



NUCLEAR/PET

The IAC Standards and Guidelines for Nuclear/PET Accreditation

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Introduction

The Intersocietal Accreditation Commission (IAC) accredits imaging facilities specific to nuclear cardiology, general nuclear medicine and positron emission tomography (PET). IAC accreditation is a means by which facilities can evaluate and demonstrate the level of patient care they provide.

A nuclear cardiology, general 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 facility utilizing the services of a mobile company 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.

The intent of the accreditation process is two-fold. It is designed to recognize facilities that provide quality Nuclear/PET services. It is also designed to be used as an educational tool to improve the overall quality of the facility.

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, myocardial sympathetic innervation imaging)
- cardiac positron emission tomography (PET)

The following are the specific areas of general nuclear medicine (other than cardiac) for which accreditation may be obtained:

- gastrointestinal system imaging
- central nervous system imaging
- endocrine system imaging
- endocrine system non-imaging (e.g., radioiodine uptake)
- musculoskeletal system imaging
- genitourinary system imaging
- pulmonary system imaging
- infection imaging
- tumor imaging
- hematopoietic, reticuloendothelial and lymphatic imaging
- nuclear medicine therapy
- other non-imaging (e.g., in vitro studies)

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

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

These accreditation Standards and Guidelines are the minimum standards for accreditation of Nuclear/PET facilities. Standards are the minimum requirements to which an accredited facility is held accountable. Guidelines are descriptions, examples or recommendations that elaborate on the Standards. *Guidelines are not required, but can assist with interpretation of the Standards.*

Standards are printed in regular typeface in outline form. *Guidelines are printed in italic typeface in narrative form.*

Standards that are highlighted are content changes that were made as part of the September 15, 2016 revision. These Standards will become effective on March 15, 2017. Facilities applying for accreditation after March 15, 2017 revision must comply with these new highlighted Standards.

In addition to all Standards listed below, the facility, including all staff, 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.

Part A:

Organization

Section 1A: Personnel and Supervision

STANDARD – Medical Director

1.1A 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.

1.1.1A Medical Director Required Training and Experience

The Medical Director must meet at least one of the following criteria:

- 1.1.1.1A Board certified (or Board eligible but within two years of finishing training) in cardiology and completion of a minimum of a four-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.
- 1.1.1.2A 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 800 nuclear cardiology studies. This requirement applies only to cardiologists who began their cardiology training before July 1995.
- 1.1.1.3A Certification in nuclear cardiology by the Certification Board of Nuclear Cardiology (CBNC).
- 1.1.1.4A Board certified (or Board eligible but within two years of finishing training) in nuclear medicine.
- 1.1.1.5A Board certified (or Board eligible but within two years of finishing training) in **diagnostic** radiology with at least four months of nuclear cardiology training.
- 1.1.1.6A Board certified (or Board eligible but within two years of finishing training) in **diagnostic** radiology with special competence in nuclear medicine.
- 1.1.1.7A Board certified (or Board eligible but within two years of finishing training) in **diagnostic** radiology and at least one year (full-time equivalent) of nuclear cardiology practice experience with independent interpretation of at least 800 nuclear cardiology studies.
- 1.1.1.8A Board certified (or Board eligible but within two years of finishing training) in **diagnostic** radiology with at least four months of nuclear medicine training with interpretation of at least 800 nuclear medicine procedures.
- 1.1.1.9A Board certified (or Board eligible but within two years of finishing training) in any other relevant medical specialty recognized by the American Board of Medical Specialties (ABMS), American Osteopathic Association (AOA), Royal College of Physicians and Surgeons of Canada or Le College des Medecins du Quebec and at least one year (full-time equivalent) of nuclear cardiology/nuclear medicine/PET practice experience with independent interpretation of at least 800 nuclear cardiology/nuclear

medicine and/or PET procedures. If performing nuclear medicine therapies, independent performance of a least 20 nuclear medicine therapies required.

- 1.1.1.10A If training before 1995, 10 years of nuclear cardiology, nuclear medicine and/or PET practice with independent interpretation of at least 800 nuclear cardiology, nuclear medicine and/or PET studies within the past 10 years of which 200 cases must have been interpreted in the past two years.

