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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.

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

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiation oncology 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 care¹. 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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also 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 sole purpose of this document is to assist practitioners in achieving this objective.

¹ *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing*, ___ N.W.2d ___ (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), and the Society for Pediatric Radiology (SPR).

The goal of therapy with unsealed radiopharmaceutical sources is to provide either cure or effective palliation of disease while minimizing untoward side effects and complications. This technical standard was developed to cover key aspects pertinent to the performance of therapeutic procedures using radiopharmaceuticals.

Facilities and their responsible staff should consult with their radiation safety officer to ensure that there are policies and procedures specific to each unsealed radiopharmaceutical source that address 1) required instrumentation, calibration, and calibration frequency and 2) ordering and receiving, recordkeeping, safe use, and waste disposal of therapeutic radiopharmaceuticals in compliance with the applicable laws and regulations as described in [ACR–AAPM Radiation Safety Officer Resources](#) [1].

II. DEFINITION

Radiopharmaceuticals are drugs 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, or any nonradioactive reagent kit or radionuclide generator that is intended to be used in the preparation of such articles. (see FDA definition of radiopharmaceutical: 21CFR315.2, 1997 FDAMA section 122[b].) [2]

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

III. 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.

A. Physician

The qualifications and responsibilities of physicians performing these therapeutic procedures should be in accordance with the [ACR Practice Parameter for the Performance of Therapy with Unsealed Radiopharmaceutical Sources](#) [3]. Application of this parameter should be in accordance with the [ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals](#) [4], as that standard relates to the handling of radiopharmaceuticals, radiation safety, and radiation protection of patients, personnel, and the public. In addition, training and experience must be in compliance with the applicable laws and regulations as pertain to Authorized Users (AU) or equivalent.

B. Nuclear Medicine Technologist

The technologist performing nuclear medicine services should meet all of the criteria as defined in the [ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals](#) [4].

C. Nuclear Pharmacist

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

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 \(CME\)](#). (ACR Resolution 17, 1996 – revised in 2012, Resolution 42) [5]

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.

In addition, the Qualified Medical Physicist must meet any qualifications imposed by the state and/or local radiation control agency.

E. Radiation Safety Officer (RSO)

The Radiation Safety Officer (RSO) must meet applicable NRC requirements for training as specified in 10 CFR 35, or equivalent state regulations [1,6].

IV. RADIOPHARMACY

For specific information related to the radiopharmacy, refer to the [ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals](#) [4].

V. INSTRUMENTATION AND EQUIPMENT

A. Dose calibrator

The dose calibrator is used for radiopharmaceutical assay and requires a specific internal setting for each radionuclide.

Requirements and methods for calibration and quality control (QC) of dose calibrators can be found in the [ACR–AAPM Radiation Safety Officer Resources](#), section V, part M [1,7].

Guidance in Preparing the Dose Calibrator for Specific Radiopharmaceutical Assay

Radiopharmaceutical	Guidance Documents
Iodine-131 (sodium iodide) Iodine-131 (meta-iodobenzylguanidine [MIBG I-131])	1. Included in the dose calibrator preprogrammed isotope library
Lutetium-177 DOTA Yttrium-90 DOTA	1. May be included in the dose calibrator preprogrammed isotope library 2. Guidelines for the calibration of Lutetium-177 DOTA, dose calibrator dial setting instructions as provided by the radiopharmacy 3. Guidelines for the calibration of Yttrium-90

	DOTA, dose calibrator dial setting instructions as provided by the radiopharmacy
Phosphorus-32 (sodium phosphate) Phosphorus-32 (colloidal chromic phosphate)	1. Refer to guidance document provided by your radiopharmacy
Radium-223 (radium dichloride)	1. May be included in the dose calibrator preprogrammed isotope library 2. Guidelines for the calibration of Radium-223 (radium dichloride), dose calibrator dial setting instructions as provided by the radiopharmacy
Samarium-153 (lexidronam ethylene diamine tetra methylene phosphonic acid [EDTMPA])	1. May be included in the dose calibrator preprogrammed isotope library 2. Guidelines for the calibration of Samarium-153, dose calibrator dial setting instructions as provided by the radiopharmacy
Strontium-89 (strontium chloride)	1. Refer to guidance document provided by your radiopharmacy: "Guidelines for the Calibration (Strontium-89-chloride injection)"
Yttrium-90 (ibritumomab tiuxetan)	1. Refer to guidance document provided by your radiopharmacy

B. Survey meters

Survey meters are used to monitor radiation levels from radioactivity contamination or radiation exposure from all therapies covered in this technical standard.

