

# The Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories (ICANL)

## STANDARDS FOR NUCLEAR CARDIOLOGY, NUCLEAR MEDICINE AND PET ACCREDITATION

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# ICANL STANDARDS FOR NUCLEAR CARDIOLOGY, NUCLEAR MEDICINE AND PET ACCREDITATION

## PART A STRUCTURE, ORGANIZATION AND DEFINITIONS

### Introduction

These standards list requirements and recommendations for nuclear medicine facilities.  
**All absolute requirements appear in bolded text.**

### Overview of the ICANL Standards

Prior to 2007 there were separate ICANL Standards for Nuclear Cardiology and Nuclear Medicine/PET. As part of the 2007 revisions, all Standards were combined into one concise document in order to be better aligned with the revised application process. For Nuclear Cardiology and cardiac PET practices the Medical Director must meet one of the pathways in A1.1.2 and all medical staff members must meet one of the pathways in A1.3.1. For general Nuclear Medicine or PET (with or without nuclear cardiology) the Medical Director must meet one of the pathways in A1.1.3 and all medical staff members must meet one of the pathways in A1.3.2.

### Definition of a Nuclear Cardiology, Nuclear Medicine and/or PET Facility

A Nuclear Cardiology, Nuclear Medicine and/or PET facility consists of at least one nuclear imaging camera, a qualified physician and a nuclear medicine technologist. Each facility must have a Medical Director and Technical Director. It may be a single site, a conglomerate of sites, a mobile facility or a combination of the above, meeting the organizational structures defined in this document. There may be additional physicians, nuclear medicine technologists, and other professional and/or technical personnel. When more than one technical member is employed, a Technical Director (e.g. chief technologist) is responsible for supervision of the technical staff.

In addition to the standards listed below, the Laboratory, the Medical Director and the Technical Director must comply at all times with all federal, state and local laws and regulations, including but not limited to laws relating to licensed scope of practice, facility operations, and billing requirements.

**The facility must be in compliance with the Nuclear Regulatory Commission (NRC) regulations or, in Agreement States, with State regulations for medical diagnostic and therapeutic (if applicable) use of radioisotopes. (Refer to Part B protocols.)**

Some procedures may be performed using single photon emission computed tomography (SPECT) or positron emission tomography (PET) imaging.

The following are the specific areas of nuclear cardiology for which accreditation may be obtained:

- myocardial perfusion imaging
- equilibrium radionuclide angiography
- other cardiovascular imaging (e.g. first-pass radionuclide angiography)
- cardiac positron emission tomography (PET)

The following are the specific areas of Nuclear Medicine for which accreditation may be obtained:

- gastrointestinal system imaging
- central nervous system imaging
- endocrine system imaging
- endocrine system non-imaging (e.g. radioiodine uptake)
- skeletal system imaging
- genitourinary system imaging
- pulmonary system imaging
- infection imaging
- tumor imaging
- hematopoietic, reticulendothelial and lymphatic imaging
- nuclear cardiology imaging
  - myocardial perfusion imaging
  - equilibrium radionuclide angiography
  - other cardiovascular imaging (e.g. first-pass radionuclide angiography)
- nuclear medicine therapy

The following are the specific areas of PET for which accreditation may be obtained:

- oncologic imaging
- neurologic imaging
- cardiac imaging
- other PET imaging

SECTION A1  
Personnel and Supervision

**STANDARD - Medical Director**

**A1.1 The Medical Director(s) must be a licensed physician and be an authorized user of radioisotopes according to NRC or state regulatory agency regulations. If the facility performs nuclear medicine therapies, the Medical Director also must be an authorized user for these procedures.**

A1.1.1 *Nuclear Cardiology and/or cardiac PET* Medical Director Required Training and Experience

**The Medical Director for nuclear cardiology and/or cardiac PET must meet at least one of the following criteria:**

- A. Certification in nuclear cardiology by the Certification Board of Nuclear Cardiology (CBNC).
- B. Board certified (or Board eligible but within two years of finishing training) in cardiology and completion of a minimum of a 4 month formal training program in nuclear cardiology [Level 2 as outlined in the ACC/ASNC COCATS Training Guidelines (2006 revision)]. This requirement applies only to cardiologists who began their cardiology training in July 1995 or later
- C. Board certified in cardiology and training equivalent to Level 2 training, or at least one year (full time equivalent) of nuclear cardiology practice experience with independent interpretation of at least 600 nuclear cardiology studies. This requirement applies only to cardiologists who began their cardiology training before July 1995.
- D. Board certified (or Board eligible but within two years of finishing training) in nuclear medicine.
- E. Board certified (or Board eligible but within two years of finishing training) in radiology with at least 4 months of nuclear cardiology training.
- F. Board certified (or Board eligible but within two years of finishing training) in radiology and at least one year (full time equivalent) of nuclear cardiology practice experience with independent interpretation of at least 600 nuclear cardiology studies.

- G. Board certified (or Board eligible but within two years of finishing training) in any other medical specialty recognized by the American Board of Medical Specialties or American Osteopathic Association and at least one year (full time equivalent) of nuclear cardiology practice experience with independent interpretation of at least 600 nuclear cardiology studies.
- H. Ten years of nuclear cardiology practice experience with independent interpretation of at least 600 nuclear cardiology studies.

A1.1.2 *Nuclear Medicine and/or PET* Medical Director Required Training and Experience

**The Medical Director for nuclear medicine and/or PET must meet at least one of the following criteria:**

- A. Board certified (or Board eligible but within two years of finishing training) in nuclear medicine.
- B. Board certified (or Board eligible but within two years of finishing training) in radiology with special competence in nuclear medicine.
- C. Board certified (or Board eligible but within two years of finishing training) in radiology with at least 4 months of nuclear medicine training with interpretation of at least 800 nuclear medicine procedures.
- D. Board certified (or Board eligible but within two years of finishing training) in any other medical specialty recognized by the American Board of Medical Specialties (ABMS) or American Osteopathic Association and at least one year (full time equivalent) of nuclear medicine practice experience with independent interpretation of at least 1000 general nuclear medicine procedures and/or, if performing nuclear medicine therapies, independent performance of a least 20 nuclear medicine therapies.
- E. Ten years of nuclear medicine practice experience with independent interpretation of at least 1000 general nuclear medicine procedures and/or, if performing therapies, independent performance of at least 20 nuclear medicine therapies.

**A1.1.3 Medical Director Responsibilities - The Medical Director is responsible for all nuclear medicine services provided including quality control, radiation safety, quality of care and appropriateness of care provided.**

Comment: The Medical Director may supervise the entire operation of the facility or delegate specific operations but is responsible for assuring compliance of medical and technical staff to the standards outlined in this document.

**These responsibilities include but are not limited to:**

**A1.1.3.1 The Medical Director will assure compliance with all policies/procedures/protocols and will review and update all manuals periodically as necessary (minimum every three years) or as new policies are introduced. This review must be documented via signature (or initials) and date on the reviewed document or manual.**

**A1.1.3.2 Active oversight of radiation safety within the facility as evidenced by membership on the institution's radiation safety committee or periodic review of radiation safety issues and documentation (if no radiation safety committee). The Radiation Protection Program content and implementation must be reviewed at least annually.**  
Comment: The Medical Director may delegate the supervision of radiation safety standards to the Technical Director, Radiation Safety Officer or health physics consultant.

#### **A1.1.4 Maintenance of Qualifications**

##### **A1.1.4.1 Continuing Education Requirements**

**A. The Medical Director must obtain at least 15 hours of AMA Category I continuing medical education (CME) credits, relevant to nuclear medicine, every three years.**

Comment: "Relevant" to nuclear medicine includes content that is directly related to the performance or interpretation of nuclear cardiology, nuclear imaging or interventions used during nuclear testing (such as stress testing). This does not include education primarily concerning echocardiography/ultrasound, MRI, CT, cardiac catheterization, general medicine, or the treatment of diseases unless related to the interpretation of nuclear imaging or radionuclide therapies.

