ACR–AAPM–ACNM–SNMMI–SPR TECHNICAL STANDARD FOR THERAPEUTIC PROCEDURES USING RADIOPHARMACEUTICALS

The American College of Radiology, with more than 40,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

The American College of Radiology will periodically define new practice parameters and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care[1]. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The purpose of this document is to assist practitioners in achieving this objective.

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1 *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the "ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008)" sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.*

I. INTRODUCTION

This technical standard has been developed collaboratively by the American College of Radiology (ACR), the American Association of Physicists in Medicine (AAPM), the American College of Nuclear Medicine (ACNM), the Society of Nuclear Medicine and Molecular Imaging (SNMMI), and the Society for Pediatric Radiology (SPR).

The goal of therapy with radiopharmaceuticals and other radionuclide sources is to provide cure or palliation of disease while minimizing side effects and complications. This technical standard was developed to cover key

aspects pertinent to the performance of therapeutic procedures using radiopharmaceuticals.

This technical standard is intended to set practice parameters and technical standards covering the use of radiopharmaceuticals for therapy.

Radiopharmaceuticals are agents that are intended for use in the diagnosis, therapy, or monitoring of a disease or a manifestation of a disease in humans and that exhibit spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons. Radiopharmaceuticals also include any nonradioactive reagent kit or radionuclide generator that is intended to be used in the preparation of such agents (see FDA definition of radiopharmaceutical: 21CFR315.2, 1997 FDAMA section 122[b].) [1].

Facility management and their responsible staff using radioactive materials should consult with their Radiation Safety Officer to ensure that there are policies and procedures specific to unsealed diagnostic and therapeutic radiopharmaceuticals that address all duties and equipment from ordering, receipt, use, administration, storage, and disposal in compliance with all applicable laws and regulations ACR–AAPM Radiation Safety Officer Resources [2].

The term "dosage" is used by the Nuclear Regulatory Commission (NRC) and Agreement States in their regulatory language for what is the administered activity. Both terms are used in this document.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Qualifications and responsibilities of personnel should adhere to Nuclear Regulatory Commission (NRC) requirements for training as specified in 10 CFR 35, as appropriate.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician (Authorized User [AU])

The qualifications and responsibilities of physicians performing these therapeutic procedures should be in accordance with the ACR–ACNM–ARS-ASTRO–SNMMI Practice Parameter for the Performance of Therapy with Radiopharmaceuticals. In addition, training and experience must be in compliance with the applicable laws and regulations as pertain to AUs or equivalent.

The physician authorized to use the therapeutic radiopharmaceutical to be administered is ultimately responsible for supervision of the entire procedure and all aspects related to of its use. The qualifications of the physician performing therapy procedures must meet the appropriate training and experience requirements of 10 CFR Part 35, Subpart E (or its Agreement State equivalent) and be specified on the license. This physician is called the AU.

The AU may delegate tasks to qualified personnel, subject to applicable federal, state, or local regulations. The AU remains responsible for supervising those persons to whom tasks are delegated [3].

An AU must be immediately available in the facility during the administration of the radiopharmaceutical therapy. This may require being in the room if so constrained by license condition or licensee protocol.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

B. Nuclear Medicine Technologist

1. The technologist performing nuclear medicine services should meet all of the following criteria: Successful completion of an accredited program in nuclear medicine technology. This program must include education in the basic and medical sciences as they apply to nuclear medicine technology and practical experience in performing nuclear medicine procedures. The technologist must satisfy all state and federal regulations that pertain to the in vivo and in vitro use of radiopharmaceuticals and performance of imaging examinations.
   or
2. Hold current registration in Nuclear Medicine Technology with the American Registry of Radiologic Technologists (ARRT) or equivalent body as recognized by the American College of Radiology or certification

in Nuclear Medicine Technology by the Nuclear Medicine Technology Certification Board (NMTCB). and

3. Licensure, if required by state regulations.
4. In addition to the general certification requirements, nuclear medicine technologists also must complete continuing education hours to maintain certification. Documented regular participation in continuing education to maintain competence in the workplace.
5. Have knowledge of radiation safety, administration of radiopharmaceuticals, operation of equipment, handling of medical and radioactive waste, patient release instructions, and applicable regulations.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