1.1.2A Medical Director Responsibilities

- 1.1.2.1A Responsible for all nuclear medicine services provided including quality control (QC), radiation safety, quality of care and appropriateness of care.

These responsibilities include but are not limited to:

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

Comment: The Medical Director must delegate, in writing, the review of policies/procedures/protocols to an appropriate designee, for areas in which the Medical Director does not have the education/training/experience. The designee must be a physician who meets the criteria outlined in 1.1.1A that is relevant to the delegated responsibility.

- ii. 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 compliance must be reviewed at least annually.

Comment: The Medical Director may delegate, in writing, the supervision of compliance with radiation safety standards to the Technical Director, Radiation Safety Officer or health physics consultant.

- iii. The Medical Director **must be a member of the facility and** provide the final interpretation/report of some nuclear medicine procedures for the facility.

Comment: The Medical Director may supervise the entire operation of the facility or delegate, in writing, specific operations but is responsible for assuring compliance of medical and technical staff to the Standards outlined in this document. Where the Medical Director is not the radiation safety officer, the Medical Director's responsibility regarding radiation safety is to assure compliance with the facility's radiation protection program, as implemented by the radiation safety officer.

1.1.3A Continuing Medical Education (CME) Requirements

- 1.1.3.1A The Medical Director must obtain at least 15 hours of AMA Category I 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, **general nuclear medicine, PET or interventions used during nuclear testing (such as stress testing) or content that is directly related to one of the IAC Nuclear/PET Standards. **This may include no more than five credits of MR and/or CT CME.** This does not include education primarily concerning echocardiography/ultrasound, cardiac catheterization, general medicine or the treatment of diseases unless directly related to the interpretation of nuclear imaging or radionuclide therapies.**

Comment: If the Medical Director has successfully attained ONE or more of the following within the three years prior to the application submission date, the CME requirement will be considered fulfilled: completion of an Accreditation Council for Graduate Medical Education (ACGME) approved relevant residency or fellowship; attaining initial certification by a relevant ABMS recognized board; attaining initial certification by the CBNC; or re-certification by the American Board of Nuclear Medicine (ABNM), American Board of Radiology (ABR) or CBNC.

- 1.1.3.2A Documentation of CME credits must be kept on file and available for inspection.
- 1.1.3.3A A maximum of five of the 15 required credits may come from MR and/or CT education or Certification Board of Cardiovascular Computed Tomography (CBCCT) certification/recertification.

(See Guidelines on Page 14 for further recommendations.)

STANDARD – Technical Director

1.2A A qualified Technical Director(s) is designated for the facility. The designated Technical Director must be a nuclear medicine technologist with the following qualifications:

1.2.1A Technical Director Required Training and Experience

The Technical Director must meet the following criteria:

1.2.1.1A All Technical Directors must possess an appropriate credential in nuclear medicine technology [Certified Nuclear Medicine Technologist (CNMT, NCT or PET) 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]. However, if the Technical Director was appointed prior to January 1, 2010, a state license to practice as a nuclear medicine technologist is also acceptable.

1.2.1.2A Current Basic Life Support (BLS) certification.

1.2.2A Technical Director Responsibilities

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

1.2.2.1A the day-to-day operations of the facility;

Comment: The Technical Director is generally a full-time position. If the Technical Director is not on-site full time, he/she must work a minimum of at least 20% of normal business hours each month in the facility AND an appropriately credentialed technologist must be appointed in the Technical Director's physical absence during normal business hours and report to the Technical Director.

i. The appointed technologist acting as Technical Director:

- may supervise and assist others in performing examinations;
- may oversee day-to-day activities;
- must communicate at least weekly with the Technical Director to maintain compliance with the IAC Nuclear/PET Standards.

- 1.2.2.2A the written delegation, as necessary, of specific responsibilities to the technical and/or ancillary staff;
- 1.2.2.3A verification and documentation of proper training and, at least annually, assessment of competence of technical staff and/or any ancillary staff who report to the Technical Director.