If the medical director has successfully attained one or more of the following within the three years prior to the application date, the CME requirement will be considered fulfilled: completion of an ACGME approved residency or fellowship, attaining certification by an ABMS recognized board, or attaining certification by the CBNC.

**B. Documentation of CME credits must be kept on file and available for inspection.**

## **STANDARD - Technical Director**

### **A1.2 A qualified Technical Director(s) is designated for the facility.**

The designated Technical Director must be a nuclear medicine technologist with the following qualifications:

#### A1.2.1 Technical Director Required Training and Experience

**The Technical Director must meet the following criteria:**

- A. An appropriate credential in nuclear medicine technology, i.e. certification [Certified Nuclear Medicine Technologist (CNMT) or Registered Technologist (Nuclear) RT(N) credential in the U.S. or Registered Technologist Nuclear Medicine (RTNM) or Medical Radiation Technologist (Nuclear) MRT(N) credential in Canada] and/or state license to practice as a nuclear medicine technologist.**
- B. Three years of clinical experience in nuclear medicine.**
- C. Current BLS (Basic Life Support) certification**

#### A1.2.2 Technical Director Responsibilities

The Technical Director has a reporting relationship with the Medical Director. **Responsibilities must include, but are not limited to:**

- A. The day-to-day operations of the facility.**
- B. The delegation, as necessary, of specific responsibilities to the technical and/or ancillary staff.**
- C. Verify/document proper training and, at least annually, assess competence of technical staff and/or any ancillary staff who report to the Technical Director.**

### A1.2.3 Continuing Education Requirements

- A. The Technical Director must obtain at least 15 hours of accredited continuing education (CE) in nuclear medicine, every three years.** The 15 hours should include the following categories: imaging, quality control/instrumentation, and radiopharmaceuticals in nuclear medicine. **All continuing education hours must be approved CE (VOICE, ARRT-Category A, ASRT, AMA Category I).**

Comment: If the technical director has successfully attained an appropriate technical credential within the three years prior to the application date, the CME requirement will be considered fulfilled.

- B. Documentation of CE credits must be kept on file and available for inspection.**

#### STANDARD - Medical Staff

- A1.3 All members of the medical staff must be licensed physicians. Any physician authorizing administration of radiopharmaceuticals must be an authorized user of radioisotopes according to NRC or State regulatory agency regulations.** All members of the medical staff are encouraged to be authorized users of radioisotopes for the type(s) of procedure(s) they will be interpreting/performing (i.e. diagnostic and/or therapeutic nuclear medicine).

##### A1.3.1 *Nuclear Cardiology and/or Cardiac PET* Interpreting Medical Staff Required Training and Experience:

**The interpreting medical staff member(s) must meet at least one of the following criteria:**

- A. Certification in nuclear cardiology by the Certification Board of Nuclear Cardiology (CBNC).
- B. Board certified (or Board eligible but within two years of finishing training) in cardiology and completion of a minimum of a 4 month formal training program in nuclear cardiology [Level 2 as outlined in the ACC/ASNC COCATS Training Guidelines (2006 revision)]. This requirement applies only to cardiologists who began their cardiology training in July 1995 or later
- C. Board certified in cardiology and training equivalent to Level 2 training, or at least one year (full time equivalent) of nuclear cardiology practice experience with independent interpretation of at least 600 nuclear cardiology studies. This requirement applies only to cardiologists who began their cardiology training before July 1995.

- D. Board certified (or Board eligible but within two years of finishing training) in nuclear medicine.
- E. Board certified (or Board eligible but within two years of finishing training) in radiology with at least 4 months of nuclear cardiology training.
- F. Board certified (or Board eligible but within two years of finishing training) in radiology and at least one year (full time equivalent) of nuclear cardiology practice experience with independent interpretation of at least 600 nuclear cardiology studies.
- G. Board certified (or Board eligible but within two years of finishing training) in any other medical specialty recognized by the American Board of Medical Specialties or American Osteopathic Association and at least one year (full time equivalent) of nuclear cardiology practice experience with independent interpretation of at least 600 nuclear cardiology studies.
- H. Ten years of nuclear cardiology practice experience with independent interpretation of at least 600 nuclear cardiology studies.

**A1.3.2 Nuclear Medicine and/or PET Interpreting Medical Staff Required Training and Experience (including physicians doing radionuclide therapies):**

**The interpreting medical staff member(s) must meet at least one of the following criteria:**

- A. Board certified (or Board eligible but within two years of finishing training) in nuclear medicine.
- B. Board certified (or Board eligible but within two years of finishing training) in radiology with special competence in nuclear medicine.
- C. Board certified (or Board eligible but within two years of finishing training) in radiology with at least 4 months of nuclear medicine training with interpretation of at least 800 nuclear medicine procedures.
- D. Board certified (or Board eligible but within two years of finishing training) in any other medical specialty recognized by the American Board of Medical Specialties or the American Osteopathic Association and at least one year (full time equivalent) of nuclear medicine practice experience with independent interpretation of at least 1000 nuclear medicine procedures and/or, if performing nuclear medicine therapies, independent performance of at least 20 nuclear medicine therapies.

- E. Ten years of nuclear medicine practice experience with interpretation of at least 1000 procedures and/or if performing nuclear medicine therapies, independent performance of at least 20 nuclear medicine therapies.

### A1.3.3 Interpreting Medical Staff Responsibilities

**The interpreting medical staff provide the final interpretation/report of the nuclear medicine procedures.**

### A1.3.4 Maintenance of Qualifications

#### A1.3.4.1 Continuing Education Requirements

- A. **The interpreting medical staff members must obtain at least 15 hours of AMA Category 1 CME credits, relevant to nuclear medicine, every three years.**

Comment: "Relevant" to nuclear medicine includes content that is directly related to the performance or interpretation of nuclear cardiology, nuclear imaging or interventions used during nuclear testing (such as stress testing). This does not include education primarily concerning echocardiography/ultrasound, MRI, CT, cardiac catheterization, general medicine, or the treatment of diseases unless related to the interpretation of nuclear imaging or radionuclide therapies.

If the medical staff has successfully attained one or more of the following within the three years prior to the application date, the CME requirement will be considered fulfilled: completion of an ACGME approved residency or fellowship, attaining certification by an ABMS recognized board, or attaining certification by the CBNC.

- B. **Documentation of CME credits must be kept on file and available for inspection.**

## STANDARD - Nuclear Medicine Technologist(s)

### A1.4 Nuclear Medicine Technologists

**All imaging personnel must be nuclear medicine technologists who have the following qualifications:**

#### A1.4.1 Nuclear Medicine Technologist Required Training and Experience

**The technical staff must meet the following criteria:**

- A. An appropriate credential in nuclear medicine technology, i.e. certification [Certified Nuclear Medicine Technologist (CNMT) or Registered Technologist (Nuclear) RT(N) credential in the U.S. or Registered Technologist Nuclear Medicine (RTNM) or Medical Radiation Technologist (Nuclear) MRT(N) credential in Canada] and/or state license to practice as a nuclear medicine technologist.**
- B. Current BLS (Basic Life Support) certification**

#### A1.4.2 Nuclear Medicine Technologist Responsibilities

**The nuclear medicine technology staff must report to the Technical Director. The nuclear medicine technologists are responsible for image acquisition and the performance of procedures and other duties, as assigned.**

#### A1.4.3 Continuing Education Requirements

- A. The nuclear medicine technology staff must obtain at least 15 hours of accredited continuing education (CE) in nuclear medicine, every three years. The 15 hours should include the following categories: imaging, quality control/instrumentation, and radiopharmaceuticals in nuclear medicine. All continuing education hours must be approved CE (VOICE, ARRT-Category A, ASRT, AMA Category I).**

**Comment: If the technical staff member has successfully attained an appropriate technical credential within the three years prior to the application date, the CME requirement will be considered fulfilled.**

- B. Documentation of CE credits must be kept on file and available for inspection.**

