, Sm-153, Yb-169, Lu-177, Au-198 | Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201 |
| Restricted areas, protective clothing used only in restricted areas | 200 | 2000 | 20,000 |

2. Establishing Alternate Trigger Levels for Restricted Areas

The following guidance is provided for those applicants who plan to develop procedures for surveying and controlling contamination using action levels for controlling contamination that differ from those provided in Tables R.1 and R.2 in Appendix R of [NUREG-1556, Volume 9, Revision 2](#):

Alternate action levels for cleanup of contamination in restricted areas may be developed without prior NRC approval if:

- Acceptable unrestricted area trigger levels are implemented (e.g., Tables R.1 and R.3 found in Appendix R of [NUREG-1556, Volume 9, Revision 2](#));
- The action levels maintain occupational doses ALARA; and
- The action levels meet all other regulatory requirements (e.g., they should also be designed to minimize, to the extent practicable, contamination of the facility and the environment; facilitate eventual decommissioning; and minimize, to the extent practicable, the generation of radioactive waste).

The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 mrem/hr at 1 centimeter and 1.0 mrem/hr at 1 centimeter, respectively, measured through not more than 7 milligrams/cm² of total absorber.

3. References

- [U.S. Nuclear Regulatory Commission Glossary](#): Restricted Area
- [NRC 10 CFR 20.1601](#): Control of Access to High Radiation Areas
- [NRC 10 CFR 20.1602](#): Control of Access to Very High Radiation Areas

- [NUREG-1556, Volume 9, Revision 2](#). Table R.1. Ambient Dose Rate Trigger Levels. P R-2.
- [NUREG-1556, Volume 9, Revision 2](#). Table R.2. Surface Contamination Levels in Restricted Areas. P R-3.
- [NUREG-1556, Volume 9, Revision 2](#). Table R.3. Surface Contamination Levels in Unrestricted Areas. P R-4.

M. Hot Lab Quality Control - Dose Calibrators

1. General Requirements

[NRC 10 CFR 35.63](#) requires that a licensee determine and record the activity of each dosage before medical use. For a unit dosage, the licensee has the option of relying on the radiopharmacy's determination of activity or activity concentration provided that a decay correction to the time of administration is made. However, [AAPM Task Group 181](#) recommends that all dosages be assayed prior to administration. The National Council on Radiation Protection and Measurements (NCRP) in [NCRP Report No. 99, Quality Assurance for Diagnostic Imaging](#), states that "good practice requires that all individual doses be checked to minimize the possibility of error."

For other than unit dosages, a measurement of activity is more often performed, although volumetric measurements may be used in conjunction with calculations and the radiopharmacy's measurements. The latter is typically reserved for beta-emitting isotopes where accurate measurement may be difficult in a dose calibrator. Most nuclear medicine facilities therefore will have a dose calibrator to enable compliance with dosage determination requirements. Note that [NRC 10 CFR 35.63\(d\)](#) states that "unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent." When using a dose calibrator to ensure compliance with this requirement the licensee must ensure that it has been properly calibrated even if it is only being used to check unit dosages with no intended modification of the dosage.

A now outdated document, U.S. Nuclear Regulatory Commission Regulatory Guide 10.8, provided a model procedure for performing some of the tests outlined in this topic, specifically: accuracy, linearity, geometry, and constancy. Current NRC regulations and the associated guidance do not provide such a model procedure, but instead state in [NRC 10 CFR 35.60](#) that "a licensee shall calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions." In addition, "a licensee shall retain a record of each instrument calibration required by this section in accordance with [NRC 10 CFR 35.2060](#)." Generally, licensees will choose to follow the manufacturer's instructions. Alternatively, there is the American National Standards Institute (ANSI) standard [ANSI N42.13-2004: Calibration and Usage of "Dose Calibrator" Ionization Chambers for the Assay of Radionuclides](#), which may be purchased. Or, a licensee may consult the report of [AAPM Task Group 181: The Selection, Use, Calibration, and Quality Assurance of Radionuclide Calibrators Used in Nuclear Medicine](#), which is available for free

from the AAPM. The AAPM report recommends the following tests for routine quality assurance:

- Physical inspection
- System electronics
- Clock accuracy
- High voltage
- Zero adjust
- Background response/contamination check
- Check source (constancy and relative response)
- Accuracy test
- Reproducibility (precision)
- System linearity
- Supplier equivalence

Some of these dose calibrator tests are outlined in the following subtopics. They have varying requirements for frequency of testing and acceptability depending on the standards or instructions chosen by the licensee and typically committed to in the license application or other tie-down conditions. Only a general description of the tests is provided. An additional reference that discusses the hot lab quality control measurements outlined in the following subtopics is an article by Pat Zanzonico, [Routine Quality Control of Clinical Nuclear Medicine Instrumentation: A Brief Review](#).

2. Accuracy

Accuracy is a measure of the dose calibrator response to traceable standards of radioactivity. Typically two standard sources (e.g., Co-57, Ba-133, Cs-137) in a solid plastic matrix in a vial format are assayed and the measured activity compared with the decay-corrected activity provided with the standard. The source activity should be no less than 100 μCi . If the measurements are in agreement with the standard activity, it is assumed that the dose calibrator is functioning correctly over the range of energies and isotopes that will be assayed clinically.

Frequency of testing for dose calibrator accuracy may be annual or some other extended interval, depending on licensing requirements, and therefore is often performed by a consulting medical physicist during routine audits of the radiation protection program.

3. Linearity

Linearity is a measure of the dose calibrator response over a range of activities. There are several methods used for measuring linearity, including the decaying source method, the shield method, and the graded source method, the latter of which is seldom used in clinical nuclear medicine practices and so will not be discussed.

The decaying source method is performed by simply making repeated measurements of a source while its activity decays over an extended period of time. The test is typically performed using a vial or syringe of Tc-99m and takes several days to decay through the clinical operating range of a dose calibrator. The measured activities and measurement times are then analyzed (e.g., plotted and least squares fit on a semilog graph) to determine the deviation of each point from the expected exponential decay.

The shield method uses a set of lead shields or sleeves that attenuate the source to simulate a number of time points in the decaying source method. Since this method should be completed within a short time span, e.g., 6 minutes, it is simpler to perform and is more commonly used than the decaying source method. The calculations typically involve a comparison to baseline measurements. The baseline measurements need to be performed when it is known that the dose calibrator is working in a linear manner. As a result, if a new set of lead sleeves is obtained, it is necessary to perform the decaying source method at the time of baseline calibration of the sleeves. The manufacturers of linearity sleeves provide guidance on performing sleeve calibration, as well as on the recommended use and analysis of the sleeve measurements.

Frequency of testing for dose calibrator linearity may be quarterly or some other extended interval, depending on licensing requirements, and therefore is often performed by a consulting medical physicist during routine audits of the radiation protection program.

4. Geometry

Geometry is a test of the dose calibrator response to differing volumes for the same activity. This test was included by the NRC in [Regulatory Guide 10.8, Guide for the Preparation of Applications for Medical Use Programs](#). The test is performed by assaying a small volume of activity in a syringe and/or vial commonly used clinically by the licensee. Subsequent assays are performed after drawing up fixed quantities of a non-radioactive solution, e.g., water, until the syringe and/or vial contains the maximum volume that might be used. Performance of the system is determined by comparing the measurements to determine the maximum deviation, e.g., from the initial measurement. Since dose calibrator geometry is an infrequent test, it is often performed by a consulting medical physicist.

5. Constancy

Constancy is a relative response test used to track the stability of the dose calibrator performance, typically from day to day. Measurements should be within $\pm 5\%$ of the most recent few measurements and should be within $\pm 5\%$ of the decay-corrected initial values for the test source, typically a vial standard of Cs-137. Pass/fail limits may vary depending on licensing requirements. Measurements are made on the setting for the standard source, as well as for all commonly used settings. Unlike the tests for accuracy, linearity, and geometry, as a daily task this test is performed by the technologist in conjunction with other routine tests listed above, such as physical inspection, system electronics, clock accuracy, high voltage, zero adjust, and background response/contamination check.