1.2.3A Continuing Education (CE) Requirements

- 1.2.3.1A The Technical Director must obtain at least 15 hours of accredited CE relevant to nuclear medicine, every three years. All CE hours must be approved CE (i.e., VOICE, ASRT, ACE, AMA Category I).

Comment: “Relevant” to nuclear medicine includes content that is directly related to the performance or interpretation of nuclear cardiology, **general nuclear medicine, PET** or interventions used during nuclear testing (such as stress testing) or content that is directly related to one of the IAC Nuclear/PET Standards. **This may include no more than five credits of MR and/or CT CME.** This does not include education primarily concerning echocardiography/ultrasound, cardiac catheterization, general medicine or the treatment of diseases unless directly related to the interpretation of nuclear imaging or radionuclide therapies.

Comment: If the Technical Director has successfully attained ONE of the following within the three years prior to the application submission date, the CE requirement will be considered fulfilled: completion of an accredited nuclear medicine training program; attainment of an appropriate technical credential in nuclear medicine; or attainment of advanced technical credential (**NCT, PET or Nuclear Medicine Advanced Associate [NMAA]**).

- 1.2.3.2A Documentation of CE credits must be kept on file and available for inspection.
- 1.2.3.3A **A maximum of five of the 15 required credits may come from MR and/or CT education or attainment of an advanced technical credential in MR and/or CT.**

(See Guidelines on Page 14 for further recommendations.)

STANDARD – Medical Staff

- 1.3A 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.

1.3.1A Medical Staff Required Training and Experience

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

- 1.3.1.1A Board certified (or Board eligible but within two years of finishing training) in cardiology and completion of a minimum of a four-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.
- 1.3.1.2A 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 800 nuclear cardiology studies. This requirement applies only to cardiologists who began their cardiology training before July 1995.

- 1.3.1.3A Certification in nuclear cardiology by the Certification Board of Nuclear Cardiology (CBNC).
- 1.3.1.4A Board certified (or Board eligible but within two years of finishing training) in nuclear medicine.
- 1.3.1.5A Board certified (or Board eligible but within two years of finishing training) in **diagnostic** radiology with at least four months of nuclear cardiology training.
- 1.3.1.6A Board certified (or Board eligible but within two years of finishing training) in **diagnostic** radiology with special competence in nuclear medicine.
- 1.3.1.7A Board certified (or Board eligible but within two years of finishing training) in **diagnostic** radiology and at least one year (full-time equivalent) of nuclear cardiology practice experience with independent interpretation of at least 800 nuclear cardiology studies.
- 1.3.1.8A Board certified (or Board eligible but within two years of finishing training) in **diagnostic** radiology with at least four months of nuclear medicine training with interpretation of at least 800 nuclear medicine procedures.
- 1.3.1.9A Board certified (or Board eligible but within two years of finishing training) in any other relevant medical specialty recognized by the American Board of Medical Specialties, American Osteopathic Association, Royal College of Physicians and Surgeons of Canada or Le College des Mediciens du Quebec and at least one year (full-time equivalent) of nuclear cardiology/nuclear medicine/PET practice experience with independent interpretation of at least 800 nuclear cardiology/nuclear medicine and/or PET procedures. If performing nuclear medicine therapies, independent performance of a least 20 nuclear medicine therapies required.
- 1.3.1.10A If training before 1995, 10 years of nuclear cardiology, nuclear medicine and/or PET practice with independent interpretation of at least 800 nuclear cardiology, nuclear medicine and/or PET studies within the past 10 years of which 200 cases must have been interpreted in the past two years.

1.3.2A Interpreting Medical Staff Responsibilities

Medical staff responsibilities include but are not limited to:

- 1.3.2.1A The interpreting medical staff must provide the final interpretation/report of the nuclear medicine procedures.

1.3.3A Continuing Medical Education (CME) Requirements

- 1.3.3.1A 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, **general nuclear medicine, PET** or interventions used during nuclear testing (such as stress testing) or content that is directly related to one of the IAC Nuclear/PET Standards. **This may include no more than five credits of MR and/or CT CME.** This does not include education primarily concerning echocardiography/ultrasound, cardiac catheterization, general medicine or the treatment of diseases unless directly related to the interpretation of nuclear imaging or radionuclide therapies.

