ACR-ACNM-SNMMI-SPR PRACTICE PARAMETER FOR THE USE OF RADIOPHARMACEUTICALS IN DIAGNOSTIC PROCEDURES

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 $\frac{1}{2}$. 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.

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, <u>Stanley v. McCarver</u>, 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 practice parameter was revised collaboratively by the American College of Radiology (ACR), the American College of Nuclear Medicine (ACNM), the Society of Nuclear Medicine and Molecular Imaging (SNMMI), and the Society for Pediatric Radiology (SPR).

This practice parameter was developed to cover key aspects pertinent to the performance of nuclear imaging examinations, *in vivo* nonimaging diagnostic studies, and *in vitro* nonimaging diagnostic studies using radioactive drugs (radiopharmaceuticals).

Diagnostic radiopharmaceuticals are used in the diagnosis or monitoring of a disease or a manifestation of a disease in humans. They exhibit spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons [1]. (Food and Drug Administration (FDA) definition of diagnostic radiopharmaceutical: 21CFR315.2, 1997 FDAMA section 122(b).)

This practice parameter is intended to be antecedent to all practice parameters and technical standards addressing the use of diagnostic radiopharmaceuticals. This parameter also applies to nonradioactive reagent kits and radionuclide generators used in the preparation of diagnostic radiopharmaceuticals.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

The physician supervising the administration of diagnostic radiopharmaceuticals must meet all of the following criteria:

 Certification in Radiology, Diagnostic Radiology, Nuclear Radiology, or Nuclear Medicine by one of the following organizations: the American Board of Radiology (ABR), the American Board of Nuclear Medicine (ABNM), the American Osteopathic Board of Radiology (AOBR), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, and/or the American Osteopathic Board of Nuclear Medicine (AOBNM). In addition, the physician should have appropriate training and experience in specific examinations as defined in procedure-specific parameters when applicable.

OR

At a minimum, completion of a formal nuclear medicine program approved by the Accreditation Council for Graduate Medical Education (ACGME), the RCPSC, the Collège des Médecins du Québec, or the American Osteopathic Association (AOA) that must meet all Nuclear Regulatory Commission (NRC) requirements as cited in 10 CFR 35.290(c)(1)(i) [2]. In addition, clinical training in nuclear medicine is required. The training must cover technical performance, calculation of administered activity, evaluation of images, and correlation with other diagnostic modalities, interpretation, and formal reporting. Physicians trained prior to the availability of formal instruction in nuclear medicine–related sciences may be exempted from this requirement, provided they have been actively involved in providing nuclear medicine services.

AND

- 2. Have documented regular participation in continuing medical education (CME) related to diagnostic procedures using radiopharmaceuticals, in accordance with the <u>ACR Practice Parameter for</u> <u>Continuing Medical Education (CME)</u> [3]. In addition, expertise should be maintained on a continual basis to ensure the quality and safety of patient care through ongoing experience as defined in procedure-specific parameters and maintenance of certification as appropriate.
- 3. In addition to meeting institutional credentialing requirements, be an authorized user on the institution's radioactive materials license, or when permitted by and in accordance with applicable policies and NRC (or Agreement State) rules, be an authorized user on another NRC or Agreement

State license. When required by the NRC or by the state, at least one physician member of the facility must be a participating member of the committee that deals with radiation safety [4].

- 4. Supervise the preparation and administration of diagnostic radiopharmaceuticals and have a thorough understanding of each procedure using diagnostic radiopharmaceuticals with which they are involved. The physician is furthermore responsible for ensuring appropriate utilization of services, for the quality of procedures, for all aspects of patient and facility safety, and for compliance with applicable government regulations (eg, federal, state, and local) and institutional policies regarding the use of radiopharmaceuticals.
- 5. Be responsible for developing and maintaining a program of quality control and continued quality improvement (see Sections IV and V) or accept responsibility for adhering to such an established program.

B. Nuclear Medicine Technologist

The technologist preparing or administering diagnostic radiopharmaceuticals must meet all of the following criteria:

1. 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

Hold current registration with the American Registry of Radiologic Technologists (ARRT)(N) or equivalent body as recognized by the ACR, or certification by the Nuclear Medicine Technology Certification Board (NMTCB).