STANDARD - Direct Patient Care Personnel

**A1.5** All personnel involved in direct patient care should have current BLS (Basic Life Support) certification. While physician presence during stress testing is not required, **the facility must assure that appropriate staff is present based upon the types of procedures being performed and the patients' risks of adverse events.**

**A1.5.1 Basic Life Support - All personnel, including physicians, directly supervising stress procedures must have appropriate training/experience and must be certified in basic life support.**

**A1.5.2 Advanced Cardiac Life Support - There must be ACLS certified personnel on site during cardiac stress procedures.**

**A1.5.3 Stress testing oversight - There must be a system in place for the assurance of the proper administration, including timing, of radiopharmaceuticals relative to the performance of stress testing. If the personnel who conduct stress testing for nuclear imaging procedures are not under the supervision of the Medical Director (e.g., if the stress testing is done by staff in or from another department), there must be a policy in place that assures the proper administration of radiopharmaceuticals (especially timing).**

STANDARD - Physician and Nuclear Medicine Technologist Trainees

**A1.6** Physicians and nuclear medicine technologists in training must not compromise patient care.

**A1.6.1 Physician and Nuclear Medicine Technologist Trainee Supervision**

All trainees must be under the overall supervision of the Medical Director or Technical Director, as appropriate, who determines and outlines all responsibilities. The day-to-day supervision can be carried out by a medical or nuclear medicine technologist staff member. Qualified nuclear medicine technologists and physicians must supervise all clinical procedures and record keeping. The Medical Director or a medical staff member must provide the final interpretation of all studies.

STANDARD - Nuclear Medicine Assistants

**A1.7** All personnel who assist nuclear medicine technologists with direct patient care must have documented training, experience, and competency consistent with their duties. These duties must be acceptable under local, state, and federal law/regulations.

**A1.7.1 If the nuclear medicine assistant is performing duties that are typically performed only by a certified/licensed nuclear medicine technologist (such as radiopharmaceutical preparation or administration, patient positioning, image acquisition or processing), there must be a certified/licensed nuclear medicine technologist identified, in writing, as the assistant's supervising technologist. The supervising technologist is responsible for the assistant's actions.**

**A1.7.2 There must be a certified/licensed nuclear medicine technologist immediately available in the laboratory during nuclear medicine patient care (may be the individual assistant's supervising technologist or another certified/licensed nuclear medicine technologist to whom this oversight responsibility has been delegated).**

**A1.7.3 A nuclear medicine assistant may not perform therapeutic nuclear medicine procedures.**

## SECTION A2 Ancillary Personnel

### STANDARD - Ancillary Personnel

**A2.1 Ancillary personnel necessary for safe and effective patient care must be available. Ancillary personnel staffing must be appropriate for the level of service such that direct care personnel can devote appropriate attention to delivering effective care and patient safety is not compromised. The specific needs of a facility must be determined by evaluation of the types and volumes of procedures as well as facility configuration.**

A2.1.1 Ancillary personnel may consist of:

- A. Clerical and administrative assistants
- B. Physicist or consulting physicist
- C. Radiopharmacist
- D. Computer support staff
- E. Other support personnel

#### **A2.1.2 Ancillary Personnel Supervision**

**All ancillary personnel within the department must be supervised by the Medical Director or a qualified designee. The supervisor must document/verify proper training, at least annually, and current competence of the ancillary personnel appropriate to the assigned duties.**

## SECTION A3 Physical Facilities

### STANDARD – Physical Space

**A3.1 Adequate facilities must be provided for all operations of the facility so that patient comfort, safety, dignity, and privacy are ensured as well as staff comfort and safety. Areas must have sufficient space, be well maintained and be clean. This also includes meeting all federal, state, and local requirements regarding health, radiation, and occupational safety. This includes:**

**A3.1.1 Waiting, reception, and patient/staff bathrooms**

**A3.1.2 Radioactive materials use and storage areas**

**A3.1.3 Diagnostic imaging and processing areas must include adequate space and proper orientation to eliminate “cross talk” (counts being acquired from other than the patient being imaged) into images from other patients, radioactive materials, or radioactive waste.**

**A3.1.4 Patient education, consultation and examination areas including accessible hand washing for staff**

**A3.1.5 Performance of stress procedures within appropriate proximity of the imaging area including adequate space for performing resuscitation in case of emergency**

**A3.1.6 Adequate space, facility configuration, and doorways for the emergency transport of patients from patient care areas and for emergency exit of staff.**

**A3.1.6.1 Interpretation areas**

**A3.1.6.2 Patient records, reports, and digital data storage areas**

**A3.1.6.3 Administration records and support areas**

**A3.1.6.4 Equipment/supply storage areas**

**A3.1.6.5 Therapeutic procedures areas, if applicable**

**A3.2 Adequate utilities must be available, based upon the types of procedures and workload. These utilities include water taps, lighting, electrical outlets, emergency power, telephones, heating/cooling and ventilation.**

**A3.3 Adequate space must be provided for the storage of digital data. The storage must ensure confidentiality of data and should be safe from fire/flood.**

SECTION A4  
Equipment and Instrumentation

STANDARD - Equipment and Instrumentation

**A4.1 Equipment and instrumentation used in the nuclear medicine facility must be in good working condition. Equipment and instrumentation must be routinely inspected for safety and proper functionality and records kept on file. Equipment and instrumentation will include at least the following:**

- A. Dose calibrator or decay correction calculation system, as applicable**
- B. Imaging/counting equipment**
- C. Radiation monitoring devices including**
  - i. portable survey meter (required)**
  - ii. removable contamination counting equipment (as applicable)
  - iii. fixed area survey meter for dose preparation/storage areas (as applicable)
- D. Resuscitation equipment and supplies (appropriate to the types of procedures being performed)**
  - i. oxygen**
  - ii. defibrillator/AED (checks scored in B3.3.1)**
  - iii. emergency drugs (including a master list; all unexpired)**
- E. Exercise equipment (as applicable)**
- F. ECG equipment (as applicable)**
- G. Ancillary monitoring equipment (as applicable)**
- H. Infusion pumps/automated injectors (as applicable)**
- I. Glucometers (as applicable)**
- J. Hood for volatile radionuclides or cell handling (as applicable)**
- K. Xenon (or other gas) trap (as applicable)**

SECTION A5  
Volume of Clinical Procedures

- A5.1 The annual procedure volume is sufficient to maintain proficiency in examination interpretation and performance.** It is recommended that a facility should perform a minimum of 600 nuclear medicine patient procedures annually.

SECTION A6  
Multiple Sites and Mobile Services

STANDARD – Multiple Sites

- A6.1** When procedures are performed at more than one physical facility, the laboratory may be eligible to apply for a single accreditation as a multiple site laboratory if the following criteria are met:

**A6.1.1 All facilities have the same Medical Director and Technical Director.**

**A6.1.2 Identical clinical, administrative and radiation safety procedures are used at all sites (with variance only for differences in equipment and physical facilities).**

**A6.1.3 The quality improvement program must include all sites.**

**A6.1.4 Staff at all sites must be included in periodic staff meetings (e.g. for education, QA, etc.).**

**A6.1.5 The Medical Director and Technical Director must assure that they have adequate contact with each site including periodic observation of operations.**

STANDARD – Mobile Services

- A6.2** A mobile service is comprised of one or more gamma/PET camera units that provide imaging services at one or more locations. This may or may not include one primary laboratory site (fixed site). The laboratory may be eligible to apply for a single accreditation with a mobile component if the following criteria are met:

**A6.2.1 The entire mobile service has the same Medical and Technical Director.**

**A6.2.2 Identical clinical, administrative and radiation safety procedures are used at all sites (with variance only for differences in equipment and physical facilities)**

**A6.2.3 The quality assurance program must include all mobile teams and procedures performed at all sites.**

**A6.2.4 All mobile teams must be included in periodic staff meetings (e.g. for education, QA, etc.)**

**A6.2.5 The Medical Director and Technical Director must assure that they have adequate contact with each mobile team including periodic observation of operations.**