Comment: If the medical staff member has successfully attained ONE or more of

the following within the three years prior to the application submission date, the CME requirement will be considered fulfilled: completion of an ACGME approved relevant residency or fellowship, attaining initial certification by a relevant ABMS recognized board, attaining initial certification by the CBNC or re-certification by the American Board of Nuclear Medicine, American Board of Radiology or CBNC.

1.3.3.2A Documentation of CME credits must be kept on file and available for inspection.

1.3.3.3A A maximum of five of the 15 required credits may come from MR and/or CT education or Certification Board of Cardiovascular Computed Tomography (CBCCT) certification/recertification.

(See Guidelines on Page 14 for further recommendations.)

STANDARD – Technical Staff

1.4A All **technical staff** must be nuclear medicine technologists who have the following qualifications:

1.4.1A **Technical Staff** Required Training and Experience

The technical staff must meet the following criteria:

1.4.1.1A An appropriate credential in nuclear medicine technology (i.e., certification [Certified Nuclear Medicine Technologist (CNMT, NCT or PET) 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).

1.4.1.2A Current Basic Life Support (BLS) certification.

1.4.2A **Technical Staff** Responsibilities

Technical staff responsibilities include but are not limited to:

1.4.2.1A The **technical staff** must report to the Technical Director. The technical staff are responsible for image acquisition and the performance of procedures and other duties, as assigned.

1.4.3A Continuing Education (CE) Requirements

1.4.3.1A The **technical staff** must obtain at least 15 hours of accredited CE relevant to nuclear medicine, every three years. All CE hours must be approved CE (i.e., VOICE, ASRT, ACE, AMA Category I).

Comment: “Relevant” to nuclear medicine includes content that is directly related to the performance or interpretation of nuclear cardiology, **general nuclear medicine, PET**, or interventions used during nuclear testing (such as stress testing) or content that is directly related to one of the IAC Nuclear/PET Standards. **This may include no more than five credits of MR and/or CT CE.** This does not include education primarily concerning echocardiography/ultrasound, cardiac catheterization, general medicine or the treatment of diseases unless directly related to the interpretation of nuclear imaging or radionuclide therapies.

Comment: If the technical staff member has successfully attained ONE of the following within the three years prior to the application submission date, the CE

requirement will be considered fulfilled: completion of an accredited nuclear medicine training program, attainment of an appropriate technical credential in nuclear medicine or attainment of advanced technical credential (NCT, PET or Nuclear Medicine Advanced Associate [NMAA]).

1.4.3.2A Documentation of CE credits must be kept on file and available for inspection.

1.4.3.3A A maximum of five of the 15 required credits may come from MR and/or CT education or attainment of an advanced technical credential in MR and/or CT.

(See Guidelines on Page 14 for further recommendations.)

STANDARD – Direct Patient Care Personnel

1.5A All direct patient care personnel must meet the following qualifications:

1.5.1A All personnel directly supervising stress procedures must have appropriate training/experience. 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.

1.5.1.1A If a non-physician (e.g., properly trained nurse, physician assistant, nurse practitioner, exercise physiologist) practicing under the physician's license is supervising the stress test, the facility or Medical Director must document appropriate training and competence as outlined in the *American College of Cardiology/American Heart Association Clinical Competence Statement on Stress Testing and the AHA Scientific Statement: Supervision of Exercise Testing by Nonphysicians* (See [Bibliography](#)).

Comment: See [Appendix A](#) for specific training and competence requirements.

1.5.1.2A If a non-physician is supervising the stress test, a physician must be in the immediate vicinity on the premises and available for emergencies.⁵

1.5.2A A minimum of two qualified people are required to be in attendance at the time of radionuclide injection during stress testing (e.g., person supervising the stress test and person authorized to inject the radionuclide). It is preferable that two people be in attendance during the entire stress test.

1.5.3A Basic Life Support – All personnel, including physicians, directly supervising stress procedures must have appropriate training/experience and must be certified in basic life support.

(See Guidelines on Page 14 for further recommendations.)