6. References

- [NUREG-1556, Volume 9, Revision 2](#). Section 8.46: Leak Tests.
- [NRC 10 CFR 35.2060](#): Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Byproduct Materials
- [NRC 10 CFR 35.65](#): Authorization for Calibration, Transmission, and Reference Sources
- [NRC 10 CFR 35.60](#): Possession, Use, and Calibration of Instruments Used to Measure the Activity of Unsealed Byproduct Material
- [AAPM Report No. 181](#): The Selection, Use, Calibration, and Quality Assurance of Radionuclide Calibrators Used in Nuclear Medicine
- Zanzonico P. [Routine Quality Control of Clinical Nuclear Medicine Instrumentation: A Brief Review](#). J Nucl Med. 2008;49(7):111–1131.
- [NRC 10 CFR 35.63](#): Determination of dosages of Unsealed Byproduct Material for Medical Use,
- American National Standards Institute. [Calibration and Usage of “Dose Calibrator” Ionization Chambers for the Assay of Radionuclides](#). ANSI N42.13-2004.

N. Hot Lab Quality Control - Well Counters

1. General Requirements

A NaI(Tl) well counter (gamma counters) is a stationary instrument used to measure wipe, bioassay or effluent samples and as such is classified as a radiation monitoring instrument by the NRC. The requirements for routine testing are not clearly laid out by the NRC in rule. Agreement State requirements may be more specific. Nevertheless, a well counter is an integral component of a nuclear medicine department and should be monitored for acceptable performance in order to ensure compliance with applicable regulations, e.g., [NRC 10 CFR 20.1101](#).

NUREG-1556, Volume 9, Section 8.17, states that “licensees shall possess instruments used to measure radiation levels, radioactive contamination, and radioactivity, as applicable. Instruments used for quantitative radiation measurements must be calibrated for the radiation measured.” Due to the infrequent nature of the tests described in the following subtopics, they are often performed by a consulting medical physicist during routine audits of the radiation protection program. Appendix K of [NUREG-1556, Volume 9](#), states that “Operational and calibration checks, using a dedicated check source, should be conducted on each day the instrument is used” and are therefore typically performed by the technologist. The well counter manufacturer’s operator’s manual is often a good source of detailed information for performing routine quality control and should be consulted when setting up a new system. An additional reference that discusses the hot lab quality control measurements outlined in the following subtopics is an article by Pat Zanzonico, [Routine Quality Control of Clinical Nuclear Medicine Instrumentation: A Brief Review](#).

2. Efficiency

NRC licensing guidance in [NUREG-1556, Volume 9, Appendix K](#), provides a brief procedure for determining the efficiency of a well counter using a National Institutes of Standards and Technology (NIST) traceable standard. The guidance states that the efficiency of all instruments used for assaying wipe tests should be determined on an annual basis, before first use, and/or after repair. The determined efficiency allows the licensee to convert sample counts, e.g., in counts per minute, to activity, e.g., in disintegrations per minute (dpm) or microcuries.

3. Chi-Square (χ^2)

The chi-square (χ^2) test is used to test whether the well counter provides consistent counts (count rates) for a standard source over a number of sample counts, e.g., 10 or 20 samples, during a short time period, e.g., 30 minutes. Since the counts from a radioactive source are random in time following a Poisson distribution, a statistical test like the chi-square can help determine if there is too great a spread in the distribution and hence the well counter results are not reproducible, or if there is too little spread in the distribution and hence the well counter results may be affected by systematic noise.

Many of the newer well counters have automated procedures for calculating chi-square, although it may be up to the licensee to determine either the resulting probability for the calculated chi-square and/or what probability limits are to be used as pass/fail criteria. Chi-square is not specified as a required test by the NRC. Many licensees perform this test on a quarterly basis as part of the radiation program audit by the medical physicist.