**A6.2.6 There must be a system in place to assure:**

- A. Proper signage (radiation use, pregnancy/breast feeding) is used at temporary use locations, as appropriate for the activities performed.**
- B. Proper radiation surveys are conducted and documented before returning any temporary radiation use site for general use.**
- C. Emergency patient care procedures are known at all sites used for patient care.**
- D. There is a policy for review and interpretation of studies for which a result is needed emergently.**

**PART B**  
**PROCEDURES AND PROTOCOLS**

**SECTION B1**  
**General Protocol Guidelines**

- B1.1 To ensure standardized operation the facility must have and follow site-specific written protocols that accurately describe the details for all procedures performed within the facility.**
- B1.1.1 Complete procedure manuals must be present in the facility and include corresponding references.**
- B1.1.2 Protocols must be organized for easy use (such as in notebook form with a table of contents) and be readily accessible to appropriate staff members during operational hours. Where appropriate, records must be maintained to document compliance with protocols. (e.g. radiopharmaceutical receipt/disposal records, spill records etc.). Availability of protocols in digital format is desirable.**
- B1.1.3 Protocols must be reviewed and updated periodically, and as needed by the Medical Director or an appropriate designee, at a minimum of every three years. All procedures and/or revisions must be dated and initialed/signed by the supervisor or an appropriate designated person. [Note that the Radiation Safety Program must be reviewed annually; see section B.4.1]**
- B1.1.4 Personnel must have read, be appropriately trained in, and have current competence documented to perform/comply with relevant protocols. Documentation is typically found as initial orientation and training records.**
- B1.1.5 The protocols and the facility's performance must be in compliance with:**
- B1.1.5.1 All applicable federal, state and local requirements, including Nuclear Regulatory Commission (NRC) regulations or, in Agreement States, with state regulations for medical use of radioisotopes.**
- B1.1.5.2 Accepted practices such as those in published guidelines<sup>1,2,3,4,5,6</sup>. Sample protocol information is available on the ICANL website at [www.ICANL.org](http://www.ICANL.org). References are listed in the bibliography.**

## SECTION B2 Clinical Procedure Protocols

**B2.1** There must be a clinical procedure manual that includes every clinical procedure performed at the facility, even those performed only occasionally. All procedures that are performed must have detailed, site specific written protocols. All clinical procedures must be performed under conditions that ensure patient and staff safety.

Note: Some components of clinical protocols, such as patient identification or image labeling, may apply to a group of procedures and therefore may be established separately from the individual procedure protocols. In such cases the blanket policy does not need to be fully reproduced in each individual procedure protocol.

**B2.1.1 Patient Identification** - For all clinical procedures there must be a process that assures accurate patient identification prior to initiating the procedure. The procedure must assure that patient identity is verified by the person administering the radiopharmaceutical prior to any radiopharmaceutical administration. It is preferable that this be done using at least two pieces of information that are provided by the patient and compared with existing documents. For dosages of  $^{131}\text{I}$ -sodium iodide > 30 microcuries and any nuclear medicine therapies, the procedure must provide high confidence that the patient will be properly identified.

**B2.1.2 Pregnancy screening** - For all clinical procedures there must be a process that assures that patients who could be pregnant are identified. This must be documented and should contain the signature/initials of the patient and/or technologist verifying the information. This procedure must include an explanation of the proper steps to be taken if a patient may be or is pregnant. For nuclear medicine therapies or diagnostic procedures using  $^{131}\text{I}$ -sodium iodide for thyroid carcinoma, the pregnancy screening protocol must assure that patients who are pregnant are not administered the radiopharmaceutical.

**B2.1.2.1** If a diagnostic study (e.g. lung perfusion) is needed for a patient who is pregnant, knowledgeable staff (e.g. medical director, authorized user, consultant physicist, or other designee) must discuss the potential risk to the fetus and document the general content of the discussion.

**B2.1.2.2** If it is determined that the study will not be performed then the patient must receive options for alternative care.

**B2.1.2.3** There must be a protocol for determining fetal dose (intended or unintended) and providing this information to the patient after radiopharmaceutical administration to a pregnant patient.

**B2.1.2.4** There must be a protocol for reporting any unintended radiation exposure greater than 5 rem to an embryo/fetus or nursing child, if this is possible based on type and amounts of radioactivity being administered.

**B2.1.3 Breast Feeding Screening** - For all clinical procedures there must be a process that assures that patients who are breast feeding are identified. This must be documented and should contain the signature/initials of the patient and/or technologist verifying the information. This procedure must include an explanation of the proper steps to be taken if a patient is breast feeding. To enable mothers to receive needed medical care and yet minimize the disruption of breast feeding, appropriate guidelines must be available so that breast feeding may be discontinued and, whenever possible, resumed as soon as safe for the child being breast fed. The staff (medical director, RSO, authorized user, medical physicist, or other appropriate designated staff) must be able to instruct the patient regarding timing of pumping breast milk rather than breast feeding and appropriate discard versus storage/use of pumped breast milk.

**B2.1.3.1** For nuclear medicine therapies or diagnostic procedures for thyroid carcinoma using  $^{131}\text{I}$ -sodium iodide, the breast feeding screening protocol must assure that any patient who is breast feeding is not administered the radiopharmaceutical. A patient who is breast feeding should also be given the opportunity to stop lactating for an appropriate time (usually at least three weeks) prior to receiving  $^{131}\text{I}$  therapy to reduce the radiation to the breasts.

**B2.1.4** Warning signs must be present to help prevent inadvertent administration of radiopharmaceuticals to patients who are pregnant or breast feeding. At a minimum, these must be easily seen by the patient (and in a language understandable to most patients) in the area where initial radiopharmaceutical administration is performed.

**B2.2** Diagnostic imaging protocols and their implementation must result in an accurate depiction of the distribution of the radiopharmaceutical(s) within the patient and provide data (images and/or quantitation) that is interpretable by the responsible physician. This includes following accepted practices<sup>2,3,4</sup> (or providing published justification for variance) and performing optimal acquisition, processing and display of data as well as minimization of distortion due to such factors as motion and artifacts. Protocols must include, as appropriate:

**B2.2.1** Clinical indications<sup>5</sup>

**B2.2.2** Patient preparation and education/instructions such as food/diet restrictions, if any, withholding or non-withholding of medications, or other relevant

**information.** Other patient instruction/preparation may include skin preparation, wound care, changing or removal of dressings or casts.

**B2.2.3 Radiopharmaceutical identity, dosage, and route of administration. (see also B.4.3.4 for additional dosage protocol requirements).**

B2.2.3.1 Radiation dosimetry: effective dose and critical organ dose for each radiopharmaceutical given should be included. If relevant, pediatric exposures should be included.<sup>6</sup>

**B2.2.3.2 For <sup>131</sup>I-sodium iodide dosages greater than 30 microcuries, there must be a written directive (containing the patient's name, radiopharmaceutical, dosage, and route of administration with the authorized user's signature and date).** The written directive dosage may be written as an amount plus or minus an amount or percentage. Alternatively, the dosage may be written as a range appropriate for the specific patient's procedure.

**B2.2.4 Non-radioactive drugs used in the procedure including dosage, timing, route of administration, patient instruction, patient monitoring and any precautions or restrictions**

**B2.2.5 Camera setup (collimator, window setting, etc.)**

**B2.2.6 Patient and camera positions**

**B2.2.7 Camera/computer specific acquisition protocols including timing of views, time/counts per view, and number of views as well as SPECT/PET specific parameters and filtering (reconstruction)**

**B2.2.8 Camera/computer specific processing protocols including filtering, reconstruction parameters, curve generation, and quantitative analysis requirements.**

**B2.2.9 Camera/computer specific display protocols (may be preset in computer).**

**B2.2.10 Image labeling including name, patient identification, date of study, time interval (as appropriate), view or projection and anatomical markers (as appropriate) [if not pre-defined in computer display protocol].**

Note: If acquisition/processing/display protocols are in the computer software, they may be listed in the protocol manual by the name of the protocol as on the computer. However, if the computer protocol has any portions that allow or require site/user selection/interaction (e.g. choosing filters, drawing ROI's), the protocol manual must document the proper choices/technique (may elect to "print screen" showing selections and location in manual).

