Revised 2016 (Resolution 27)*

ACR–SPR TECHNICAL STANDARD FOR DIAGNOSTIC PROCEDURES USING RADIOPHARMACEUTICALS

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 physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, 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 the guidelines 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 the practice parameters. However, a practitioner who employs an approach substantially different from these practice parameters 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 these practice parameters 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

[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.

and safe medical care. The sole purpose of these practice parameters is to assist practitioners in achieving this objective.

I. INTRODUCTION

This technical standard was revised collaboratively by the American College of Radiology (ACR) and the Society for Pediatric Radiology (SPR).

This technical standard was developed to cover key aspects pertinent to the performance of nuclear imaging examinations, *in vivo* and *in vitro* nonimaging diagnostic studies using radiopharmaceuticals.

II. DEFINITION

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

III. QUALIFICATIONS OF PERSONNEL

A. Physician

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

1. Certification in Radiology, Diagnostic Radiology, Interventional Radiology/Diagnostic Radiology (IR/DR), Nuclear Radiology, or Nuclear Medicine by one of the following organizations: the American Board of Radiology (ABR), the American Board of Nuclear Medicine, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, the Collège des Médecins du Québec, and/or the American Osteopathic Board of Nuclear Medicine. 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 Royal College of Physicians and Surgeons of Canada (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 ACR Practice Parameter for Continuing Medical Education (CME) [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. Be listed as an authorized user on the radioactive materials license of his or her institution. 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. Have a thorough understanding of each procedure with which he or she is involved. The physician is further 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 and institutional regulations 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 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 American College of Radiology, or certification by the Nuclear Medicine Technology Certification Board (NMTCB).

   and

2. Licensure, 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, 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) [3]

The appropriate subfield of medical physics for this technical standard is Nuclear Medical Physics. (Previous medical physics certification categories including Radiological Physics and Medical Nuclear Physics are also acceptable.)

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

D. Radiation Safety Officer (RSO)

The Radiation Safety Officer (RSO) must meet applicable NRC requirements for training as specified in 10 CFR 35.50 [4], 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.

IV. 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 his or her direction.
2. Handling, aseptic preparation, and administration of radiopharmaceuticals may be delegated to qualified personnel, subject to applicable federal, state, or local 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

1. Prescription: The quantity of radioactivity to be administered must be prescribed (either individually by prescription or by protocol). When the radiopharmaceutical and administered activity[2] are such that a written directive is required, such a directive must be signed by an authorized user. 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. When unit administered activity are obtained from commercial radiopharmacies, quality control need not be repeated.
3. Administration and Documentation: Administered activity must fall within the tolerance of applicable state and federal regulations. 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. Care must be taken to minimize radiation exposure to personnel at all steps in setting up, eluting, and assaying the eluate. The volume and radioactivity of the generator eluate must be measured and recorded.
2. Radiopharmaceuticals should be prepared according to the manufacturer's package insert. Exceptions should be documented in the policies and procedures manual.
3. Aseptic handling procedures must be followed whenever preparing, dispensing, administering, or otherwise handling radiopharmaceuticals that are intended to be sterile, in accordance with US Pharmacopeia (USP) General Chapter <797> Pharmaceutical Compounding—Sterile Preparations [5].

[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.

4. Generator eluates must be assayed for the presence of parent or other radionuclide contaminants ("breakthrough"). Required testing is specified in 10 CFR 35.204 [6]. Eluates testing positive for contaminants of greater concentration than specified above must not be used. The facility must report exceeding breakthrough limits to the manufacturer/distributor.
5. Radiopharmaceuticals prepared on site should be subjected to quality control testing, especially for radiochemical purity. Radiopharmaceuticals should not be administered if the level of impurity exceeds package insert or USP monograph specifications [5].
6. Radiopharmaceuticals prepared by radiolabeling kits should be used by the expiration time recommended in the package insert.

D. Records

1. 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, reagent lot numbers, results of quality control tests, and subsequent disposition or disposal with an identifying signature of the person performing the task.
2. All packages containing radioactive materials must be inspected upon receipt for physical damage and tested for external contamination, as required by the appropriate regulatory agency. The label and contents must agree. Any discrepancies must be reported to the manufacturer and to regulatory agencies, as required.
3. For all radiopharmaceuticals, the patient identity, identify 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. If a radionuclide dose calibrator is used on site for the quantitative assay of radiopharmaceutical activity, 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 (excepting patient excreta, which may be released into a sanitary sewer) with radiation levels greater than background cannot be discarded into regular trash containers.
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. 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 federal, state, and local regulations. Disposal must be in accordance with license conditions and applicable federal, state, and local regulations. Records must be maintained.
7. Adverse reactions attributable to 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 office, the NRC, or the state regulatory agency and the referring provider must be notified. Unless medically contraindicated, the patient must also be notified.