C. Nuclear Pharmacist

The Nuclear Pharmacist must meet applicable NRC requirements for training as specified in 10 CFR 35, or equivalent Agreement State regulations.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

D. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields in medical physics. The American College of Radiology (ACR) considers certification, continuing education, and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice one or more of the subfields in medical physics and to be a Qualified Medical Physicist. The ACR strongly recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, or by the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the ACR Practice Parameter for Continuing Medical Education (CME) [4].

The appropriate subfield of medical physics for this technical standard is Nuclear Medical Physics (including medical physics certification categories of Radiological Physics, Medical Nuclear Physics and Nuclear Medicine Physics).

Certification by the American Board of Science in Nuclear Medicine in Nuclear Medicine Physics and Instrumentation is also acceptable. (ACR Resolution 17, 1996 – revised in 2012, Resolution 42)

Individuals who are ABR certified in either the Therapeutic Medical Physics or Diagnostic Medical Physics subfield may be qualified with appropriate training in radiopharmaceutical therapy consistent with AAPM Report 249 and procedure-specific training in the radiopharmaceutical therapies being performed at their institutions [5].

In addition, the Qualified Medical Physicist must meet any qualifications imposed by licensure of an Agreement State, if applicable.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

E. Radiation Safety Officer (RSO)

Each licensee must designate the Radiation Safety Officer (RSO) who meets applicable NRC requirements for training as specified in 10 CFR 35, Subpart B, or equivalent Agreement State regulations [6].

III. RADIOPHARMACY

A. Responsibility

The physician authorized to use the therapeutic radiopharmaceutical to be administered is ultimately responsible for the safety and appropriate preparation and/or administration under their direction.

Radiopharmaceutical tasks, such as handling, aseptic preparation, and administration of the radiopharmaceutical may be delegated to qualified personnel, subject to applicable federal, state, or local regulations. The AU remains

responsible for supervising those persons to whom tasks are delegated.

The delegated qualified individual performing radiopharmaceutical tasks shares responsibility for the safety and quality of all radiopharmaceuticals with which they are involved, under the supervision of the authorized physician.

III. RADIOPHARMACY

B. Radiopharmaceuticals (prescription, assay)

1. Written Directive: This is the prescription of the quantity of radioactivity to be administered. A written directive is required prior to administration that includes the patient's name, radiopharmaceutical (not just radionuclide), route of administration, specified activity or range of activity to be administered, and signature of an authorized user. In an emergency situation, 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 completed within 48 hours of the emergency oral directive [7]. If the quantity of activity to be administered is based on dosimetry, then information regarding the dosimetric quantity upon which the activity prescription is based should be included (eg, absorbed dose, BED, EQD2, etc). The term "dosage" is used by the Nuclear Regulatory Commission (NRC) and Agreement States in their regulatory language for what is administered activity. Both terms are used in this document.
2. Assay: The quantity of administered activity must be assayed by the AU or by a person whom the AU has delegated the task prior to administration even if the unit dose was assayed by a commercial radiopharmacy. Dual verification of the assay should be performed. If there are any discrepancies, they must be resolved, per licensee protocol.
3. Administration and Documentation: Administered activity must fall within the tolerance of the prescribed activity according to applicable state and federal regulations. The identity of the patient using at a minimum of 2 identifiers, per a written procedure (patient's name, date of birth, picture identification, etc), the radiopharmaceutical, the route of administration, and pregnancy and breastfeeding status in patients of childbearing age, must be verified prior to administration and documented in the patient's record.
4. Informed consent must be obtained and documented. Refer to the ACR Practice Parameter on Informed Consent – Radiation Oncology [8].
5. Preferably within 24 hours prior to administration, a human chorionic gonadotropin (hCG) blood test must be performed to verify the patient's pregnancy status. If the patient is found to be pregnant, then the AU (with consultation with involved parties) will decide whether to proceed with the administration.
6. If applicable, breastfeeding precautions must be made prior to administration. The patient's acknowledgement must be documented.
7. For the radiopharmaceuticals that are potentially marrow radiotoxic, a complete blood count with differential and platelet count should be part of the pretreatment assessment within 1 week of the therapy procedure. Other laboratory tests may be indicated, as stated in the product description or per protocol.
8. Assay radiopharmaceutical dosage container after administration to assess the amount of the residual activity and verify the appropriate amount of activity has been given.