**B2.3 Exercise and/or Pharmacologic Stress Testing. All exercise/pharmacologic protocols must follow accepted practices<sup>1</sup> (or have published justification for variance) and include the following:**

**B2.3.1 Detailed description of graded protocols (e.g. including charts showing speed, incline and workload, if applicable) and/or infusion protocols used.**

**B2.3.2 Timing of assessing symptoms, heart rate, blood pressure, and electrocardiographic tracings**

**B2.3.3 Exercise/testing end points including any specific events that are reasons for stopping the stressing activity (such as duration of pharmaceutical administration, level of exercise attained, ECG findings, specific symptoms, etc.). It should be noted that, in general, exercise stress tests should be symptom-limited unless indications for stopping the test early are achieved.**

**B2.3.4 Radiopharmaceutical injection criteria including the timing of radiopharmaceutical injection relative to the stressing activity and/or other criteria for optimal results (e.g. ECG changes, symptoms).**

**B2.2.5 Post stress monitoring including timing of assessing symptoms, heart rate, blood pressure, and electrocardiographic tracings as well as criteria for terminating post stress monitoring.**

**B2.3.6 Identification and treatment of common adverse effects of exercise and/or pharmaceutical stress.**

**B2.4 Therapy protocols must describe in detail:**

**B2.4.1 Clinical indications.**

**B2.4.2 Patient education/instruction such as food/diet restrictions, if any, withholding or non-withholding of medications, or other relevant information.**

**B2.4.3 Radiopharmaceutical identity, dosage and route of administration – must be written prescription signed and dated by the treating physician who is an authorized user.**

**B2.4.3.1 The written directives must be retained for at least three years.**

**B2.4.3.2 The prescription (also known as a written directive) may be for a specific amount, an amount plus or minus an amount/percentage, or a range appropriate for the specific patient's therapy.**

**B2.4.4 The treating physician must directly supervise the administration of the therapeutic radiopharmaceutical.**

**B2.4.5 Non-radioactive drugs used in the procedure including dosage timing, route of administration and any precautions or restrictions.**

**B2.4.6 Treatment procedure including counseling, informed consent, pregnancy and/or breast feeding status check, supervision of dosage administration, medical record documentation. (Note: If nuclear imaging is needed as part of a therapy protocol see B2.2 for components of imaging protocols.)**

**B2.4.7 Radiation precautions following treatment, as appropriate (none required for pure beta emitters or  $^{153}\text{Sm}$ ).**

**B2.4.7.1** When needed, patient instructions should include maintaining distance from others (including during sleep and time in public), control of body fluids, handling of potentially radioactive household trash (to reduce it triggering overly sensitive landfill monitors), and the duration of these restrictions. Additionally, if relevant, guidance concerning breast feeding or the cessation thereof must also be included.

**B2.4.7.2** When nuclear medicine therapy patients are released rather than being hospitalized [when exposure to others is likely to exceed 0.1 rem (1 mSv) but not likely to exceed 0.5 rem (5 mSv)], a record of the basis for the release and instructions provided must be maintained.

**B2.4.7.3** When patients must be hospitalized due to radiation exposure restrictions, protocols must address radiation safety instruction to direct care (e.g. nursing) and housekeeping staff, hospital room/signage requirements, radiation monitoring requirements, visitation policy, handling of materials used by the patient, and response to medical emergencies or patient death.

SECTION B3  
Equipment Quality Control Protocols

**B3.1 The facility must have acceptable site-specific written protocols for and maintain records of all routine quality control of imaging and non-imaging equipment. There must also be records of service and maintenance.**

**B3.2 Imaging Equipment Quality Control**

**All imaging devices must be FDA approved (or used under an approved research protocol with informed consent by the patient). Imaging equipment must be in good working condition. Routine assessment of basic parameters and calibration of imaging equipment must be performed according to approved written standards, and records must be retained for comparison. The results must be reviewed by appropriate staff in a timely manner and action taken (and documented) if not within specifications. These include:**

<b>Test (PM Tube based Scintillation cameras)</b>	<b>Frequency</b>
<b>Energy peaking</b>	<b>Daily (prior to use; documentation not required)</b>
<b>Intrinsic or extrinsic uniformity (approximately 2-5 million counts)</b>	<b>Daily (prior to use)</b>
<b>Resolution and linearity (bar phantoms)</b>	<b>Weekly</b>
<b>High count floods (<math>\geq 30</math> million count)</b>	<b>Monthly, or per manufacturer's recommendations</b>
<b>Center of rotation (SPECT)</b>	<b>Monthly</b>
<b>Collimator integrity</b>	<b>Annually</b>
<b>Uniformity calibration</b>	<b>Monthly or per manufacturer's recommendations</b>
<b>Preventive maintenance</b>	<b>Every 6 months</b>

<b>Test (PET only)</b>	<b>Frequency</b>
<b>Blank scan</b>	<b>Daily</b>
<b>Normalization</b>	<b>After a hardware change or per manufacturer's recommendations</b>
<b>Absolute activity calibration</b>	<b>After a hardware change or per manufacturer's recommendations</b>
<b>Preventive maintenance</b>	<b>Every 6 months, or per manufacturer's recommendations</b>

**Imaging equipment quality control notes:**

- 3.2.1 If imaging equipment is physically moved from site to site, (other than planar mobile gamma cameras or non-PMT mobile planar/SPECT cameras used within a building) these items must be repeated after each move and prior to equipment use.**
- 3.2.2 If frequency varies from the above, justification must be based on scientific data or manufacturer's recommendation. If a less frequent schedule is being used, there must be clear documentation of the justification (such as based on scientific data).**
- 3.2.3 Energy peaking and uniformity testing must be appropriate for the energy of the radioisotopes being imaged (e.g. low energy and medium energy).**
- 3.2.4 Initial acceptance results should be retained and used for comparison.**

**B3.3 Non-imaging Equipment Quality Control**

**B3.3.1 A policy must exist and be followed for routine inspection and testing of all non-imaging equipment, such as dose calibrators, uptake probes, survey meters, and glucometers and be in accordance with the federal, state and local requirements. The dose calibrator must be calibrated in accordance with nationally recognized standards or the manufacturer's instructions. When abnormal results are obtained, appropriate actions/corrections must be made and documented.**

Typical calibration schemes are shown below.

<b>Equipment</b>	<b>Test</b>	<b>Frequency</b>
Dose calibrator	Constancy	Daily
Dose calibrator	Linearity	Quarterly
Dose calibrator	Accuracy	Annually
Survey meter	Calibration	Annually
Glucometer (if applicable)	Accuracy	Daily
<b>Defibrillator/AED</b>	<b>Functionality</b>	<b>Based on device and use (minimum: monthly)</b>

**B3.3.2 An emergency response cart or kit, appropriate for the types of procedures being performed, must be present. There must be documentation that it is checked at least monthly to assure that all expected items are present and none are expired.**

**B3.3.3 Radiation monitoring devices, especially a portable survey meter, must be on site. These must be calibrated upon initial acquisition, annually, and after any repairs that might affect calibration.**

**B3.3.4 Appropriate reference standards for quality control of radiation counting instruments must be used.**

SECTION B4  
Radiation Safety and Radioactive Materials Handling Protocols

**B4.1 There must be written radiation safety and radioactive materials handling protocols.**

**B4.1.1 The Radiation Protection Program content and implementation must be reviewed at least annually. Records of this review must include program changes, noted deficiencies, and actions taken (or a statement that none are needed). This must be signed/initialed and dated by the Medical Director or an appropriate designee.**

**B4.1.2 There must be written designation of a Radiation Safety Officer. This is generally found on the radioactive materials license.**

**B4.1.3 Designation of who may handle/administer radionuclides (i.e. by name list of authorized user physicians, nuclear medicine technologists, trained nurses, and/or others who are properly trained and approved, as appropriate).**