Requirements and methods for calibration and QC of survey meters can be found in the ACR–AAPM Radiation Safety Officer Resources, section V, part I [1], as well as NRC 10 CFR 35.61 [8] and NUREG-1556, Volume 9, Revision 2 [9].

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 or readout units of such devices are counts per minute (cpm) and/or microroentgens per hour ($\mu\text{R/hr}$) or microsieverts per hour ($\mu\text{Sv/hr}$).

To survey patient exposure rates, GM dose rate survey meters, solid state detectors, ionization chambers, or handheld scintillation counters that are calibrated to accurately measure exposure rate or dose rate across the entire spectrum of emitted photons should be used. Common display or readout units are milli- or micro-roentgens per hour (mR/hr; $\mu\text{R/hr}$) or milli- or microsievert per hour (mSv/hr; $\mu\text{Sv/hr}$). Limitations of radiation exposure survey instruments are that they are generally not as sensitive as contamination survey instruments and may not efficiently detect some types of contamination.

C. Uptake probes and intraoperative probes

Intraoperative probes and organ uptake probes such as thyroid probes are radiation detection counting instruments that are used to measure the presence or amount of radioactivity in specific locations.

Quality control testing of uptake probes and their frequency can be found in the [ACR–AAPM Radiation Safety Officer Resources](#), section V, part O [1], as well as in the article by Zanzonico [10]. These tests include efficiency, chi square, energy calibration, energy resolution, and activity calibration.

D. Well counters

All radiopharmaceutical therapies require a well counter to measure radioactive contamination on surfaces. The measured results are expressed in units of counts/minute, which must be transformed to activity by including an efficiency factor for different radionuclides that are built into the system.

Requirements and methods for calibration and QC of well counters can be found in the [ACR–AAPM Radiation Safety Officer Resources](#), section V, part N. [1].

E. Infusion

Various parenteral therapies require the infusion of the radiopharmaceutical through slow hand infusion or via infusion pump. Infusion pumps are mainly 2 types: large or small volume. Large volume infusion pumps are based on peristaltic infusion, whereas small volume infusion pumps use direct infusion. 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 be shielded; some infusion pumps can accommodate syringe shields or are equipped with shielding enclosures to reduce personnel radiation exposure.

F. Shielding (syringe shields, L-Blocks, pigs/shielded containers, staff protection)

Together with (shorter) time and (greater) distance, passive shielding is a simple yet effective technique to decrease the radiation exposure of workers from nuclear medicine therapeutic procedures. Passive shields such as L-Blocks, syringe shields, 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). In high-volume facilities the use of structural shielding should be considered.

For further information, refer to the US NRC NUREG-1556 Volume 11, Rev 2 Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses and the [ACR–AAPM Radiation Safety Officer Resources](#) [1].

G. Fume hood

Nuclear medicine therapeutic procedures involving aerosols or gaseous products that might produce airborne contamination may require the use of a fume hood. These systems should have a method of verification to ensure that effluents are ALARA, 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). For further information, refer to the US NRC NUREG-1556 Volume 11, Rev 2 Consolidated Guidance About Materials Licenses- Program Specific Guidance About Medical Use Licenses and the [ACR–AAPM Radiation Safety Officer Resources](#) [1].

H. Personnel dosimeters

Personnel dosimeters such as thermoluminescent dosimeters and optically stimulated luminescent dosimeters capture the radiation exposure received by the radiation workers.

The American National Standards Institute and the Health Physics Society have established a standard procedure and criteria for the testing and performance of personnel dosimetry in ANSI/HPS N13.11-2009 [11].

VI. PATIENT AND PERSONNEL SAFETY

A. Shipping, delivery, and receipt of radioactive materials

Radioactive material must be received by personnel with appropriate training and surveyed for contamination. Requirements for shipping and receiving radioactive materials are described in the [ACR–AAPM Radiation Safety Officer’s Resources](#), section V, part D [1].

B. Patient release criteria

Patient release criteria following a radionuclide therapy procedure are codified in the federal guidelines 10 CFR 35.75 [9,12] and key sections of NUREG 1556 [13]. These criteria are independent of the radiopharmaceutical therapy 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). Instructions, including written instructions, must be provided to the patient on actions to maintain doses to others by following ALARA principle, if the total effective dose equivalent to any individual is likely to exceed 1 mSv (0.1 rem). Agreement States may have specific rules and regulations regarding release of patients with significant residual activity [9,14,15].