AND

- 2. Licensure or other credential, if required by state regulations.
- 3. Documented regular participation in continuing education to maintain competence in the workplace.
- 4. Have knowledge of radiation safety and protection, the compounding, preparation, and administration of radiopharmaceuticals, all aspects of performing examinations, operation of equipment, handling of medical and radioactive waste, patient safety, and applicable rules and regulations.

C. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently one or more of the subfields in medical physics. The American College of Radiology 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 (CCPM), the American Board of Science in Nuclear Medicine (ABSNM), or the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the <u>ACR Practice Parameter for Continuing Medical Education</u> (<u>CME</u>) [3].

The appropriate subfield of medical physics for this technical standard is Nuclear Medical Physics. (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f)

Certification in Nuclear Medicine Physics and Instrumentation by the American Board of Science in Nuclear Medicine (ABSNM) is also acceptable.

D. Radiation Safety Officer

The radiation safety officer (RSO) must meet applicable NRC requirements for training as specified in 10 CFR 35.50 [5], or equivalent state regulations.

E. Nuclear Pharmacist

The nuclear pharmacist must meet applicable NRC requirements for training as specified in 10 CFR 35.55, or equivalent state regulations.

III. RADIOPHARMACY

- A. Responsibility
 - 1. The nuclear medicine physician is ultimately responsible for the safety and appropriate utilization of all radiopharmaceuticals prepared and/or administered under their direction and supervision.
 - 2. Handling, preparation, and administration of radiopharmaceuticals may be delegated to qualified personnel, subject to applicable government regulations. The nuclear medicine physician remains responsible for supervising those persons to whom tasks are delegated.
 - 3. The qualified individual performing radiopharmaceutical tasks shares responsibility for the safety and quality of all radiopharmaceuticals with which he or she is involved.
- B. Radiopharmaceuticals
 - Prescription (or medication order): The quantity of radioactivity to be administered must be
 prescribed (either individually by prescription or by protocol). When the radiopharmaceutical and
 administered activity¹/₂ are such that a written directive is required, such a directive must be signed
 by an authorized user [6]. In an emergent 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 prepared within 48 hours of the oral directive.
 - 2. Assay: The quantity of radioactivity to be administered must be assayed prior to administration [7] by the licensee.
 - 3. Administration and documentation: Administered activity must fall within the tolerance of applicable government regulations and institutional policies. The identity of the patient, the radiopharmaceutical, the route of administration, and, in females of childbearing age, pregnancy and breastfeeding status must be verified prior to administration and documented in the patient's record.
- C. Elution of Generators and On-Site Preparation of Radiopharmaceutical Kits
 - 1. Ensure proper function of generators according to the manufacturer's specifications and within applicable government regulations.
 - 2. Care must be taken to minimize radiation exposure to personnel at all steps in generator set up, elution, and eluate assay. The radioactivity of the generator eluate must be measured, and the eluate radioactivity and volume must be recorded.
 - 3. Radiopharmaceuticals should be prepared according to the manufacturer's package insert. Preparation with minor deviation(s) from the manufacturer's instructions must be described in a Master Formulation Record and records maintained [8].
 - Appropriate handling procedures must be followed whenever preparing, dispensing, or otherwise handling radiopharmaceuticals, in accordance with the current US Pharmacopeia (USP) General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging [8].
 - 5. Generator eluates must be assayed for the presence of parent or other radionuclide contaminants ("breakthrough"). Required testing is specified in 10 CFR 35.204, and specific licensing guidance's

issued under 10 CFR 35 1000 [9]. Eluates containing contaminants of greater concentration than specified above within the time of intended use must not be used. The facility must report exceeding breakthrough limits within the time of intended use to the manufacturer.

- 6. Radiopharmaceuticals prepared on site should be subjected to quality control testing, especially for radiochemical purity. Radiopharmaceuticals prepared with minor deviations or radiopharmaceuticals that are compounded must undergo appropriate quality control testing. Radiopharmaceuticals should not be administered if the level of impurity exceeds package insert or USP monograph specifications [10].
- Radiopharmaceuticals prepared by radiolabeling kits should be used by the use-by time recommended in the package insert or as otherwise assigned (see Section 8, Assigning BUD in USP <825>).