**B4.2 Facility operations must be in compliance with accepted federal, state and local radiation safety standards for medical diagnostic and/or therapeutic use of radioisotopes. The facility must retain copies of any facility inspections/surveys as well as evidence of correction of any deficiencies found.**

**B4.3 Radiation Safety Protocols must address the following topics:**

**B4.3.1 General Radioactive Materials Handling and Radiation Safety**

**B4.3.1.1 Provision for a safe working environment, including an ALARA (as low as reasonably achievable) radiation exposure policy (for workers and general public).**

**B4.3.1.2 The use of signage for radioactive materials use and storage areas, as required by applicable regulations.**

**B4.3.1.3 Monitoring for and reporting of excessive radiation levels, including trigger levels, reporting requirements and any excessive radiation exposures for the general public.**

**B4.3.1.4 Radiation safety instruction upon hire and annually thereafter for all personnel in the facility who are handling, or are potentially exposed to, radioactive materials, including all authorized users. Records of this training must be retained.**

**B4.3.1.5 Monitoring of all staff for radiation exposure as required by federal or state guidelines. This includes the use of hand monitoring ("ring badge") of those directly handling radiopharmaceuticals.**

**B4.3.1.5.1 Personnel dosimeters that require processing must be processed by an approved and accredited dosimetry processor.**

**B4.3.1.5.2 Employees who are monitored must be advised of their dose at least annually.**

**B4.3.1.5.3 Exposure records must be easily retrievable and made available to the employee.**

**B4.3.1.5.4 Results of personnel monitoring must be reviewed periodically to assure that exposures are as low as reasonably achievable. This must be documented (such as by signature/initials and date indicated by the responsible reviewer) and any excess exposures reported as appropriate. Additionally results of personnel monitoring must also reflect appropriate use of monitoring device (e.g. for a technologist who is preparing radiopharmaceuticals for use, their ring badge exposure result should not routinely be background level).**

**B4.3.1.6 Information for employees, who are or may become pregnant, regarding their responsibility to declare the pregnancy to management and the facility's plan for addressing the employee's radiation safety needs.**

**B4.3.1.7 Proper use of shielding, radiation protection devices (e.g. syringe shields, glass shields, etc.), and protective clothing (e.g. lab coats) as well as refraining from eating or drinking in radiation use areas.**

**B4.3.1.8 Each syringe and vial that contains a radiopharmaceutical must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded (10 CFR 35.69)**

**B4.3.1.9 Spill confinement/decontamination procedures include having guidelines posted in the facility (with the radiation safety officer's phone number for work and after hours contact) and having documentation requirements for reporting spills/decontamination.**

**B4.3.1.10 Proper use of radiation monitoring devices.**

- B4.3.1.11 Periodic area surveys (particularly sinks and dose preparation areas) and wipe tests including tolerance limits and response to trigger levels. (For facilities performing only routine diagnostic nuclear cardiology, unless there is a more stringent state or local requirement, area surveys and wipe tests may be performed weekly or even less frequently if site experience shows that the extended interval is appropriate based on historical data at the site. Alternatively, at facilities where there is a greater risk of contamination [training sites], more frequent monitoring may be appropriate. The facility protocol must document the chosen frequency).**
- B4.3.1.11.1 For sites performing nuclear medicine therapies or using dosages greater than 30 microcuries of <sup>131</sup>I-sodium iodide, area surveys must be performed daily in areas of dosage preparation or administration.**
- B4.3.1.12 Sealed sources wipe/leak testing protocol and documentation including frequency, identity, activity, and location of all sources, name of person conducting the inventory, and results of wipe/leak testing.** The frequency of the sealed source wipe/leak test is a minimum of every six months.
- B4.3.1.13 Protocol for reporting theft or loss of radioactive materials based on types and amounts of materials and the risk to the public.**
- B4.3.1.14 Procedure for monitoring radiation exposure for visitors to radiation use areas, if needed based on the potential exposure (this is generally not needed if performing only routine diagnostic procedures).**
- B4.3.1.15 Instruction of patients, family members and, as needed, hospital staff (e.g. nursing personnel) regarding radiation precautions for all therapeutic procedures and/or when appropriate for diagnostic procedures.**
- B4.3.1.16 Protocols establishing, defining and explaining specific procedures for following and adhering to the “written directive” policy for all personnel involved in administration of nuclear medicine therapies or diagnostic dosages of <sup>131</sup>I-sodium iodide greater than 30 microcuries.** When protocols regarding written directives are not followed, the cause of the deviation and the actions to prevent recurrence should be identified.

## **B4.3.2 Receipt of Radioactive Materials**

**B4.3.2.1 Designation of a specific secured area for placing shipments of radionuclides**

**B4.3.2.2 Recording of receipt of all shipments of radionuclides**

**B4.3.2.3 Survey of shipments of radionuclides, prior to opening, including tolerance limits and response to triggers (including proper notification if damage or leak)**

## **B4.3.3 Preparation of Radiopharmaceuticals as applicable (if ONLY unit doses are used, no protocols are needed since this is done by supplier)**

**B4.3.3.1 Assay of generator eluate for total activity**

**B4.3.3.2 Assay of generator eluate for breakthrough of parent radionuclide**

**B4.3.3.3 Preparation of radiopharmaceuticals according to product insert or other written protocol**

**B4.3.3.4 Verification of radiochemical purity of radiopharmaceuticals**

**B4.3.3.5 Documentation of lot or batch numbers of components used in radiopharmaceutical preparation**

**B4.3.3.6 Verification of pH of radiopharmaceutical preparations when appropriate**

**B4.3.3.7 Performance of sterility testing on radiopharmaceuticals prepared using non-commercial kits**

**B4.3.3.8 Performance of endotoxin testing on radiopharmaceuticals prepared using non-commercial kits**

**B4.3.3.9 Proper storage of kits and prepared radiopharmaceuticals**

## **B4.3.4 Administration of Radiopharmaceuticals to patients**

**B4.3.4.1 Determination of patient dosages using standardized protocols (approved by the Medical Director) or by individually written prescriptions (only by authorized users). The authorized user responsible for prescribing the radiopharmaceuticals must be clearly identified for each patient dose (via prescription or protocol signed by an authorized user).**

**B4.3.4.1.1 A documented system for adjusting radiopharmaceutical dosages by weight or appropriate adjustment in imaging acquisition parameters to compensate for patient size/weight. If adjusting radiopharmaceutical dosages, this must be signed by the medical director or a designated authorized user.**

**B4.3.4.1.2 Individual determination of doses for pediatric patients prior to administration. These must be signed by the medical director or other authorized user (as a protocol or individual dosages).**

- B4.3.4.2 Assay of patient dosages of radiopharmaceuticals (using a dose calibrator) on-site prior to administration. Alternatively, for sites using unit doses, where permitted, the dosages may be determined based on decay correction of the unit dose. For sites using other than unit doses, the dosages being administered may be determined using a combination of measurement and mathematical calculations or a combination of volumetric measurements and mathematical calculations based on measurements done by an appropriate preparer (radiopharmacy/supplier).**
- B4.3.4.3 Recording of specific patient dosages (as determined by methods noted in B.4.3.4.1) prior to administration.**
- B4.3.4.4 Verification of patient identity prior to radiopharmaceutical administration as well as pregnancy/breast feeding status, as described in B.2.1).**
- B4.3.4.5 Verification of the radiopharmaceutical identity and dosage immediately prior to administration by the prescribed route.**
- B4.3.4.6 Verification of the expiration date/time of the radiopharmaceutical and assurance it is administered prior to its expiration date.**
- B4.3.4.7 Clear documentation of the administration of radiopharmaceuticals (substance, amount, route, site, date, time, identity of person administering).**

### **B4.3.5 Radioactive Materials Storage and Disposal**

**B4.3.5.1 Radioactive trash (wipes, syringes, alcohol swabs, etc) is kept separate from normal trash, stored and appropriately discarded.**