4. Energy Calibration

Well counter instruments that provide energy windowing capability typically require a calibration of the energy scale of the multichannel analyzer. This calibration is often included as part of the well counter's automatic quality control/calibration procedures. If provided as part of the built-in daily quality control, this test will be performed by the technologist. Energy calibration is not specified as a required test by the NRC. It should be performed by the medical physicist during quarterly radiation program audits to verify the integrity of the NaI(Tl) crystal.

5. Activity Calibration

Well counter instruments may include a check of the activity of a standard source as part of the well counter's automatic quality control/calibration procedures. If provided as part of the built-in daily quality control, this test will be performed by the technologist. Activity calibration is essentially a verification of the stability of the well counter efficiency but is not specified as a required test by the NRC. If available, the built-in quality control should be performed by the medical physicist during quarterly radiation program audits to verify the integrity of the NaI(Tl) crystal and the accuracy of the quality control results.

6. Energy Resolution

Well counter instruments have energy discrimination capability due to the use of NaI(Tl) based scintillators. On systems which provide MCA/energy spectrum display or built-in energy resolution options it is usually possible to determine the full width at half maximum (FWHM) of the photpeak of a reference standard. Commonly used standards for this purpose are Co-57 and Cs-137. Energy resolution is not specified as a required test by the NRC. It should be performed by the medical physicist during quarterly radiation program audits to verify the integrity of the NaI(Tl) crystal.

7. References

- [NUREG-1556, Volume 9, Revision 2](#). Appendix K: General Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program; K-1.
- Zanzonico P. [Routine Quality Control of Clinical Nuclear Medicine Instrumentation: A Brief Review](#). J Nucl Med. 2008;49(7):1114-1131.
- [NRC 10 CFR 20.1101](#): General Requirements for Radiation Protection Programs.
- [NUREG-1556, Volume 9, Revision 2](#): Radiation Monitoring Instruments, P.8-41.

O. Hot Lab Quality Control - (Thyroid) Uptake Probes

1. General Requirements

A NaI(Tl) (thyroid) uptake probe is a stationary instrument typically used to measure thyroid uptake, both for patients as well as for workers who may have had an intake of radioactive I-131 and require a bioassay. As such, an uptake probe is classified as a radiation monitoring instrument by the NRC. The requirements for routine testing are not clearly laid out by the NRC in rule. Agreement State requirements may be more specific. Nevertheless, an uptake probe is an integral component of many nuclear medicine departments and should be monitored for acceptable performance in order to ensure compliance with applicable regulations, e.g., [NRC 10 CFR 20.1101](#). NRC licensing guidance in [NUREG-1556, Volume 9, Section 8.17](#), states that “licensees shall possess instruments used to measure radiation levels, radioactive contamination, and radioactivity, as applicable. Instruments used for quantitative radiation measurements must be calibrated for the radiation measured.” Due to the infrequent nature of the tests described in the following subtopics, they are often performed by a consulting medical physicist during routine audits of the radiation protection program.

According to Appendix K of [NUREG-1556, Volume 9](#), “Operational and calibration checks, using a dedicated check source, should be conducted on each day the instrument is used” and are therefore typically performed by the technologist. The uptake probe manufacturer’s operator’s manual is often a good source of detailed information for performing routine quality control and should be consulted when setting up a new system. An additional reference that discusses

the hot lab quality control measurements outlined in the following subtopics is an article by Pat Zanzonico, [Routine Quality Control of Clinical Nuclear Medicine Instrumentation: A Brief Review](#).

2. Efficiency

NRC licensing guidance in [NUREG-1556, Volume 9, Appendix K](#), provides a brief procedure for determining the efficiency of an uptake probe using a NIST-traceable standard. The guidance states that the efficiency of an instrument used for performing bioassays of personnel should be determined on an annual basis, before first use, and/or after repair. The determined efficiency allows the licensee to convert bioassay counts, e.g., in counts per minute, to activity, e.g., in dpm or microcuries.