D. Records

- Records of receipt, usage, administration, and disposal of all radioactive materials must be kept in compliance with license conditions and applicable medical records and radiation control regulations. For radiopharmaceuticals prepared on site, records must document the date and time of preparation, amount of radioactivity used, ingredient and component lot numbers and expiration, results of quality control tests, and subsequent disposition or disposal with an identifying signature or initials of the person performing the task.
- 2. All packages containing radioactive materials must be inspected upon receipt for physical damage, monitored for external radiation levels, and monitored for external surface contamination, as required by the applicable government regulations. The label and contents must agree. Any discrepancies must be reported to the manufacturer and to the applicable government regulatory agencies, as required.
- 3. For all radiopharmaceuticals, the patient identity, identity of administering technologist or physician, amount of radioactivity administered, route of administration, date and time of use, and, if unused, date of disposal must be recorded.
- 4. A dose calibrator used on site for the quantitative assay of radiopharmaceutical activity must be checked. The instrument must be checked for constancy, accuracy, linearity, and geometric dependence in accordance with nationally recognized standards or the manufacturer's instructions. Records must be maintained.
- 5. Material with radiation levels greater than background must not be discarded into the nonradioactive waste stream, and shall be disposed of consistent with institutional, local, and NRC (or applicable Agreement State) regulations and policies as appropriate. Human waste generally is permitted to be disposed of without regard for radioactivity; however, the institution shall promulgate policies to keep staff exposure ALARA (as low as reasonably achievable), particularly regarding exposure to soiled items such as urine drainage bags, bedding, and diapers. The policy should specifically address both the quantity of expected excretion and radionuclide.
- 6. The radiation labels on empty packages must be destroyed or defaced before disposal. All containers should be surveyed to determine that levels of radiation do not exceed background. Those with residual activity must be stored in a shielded container or in an area that is designed for the storage of radioactive materials until radiation levels do not exceed background, which generally approximates storing them for at least 10 half-lives. Radioactive gaseous wastes must be stored or ventilated in accordance with applicable government regulations. Disposal must be in accordance with license conditions and applicable government regulations. Records must be maintained.
- 7. Adverse events associated with any radiopharmaceutical, or defects in any radiopharmaceutical product, should be reported to the manufacturer and, when appropriate, to the FDA.
- 8. There must be policies and procedures to ensure that the identity of the patient, the radiopharmaceutical, the administered activity, and the route of administration are correct. Exceptional care in proper identification of patient and product is required when handling and administering radiolabeled blood components. Policies and procedures must be in place to ensure the traceability of autologous blood components whenever radiolabeled blood labeling procedures are performed. Medical events related to the administration of radiopharmaceuticals must be reported within the specified time frame as required by the appropriate regulatory agencies. Where

required, the radiation safety officer, the NRC, or the state regulatory agency and the referring provider must be notified. Unless medically contraindicated, the patient must also be notified.

- 9. Each radiation survey instrument must be calibrated before first use as well as annually and following repair, in accordance with appropriate regulations [11]. Each radiation survey instrument must be checked for proper operation with a dedicated check source before each use, if required by state or local regulations.
- 10. A daily patient log should be maintained and include the patient name, patient identification number, hospital or office, procedure, radiopharmaceutical, radiopharmaceutical prescription number, product number, control or lot number, administered activity, and comments.
- 11. For each examination, the following information should be recorded: instrument, collimator, photon energy (window) setting, acquired views, number of counts in each image, start time of examination, and duration of image acquisition. (These may be part of a standard protocol (section VII.B) and need be recorded only if different from the protocol in the procedure manual.) This information should be retrievable as long as the images are archived. This information need not be separately recorded if it is included in the DICOM headers of the archived images.
- 12. For SPECT, record matrix size, number of stops, time per image, type of rotation, and type of filter used. (These may be part of a standard protocol (section VII.B) and need be recorded only if different from the protocol in the procedure manual.) This information should be retrievable as long as the images are archived.
- 13. All equipment manuals must be available.

 $\frac{1}{2}$ Dosage is the term used by the U.S. Nuclear Commission and other agencies that regulate radioactive materials to describe the patient administered activity and differentiate it from absorbed dose.