**B4.3.5.2 Security (e.g. locking) of areas containing radioactive materials (including hot lab, other radioactive use, and storage/decay areas) when not under supervision of clinic personnel must ensure that non-authorized personnel (including visitors, patients, and non-authorized staff) cannot access any radioactive materials.**

**B4.3.5.3 Adequate shielding of radioactive materials storage areas based on the types and amounts of radionuclides as well as the types of use of surrounding areas.**

SECTION B5  
Administrative and Other Protocols

**Written protocols must be in place for the following [note: as required, there also must be documentation for initial and recurrent training (such as for HIPAA, OSHA, etc.) as required by local, state, or federal rules]:**

- B5.1 Procedure Availability - The hours of operation of the facility as well as the types and availability of procedures must be appropriate for the institutional setting.**
- B5.2 Request for Services - There must be a written policy for requesting clinical nuclear medicine procedures. Documentation of a request, including the identity of the patient, the referring health care provider, and clinical information that indicates the rationale for the procedure, must be present prior to performing any procedure.**
- B5.3 Duties and Responsibilities - There must be written descriptions of the duties and responsibilities for each staff position.**
- B5.4 Safety/Security for Staff and Patients - There must be a written procedure for responding to disasters or other threats to staff or patient safety/security. This includes when staff may be present after normal facility hours.**
- B5.5 Confidentiality - All patient records are maintained confidentially. Responsibility for patient confidentiality extends to all staff including trainees and must be HIPAA compliant.**
- B5.6 Informed Consent - When required by local policy or state/federal statutes/regulations, informed consent must be obtained from the patient or guardian for nuclear medicine procedures. There must be informed consent for therapeutic procedures.**
- B5.7 Investigational radiopharmaceuticals - These are used only in accordance with research protocols.**
- B5.8 Infection Control - Appropriate precautions are taken, in accordance with universal precautions, when handling toxic or biologic materials (i.e., used syringes, needles, blood and/or body fluid etc.) or when in contact with communicable diseases. This includes policies/procedures regarding decreasing the probability of needle stick of staff and what to do if a worker is punctured by a used needle.**
- B5.9 Communicable diseases - Appropriate precautions are taken to protect patients from blood borne, airborne, and contact pathogens whether from other patients or facility personnel who have communicable diseases.**
- B5.10 Hazardous Materials - Appropriate precautions are taken when using and storing flammable and/or toxic materials.**

- B5.11 Medical Emergencies - There must be written plan for responding to medical emergencies. All staff and trainees must be familiar with their role in the plan.**
- B5.12 Special Needs Patient Care - Personnel must be trained to deal with patients with language barriers, physical disabilities, serious illness, or who are unable to cooperate.**
- B5.13 Handling of Non-Radioactive Pharmaceuticals - Must be performed correctly.**
- B5.13.1 Pharmaceuticals are properly stored. If controlled substances are kept on site (e.g. such as in a crash cart) they must be locked with controlled access.**
- B5.13.2 Pharmaceuticals are properly prepared.**
- B5.13.3 Patient dosages are determined using standard protocols approved by the Medical Director, or individually written prescriptions. For pediatric patients, dosages are determined individually.**
- B5.13.4 The health care provider responsible for prescribing the pharmaceutical must be clearly identified for each patient dose (via prescription or protocol) and properly recorded.**
- B5.13.5 Patient identity is verified prior to pharmaceutical administration.**
- B5.13.6 The identity and dosage of each pharmaceutical are verified immediately prior to administration by the prescribed route.**
- B5.13.7 The expiration date of the pharmaceutical is checked and the dosage is administered prior to the expiration.**
- B5.13.8 There must be clear documentation of the administration of pharmaceuticals (substance, amount, route, site, time and identity of person administering).**
- B5.14 Adverse Drug Events - There must be a procedure for reporting and maintaining the reports of adverse effects of radiopharmaceuticals and other medications.**
- B5.15 Drug Administration Errors - Records of radiopharmaceutical or other medication administration errors must be maintained. Events must be reported as required and records must be maintained. Actions taken in response to identified problems must be available.**

## SECTION B6 Image Interpretation and Reporting

**B6.1 Examinations are interpreted and a final report provided by the Medical Director or qualified members of the medical staff as defined in A1.1 and A1.3.**

**B6.1.1 All dynamic studies (e.g. gated, flow, etc) must be interpreted on the computer. For SPECT studies raw data images must be reviewed. Although static images may be interpreted from film or other hard copy, it is preferable that they be interpreted on the computer.**

B6.1.2 All diagnostic procedures must be reviewed promptly after the study is completed as appropriate for the risk of clinically significant results at least within one working day. Results of examinations with critical results must be communicated to the referring physician as quickly as clinically indicated. A record of the communication should be maintained.

B6.1.3 **An interpretation (initial or final) must be available within two (2) working days of the examination.** An initial interpretation may be in the form of paper, digital storage or accessible voice system.

**B6.1.4 The final report must be reviewed and signed manually or electronically (with password protection) by the interpreting physician (who must be the medical director or a qualified member of the medical staff). Stamped signatures or signing by non-physician staff is unacceptable. In unusual circumstances, when the interpreting physician is not available, another qualified member of the medical staff may sign for them, if they choose to take such responsibility.**

**B6.1.5 The final signed report must be transmitted to the referring health care provider within 4 working days.**

**B6.1.6 All patient records must be confidentially maintained and be retained. They must be accessible for the appropriate period of time as prescribed by state, institution or other rules/regulations.**

B6.1.6.1 Any retained hard copy images should be of high quality and reflect the findings described in the final interpretation. **If the only images that are retained are hard copy, then they MUST be of high quality.**

B6.1.6.2 It is strongly recommended that raw digital image data be retained for a minimum of three years.

**B6.1.6.3** Technical data that are not included as part of the final report must be maintained as part of the facility records. The specific imaging and processing parameters used should be retrievable for each clinical study.

**B6.1.6.4** Specific worksheets for non-imaging studies must be maintained as part of the facility records.

**B6.1.6.5** The facility must be able to transmit current or archived patient studies to an outside, non-affiliated entity in a format that is of interpretable quality.

**B6.1.7** There must be a system for identification and retrieval of a patient's prior similar studies for comparison.

**B6.1.8** If images are transmitted to another (affiliated) location for remote interpretation, a method of validating the quality of the transmitted image should be done to assure that it is of comparable diagnostic quality.

**B6.2** Final interpretation of examinations must be based on quality images/data as well as relevant clinical information. This includes, but is not limited to:

**B6.2.1** Relevant clinical information and clinical indication/question

**B6.2.2** Relevant patient response to stress or other pharmacologic intervention (such as symptoms, heart rate/BP data, ECG data, etc., as appropriate for the type of stress or pharmacologic intervention; relevant data must be included in the final report as noted in B.6.3).

**B6.2.3** Acceptable quality radionuclide images and/or derived quantitative data including acceptable:

**B6.2.3.1** Count density

**B6.2.3.2** Processing/Filtering

**B6.2.3.3** Data Display [includes image data (slice line-up, normalization, color, standardization, as relevant) and quantitative data (including ROI display, graphs, raw data, and calculated values, as relevant)]

**B6.2.3.4** Lack of artifacts (e.g. patient motion, attenuation, subdiaphragmatic activity)

**B6.2.4** Other relevant imaging modalities (i.e. echo/ultrasound, CT, MRI etc.), if available. If not available, this should be noted in the report.