For specific information related to other records maintained for radiopharmacy operations, refer to the ACR–ACNM–SNMMI–SPR Practice Parameter for the Use of Radiopharmaceuticals in Diagnostic Procedures [9].

IV. INSTRUMENT AND EQUIPMENT

A. Dose calibrator

The dose calibrator (also known as activity meter) is a pressurized ion chamber used to assay radiopharmaceutical activity in a syringe or vial. The assay of the intended administered activity is displayed in units of Curies or Becquerels. The assay requires a specific dose calibrator setting for each radionuclide. Sources for the radionuclide setting of a specific dose calibrator are 1) the dose calibrator preprogrammed isotope library; 2) based on guidelines/instructions for the calibration of a dose calibrator dial setting as provided by the centralized radiopharmacy supplier; or 3) the dose-calibrator manufacturer's user manual or website.

Requirements and methods for acceptance testing and routine quality control (QC) of dose calibrators can be found in the ACR–AAPM Radiation Safety Officer Resources, section V, part M [2,10]. Tests should evaluate

constancy or precision, linearity of response with activity, accuracy of radionuclide assays, and effects of source (volume) geometry. Depending on the test, the frequency will vary from daily, quarterly, annually, at acceptance, or after repair.

IV. INSTRUMENT AND EQUIPMENT

B. Survey meters

Survey meters are used to monitor radiation levels from radioactivity contamination or assess radiation exposure rates from patients receiving radionuclide therapies. The survey instruments must be sufficiently sensitive to detect the type and energy of radiation used [11].

To survey for personnel and equipment contamination, a Geiger-Müller (GM) detector with or without detachable probes (pancake or cylinder style) or a handheld scintillation counter also with or without detachable probes as appropriate depending on radionuclide and emissions should be used. Common display units of such devices are counts per minute (cpm) and/or microroentgens per hour (μR/hr) or microsieverts per hour (μSv/hr).

To survey patient and received radiopharmaceutical package exposure rates, a survey meter using either an energy-compensated GM probe, a solid-state detector, or an ionization chamber may be used. The meter must be calibrated to accurately measure exposure rate or dose rate across the entire spectrum of emitted photons from the therapeutic radionuclide being used.

Common display or readout units are milli- or microroentgens per hour (mR/hr; μR/hr) or milli- or microsieverts per hour (mSv/hr; μSv/hr). Instruments designed to measure exposure may not be sufficiently sensitive to detect some contamination.

Survey meters must be calibrated to a NIST traceable source annually and after repair unless a regulatory license condition specifies differently. Calibrations must be performed by a licensee specifically authorized to perform such calibration service. Each instrument should be checked for proper operation with a dedicated check source (if present) before the first use on each day of use.

IV. INSTRUMENT AND EQUIPMENT

C. Uptake probes

Organ uptake probes such as thyroid probes are radiation detection and counting instruments that are used to measure the quantitative or relative amount of radioactivity in specific anatomical location. Most commonly uptake probes are in the form of a solid NaI(Tl) scintillation detector or a solid-state detector interfaced to a multichannel analyzer for energy discrimination.

QC testing of uptake probes must be done if used to assess internal activity and should include radionuclide efficiency, background correction, $\chi 2$, energy calibration, and energy resolution. The frequency of the tests can vary from daily, monthly, or quarterly. Acceptable QC programs can be found in the ACR–AAPM Radiation Safety Officer Resources section V, part O [2] or Zanzonico [12].

