Revised 2011 (Resolution 5)*

ACR–SNM TECHNICAL STANDARD FOR DIAGNOSTIC PROCEDURES USING RADIOPHARMACEUTICALS

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiation oncology care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines 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 guidelines. However, a practitioner who employs an approach substantially different from these guidelines 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 guidelines 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 these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

This standard was revised collaboratively by the American College of Radiology (ACR) and the Society of Nuclear Medicine (SNM).

This standard was developed to cover key aspects pertinent to the performance of nuclear imaging and in-vivo nonimaging diagnostic studies using radiopharmaceuticals.

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. (FDA definition of radiopharmaceutical: 21CFR315.2, 1997 FDAMA section 122(b) [1].)

This standard is intended to be antecedent to all guidelines and standards covering the use of radiopharmaceuticals for diagnosis.

III. QUALIFICATIONS OF PERSONNEL

A. Physician

The physician providing nuclear medicine services must meet all of the following criteria:

1. 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, 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 guidelines 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 Guideline 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 guidelines 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 performing nuclear medicine services should 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 procedures.

   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. Knowledge of radiation safety and protection, the compounding, preparing, 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 or Other Qualified Scientist-

A Qualified Medical Physicist is an individual who is competent to practice independently one or more of the subfields in medical physics. The ACR considers certification and 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 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 for MRI, by the American Board of Medical Physics (ABMP) in magnetic resonance imaging physics.

The appropriate subfields of medical physics for this standard are Radiological Physics and Medical Nuclear Physics.

A Qualified Medical Physicist should meet the ACR Practice Guideline for Continuing Medical Education (CME). (ACR Resolution 17, 1996 – revised in 2008, Resolution 7)

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, or equivalent state regulations [4].

E. Nuclear Pharmacist

The Nuclear Pharmacist must meet applicable NRC requirements for training as specified in 10 CFR 35.55, or equivalent state regulations [5].

IV. RADIOPHARMACY

A. Responsibility

1. The nuclear medicine physician is ultimately responsible for the safety and appropriate utilization of all radiopharmaceuticals prepared and/or used 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 dose 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. If specifically permitted by state or NRC regulations, facilities receiving diagnostic radiopharmaceuticals as unit administered activity ("unit dose") need not perform direct measurement of the radioactivity but may perform a decay correction, based on the activity or the activity concentration determined by the manufacturer or preparer licensed by the state or federal agency. However, it is desirable that administered activity still be assayed on site at the medical facility prior to administration. When unit administered activities are obtained from commercial radiopharmacies, quality control need not be repeated.
3. Administration: Administered activity must fall within tolerances of applicable state and federal regulations. The identity of the radiopharmaceutical and the patient, route of administration, and the pregnancy and breastfeeding status of the patient must be verified prior to administration.
4. Recording: The radiopharmaceutical and the administered activity must be 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 USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations [6].
4. Generator eluates must be assayed for the presence of parent or other radionuclide contaminants. Required testing is specified in 10 CFR 35.204 [7]. Eluates testing positive for contaminants of greater concentration than specified above may not be used for patient doses.
5. Radiopharmaceuticals prepared on site should be subjected to quality control testing, especially radiochemical purity. Radiopharmaceuticals should not be administered if the level of impurity exceeds package insert or USP monograph specifications [6].
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 amount of radioactivity administered, patient identity, technologist identity, 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 assay of radiopharmaceutical administered activity, the instrument must be checked for constancy, accuracy, linearity, and geometric dependence per manufacturer's recommendation and the requirements of the appropriate regulatory agency. 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 Food and Drug Administration (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 physician 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 upon installation and routinely thereafter. (See the ACR Technical Standard for Medical Nuclear Physics Performance Monitoring of Gamma Cameras [8].) Routine testing and evaluation of nuclear medicine equipment may be performed by the technologists 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 physicist's recommendations.

A. For All Standard 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 (e.g., 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 three-dimensional phantom according to the manufacturer's recommendations.

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

1. A quality control program for the routine assessment of cameras performance must be performed and documented in accordance to the manufacture'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 no use it until it is repaired.
4. Maintain all service records.

D. For Xenon or DTPA Aerosol Delivery System

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

E. 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.

F. Film Processors

1. Chemical (wet) systems
   a. Perform daily sensitometric checks.
   b. Perform periodic cleaning and maintenance.
   c. Perform chemical checks.

2. Nonchemical (dry) systems
   Perform periodic calibration and maintenance as recommended by the manufacturer.

For information on picture archiving and communication systems (PACS), see the ACR Technical Standard for Electronic Practice of Medical Imaging [9].

G. Radiation Detectors and Radiation Survey Instruments

Each instrument must be calibrated before first use 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. Radionuclide Dose Calibrators

A licensee shall test the instrumentation required for determining administered activity of unsealed byproduct material for medical use in accordance with nationally recognized standards or the manufacturer's instructions. The following tests and frequencies are provided as recommendations:

1. Test for precision (constancy) each day of use after equipment repair**.**
2. Test for linearity at installation, quarterly, and after equipment repair.
3. Test for accuracy at installation, annually, and after equipment repair.
4. Test for geometry at installation, after equipment repair, and whenever the chamber is moved.
5. An assessment must be made of the radionuclide's emission spectrum characteristics and a determination made as to whether

correction factors are required for measurement of containers with different composition or geometry configuration, if this geometry has not been previously established.

Records of these tests must be maintained for 3 years or as otherwise required by applicable regulations.

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

J. For each study, the following information should be recorded: instrument, collimator, pulse height analyzer (window) setting, acquired views, number of counts in each image, start time of procedure, 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 kept.

K. 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 kept.

L. 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 dose preparation area or used for another patient dose.

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 which, 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 female 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 study, and this counseling must be documented in writing. Similarly, if the patient is known to be breastfeeding, the potential radiation risks to the breastfeeding 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 of weekly surveys of removable contamination and daily surveys 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 agents 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 study, radiopharmaceutical, administered activity, route of administration, preparation of patient, nonradioactive drugs and dosages, required views, timing, preset counts or time, and any contraindications. Pediatric dosages will be derived from appropriate guidelines or standards (e.g., body weight or other accepted dosing formulas).

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 physicians.

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 studies 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 Guideline for Communication of Diagnostic Imaging Findings [10].

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, radiologic technologists, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, to staff, and to society as a whole, while maintaining the necessary diagnostic image quality. This concept is known as "as low as reasonably achievable (ALARA)."

Facilities, in consultation with the medical physicist, should have in place and should adhere to policies and procedures, in accordance with ALARA, to vary examination protocols to take into account patient body habitus, such as height and/or weight, body mass index or lateral width. The dose reduction devices that are available on imaging equipment should be active; if not; manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Periodically, radiation exposures should be measured and patient radiation doses estimated by a medical physicist in accordance with the appropriate ACR Technical Standard. (ACR Resolution 17, adopted in 2006 – revised in 2009, Resolution 11)

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 web site (http://www.acr.org/guidelines).

Equipment performance monitoring should be in accordance with the ACR Technical Standard for Medical Nuclear Physics Performance Monitoring of Gamma Cameras.

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