IV. INSTRUMENT QUALITY CONTROL

A Qualified Medical Physicist should be responsible for overseeing the equipment quality control program and for monitoring performance at installation and at least annually thereafter (see the <u>ACR–AAPM Technical Standard</u> for Nuclear Medical Physics Performance Monitoring of Gamma Cameras, <u>ACR–AAPM Technical Standard for</u> <u>Medical Physics Performance Monitoring of PET/CT Imaging Equipment</u>, and <u>the ACR–AAPM Technical Standard</u> for <u>Medical Physics Performance Monitoring of SPECT-CT Equipment</u>) [12-14]. A continuous quality control (QC) program must be established for the nuclear medicine imaging equipment with the assistance of a Qualified Medical Physicist. An on-site technologist responsible for conducting routine QC under the supervision of the responsible physician should be identified. A QC program for the routine assessment of camera performance must be maintained in accordance with the manufacturer's or Qualified Medical Physicist's recommendations.

A. For Single-Crystal Gamma Cameras

For further information, see the <u>ACR–AAPM Technical Standard for Nuclear Medical Physics Performance</u> <u>Monitoring of Gamma Cameras</u> and the <u>ACR–AAPM Technical Standard for Medical Physics Performance</u> <u>Monitoring of SPECT-CT Equipment</u> [12,14].

B. For PET or PET/CT

For further information, see the <u>ACR–AAPM Technical Standard for Medical Physics Performance</u> <u>Monitoring of PET/CT Imaging Equipment</u> [13].

V. PATIENT AND PERSONNEL SAFETY

- A. The facility must comply with all applicable radiation safety regulations and conditions of licensure imposed by the NRC, state, and other regulatory agencies.
- B. Sufficient numbers of syringe shields and shielded containers must be available in good condition and be used unless contraindicated for a specific patient or otherwise deemed unnecessary based on radiation emissions, amount of radioactivity, use, and other handling consideration. Any shield that has been in contact with a patient or used in a patient care area must be properly sanitized before being returned to

any radiopharmaceutical preparation area or used for another patient.

- C. Pipetting of any materials by mouth is never permitted.
- D. Under no circumstances may cosmetics or lip balm be applied, nor may food, drink, or chewing gum be brought into, stored, or consumed in areas where radioactive materials are prepared, used, or stored. Gloves and appropriate apparel and footwear should be worn that, in case of a spill, would prevent direct contact of radioactive material with skin.
- E. In accordance with applicable government regulations, there must be a policy on administration of radiopharmaceuticals to pregnant or potentially pregnant patients and to patients who are breastfeeding. If the patient is known to be pregnant, the potential radiation risks to the fetus and clinical benefits of the procedure should be considered. The patient should be counseled before proceeding with the examination, and this counseling must be documented in writing. Similarly, if the patient is known to be breastfeeding, the potential radiation risks to the breastfeed child should be considered, and guidance specific to the administered radiopharmaceutical should be given to the mother regarding interruption or discontinuation of direct breastfeeding with discussion of options for pumping and storing expressed milk when applicable [15]. There should be signs posted requesting that patients inform the staff if they are or could be pregnant or if they are breastfeeding.
- F. There must be a policy for surveys, including frequency, of removable contamination and surveys of ambient radiation dose rates in all areas in which radionuclides are used and stored, in accordance with government regulations.
- G. There must be a policy on containment and cleanup of radioactive spills. Radioactive gases should only be used in rooms with appropriate airflow and exhaust rate according to applicable government regulatory requirements.
- H. Personnel who routinely handle radionuclides must be monitored for radiation exposure. Records of exposure must be made available to individuals, as per regulations of the NRC or state regulatory agency.
- I. All professional and technical staff in nuclear medicine are responsible for maintaining radiation exposures at ALARA levels for both patients and staff.
- J. There must be a written policy for the handling of radiolabeled autologous blood products that will ensure that all samples are positively identified as to source and that reinjection of these radiopharmaceuticals occurs only into the correct patient.
- K. There must be documented policies on:
 - 1. Hazardous biological or chemical materials (if any are present in the workplace)
 - 2. Electrical and mechanical safety
 - 3. Fire safety and evacuation
 - 4. Handling of infectious wastes and patients with communicable diseases
 - 5. Handling of "sharps"
 - 6. Procedures for safe use of medical equipment
- L. There should be posting of:
 - 1. Information placards required by regulatory agencies
 - 2. Radiation caution signs in areas in which radioactive agents are used or stored
 - 3. Signs requesting patients to inform the staff if they are or could be pregnant or if they are breastfeeding