**B6.2.5 Comparison with prior nuclear medicine examinations, if available. It is preferable that “no previous studies” be stated to document that there were none.**

**B6.2.6 The integration of imaging and non-imaging information into a final impression that resolves any potential inconsistencies.**

**B6.3 The final report must be typed or computer generated and must accurately reflect the content and results of the study. This includes, but is not limited to:**

**B6.3.1 Patient’s name, gender, age (or date of birth) and identification number, if applicable**

**B6.3.2 Requesting health care provider’s name**

**B6.3.3 Date of the examination**

**B6.3.4 Date of the report**

**B6.3.5 Clinical indications and pertinent history leading to the performance of the examination**

**B6.3.6 Name of the procedure [type of examination(s)]**

**B6.3.7 An adequate description of the procedure performed. The description must include the name of the procedure [type of the examination(s)]. It must also include the type, amount and route of administration of any radioactive or non-radioactive material administered. The type of stress, if applicable, must be described.**

**B6.3.8 A description of the results of the examination including pertinent positive and negative findings. This includes:**

**B6.3.8.1 Non-imaging data such as stress test responses and summarized findings, when applicable. Stress testing data reported must include patient response to stress (critical HR, BP, ECG findings), stress duration, reason for termination of stress, and timing of administration of radiopharmaceuticals as it relates to pharmaceutical or other stress administration.**

**B6.3.8.2 Image description, including location and types of findings (such as size and intensity of cardiac defects). When possible, the description should use standard nomenclature such as the 17-segment cardiac model for myocardial perfusion imaging.**

- B6.3.8.3 Findings which may affect the quality or reliability of the results such as attenuation (general soft tissue, breast, diaphragm), patient/organ motion (limb/body movement, upward creep of the heart), activity in non-target organs (e.g. subdiaphragmatic activity on cardiac studies), or other imaging artifacts.**
- B6.3.9 The reasons for limited examinations and/or deviations from standard protocols, if applicable.**
- B6.3.10 An accurate, succinct impression. This must clearly communicate the result of the study and, when possible, answer the clinical question that was the cause for the examination. This final conclusion must resolve any inconsistencies or discrepancies (e.g. abnormal stress test with normal myocardial perfusion images) or provide guidance for further studies to do so.**
- B6.3.11 Any need for additional studies based on the results of the procedure being reported.**
- B6.3.12 Identification of and manual or electronic signature (password protected) of the interpreting physician as described in B6.1 and B6.1.4.**



SECTION B7  
Therapy Performance and Reporting Protocols

- B7.1 Nuclear Medicine therapies are performed and a final report provided by the Medical Director or members of the medical staff who are qualified as defined in A1.1.1 and A1.1.3. The treating physician must be an authorized user for the radioisotope administered if it is controlled under the radioactive materials license.**
- B7.1.1 The treating physician must review the pertinent elements of the patient's history, physical findings, laboratory and imaging data to determine that the proposed treatment is appropriate. The treating physician is taking responsibility for the proper administration of the therapy and its potential side effects.**
- B7.1.2 The treating physician is responsible for assuring that the facility's therapy protocol is followed (B2.4) as well as radiation safety protocols specifically relevant to radionuclide therapies (B.4). If deviations from the protocols are made, these must be documented in the patient's medical record and/or the final report.**
- B7.1.3 Prior to administration of the therapeutic dosage, the treating physician must assure that the patient is fully informed regarding the risks (including side effects), benefits, alternatives, and expected outcome (including likelihood of success) of the therapy; written consent is obtained; the patient is not pregnant; and the patient is not lactating or is specifically counseled about the risks of breast feeding (if any) based on the specific treatment.**
- B7.1.4 The treating physician must assure that the patient is properly identified prior to radionuclide therapy dosage administration and that the dosage is administered properly.**
- B7.1.5 The treating physician must assure that the patient is given appropriate post-therapy instructions and specific information concerning his/her follow-up appointment(s) [with whom, when, and where].**
- B7.1.6 The treating physician is responsible for post-therapy care unless coordinated with and transitioned to the referring physician or other healthcare provider (including providing any specific subject-area information needed for proper care following the therapy).**

- B7.2 The report of the therapy must be typed or computer generated and must accurately reflect the treatment performed. This must include, but is not limited to:**
- B7.2.1 Patient's name, gender, age (or date of birth) and identification number, if applicable**
  - B7.2.2 Requesting health care provider's name**
  - B7.2.3 Date of the examination**
  - B7.2.4 Date of the report**
  - B7.2.5 Patient's diagnosis including a summary of relevant history, physical findings, laboratory, and imaging data to confirm the diagnosis**
  - B7.2.6 Justification for therapy including alternatives, risks (including side effects), benefits, and expected outcomes (including likelihood of success)**
  - B7.2.7 That the patient was informed of the B7.2.6 above and consent obtained**
  - B7.2.8 When applicable, evidence that the patient is not pregnant**
  - B7.2.9 When applicable, that the patient is not breast feeding or has been properly counseled regarding risks of breast feeding (if any)**
  - B7.2.10 The specific radiopharmaceutical administered including identity, amount, and route and any other relevant procedures that were part of the therapy.**
  - B7.2.11 Post-therapy instructions given to the patient including planned follow-up (with whom, when, and where or how to arrange the appointment).**
  - B7.2.12 Any unusual occurrences or variations from clinic protocols**
  - B7.2.13 Identification of and manual or password protected electronic signature of the responsible physician. Stamped signatures or signing by non-physician staff is unacceptable. (The treating physician must be qualified as noted in B.7.1).**

**PART C**  
**QUALITY IMPROVEMENT**

**SECTION C1**  
**Quality Improvement Program**

**C1.1 The facility must conduct internal quality assessment and improvement at regular intervals that are appropriate for the facility's stated purpose.** Typically, assessments are an ongoing process with monthly or quarterly review of results.

**C1.1.1 The Medical Director and appropriate staff must review and maintain minutes or reports of quality improvement evaluations and document, as applicable, corrective measures taken.**

**C1.1.2 The performance of all staff physicians and nuclear medicine technologists must be assessed as part of the quality improvement program.**

**C1.1.3 The program must show evidence of improvement activities or, if an assessment confirms acceptable quality of a measure, the program must demonstrate improvement by selecting a new or an additional area for assessment.**

C1.1.4 The program should have pre-defined indicators of quality and pre-defined thresholds that indicate the need for corrective action. Reference or pooled data based criteria are desirable. An inter-facility comparison testing (phantom program) may be included as part of the quality assessment program.

**SECTION C2**  
**Quality Improvement Measures**

**C2.1 The quality improvement program must include at least one measure from each of the following three areas (note that some measures may assess multiple areas, depending on the design of the measure):**

**C2.1.1 Administrative Quality: to assess and improve the administrative quality of the facility's operation.**

Areas that may be assessed include but are not limited to:

- i. Appropriateness of procedures
- ii. Scheduling back logs
- iii. Patient wait times
- iv. Accuracy of patient information during scheduling
- v. Late reports
- vi. Time from completion of procedure to distribution of final report
- vii. Patient satisfaction
- viii. Referring physician satisfaction

**C2.1.2 Technical Quality: to assess and improve the technical quality of the images and procedures being performed.**

Areas that may be assessed include but are not limited to:

- i. Completeness of documentation
- ii. Image quality
- iii. Reproducibility of processed images and/or quantitative results
- iv. Image display/labeling
- v. Radiopharmaceutical administration errors
- vi. Radioactive spills
- vii. Pharmaceutical/radiopharmaceutical adverse effects documentation
- viii. Patient satisfaction

**C2.1.3 Physician Performance: to assess and improve the performance of physicians regarding the quality of medical practice (such as report accuracy, appropriateness of care, effectiveness of radionuclide therapies) and physician behaviors (communication and professionalism).**

Areas that may be assessed include but are not limited to:

- i. Interobserver agreement (peer review)
- ii. Correlation of interpretation with other diagnostic studies, pathology/surgical results and/or patient outcomes
- iii. Time from completion of procedure to distribution of final report
- iv. Referring physician satisfaction
- v. Patient satisfaction
- vi. Correlation of intended therapeutic effects with patient response to therapy

## SECTION C3

### Quality Improvement Meetings

- C3.1 All personnel assessed in the quality improvement program must participate in periodic facility meetings to review findings and determine actions for improvement of performance. At a minimum, these meetings must occur at least every six months.**
  
- C.3.2 All personnel must be included in periodic facility meetings to provide in-service education containing relevant topics.** Topics should include safety procedures, technical information, and improvements to be made based on quality assessments and other information.

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