IV. INSTRUMENT AND EQUIPMENT

D. Well counters

The use of unsealed radiopharmaceuticals requires radiation detection and counting instruments to measure and quantitate removable radioactive contamination from work surfaces, radionuclide packaging, or leakage from radioactive sources. The well counter is the recommended instrument for this use and may also be used for in vitro radioactive samples. The measured output is expressed in units of counts per minute, which must be transformed to activity by applying an efficiency factor (dpm/cpm or microcurie/cpm or Becquerel/cpm) for different radionuclides. The efficiency factor may be built into the system or may need to be empirically determined for the system by the user. Most commonly, the well counter is a well-shaped, solid NaI(Tl) scintillation detector interfaced to a multichannel analyzer for energy discrimination.

QC testing of well counters must be done to demonstrate that counting results used to demonstrate regulatory and license compliance are valid and accurate. The tests and their frequency should be the same as that for

scintillation uptake probes indicated above.

IV. INSTRUMENT AND EQUIPMENT

E. Infusion

Parenteral therapies require the infusion of the radiopharmaceutical through slow hand infusion or via infusion pump. Infusion should not be done via a “straight stick” directly into the blood vessel, and infusions should employ a 3-way stopcock system using an intracatheter, the shielded syringe, vial, or infusion pump containing the radiopharmaceutical dosage, and a saline flush. Patency of the infusion setup must be confirmed, immediately prior to administration of the radiopharmaceutical to prevent infiltration or extravasation.

Infusion pumps are mainly large or small volume. Large-volume infusion pumps are based on peristaltic movement to pulse medication through additional infusion tubing, whereas small volume infusion pumps use a piston or plunger for direct infusion from a syringe. Infusion pumps are equipped with safety features that activate in the event of a problem such as the presence of air, blockage in the tubing, or pressure buildup beyond a preset value. When used to deliver radiopharmaceuticals, it is advisable that the infusion pump or the radioactive dosage syringe or vial be shielded. Some infusion pumps can accommodate syringe shields or are equipped with shielding enclosures, otherwise portable L-blocks or other shielding should be used to reduce personnel radiation exposure.

During the use of these devices, prevention of skin contamination is critical requiring precautionary measures and close visual monitoring until the end of administration [13].

IV. INSTRUMENT AND EQUIPMENT

F. Shielding

Together with (shorter) time and (greater) distance, passive shielding is a simple yet effective technique to decrease the radiation exposure from nuclear medicine therapeutic procedures. Shielding should be of the material thickness that is appropriate for the radiopharmaceutical emission energies and activity. Shields of the appropriate material thickness such as L-Blocks for dosage handling and assay stations, shielded cabinets, syringe/vial transport carriers, and shielded waste containers are commercially available and are recommended for use with all nuclear medicine therapeutic procedures in order to keep occupational exposure as low as reasonably achievable (ALARA).

For inpatient and outpatient therapies, shielded walls, floors, ceilings and doors, or rolling shields that are properly positioned and of the appropriate material thickness can minimize exposure and assure radiation levels in adjacent public areas are below actionable levels. These are highly effective for energies up to that of I-131. Adjacent room(s) may need to be kept empty, when room shielding cannot provide radiation levels below the actionable general public limit.

Administration of the radiopharmaceutical therapy from a syringe or vial must be done using an appropriate syringe or vial shield. Administration of the radiopharmaceutical therapy from an infusion pump must be done using appropriate shielding.

IV. INSTRUMENT AND EQUIPMENT

G. Fume hood

Nuclear medicine therapeutic procedures involving volatile liquid forms of radiopharmaceuticals (eg, radioiodine) have the potential for airborne contamination and may require the use of a fume hood. Fume hood systems for such forms must be under negative pressure and vent either directly outside or through a proper filter. These systems should be checked annually for proper operation and to ensure that effluents are within the dose limits of 10 CFR 20.1301, and are within the ALARA constraints for air emissions established under 10 CFR 20.1101(d).