For further information on patient release including instructions, refer to the [ACR–AAPM Radiation Safety Officer’s Resources](#) [1] and refer to your facility’s radiation safety officer.

C. Emergency procedures (radioactive spill or contamination)

A radioactive spill may occur when treating a patient with solutions, colloidal suspensions, or microspheres. There is a possibility of accidental contamination of staff by contact with patients or their excreta or vomitus. The following table provides resource guides for these emergency situations.

Refer to your facility’s radiation safety officer for further information.

Radiopharmaceutical	Guidance Documents
Iodine-131 (sodium iodide)	1. ACR–AAPM Radiation Safety Officer Resources Section V. A. [1] 2. NUREG-1556, Vol. 9, Rev 2, page 8-59, and Appendix N 3. Manufacturer website 4. Package insert
Iodine-131 (meta-iodobenzylguanidine MIBG iodine-131)	
Lutetium-177 DOTA	
Yttrium-90 DOTA	
Phosphorus-32 (sodium phosphate)	
Phosphorus-32 (colloidal chromic phosphate)	
Radium-223 (radium dichloride)	
Samarium-153 (lexidronam ethylene diamine tetra methylene phosphonic acid [EDTMPA])	
Strontium-89 (strontium chloride)	
Yttrium-90 (ibritumomab tiuxetan)	

D. Radioactive waste disposal/decay-in-storage

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 an appropriate survey meter. If material is ineligible for decay-in-storage and disposal through standard waste streams, a licensed and authorized disposal company must be used to properly dispose of material. Records of disposal must be maintained.

For further information, refer to the [ACR–AAPM Radiation Safety Officer Resources](#), section V, part J [1].

E. Inpatient therapy

The following documents serve as radiation protection guidance for personnel caring for inpatients who have received a therapeutic dosage of a radionuclide.

For further information, refer to your facility radiation safety officer, the [ACR Practice Parameter for the Performance of Unsealed Radiopharmaceutical Sources](#) [3], and the [ACR–AAPM Radiation Safety Officer Resources](#), section F [1].

F. Written request for therapy

The written or electronic request for a radiopharmaceutical procedure should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason for the procedure or diagnosis would be helpful and may at times be needed to allow for the proper performance of the procedure.

The request for the procedure must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state's scope of practice requirements. (ACR Resolution 35, adopted in 2006).

Informed consent must be obtained and documented. Refer to the ACR Practice Parameter on Informed Consent – Radiation Oncology [16]. Pregnancy should be excluded and breastfeeding precautions must be considered prior to therapeutic radiopharmaceutical administration. For the radiopharmaceuticals that are potentially marrow toxic, a complete blood count with differential and platelet count should be part of the pretreatment assessment.

The procedure should include duplicative procedures for identifying patients. The final report should include the radiopharmaceutical used, dosage, and route of administration. For additional information, refer to the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [4].

VII. PROCEDURE MANUAL

Refer to the [ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals](#) [4].

VIII. RECORDKEEPING

Refer to the [ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals](#) [4].

IX. RADIATION SAFETY

Radiologists, medical physicists, registered radiologist assistants, nuclear medicine technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff and to society as a whole ALARA and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure necessary to achieve the clinical objective. All personnel that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection, and application of dose limits) and the principles of proper management of radiation dose to patients (justification and optimization): http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf.

Facilities and their responsible staff should consult with the radiation safety officer to ensure that there are 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 conditions of licensure imposed by the NRC and by state and/or other regulatory agencies.

Quantities of radiopharmaceuticals should be tailored to the individual patient by prescription or protocol. 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 [14].

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

Policies and procedures related to quality, safety, infection control, and patient education should be developed and implemented in accordance with the [ACR Position Statement on Quality Control and Improvement, Safety, Infection Control, and Patient Education](#).

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Collaborative Committee – members represent their societies in the initial and final revision of this technical standard.