1.5.4A Advanced Cardiac Life Support (ACLS) – There must be ACLS-certified personnel on-site and immediately available during cardiac stress procedures.

1.5.5A 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).

(See Guidelines on Page 14 for further recommendations.)

STANDARD – Physician and Nuclear Medicine Technologist Trainees

1.6A Physicians and nuclear medicine technologists in training must not compromise patient care.

1.6.1A Physician and Nuclear Medicine Technologist Trainee Supervision

1.6.1.1A 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.

(See Guidelines on Page 14 for further recommendations.)

STANDARD – Nuclear Medicine Assistants

1.7A 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.

1.7.1A 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.

1.7.2A There must be a certified/licensed nuclear medicine technologist immediately available in the facility 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).

1.7.3A A nuclear medicine assistant must not perform therapeutic nuclear medicine procedures.

(See Guidelines on Page 14 for further recommendations.)

STANDARD – Ancillary Personnel

1.8A Ancillary personnel necessary for safe and effective patient care must be available.

1.8.1A 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.

1.8.1.1A Ancillary personnel may consist of:

- i. clerical and administrative assistants;
- ii. physicist or consulting physicist;
- iii. radiopharmacist;
- iv. computer support staff; and/or
- v. other support personnel.

1.8.1.2A Supervision:

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

[\(See Guidelines on Page 14 for further recommendations.\)](#)

Section 1A: Personnel and Supervision *Guidelines*

1.1A, 1.2A, 1.3A, 1.4A, 1.5A, 1.6A, 1.7A and 1.8A - *Duties and responsibilities: The facility should have written descriptions of the duties and responsibilities, not outlined in the Standards, for each staff position*

1.3A *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.*

1.5.3A *Basic Life Support – All personnel involved in direct patient care during all nuclear medicine and PET procedures should be certified in basic life support.*

Section 2A: Facility

STANDARD – Examination Areas

- 2.1A 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:
- 2.1.1A waiting, reception and patient/staff bathrooms;
(See Guidelines on Page 16 for further recommendations.)
 - 2.1.2A radioactive materials use and storage areas;
 - 2.1.3A 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;
 - 2.1.4A patient education, consultation and examination areas with accessible hand washing for staff;
 - 2.1.5A performance of stress procedures within appropriate proximity of the imaging area including adequate space for performing resuscitation in case of emergency;
 - 2.1.6A adequate space, facility configuration and doorways for the emergency transport of patients from patient care areas and for emergency exit of staff;
 - 2.1.7A therapeutic procedures areas (if applicable);
 - 2.1.8A 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.

STANDARD – Interpretation Areas

- 2.2A Adequate designated space must be provided for the interpretation of exam results and preparation of reports.

STANDARD – Storage

- 2.3A Adequate space **that ensures confidentiality and security** must be provided for:
- 2.3.1A patient records, reports and digital data storage areas;
 - 2.3.2A administration records and support areas;
 - 2.3.3A equipment/supply storage areas.

Section 2A: Facility Guidelines

2.1.1A *It is preferable that separate rest room facilities be provided for patients and staff.*

Section 3A: Examination Reports and Records

STANDARD – Records

- 3.1A 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.
 - 3.1.1A Any retained hard copy images must be of high quality and reflect the findings described in the final interpretation.
 - 3.1.2A Technical data that are not included as part of the final report (e.g., worksheets, calculations) must be maintained as part of the facility records. The specific imaging and processing parameters used should be retrievable for each clinical study.
 - 3.1.3A Data from non-imaging studies (e.g., thyroid uptake) must be maintained as part of the facility records, if not included in the final report.
 - 3.1.4A 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.

(See Guidelines on Page 23 for further recommendations.)