VI. PROCEDURE MANUAL

- A. A policy and procedure manual must be prepared and maintained. The physician(s) responsible for nuclear medicine procedures must review and update it at least annually.
- B. Detailed information about the performance of each examination on each instrument must be developed to include type of examination, radiopharmaceutical, administered activity, route of administration, preparation of patient, nonradioactive drugs and dosages, required views, timing, preset counts or time, and any contraindications. Recommended adult and pediatric administered activities can be found in Table 1 and Table 2 of the <u>ACR-AAPM-ACNM-SNMMI Practice Parameter for Reference Levels and Achievable Administered Activity for Nuclear Medicine and Molecular Imaging</u> [16] or the pediatric injected activity tool at <u>Image Gently</u>[®]
- C. There must be standard operating procedures with detailed information about performance, recording, and action regarding all radiopharmaceutical and instrument QC.
- D. There must be standard operating procedures with detailed information on appropriate aspects of radiation safety, including emergency procedures.
- E. There must be standard operating procedures in place with detailed information on appropriate aspects of the aseptic preparation of sterile radiopharmaceuticals and sterile pharmaceuticals used in nuclear medicine procedures [8,10].

VII. DOCUMENTATION

- A. Information on how to request procedures should be available to referring providers.
- B. Technical data on procedures should be retrievable from the policy and procedure manual.
- C. Procedures should be traceable to the technologist performing them.
- D. Calculations or raw data for quantitative examinations should be retrievable.
- E. Appropriate technical data must appear in the report of the procedure. These include, at a minimum, the radiopharmaceutical, administered activity, route of administration, and views obtained. Also to be included are administered doses and routes of pharmacologic drugs used for pretreatment, concurrent intervention, or treatment of symptoms, as well as other interventions related to the procedure. The reporting of nuclear medicine procedure interpretations should be in accordance with the <u>ACR Practice Parameter for Communication of Diagnostic Imaging Findings</u> [17].
- F. Studies, data, and reports must be archived for a time consistent with the mandates of state regulatory agencies, license conditions, or radiation protection regulations.

VIII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, non-physician radiology providers, radiologic 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, "as low as reasonably achievable" (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel who work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection, application of dose constraints and limits) and the principles of proper management of radiation dose to patients (justification, optimization including the use of dose reference levels). https://www-pub.iaea.org/MTCD/Publications/PDF/PUB1775_web.pdf

Nationally developed guidelines, such as the <u>ACR's Appropriateness Criteria</u>[®], should be used to help choose the most appropriate imaging procedures to prevent unnecessary radiation exposure.

Facilities should have and adhere to policies and procedures that require ionizing radiation examination protocols (radiography, fluoroscopy, interventional radiology, CT) to vary according to diagnostic requirements and patient body habitus to optimize the relationship between appropriate radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used, except when inappropriate for a specific exam. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available from the following websites – Image Gently[®] for children (<u>www.imagegently.org</u>) and Image Wisely[®] for adults (<u>www.imagewisely.org</u>). These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be periodically measured by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Monitoring or regular review of dose indices from patient imaging should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry and relevant publications relying on its data, applicable ACR Practice Parameters, NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director's National Evaluation of X-ray Trends; 2006, 2009, amended 2013, revised 2023 (Res. 2d).

IX. 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 ACR 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).

ACKNOWLEDGEMENTS

This practice parameter was revised according to the process described under the heading *The Process for Developing ACR Practice Parameters and Technical Standards* on the ACR website (<u>https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards</u>) by the Committee on Practice Parameters and Technical Standards – Nuclear Medicine and Molecular Imaging of the ACR Commission on Nuclear Medicine and Molecular Imaging and the Committee on Practice Parameters – Pediatric Imaging of the ACR Commission on Pediatric Radiology, in collaboration with the ACNM, the SNMMI, and the SPR.