V. 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 ACR–AAPM Technical

Standard for Medical Nuclear Physics Performance Monitoring of Gamma Cameras, ACR–AAPM Technical Standard for Medical Nuclear Physics Performance Monitoring of PET Imaging Equipment, ACR–AAPM Technical Standard for Medical Physics Performance Monitoring of PET/CT Imaging Equipment, and the ACR–AAPM Technical Standard for Medical Physics Performance Monitoring of SPECT-CT Equipment [7-10]). 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 should be identified to be responsible for conducting routine QC under the supervision of the responsible physician. A quality control program for the routine assessment of cameras performance must be maintained in accordance with the manufacturer's or Qualified Medical Physicist's recommendations.

A. For Single-Crystal Gamma Cameras

1. Test field uniformity daily using either a uniform sheet flood source and collimator or a point source and no collimator.
2. Use a resolution test pattern (eg, a bar phantom) designed to test linearity, spatial resolution, distortion, and field of view weekly or according to the manufacturer's recommendations. Comparison with prior test images is advisable. Retention of these images may be required by state or federal regulations.
3. Inspect collimators regularly for damage. Test with a very high-count flood image annually or when collimator damage is suspected.
4. Inspect systems regularly for mechanical or electrical hazards. If a system is malfunctioning in a manner that would compromise safety or patient care, do not use it until it is repaired.
5. Maintain a log of all quality control testing and problems identified and ascertain if any trends exist.
6. Maintain all service records.

B. For Single-Photon Emission Computed Tomography (SPECT) (in addition to section V.A.1-6 above)

1. Assess center of rotation according to the manufacturer's or physicist's recommendations.
2. Assess flood uniformity according to the manufacturer's or physicist's recommendations. This often requires a 30-million-count flood for a 64 x 64-pixel matrix and a 120-million-count flood for a 128 x 128-pixel matrix.
3. Assess system uniformity, spatial resolution, and contrast resolution using a 3-D phantom according to the manufacturer's recommendations.

C. For SPECT Cameras Utilizing Solid-State Detectors or Other Dedicated SPECT Devices

1. Establish and document a quality control program for the routine assessment of camera performance in accordance with the manufacturer's or physicist's recommendation.
2. Maintain a log of all quality control testing and problems identified and ascertain if any trends exist.
3. Inspect system regularly for mechanical or electrical hazards. If a system is malfunctioning in a manner that would compromise safety or patient care, do not use it until it is repaired.
4. Maintain all service records.

D. For Positron Emission Tomography (PET) or PET Computed Tomography (PET/CT)

1. Perform daily QC tests as defined by the manufacturer of the system as well as quarterly scanner testing to evaluate uniformity, resolution, and contrast.

2. Evaluate the following characteristics on at least an annual basis as applicable to the design of the scanner:

    a. Spatial resolution
    b. Count rate performance (count rate versus activity), including count loss correction

c. Sensitivity (cps/MBq/mL)
d. Image uniformity
e. Image quality
f. Accuracy of attenuation and scatter correction, and SUV measurement

3. Perform additional testing of combined PET/CT systems to examine PET image coregistration (alignment) and attenuation correction at least annually.

E. For Xenon or DTPA Aerosol Delivery System

Assure proper function according to the manufacturer's specifications and within applicable federal or state regulations.

F. Hard-Copy Image Output Device

Quality control testing should be performed according to the manufacturer's recommendations, with comparison of current results to baseline results obtained in acceptance testing.

G. Radiation Detectors and Radiation Survey Instruments

Each instrument must be calibrated before first use as well as annually and following repair, in accordance with local regulations. Each instrument must be checked for proper operation with a dedicated check source before each use, if required by state or local regulations.

H. A daily patient log should be maintained and include the patient name, patient identification number, hospital or office, procedure, radiopharmaceutical, administered activity, and comments.

I. For each examination, the following information should be recorded: instrument, collimator, pulse height analyzer (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.

J. For SPECT, one should also 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.

K. All equipment manuals must be available.

VI. 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/or 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. 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 federal and state 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 breastfed child should be considered and guidance given to the mother regarding discontinuation of breastfeeding. 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 radiation levels of ambient dose rate in all areas where radionuclides are used and stored, in accordance with state or federal 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 state or federal 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 (as low as reasonably achievable) 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 where 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

VII. 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 ACR–AAPM Practice Parameter for Reference Levels and Achievable Administered Activity for Nuclear Medicine and Molecular Imaging or the pediatric injected activity tool at Image Gently®[11,12].

C. There must be standard operating procedures with detailed information about performance, recording, and action regarding all radiopharmaceutical and instrument quality control.

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.

VIII. RECORDS

A. Information on how to request procedures should be available to referring providers.

B. Generic 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, dosage, route of administration, and views obtained. Pharmacologic enhancement and other interventions should be documented. The reporting of nuclear medicine procedure interpretations should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [13].

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.

IX. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, registered radiologist assistants, 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 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, optimization and the use of dose reference levels)
http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf.

Nationally developed guidelines, such as the ACR Appropriateness Criteria®, should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Facilities should have and adhere to policies and procedures that require varying ionizing radiation examination protocols (plain radiography, fluoroscopy, interventional radiology, CT) to take into account patient body habitus (such as patient dimensions, weight, or body mass index) to optimize the relationship between minimal radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used whenever appropriate. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available at the Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org) websites. 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 measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR technical standards. Regular auditing of patient dose indices should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry, the 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. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52).