IV. INSTRUMENT AND EQUIPMENT

H. Personnel dosimeters

Staff handling and administering unsealed radiopharmaceuticals must be issued personnel dosimeters to

measure their whole body and hand dose equivalents (ie, reported in units of millirem). These dosimeters are typically either thermoluminescent dosimeters (TLD) or optically stimulated luminescent dosimeters (OSLD). The dosimeters measure the dose received by the wearer to evaluate whether or not occupational dose limits have been exceeded and that the licensee is maintaining doses ALARA. These dosimeters are also used by workers and caregivers, who may be providing inpatient assistance (eg, pediatric therapy). For some situations, calibrated electronic dosimeters may be employed for special-case, one-time potentially high exposures.

The dosimeters and their records must be processed and evaluated by a dosimetry processor that complies with NRC regulations 10 CFR 20.1501, or equivalent Agreement State regulations. The licensee must maintain occupational dose monitoring records in an available format for the duration of the license or as required by the NRC regulations 10 CFR 20.2106, or equivalent Agreement State regulations.

V. PATIENT AND PERSONNEL SAFETY

A. Receipt of radioactive materials

Packages containing diagnostic or therapy radioactive material must be received by personnel with appropriate training. Opening and surveying of packages for contamination must be done within 3 hours of receipt. Requirements for shipping and receiving radioactive materials are described in the ACR–AAPM Radiation Safety Officer Resources section V, part D [2].

V. PATIENT AND PERSONNEL SAFETY

B. Patient release

Patient release criteria following a radionuclide therapy procedure are codified in NRC regulation 10 CFR 35.75 [14] and sections of the NRC regulatory guidance document NUREG 1556 [11]. These criteria apply to any radiopharmaceutical administered. The patient may be released if the total effective dose equivalent to any other individual (including any caregiver or family member) who is exposed to the patient is not likely to exceed 5 mSv (0.5 rem). This limit is per event and not an annual total if additional treatments or other radionuclides are administered within the year of the radionuclide therapy procedures. Calculations following an acceptable methodology must document that the patient dose to other individuals will not exceed this limit before the patient is released from the licensee's control/facility [2,15].

Instructions, including written instructions, must be provided to the patient or the patient's guardian on precautions or restrictions to minimize doses and radioactive contamination to others by following ALARA principle if the total effective dose equivalent to any individual is likely to exceed 1 mSv (0.1 rem). It is important that the patient understands any precautions that are provided and documented acknowledgement by patient should be done. Patient ability to understand instructions because of age or language barriers need to be considered and resolved before administration. Agreement States may have specific rules and regulations regarding release of patients with significant residual activity. The precautions and their durations will depend on the specific radiopharmaceutical therapy and patient circumstances [16].

After the patient has been released, wipe survey (for removable contamination) and radiation level survey must be done of the room where the therapy dosage was handled and administered, even if the treatment was outpatient.

V. PATIENT AND PERSONNEL SAFETY

C. Emergency procedures

The 2 most likely, although uncommon, emergency situations to arise with unsealed radiopharmaceuticals are radioactive spill or patient death. The RSO must be notified and consulted in any case as soon as possible.
A radioactive spill may occur from handling or administering unsealed radiopharmaceuticals. Accidental contamination of staff or surfaces can occur from patient's bodily fluids. Staff must be trained in management of and cleaning up a spill. A kit with spill clean-up materials should be immediately available. A model spill procedure [2] would be to:

- Notify persons in the area that a spill has occurred. Have all persons not involved in the spill or possibly

contaminated vacate the room.

- 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, working from the perimeter toward the center. 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’s emissions. 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.
- Document radiation survey levels at beginning of clean up, at end of clean up, and background.
- Report the incident to the RSO.

In the case of patient death before radiation restrictions have expired, immediately notify the AU, RSO, and referring physician for any needed precautions to be given to the funeral director.

V. PATIENT AND PERSONNEL SAFETY

D. Radioactive waste disposal

Radioactive waste can be disposed by decay-in-storage, return to supplier, or transfer to a licensed disposal facility. Records of disposal of radioactive material must be maintained by the licensee. Radioactive material may be held for decay-in-storage if the half-life is less than or equal to 120 days. At the time of disposal, typically 10 half-lives, the material must be indistinguishable from background radiation levels when measured with no shielding and an appropriate survey meter.