Writing Committee – members represent their societies in the initial and final revision of this practice parameter

ACR	ACNM
Elizabeth H. Dibble, MD, Chair	Yang Lu, MD, PhD, FACNM
Eric Ehman, MD	Darko Pucar, MD, PHD
Helen Nadel, MD	Mark Tulchinsky, MD, FACNM, CCD

Feng Wang, MD

<u>SNMMI</u>

<u>SPR</u>

Stephen C. Dragotakes, RPh, BCNP, FAPhA Sachin Kumbhar, MD

James A. Ponto, MS, RPh, BCNP, FASHP, FAPhA Hollie A. Lai, MD

Maria R. Ponisio, MD

S. Ted Treves, MD

<u>Committee on Practice Parameters and Technical Standards – Nuclear Medicine and Molecular</u> <u>Imaging</u>

(ACR Committee responsible for sponsoring the draft through the process)

Munir V. Ghesani, MD, FACR, Co-Chair	Andrew Kaiser, MD
Rathan M. Subramaniam, MD, PhD, MPH, Co-Chair	Jeffrey S. Kempf, MD, FACR
Esma A. Akin, MD, FACR	Justin G. Peacock, MD
Alexandru C. Bageac, MD, MBA	Syam P. Reddy, MD
Twyla B. Bartel, DO, MBA	Eric M. Rohren, MD, PhD
Elizabeth H. Dibble, MD	Levi Sokol, MD
K. Elizabeth Hawk, MD, MS, PhD	Andrew T. Trout, MD

Eric Hu, MD

Committee on Practice Parameters – Pediatric Radiology

(ACR Committee responsible for sponsoring the draft through the process)

Committee on Practice Parameters – Pediatric Radiology

Terry L. Levin, MD, FACR, Chair	Jane Sun Kim, MD	
John B. Amodio, MD, FACR	Jennifer A Knight, MD	
Jesse Berman, MD	Jessica Kurian, MD	
Tara M. Catanzano, MB, BCh	Matthew P. Lungren, MD, MPH	
Harris L. Cohen, MD, FACR	Helen R. Nadel, MD	
Kassa Darge, MD, PhD	Erica Poletto, MD	
Dorothy L. Gilbertson-Dahdal, MD	Richard B. Towbin, MD, FACR	
Lauren P. Golding, MD	Andrew T. Trout, MD	
Safwan S. Halabi, MD	Esben S. Vogelius, MD	
Jason Higgins, DO		
Don C. Yoo, MD, FACR, Chair of the Commission Nuclear Medicine and Nuclear Medicine		
Richard A. Barth, MD, FACR, Chair, Commission on Pediatric Radiology		
David B. Larson, MD, MBA, Chair, Commission on Quality and Safety		
Mary S. Newell, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards		
Comment Reconciliation Committee		
William F. Sensakovic, PhD, Chair	Paul A. Larson, MD, FACR	
Madelene C. Lewis, MD, Co-Chair	Terry L. Levin, MD, FACR	
Richard A. Barth, MD, FACR	Yang Lu, MD, PhD, FACNM	

Charles W. Bower, MD

Helen Nadel, MD

Comment Reconciliation Committee

David Brandon, MD	Mary S. Newell, MD, FACR
Elizabeth H. Dibble, MD	Maria R. Ponisio, MD
Stephen C. Dragotakes, RPh, BCNP, FAPhA	James A. Ponto, MS, RPh, BCNP, FASHP, FAPhA
Richard Duszak Jr., MD, FACR	Darko Pucar, MD, PHD
Eric Ehman, MD	Victor Seghers, MD, PhD
Munir V. Ghesani, MD, FACR	Rathan M. Subramaniam, MD, PhD, MPH
Arnold Jacobson, MD	S. Ted Treves, MD
Amy Kotsenas, MD, FACR	Mark Tulchinsky, MD, FACNM, CCD
Sachin Kumbhar, MD	Feng Wang, MD
Hollie A. Lai, MD	Don C. Yoo, MD, FACR