3. Chi-Square (χ^2)

The chi-square (χ^2) test is used to test whether the uptake probe provides consistent counts (count rates) for a standard source over a number of sample counts, e.g., 10 or 20 samples, during a short time period, e.g., 30 minutes. Since the counts from a radioactive source are random in time following a Poisson distribution, a statistical test like the chi-square can help determine if there is too great a spread in the distribution, hence the uptake probe results are not reproducible, or if there is too little spread in the distribution, hence the uptake probe results may be affected by systematic noise. Many of the newer uptake probes have automated procedures for calculating chi-square, although it may be up to the licensee to determine whether the resulting probability for the calculated chi-square and/or what probability limits are to be used as pass/fail criteria. Chi-square is not specified as a required test by the NRC. Many licensees perform this test on a quarterly basis as part of the radiation program audit by the medical physicist.

4. Energy Calibration

Uptake probe instruments typically provide energy-windowing capability and require a calibration of the energy scale of the multichannel analyzer. This calibration is often included as part of the uptake probe's automatic quality control/calibration procedures. If provided as part of the built-in daily quality control, this test will be performed by the technologist. Energy calibration is not specified as a required test by the NRC. It should be performed by the medical physicist during quarterly radiation program audits to verify the integrity of the NaI(Tl) crystal.

5. Activity Calibration

Uptake probe instruments may include a check of the activity of a standard source as part of the uptake probe's automatic quality control/calibration procedures. If provided as part of the built-in daily quality control, this test will be performed by the technologist. Activity calibration is essentially a verification of the stability of the uptake probe efficiency but is not specified as a required test by the NRC. If available, the built-in quality control should be performed by the medical

physicist during quarterly radiation program audits to verify the integrity of the NaI(Tl) crystal and the accuracy of the quality control results.

6. Energy Resolution

Uptake probe instruments have energy discrimination capability due to the use of NaI(Tl) based scintillators. On systems that provide multichannel analyzer (MCA)/energy spectrum display or built-in energy resolution options it is usually possible to determine the full width at half maximum (FWHM) of the photopeak of a reference standard. Commonly used standards for this purpose are Co-57 and Cs-137. Energy resolution is not specified as a required test by the NRC. It should be performed by the medical physicist during quarterly radiation program audits to verify the integrity of the NaI(Tl) crystal.

7. References

- [NUREG-1556, Volume 9, Revision 2](#). Appendix K: General Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program; K-1.
- Zanzonico P. [Routine Quality Control of Clinical Nuclear Medicine Instrumentation: A Brief Review](#). J Nucl Med. 2008;49(7):1114–1131.
- [NRC 10 CFR 20.1101](#): General Requirements for Radiation Protection Programs.
- [NUREG-1556, Volume 9, Revision 2](#): Radiation Monitoring Instruments, P.8-41.

P. Starting a New Program

Treatment protocols will vary by radiopharmaceutical and clinical scenario, so no single universal protocol will apply to all therapies. However, the questions and considerations below apply broadly nearly all types of radiotherapy programs.

In this section, Lu-177 Lutathera treatment of neuroendocrine tumors is used as an illustrative example. This is not meant to be a complete description of a Lutathera program, but it does illustrate in a relatively complete manner the considerations for any radiopharmaceutical treatment program.

These questions and considerations are not all-inclusive and there may be additional considerations regarding specific regulations, accreditation standards, and/or facility operations. However, the general questions and considerations below may be used to begin constructing the local policies and procedures that are needed for any radiopharmaceutical treatment program.

1. Is the new use on your radioactive materials license?

Most radioactive materials licenses specify the use of radioactive material by category of use specified by 10 CFR 35 (35.100, 35.200, 35.300, 35.400, 35.600,

35.1000) and radionuclides with specific atomic numbers and half-lives. Lu-177 is classified as 35.300. Lutetium has an atomic number of 71 and a physical half-life of 6.7 days.

2. Do you have AUs for the new use?

Lu-177 is classified as 35.300 – use of unsealed byproduct material for therapeutic administration; specifically, parenteral administration. This should be cross-referenced with existing AUs. If AUs need to be added, see guidance for adding a new AU.

3. Where will the treatment occur?

The treatment location must be an area of the facility approved for the use of radioactive materials. Administration is limited to designated rooms typically in the nuclear medicine department, radiation oncology, oncology and private (single patient) inpatient rooms (such as have been approved for high dose I-131).

