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The American College of Radiology will periodically define new practice guidelines 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 guidelines and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice guideline 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, requiring the approval of the Commission on Quality and Safety as well as the ACR Board of Chancellors, the ACR Council Steering Committee, and the ACR Council. The practice guidelines 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 guideline and technical standard by those entities not providing these services is not authorized.

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## **ACR TECHNICAL STANDARD FOR DIAGNOSTIC PROCEDURES USING RADIOPHARMACEUTICALS**

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### **PREAMBLE**

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic 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 on 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 developed by the American College of Radiology (ACR) to cover key aspects pertinent to the performance of nuclear imaging and in-vivo nonimaging diagnostic studies using radiopharmaceuticals.

### **II. DEFINITION**

Radiopharmaceuticals are unsealed radioactive agents used for diagnostic or therapeutic purposes. They may demonstrate different pharmacokinetic characteristics in normal and abnormal body tissues or fluids. Static images and dynamic, time-related information are obtained with special equipment which records the spatial and, frequently, the temporal pattern of the administered radiopharmaceutical. Altered pharmacokinetics of the

administered agent induced by physiological and pharmacological intervention can be studied as well.

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

### III. QUALIFICATIONS OF PERSONNEL

#### A. Physician

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

1. Certification in either Radiology, Diagnostic Radiology, Nuclear Radiology, or Nuclear Medicine by one of the following organizations: the American Board of Radiology (ABR), the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, Le College des Medecins du Quebec, the American Board of Nuclear Medicine, and/or the American Osteopathic Board of Nuclear Medicine.

or

At a minimum, completion of a formal Accreditation Council for Graduate Medical Education (ACGME) approved general nuclear medicine program or an American Osteopathic Association (AOA) approved program that must include training in radiation physics, instrumentation, radiochemistry, radiopharmacology, radiation dosimetry, radiation biology, radiation safety and protection, and quality control. In addition, clinical training in general nuclear medicine is required which must cover technical performance, calculation of administered activity, evaluation of images, 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 paragraph, provided they have been actively involved in providing nuclear medicine services.

and

2. Have documented regular participation in continuing medical education (CME) specifically related to diagnostic procedures using radiopharmaceuticals, in accordance with the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#).
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, quality of procedures, and all aspects of patient and facility safety and 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.

The physician may also be required to hold current Advanced Cardiac Life Support (ACLS) certification if monitoring patients undergoing cardiac stress studies.

#### B. Nuclear Medicine Technologist

The technologist performing nuclear medicine services should meet all of the following criteria:

1. Successful completion of an accredited training program in nuclear medicine technology. This program shall include training 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

Current registration by 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, handling 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 that certification and continuing education in the appropriate subfield(s) 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 ABR 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.

The continuing education of a Qualified Medical Physicist should be in accordance with the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#), 2006 (Res. 16g)

The Qualified Medical Physicist or other qualified scientist performing services in support of nuclear medicine facilities should meet all of the following criteria:

1. Advanced training directed at the specific area of responsibility (e.g., radiopharmacy, medical physics, health physics, or instrumentation).
2. Licensure, if required by state regulations.
3. Documented regular participation in continuing education in the area of specific involvement to maintain competency.
4. Knowledge of radiation safety and protection and of all rules and regulations applying to the area of practice.

## 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, preparation, and administration of radiopharmaceuticals may be delegated to qualified personnel, subject to applicable state or local laws.
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. The quantity of radioactivity to be administered must be prescribed (either individually by prescription or by protocol), assayed, and recorded. Administered activity must fall within tolerances of applicable state and federal regulations and should be recorded in the patient's record. If specifically permitted by state or NRC regulations, facilities receiving diagnostic radiopharmaceutical unit administered activity 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.
2. Administered activity must fall within tolerances of applicable state and federal regulations. Under normal circumstances, prescriptions must be in writing and signed by the prescribing physician, who must be 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.
3. The identity of the radiopharmaceutical and the patient, route of administration, and the pregnancy and breast-feeding status of the patient shall be verified prior to administration.
4. When unit administered activities are obtained from commercial radiopharmacies, quality control need not be repeated. It is desirable, however, that administered activity still be assayed on site at the medical facility prior to administration.

### C. Elution of Generators and On-Site Preparation of Radiopharmaceutical "Kits"

1. The volume and radioactivity of the generator eluate must be measured and recorded. Care must be taken to minimize exposure to personnel at all steps in setting up, eluting, and assaying the eluate.
2. Radiopharmaceuticals should be prepared according to the manufacturer's instructions. Documenting exceptions in the policy or procedure manual is desirable.
3. Aseptic procedures must be followed whenever handling parenteral radiopharmaceutical preparations or their components.
4. The first (initial) eluate after receipt of a generator shall be assayed for "breakthrough" of the parent isotope. No more than 0.15 microcurie (.006 MBq) of molybdenum-99 per millicurie (37 MBq) of the administered activity of

technetium-99m is permitted. The eluates can also be checked for aluminum ion breakthrough, although law does not require this.