X. 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 QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (http://www.acr.org/guidelines).

ACKNOWLEDGEMENTS

This technical standard was revised according to the process described under the heading *The Process for Developing ACR Practice Parameters and Technical Standards* on the ACR website (http://www.acr.org/guidelines) 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 Radiology of the ACR Commission on Pediatric Radiology, in collaboration with the SPR.

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

ACR
Chun K. Kim, MD, Chair
Hyewon Hyun, MD
Osama Mawlawi, PhD
Marguerite T. Parisi, MD, MS
Mi-Ae Park, PhD

SPR
Neha S. Kwatra, MD
Massoud Majd, MD, FACR
S. Ted Treves, MD

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

Bennett S. Greenspan, MD, MS, FACR, Co-Chair
Christopher J. Palestro, MD, Co-Chair
Kevin P. Banks, MD
Murray D. Becker, MD, PhD, FACR
Richard K.J. Brown, MD, FACR
Erica J. Cohen, DO, MPH
Shana Elman, MD
Joanna R. Fair, MD
Perry S. Gerard, MD, FACR

Erin C. Grady, MD
Edward D. Green, MD
Warren R. Janowitz, MD, JD, FACR
Chun K. Kim, MD
Charito Love, MD
Joseph R. Osborne, MD, PhD
Darko Pucar, MD, PhD
Rathan M. Subramaniam, MD, PhD, MPH

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

Beverley 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

M. Elizabeth Oates, MD, 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
Darlene F. Metter, MD, FACR, Chair
Isaac R. Kirk, III, MD, FACR, Co-Chair
Jacqueline A. Bello, MD, FACR
Bennett S. Greenspan, MD, MS, FACR
Marta Hernanz-Schulman, MD, FACR
William T. Herrington, MD, FACR
Hyewon Hyun, MD
Chun K. Kim, MD
Neha S. Kwatra, MD
Paul A. Larson, MD, FACR
Ralph P. Lieto, MS, FACR
Massoud Majd, MD, FACR
Osama Mawlawi, PhD
Beverley Newman, MB, BCh, BSc, FACR
M. Elizabeth Oates, MD
Christopher J. Palestro, MD
Marguerite T. Parisi, MD, MS
Mi-Ae Park, PhD
Matthew S. Pollack, MD, FACR

Timothy L. Swan, MD, FACR, FSIR
S. Ted Treves, MD

REFERENCES

1. US Food and Drug Administration. 21CFR315.2. 2010; Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=315.2. Accessed April 20, 2015.
2. United States Nuclear Regulatory Commission. 10 CFR 35.290 Training for imaging and localization studies. 2009; Available at: http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0290.html. Accessed April 20 2015.
3. American College of Radiology. ACR practice parameter for continuing medical education (CME). 2011; Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/CME.pdf. Accessed March 4, 2015.
4. United States Nuclear Regulatory Commission. 10 CFR 35.50 Training for Radiation Safety Officer. 2009; Available at: http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0050.html. Accessed April 20, 2015.
5. The United States Pharmacopeia (USP). USP-NF General Chapter <797> Pharmaceutical Compounding—Sterile Preparations. 2008; Available at: https://www.snmmi.org/files/docs/USP%20797.pdf. Accessed April 20, 2015.
6. United States Nuclear Regulatory Commission. 10 CFR 35.204 Permissible molybdenum-99, strontium-82, and strontium-85 concentrations. 2007; Available at: http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0204.html. Accessed April 20, 2015.
7. American College of Radiology. ACR-AAPM technical standard for medical nuclear physics performance monitoring of gamma camera. 2013; Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Gamma-Cam.pdf. Accessed March 4, 2015.
8. American College of Radiology. ACR-AAPM technical standard for medical nuclear physics performance monitoring of PET imaging equipment. 2016; Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/PET-CT-Equip.pdf. Accessed June 29, 2015.
9. American College of Radiology. ACR-AAPM technical standard for medical physics performance monitoring of PET/CT imaging equipment. 2013; Available at: http://www.acr.org/~/media/5A6923DBCB254D8F9E29D082C1B28E79.pdf. Accessed June 29, 2015.
10. American College of Radiology. ACR-AAPM technical standard for medical physics performance monitoring of SPECT-CT equipment. 2014; Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/SPECT-CT-Equip.pdf. Accessed June 29, 2015.
11. Lassmann M, Treves ST. Pediatric Radiopharmaceutical Administration: harmonization of the 2007 EANM Paediatric Dosage Card (Version 1.5.2008) and the 2010 North American Consensus guideline. *Eur J Nucl Med Mol Imaging.* 2014;41(8):1636.
12. American College of Radiology. ACR-AAPM practice parameter for reference levels and achievable administered activity for nuclear medicine and molecular imaging. 2015; Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/RefLevels-NucMed.pdf. Accessed November 19, 2015.
13. American College of Radiology. ACR practice parameter for communication of diagnostic imaging findings. 2014; Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/CommunicationDiag.pdf. Accessed March 4, 2015.

*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 Technical Standard

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)
Amended 2018 (Resolution 44)