Disposal by return to supplier (commercial radiopharmacy or manufacturer) involves shipping of radioactive material and must be done in compliance with Department of Transportation (DOT) regulations. Staff who package and document shipments must have documented training in the relevant DOT shipping requirements. Containers being returned to supplier must be assessed for residual activity for shipping document even if used dosage container is deemed “empty.”

If radioactive material is ineligible for disposal by decay-in-storage or return to supplier, a licensed and authorized disposal company must be used to properly dispose of the waste material. Some therapy radiopharmaceuticals may contain detectable quantities of long-lived contaminants that may require this disposal method [17,18].

For further information, refer to the ACR–AAPM Radiation Safety Officer Resources, section V, part J [2].

V. PATIENT AND PERSONNEL SAFETY

E. Inpatient Therapy

Radiation protection guidance and documentation for caring of inpatients receiving a therapeutic amount of a radionuclide must address the following:

- Room radiation signage to restrict room access
- Rooms should be far from nursing stations or heavily trafficked hallways (when possible) to reduce staff and public radiation exposure
- Use and positioning of portable bedside shielding, if needed
- Radiation safety training and personnel dosimetry monitoring for caregivers or staff
- Preparing and covering surfaces to prevent contamination
- Stocking room/nursing station with supplies for staff to control contamination
- Ordering disposable table service during treatment
- Provide a written copy of restrictions for nursing and other hospital staff
- Establishing restrictions for visitors, if visiting is permitted
- Containers for handling room radioactive waste
- After patient release, room decontamination and survey for release to routine use

For further information, refer to your facility radiation safety officer, the ACR–ACNM–ASTRO–SNMMI Practice Parameter for the Performance of Therapy with Unsealed Radiopharmaceutical Sources [16], and the ACR–AAPM Radiation Safety Officer Resources section V, part F [2].

VI. RECORDKEEPING

It is required that documentation be kept to verify compliance with regulations and licensee's procedures. This recordkeeping includes, but may not be limited to:

1. Written directive signed by the AU prior to administration.
2. Assay of administered activity by the user prior to administration.
3. Assay of activity container (vial/syringe) after administration.
4. Two methods used to identify the patient.
5. For patients of childbearing age, hCG pregnancy assessment <48 hours before administration.
6. For patients of childbearing age, breastfeeding status and precautions, if appropriate.
7. Test results to assess blood or other organ toxicity risk.
8. Dose calibrator QC, day of therapy use.
9. Survey meter annual calibration.
10. Contamination wipe and radiation level survey of therapy package.
11. Contamination wipes and radiation levels survey of administration room after patient release.
12. Day of use QC for well counter(s) used for contamination surveys.
13. Day of QC for uptake probe, if used for patient therapy measurements.
14. For inpatient therapy, copy of posted room precautions and visitor restrictions.
15. For inpatient therapy, radiation levels in adjacent rooms/areas.
16. Patient release calculations, noting any patient specific conditions.
17. Copy of patient release instructions signed by the patient or caregiver.
18. Hand and body personnel dosimeter reports of staff.
19. Records of patient's therapy radioactive waste storage/disposal.

The final report should include the radiopharmaceutical administered activity, and route of administration. For additional information, refer to the ACR–ACNM–SNMMI–SPR Practice Parameter for the Use of Radiopharmaceuticals in Diagnostic Procedures [9].

VII. RADIATION SAFETY IN IMAGING

Facilities and their responsible staff should consult with the radiation safety officer to ensure that there are current policies and procedures for the safe handling and administration of radiopharmaceuticals and that they are adhered to in accordance with ALARA. These policies and procedures must comply with all applicable radiation safety regulations and license conditions of the NRC, Agreement State, and/or other regulatory agencies. Policies and procedures for the safe handling and administration of radiopharmaceuticals should also comply with the radiation safety recommendations of the National Council on Radiation Protection and Measurements as provided in NCRP 155 [7].

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on Quality Control & Improvement, Safety, Infection Control*, *and Patient Education* on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

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