STANDARD – Image Interpretation and Reporting

- 3.2A Examinations must be interpreted and a final report provided by the Medical Director or qualified members of the medical staff as defined in 1.1A and 1.3A.
 - 3.2.1A All dynamic studies (e.g., gated, flow, etc.) must be interpreted on a computer. For SPECT studies, raw data images must be reviewed.
(See Guidelines on Page 23 for further recommendations.)
 - 3.2.2A An interpretation must be available within one working day of the examination. An interpretation may be in the form of paper, digital storage or accessible voice system.
 - 3.2.3A Results of examinations with critical findings must be communicated to the referring physicians as quickly as clinically indicated. A record of the communication must be maintained.
 - 3.2.4A The final report must be reviewed, signed and dated manually or electronically by the interpreting qualified member of the medical staff. Stamped signatures or signing by non-physician staff is unacceptable. In the unusual circumstance that the interpreting physician is not available, another qualified member of the medical staff may sign for them, if they choose to take such responsibility.
 - 3.2.4.1A If the report is signed manually, the date signed must also be manually recorded with the signature.
 - 3.2.4.2A If the report is signed electronically, the signatures must be password protected with sign off only by an interpreting physician. The signature must indicate it is electronically recorded and be electronically date/time stamped.
 - 3.2.5A The final signed report must be transmitted to the referring health care provider within two working days.
 - 3.2.6A There must be a system for identification and retrieval of a patient's prior similar studies for comparison.

- 3.3A Final interpretation of examinations must be based on quality images/data as well as relevant clinical information. This includes, but is not limited to:
- 3.3.1A relevant clinical information and clinical indication/question;
 - 3.3.2A relevant patient response to exercise or pharmacologic stress, including but not limited to symptoms, rest/stress heart rate, rest/stress blood pressure and rest/stress ECG findings. This information must be included in the final report as noted in Standard 3.4A.
 - 3.3.3A relevant patient response to other pharmacologic intervention (e.g., Lasix, morphine, ACE inhibitors, sincalide);
 - 3.3.4A acceptable quality radionuclide images and/or derived quantitative data including acceptable:
 - 3.3.4.1A count density;
 - 3.3.4.2A processing/filtering;
 - 3.3.4.3A 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)];
 - 3.3.4.4A lack of artifacts (e.g., patient motion, attenuation, subdiaphragmatic activity).
 - 3.3.5A other relevant imaging modalities (e.g., echo/ultrasound, CT, MRI, etc.), if available;
 - 3.3.6A comparison with prior nuclear medicine examinations, when available;
 - 3.3.7A the integration of imaging and non-imaging information into a final impression that resolves any potential inconsistencies.
- 3.4A The final report must be typed or computer generated and must accurately reflect the content and results of the study. For nuclear cardiology studies, a standardized report is recommended (e.g., *The American Society of Nuclear Cardiology Guideline on Standardized Reporting of Radionuclide Myocardial Perfusion and Function*). This includes:
- 3.4.1A identification of the name, address and phone number of the facility;
 - 3.4.2A name of the procedure [type of examination(s)];
 - 3.4.3A patient information:
 - 3.4.3.1A patient's first and last name;
 - 3.4.3.2A gender;
 - 3.4.3.3A date of birth or age;
 - 3.4.3.4A height and weight or BMI.
 - 3.4.4A requesting health care provider's name;
 - 3.4.5A interpreting physician name;
 - 3.4.6A date of the examination;
 - 3.4.7A clinical indications and pertinent history leading to the performance of the examination