David B. Larson, MD, MBA

REFERENCES

- US Food and Drug Administration. 21CFR315.2. Available at: <u>http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=315.2</u>. Accessed April 20, 2015.
- 2. United States Nuclear Regulatory Commission. 10 CFR 35.290 Training for imaging and localization studies. Available at: <u>http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0290.html</u>. Accessed April 20 2015.
- 3. American College of Radiology. ACR practice parameter for continuing medical education (CME). Available at: <u>https://www.acr.org/-/media/ACR/Files/Practice-Parameters/CME.pdf?la=en</u>. Accessed March 3, 2020.
- 4. United States Nuclear Regulatory Commission. Authorized Individuals. Available at: <u>https://www.nrc.gov/materials/miau/med-use-toolkit/auth-individuals.html</u>. Accessed April 23, 2020.
- United States Nuclear Regulatory Commission. 10 CFR 35.50 Training for radiation safety officer and associate radiation safety officer. Available at: <u>http://www.nrc.gov/reading-rm/doc-</u> <u>collections/cfr/part035/part035-0050.html</u>. Accessed April 20, 2015.
- United States Nuclear Regulatory Commission. 10 CFR 35.40 Written directives. Available at: <u>https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0040.html</u>. Accessed June 16, 2020.
- United States Nuclear Regulatory Commission. 10 CFR 35.63 Determination of dosages of unsealed byproduct material for medical use. Available at: <u>https://www.nrc.gov/reading-rm/doc-</u> <u>collections/cfr/part035/part035-0063.html</u>. Accessed June 16, 2020.

- The United States Pharmacopeia (USP). USP general chapter <825> radiopharmaceuticals preparation, compounding, dispensing, and repackaging. Available at: <u>https://www.usp.org/chemical-</u> <u>medicines/general-chapter-825</u>. Accessed June 17, 2020.
- 9. United States Nuclear Regulatory Commission. 10 CFR 35.204 Permissible molybdenum-99, strontium-82, and strontium-85 concentrations. Available at: <u>http://www.nrc.gov/reading-rm/doc-</u> <u>collections/cfr/part035/part035-0204.html</u>. Accessed April 20, 2015.
- The United States Pharmacopeia (USP). USP-NF General Chapter <797> Pharmaceutical Compounding— Sterile Preparations. Available at: <u>https://www.snmmi.org/files/docs/USP%20797.pdf</u>. Accessed April 20, 2015.
- 11. United States Nuclear Regulatory Commission. 10 CFR 35.61 Calibration of survey instruments

Available at: <u>https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0061.html</u>. Accessed June 16, 2020.

- 12. American College of Radiology. ACR–AAPM technical standard for nuclear medical physics performance monitoring of gamma camera. Available at: <u>https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Gamma-Cam.pdf?la=en</u>. Accessed March 3, 2020.
- American College of Radiology. ACR–AAPM technical standard for medical physics performance monitoring of PET/CT imaging equipment. Available at: <u>https://www.acr.org/-/media/ACR/Files/Practice-</u> <u>Parameters/PET-CT-Equip.pdf?la=en</u>. Accessed March 3, 2020.
- 14. American College of Radiology. ACR–AAPM technical standard for medical physics performance monitoring of SPECT-CT equipment. Available at: <u>https://www.acr.org/-/media/ACR/Files/Practice-Parameters/SPECT-CT-Equip.pdf?la=en</u>. Accessed March 3, 2020.
- 15. United States Nuclear Regulatory Commission. 10 CFR 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material. Available at: <u>https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0075.html</u>. Accessed June 16, 2020.
- 16. American College of Radiology. ACR–AAPM practice parameter for reference levels and achievable administered activity for nuclear medicine and molecular imaging. Available at: <u>https://www.acr.org/-/media/ACR/Files/Practice-Parameters/RefLevels-NucMed.pdf?la=en</u>. Accessed March 3, 2020.
- 17. American College of Radiology. ACR practice parameter for communication of diagnostic imaging findings. Available at: <u>https://www.acr.org/-/media/ACR/Files/Practice-Parameters/CommunicationDiag.pdf?la=en</u>. Accessed March 3, 2020.

*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

Development Chronology for This Practice Parameter

1994 (Resolution 17) Amended 1995 (Resolution 24, 54) Revised 1998 (Resolution 18) Revised 2001 (Resolution 21) Revised 2006 (Resolution 26, 16g, 17, 36) Amended 2009 (Resolution 11) Revised 2011 (Resolution 5)

Revised 2016 (Resolution 27)

Revised 2021 (Resolution 21)

Amended 2022 (Resolution 41f)

Amended 2023 (Resolution 2c, 2d)