5. Labeling efficiency of kit-prepared technetium-99m radiopharmaceuticals should be evaluated periodically, such as the first vial of a new lot. Specifically, testing for free pertechnetate and hydrolyzed-reduced radiochemical impurities should be performed. Radiopharmaceuticals should not be administered if the total level of radiochemical impurities exceeds 10%.

#### D. Records

1. Records of receipt, usage, administration, and disposal of all radionuclides shall be kept in compliance with license conditions and applicable medical records and radiation control regulations.
2. All packages containing radioactive materials will 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 radiopharmaceuticals prepared on site, records must reflect the date and time of preparation, amount of radioactivity used, reagent lot numbers, results of quality control tests, and how all radioactivity was used or disposed of.
4. 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.
5. If a radionuclide dose calibrator is used on-site for the assay of radiopharmaceutical administered activity, the instrument will 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.
6. Material (excepting excreta, which may be released into sanitary sewer) with radiation levels greater than background cannot be discarded into regular trash containers, and the labels must be destroyed or defaced before disposal. All containers should be checked for the presence of radioactivity. Disposal must be in accordance with license conditions and applicable federal, state, and local regulations.
7. Residual activity must be stored in a shielded container or in an area that is designed for the storage of radioactive materials until 10 half-

lives have passed and it is at the level of background, or until it can be shipped out as radioactive waste. Radioactive gaseous wastes must be stored or ventilated in accordance with federal, state, and local regulations.

8. Adverse reactions attributable to any radiopharmaceutical should be reported to the manufacturer and, when appropriate, to the Food and Drug Administration (FDA).
9. There must be policies and procedures to ensure that the identity of the patient, the pharmaceutical, the administered activity, and the route of administration are correct. Errors in 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 Nuclear Regulatory Commission, 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 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 Nuclear Medicine Imaging Equipment](#).) Daily testing and evaluation of nuclear medicine equipment may be performed by the technologists under the supervision of the responsible physician.

##### A. For All Scintillation 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) to test linearity, spatial resolution, distortion, and field of view weekly or according to manufacturer's recommendations. Comparison with prior test images is advisable. Retention of these images is recommended.
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 malfunctioning, do not use until repaired.
5. Maintain a log of all quality control testing and problems identified; 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 will require 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 Xenon or DTPA Aerosol Delivery System

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

D. Hard-Copy Imaging 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.

E. 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.

F. Geiger Counters, Well Counters, Ionization Chambers

Test for precision (constancy), accuracy, and linearity with energy and photon flux as specified by state regulations or license conditions, as well as after any equipment repair.

G. 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 and after equipment repair.

2. Test for linearity quarterly and after equipment repair.
3. Test for accuracy annually and after equipment repair.
4. Test for geometry upon installation and after replacement or repair of the chamber.

H. Daily Instrument Notes

Notes on technique for various radionuclides, collimators, and count rate combinations may be helpful to the technologist. It is not necessary to save these notes.

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

J. For each study, the following information should be recorded: instrument, collimator, pulse height analyzer setting, acquired views, number of counts in each image, start time of procedure, and duration of images. (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 shall be used unless contraindicated for a specific patient.

C. Under no circumstances may pipetting of any materials by mouth be permitted.

D. Under no circumstances may makeup be applied or food or drink be brought into, stored, or consumed in areas where radionuclides are prepared, used, or stored.

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 breast-feeding. If the patient is known to be pregnant, the potential radiation risks to the fetus and clinical benefits of the procedure should be considered before proceeding with the study.

F. A policy must exist for routine daily radiation surveys of all areas where radionuclides are used or stored, according to state or federal regulatory requirements.

G. There must be a policy on containment and cleanup of radioactive spills. Radioactive gases should only be used in rooms with appropriate airflow 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 should 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 shall be posting of:

1. Information placards required by regulatory agencies.
2. Radiation precaution signs in areas where radioactive agents are used or stored.
3. Warnings to patients to inform the staff if they are or could be pregnant or if they are breast-feeding.

## VII. PROCEDURE MANUAL

A. A policy and procedure manual must be prepared and maintained. The physician 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 surface area or weight).

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

D. There must be detailed information on appropriate aspects of radiation safety, including emergency 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 shall 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](#).

F. Studies, data, and reports shall 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, 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 is the concept “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 or manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Patient radiation doses should be periodically measured by a medical physicist in accordance with the appropriate ACR Technical Standard. 2006 (Res. 17)

## **X. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION CONCERNS**

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 Concerns elsewhere in the ACR Practice Guidelines and Technical Standards book.

Equipment performance monitoring should be in accordance with the [ACR Technical Standard for Medical Nuclear Physics Performance Monitoring of Nuclear Medicine Imaging Equipment](#).

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