There may be additional treatment location considerations. For Lutathera, because of its renal route of excretion, it is advised that the treatment room be an enclosed location (room) with access to a dedicated bathroom. The treatment area should be prepped with plastic wrap or an absorbent material with a liquid barrier such as Chux.

4. Determination of whether treatment is indicated

Before the first treatment, the patient's care team determines if Lutathera treatment is indicated. Sites should assess and document whether the patient meets inclusion criteria before ordering the therapeutic radiopharmaceutical. Sites need to adopt institutional-specific inclusion and exclusion criteria. Typical Lutathera criteria are given below, but the list is not necessarily complete.

Initial treatment:

- a. Documented tissue diagnosis of an appropriate neuroendocrine tumor (NET) that is locally invasive or metastatic and inoperable.
- b. Documented somatostatin receptors on targeted lesions, such as being avid on Ga-68 dotatate PET/CT or In-123 Octreotide gamma camera imaging. Documentation of imaging positivity is usually required within 6 months of treatment.
- c. Pathology evidence of well differentiated status such as Ki67 < 20%.
- d. Laboratory tests assessing renal, liver and hematologic status. Sites should determine local criteria, but for Lutathera typical values may include:

CrCl > 50 mg/min; Hg > 8 gm/dl; WBC > 2000/mm³; Plt > 75,000/mm³;
AST, ALT < 3x upper limit of normal; Total Bilirubin < 1.5x upper limit of normal

Subsequent treatment:

Lutathera therapy has hematologic, renal and hepatic toxicities. The care team should determine if the subsequent therapy is indicated. In the case of Lutathera, Grade 2, 3, or 4 adverse reactions may require a lower treatment dose of radiopharmaceutical, or result in a delay or cessation of therapy, depending on institution specific inclusion/exclusion criteria/policy.

Site should determine the inclusion and exclusion criteria to be used, and where and how they are to be documented.

5. Additional pretreatment criteria

Radiopharmaceutical therapies may have additional pretreatment inclusion criteria, such as necessary premedication or cessation of medications prior to therapy. In the case of Lutathera these criteria include:

- a. Somatostatin analogues should be discontinued prior to therapy; typically 24 hours for short-acting and four weeks for long-acting.
- b. Amino acid and antiemetic infusion is administered before/during/after the radiopharmaceutical administration.
- c. A pregnancy testing policy may be indicated for females of childbearing potential.

Prior to radiopharmaceutical ordering or administration, these additional criteria should be documented.

6. How will patients be referred to an appropriate treatment facility?

Prior to referring patients to be treated, appropriate confirmation should be obtained from the potential treatment facility that appropriate licensing, AUs, policies, and procedures are in place.

7. Are patient education or instructions required?

Education is required if it is likely that a member of the public will receive more than 1.0 mSv (0.1 rem) total effective dose equivalent as a result of being near or caring for the patient. It is up to the facility to make a determination of possible exposure to the public, including and especially the individual(s) likely to receive the highest exposure and dose. See [NRC Regulatory Guide 8.39, Release of Patients Administered Radioactive Materials](#). Note: NRC Reg. Guide 8.39 was under review for revision by the NRC at the time this document revision was published.

According to 10 CFR 35.75(b) if the total effective dose equivalent to any other individual is likely to exceed 1.0 mSv (0.1 rem), written instructions must be given to released patients. The facility RSO should determine specific release instructions for the new radiopharmaceutical.

8. Are there any other post-treatment steps?

Following therapy, imaging may be requested to confirm the treatment location or for use in patient-specific dosimetry.

9. Equipment

If your dose calibrator does not have a setting for the new radiopharmaceutical, a NIST-traceable source should be ordered in order to determine the appropriate dose calibrator setting. First patient doses are often ordered with these NIST-traceable sources for this purpose.

After delivery and prior to treatment, the radiopharmaceutical needs to be securely stored, with appropriate shielding precautions. Storage of other administration equipment, e.g. syringe shield, tubing, delivery device, needles, etc., need to also be safely and conveniently stored.