ACR

Osama Mawlawi, PhD, Chair
S. Cheenu Kappadath, PhD
David C. Madoff, MD, FACR
Marguerite T. Parisi, MD, MS
Bassem I. Zaki, MD

AAPM

Bette W. Blankenship, MS
Jessica B. Clements, MS
Mary F. Fox, MS, FACR, FAAPM

SPR

S. Ted Treves, MD
Helen R. Nadel, MD

Committee on Practice Parameters and Technical Standards – Medical Physics
(ACR Committee responsible for sponsoring the draft through the process)

Maxwell R. Amurao, PhD, MBA, Chair
Charles M. Able, MS
Ishtiaq H. Bercha, MSc
Caridad Borrás, DSc, FACR, FAAPM, FIOMP
Chee-Wai Cheng, PhD, FAAPM
William R. Geiser, MS
Mary Ann Keenan, DMP
Ralph P. Lieto, MS, FACR, FAAPM

Lijun Ma, PhD, FAAPM
Jonathon A. Nye, PhD
Matthew A. Pacella, MS, FACR
William Pavlicek, PhD
Douglas E. Pfeiffer, MS, FACR, FAAPM
Premavathy Rassiah, PhD
Thomas G. Ruckdeschel, MS
Christopher J. Watchman, PhD

Committee on Practice Parameters and Technical Standards – Nuclear Medicine and Molecular Imaging
(ACR Committee responsible for sponsoring the draft through the process)

Kevin P. Banks, MD, Co-Chair
Richard K.J. Brown, MD, FACR, Co-Chair
Twyla B. Bartel, DO
Murray D. Becker, MD, PhD, FACR
Erica J. Cohen, DO, MPH
Joanna R. Fair, MD

Edward D. Green, MD
Jennifer J. Kwak, MD
Chun K. Kim, MD
Charito Love, MD
Joseph R. Osborne, MD, PhD
Rathan M. Subramaniam, MD, PhD, MPH

Committee on Practice Parameters and Technical Standards – Nuclear Medicine and Molecular Imaging
(ACR Committee responsible for sponsoring the draft through the process)

Perry S. Gerard, MD, FACR
Erin C. Grady, MD

Stephanie P. Yen, MD

Committee on Practice Parameters – Pediatric Radiology
(ACR Committee responsible for sponsoring the draft through the process)

Beverly Newman, MB, BCh, BSc, FACR, Chair
Lorna P. Browne, MB, BCh
Timothy J. Carmody, MD, FACR
Brian D. Coley, MD, FACR
Lee K. Collins, MD
Monica S. Epelman, MD
Lynn Ansley Fordham, MD, FACR
Kerri A. Highmore, MD

Sue C. Kaste, DO
Tal Laor, MD
Terry L. Levin, MD
Marguerite T. Parisi, MD, MS
Sumit Pruthi, MBBS
Nancy K. Rollins, MD
Pallavi Sagar, MD

Richard A. Geise, PhD, FACR, FAAPM, Chair, Commission on Medical Physics
M. Elizabeth Oates, MD, Chair, Commission on Nuclear Medicine and Molecular Imaging
Rathan M. Subramaniam, MD, PhD, MPH, Vice Chair, Commission on Nuclear Medicine and Molecular Imaging
Marta Hernanz-Schulman, MD, FACR, Chair, Commission on Pediatric Radiology
Jacqueline A. Bello, MD, FACR, Chair, Commission on Quality and Safety
Matthew S. Pollack, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee

Beth A. Schueler, PhD, FACR, FAAPM, Chair
William Small, Jr., MD, FACR, Co-Chair
Maxwell R. Amurao, PhD, MBA
Kevin P. Banks, MD
Bette W. Blankenship, MS
Jacqueline A. Bello, MD, FACR
Richard K.J. Brown, MD, FACR
Jessica B. Clements, MS
William Erwin, MS
Mary F. Fox, MS, FACR, FAAPM
Richard A. Geise, PhD, FACR, FAAPM
Marta Hernanz-Schulman, MD, FACR
William T. Herrington, MD, FACR
S. Cheenu Kappadath, PhD

David C. Madoff, MD, FACR
Osama Mawlawi, PhD
Darlene F. Metter, MD, FACR
Helen R. Nadel, MD
Beverly Newman, MB, BCh, BSc, FACR
M. Elizabeth Oates, MD
Marguerite T. Parisi, MD, MS
Matthew S. Pollack, MD, FACR
Naimuddin Shaikh, PhD
Timothy L. Swan, MD, FACR, FSIR
S. Ted Treves, MD
Richard Wendt, PhD
Bassem I. Zaki, MD

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Development Chronology for this Technical Standard

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