10. Training

Beyond the credentials required to administer radioactive materials, additional training may be necessary for support personnel. In the case of Lutathera, (oncology) nurses are typically involved to administer antiemetic and amino acid solutions. At minimum, training for use of the administration tools and radiation safety precautions should be delivered.

Some therapies require special preparation such as pulling a specific activity from a bulk dose (ex. SIR Spheres) or connection to an infusion pump (Lutathera). The vendor may schedule training with nuclear medicine technologists and a provide “mock” or “cold” vial to practice in advance of patient administration.

11. Documentation

A written directive must be completed in advance of treatment. Other documentation includes evidence of area surveys, and testing for removable contamination (wipes) prior to releasing the treatment area as an uncontrolled space. Facilities should retain copies of training materials, a roster of who has attended training and when, and evidence that patient education was provided (if needed). Additional procedures may need to be developed for the detection of the new radiopharmaceutical during routine surveys.

12. Emergency procedures

A plan, i.e., policies and procedures, must be in place for how to respond during an emergency. This could include a radiopharmaceutical factors, such as a spill of the radiopharmaceutical, or patient factors, such as adverse reactions. Many of these procedures are likely already part of the institution’s existing policies and procedures (e.g. respiratory arrest, etc.). However, there may be specific procedures unique to the radiopharmaceutical.

In the case of Lutathera treatment, short-acting octreotide may be available to manage acute or urgent symptoms occurring during the treatment.

Q. Part 35.1000 Uses (Emerging Technologies)

Title 10 of the *Code of Federal Regulations* Part 35, Subpart K – Other Medical Uses of Byproduct Material or Radiation From Byproduct Material ([10 CFR 35.1000](#)) describes the process to obtain a license, or an amendment to a license, for a new medical use of byproduct material or radiation from byproduct material, which is not addressed in other parts of 10 CFR Part 35 (i.e., an emerging medical technology). Additional requirements are included in [10 CFR 35.12\(d\)](#), “Application for license, amendment, or renewal.”

The [NRC provides licensing guidance for emerging medical technologies](#). The licensing guidance consists of general licensing considerations, specific radiation safety aspects of the emerging medical technology, and training and experience expectations for those authorized to use the emerging medical technology. It also contains a list of the emerging medical technologies whose use has been evaluated for licensing by the NRC, such Y-90 microspheres. It should be noted that while most Agreement States have adopted the NRC Part 35.1000 licensing guidance document emerging technologies, they are not required to, and some have developed their own requirements for licensing of these technologies.

The licensing guidance for emerging medical technologies can be found at the following URL:

<https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html#reg>

License Maintenance Procedures

An extensive list of FAQs regarding radioactive materials and licensing is available on the NRC website: [Frequently Asked Questions About Licensing Medical Uses of Byproduct Material Under Revised 10 CFR Part 35](#)

A. Adding or Removing a Radiation Safety Officer (RSO)

A radioactive materials license amendment is required to add or remove an RSO. When adding an RSO at a facility, the licensee must demonstrate that a person is qualified.

See [Section II](#) for specific qualifications.

B. Adding or Removing Authorized Use Areas

Original applications require a facility diagram. According to [NRC 10 CFR 35.14\(b\)\(5\)](#), the NRC must be notified in writing no later than 30 days after changes to or additions to areas of use under [NRC 10 CFR 35.100](#) and/or [NRC 10 CFR 35.200](#) are made. A new diagram is needed if a change or addition of areas of use results in a change in the diagram originally submitted under [NRC 10 CFR 35.12\(b\)\(1\)](#).

C. Adding or Removing Authorized Users or Authorized Medical Physicists

A radioactive materials license amendment is required to add or remove an authorized user or an authorized medical physicist. When adding an authorized user or an authorized medical physicist at a facility, the licensee must demonstrate that the proposed authorized user or authorized medical physicist is qualified.

All applicants must have approved specialty board certification and may need to have additional training and experience beyond the specialty board training, as specified in [NRC 10 CFR 35.14\(a\)](#), [§35.51\(a\)](#), [§35.390\(a\)](#), or [§35.690\(a\)](#), as applicable.

The easiest way to add an authorized user or an authorized medical physicist for a specific radioactive material use is to provide a radioactive material license number where the proposed authorized user or an authorized medical physicist is already listed for that use.

If an authorized user or authorized medical physicist is already listed on a license for a specific type of use and he/she applies for a similar type of use, the applicant must comply with any additional case experience or training required as specified in the regulations for the medical use for which he/she is applying.

The other mechanism for adding an authorized user or authorized medical physicist is by completing and submitting [a preceptor form](#).

D. Adding or Changing Areas of Use

Original applications require a facility diagram. According to [NRC 10 CFR 35.14\(b\)\(5\)](#), the NRC must be notified in writing no later than 30 days after changes to or additions to areas of use under either [NRC 10 CFR 35.100](#) or [NRC 10 CFR 35.200](#) are made. A new diagram is needed if a change or addition of areas of use results in a change in the diagram originally submitted under [NRC 10 CFR 35.12\(b\)\(1\)](#).

E. References

- [NRC 10 CFR Part 35: FAQ](#)
- [NRC 10 CFR Part 20—Subpart E: Radiological Criteria for License Termination:](#)

Regulatory Contact Information

The following is a partial list of online directories containing contact information for radiation safety regulatory agencies within the United States. Links are accurate as of press time.

- [U.S. Nuclear Regulatory Commission Contacts](#)
- [U.S. Nuclear Regulatory Commission Agreement States Map and Contacts](#)
- [Organization of Agreement States](#)
- [Conference of Radiation Control Program Directors](#)
- [American Association of Physicists in Medicine State Map, Contacts, and Forms](#)

Radiation Safety Officer (RSO) Courses

The following is a partial list of organizations and companies RSO training courses. These links are provided for your information and do not imply endorsement by the American College of Radiology or the American Association of Physicists in Medicine. Links are accurate as of publication press time.

- [Radiation Safety and Control Services Training](#)
- [Dade Moeller® Medical Radiation Safety Officer Course](#)
- [Nevada Technical Associates Radiation Safety Officer Training Course](#)
- [Oak Ridge Associated Universities Radiation Safety Officer Training](#)
- [Oak Ridge Associated Universities Virtual Radiation Safety Officer Training](#)
- [RSO Services Training](#)
- [CURE Institute of Health Physics Radiation Safety Services and Training](#)
- [Stan A. Huber Consultants Inc. Training and Course Development](#)
- [International Radiation Safety Consulting Inc. Training](#)

Acronym List

All regulatory agencies as well as professional organizations use acronyms to make their documents more succinct and to expedite communication. However, medical personnel not familiar with radiation safety acronyms may become lost in this “alphabet soup.” Many of the acronyms that are important to radiation safety are listed and defined below. A more complete list of acronyms are available in the [NRC Collection of Abbreviations](#).

- **AAPM** - American Association of Physicists in Medicine
- **ACR** - American College of Radiology
- **ALARA** - As Low as Reasonably Achievable
- **ANSI** - American National Standards Institute
- **CFR** - Code of Federal Regulations
- **CRCPD** - Conference of Radiation Control Program Directors
- **DOT** - Department of Transportation
- **FDA** - U.S. Food and Drug Administration
- **GM** - Geiger-Mueller
- **IAC** - Intersocietal Accreditation Commission
- **MCA** - Multichannel analyzer
- **MDA** - Minimum detectable activity
- **MQSA** – Mammography Quality Standards Act
- **NCRP** - National Council on Radiation Protection and Measurements
- **NRC** - U.S. Nuclear Regulatory Commission
- **NUREG** - NRC technical report designation (Nuclear Regulatory Commission)
- **NVLAP** - National Voluntary Laboratory Accreditation Program
- **QA** - Quality assurance
- **RSO** - Radiation safety officer
- **SNMMI** - Society of Nuclear Medicine and Molecular Imaging
- **SPR** - Society of Pediatric Radiology
- **SSR** - Suggested State Regulations
- **TJC** - The Joint Commission
- **WD** - Written directive