- 3.4.8A an adequate description of the procedure, as performed. **The elements of the procedure description include:**
- 3.4.8.1A technique (e.g., rest/stress vs. stress/rest, one-day vs. two-day, gated, first pass, red cell labeling method, 3-phase, flow, blood pool, attenuation correction method, etc.);
- 3.4.8.2A pertinent laboratory results (e.g., blood glucose level for F18-FDG imaging, TSH prior to I131 whole body imaging);
- 3.4.8.3A administered radiopharmaceutical:
- i. specific identity – radionuclide and chemical form (e.g., Tc99m sestamibi, Tc99m pertechnetate, I131 sodium iodide);
 - ii. exact amount (i.e., XX.X mCi);
 - iii. route of administration (e.g., intravenous, oral, inhaled, subdermal);
 - iv. uptake time (e.g., F18-FDG time from injection to imaging, I123 or I131 oral dose to thyroid uptake measurement).
- 3.4.8.4A administered pharmaceutical (non-radioactive):
- i. specific identity (e.g., regadenoson, sincalide, furosemide, sedation);
 - ii. exact amount;
 - iii. route of administration (e.g., intravenous, oral, inhaled, subdermal);
 - iv. time of pharmaceutical administration relative to tracer administration;
 - v. time over which dose administered (e.g., regadenoson over 10-15 seconds, sincalide over 60 minutes).
- 3.4.8.5A anatomic area(s) imaged (e.g., kidney, abdomen, skull base to mid-thigh);
- 3.4.8.6A views obtained (e.g., planar, anterior, posterior, whole body, SPECT, SPECT/CT);
- 3.4.8.7A CT procedure, if applicable:
- i. CT technique (e.g., anatomic localization and attenuation correction vs. diagnostic intent);
 - ii. administered contrast;
 - iii. identity (not required for GI contrast);
 - iv. volume (not required for GI contrast);
 - v. route of administration (e.g., oral, intravenous);
 - vi. adverse reaction to contrast material (e.g., signs, symptoms and treatment), if applicable.
- 3.4.9A description of the results of the examination including pertinent positive and negative findings including:
- 3.4.9.1A **Nuclear Cardiology (Myocardial Perfusion Imaging including SPECT and PET)**
- i. description of the stress test (exercise and/or pharmacologic) procedure, if performed, and results including:
 - stress protocol (e.g., Bruce, modified Bruce, regadenoson);

- stress duration (e.g., total exercise/infusion time);
- percent of the maximum predicted heart rate or pressure-rate product;
- reason for termination of stress;
- rest and peak stress heart rate;
- rest and peak stress blood pressure;
- stress symptoms or lack thereof;
- rest and peak stress ECG finding.

Comment: Stress protocol, duration, percent of maximum predicted heart rate and reason for termination may be reported in a separate stress test report as long as the stress and imaging reports reference each other. Heart rate, blood pressure, symptoms and ECG findings must be documented in the imaging report for both exercise and pharmacologic stress.

- ii. description of the image quality (e.g., excellent, good, poor, uninterpretable or other) including identification of suboptimal or limited studies (e.g., soft tissue attenuation [breast or diaphragm], patient/organ motion, activity in non-target organs [subdiaphragmatic activity] or other artifacts);
- iii. deviation from facility's protocol, if any;
- iv. description of image results including:
 - perfusion results:
 - size/extent [e.g., small/medium/large or semi quantitatively (small (<10% of the left ventricle (LV))/medium (10-20% of the LV)/large (>20% of the LV)];
 - severity/intensity (e.g., mild, moderate, severe);
 - location (e.g., 17-segment model);
 - type (e.g., reversible, fixed, mixed).
 - function results:
 - quantitative left ventricular ejection fraction;
 - overall left ventricular function (e.g., normal, reduced [mild, moderate or severe] or hyperdynamic);
 - regional wall motion abnormalities (e.g., normal, hypokinesis [mild, moderate, severe], akinesis or dyskinesis).

Comment: All perfusion defects must be described. When a defect is due to attenuation/artifact, this must also be identified as such.

- v. comparison to previous and/or other imaging or non-imaging studies (e.g., x-ray, ultrasound, laboratory results) as appropriate. It is preferable that "no previous studies" be stated to document there was none.

(See Guidelines on Page 23 for further recommendations.)

3.4.9.2A General Nuclear Medicine

- i. description of suboptimal or limited studies (e.g., artifacts, dose infiltration, poor count density, patient motion, metal attenuation or urine contamination);
- ii. deviation from facility's protocol, if any;
- iii. description of the image results including:

- pertinent positive findings (e.g., intensity/size/location, inhomogeneity, pattern, change over time);
 - pertinent negative findings;
 - quantitative data with normal values;
 - correlative imaging results, if applicable (e.g., CT portion of SPECT/CT).
- iv. description of non-imaging data with normal values (e.g., radioiodine uptake);
- v. comparison to previous and/or other imaging or non-imaging studies (e.g., x-ray, ultrasound, laboratory results), as appropriate. It is preferable that “no previous studies” be stated to document that there was none.

3.4.9.3A PET or PET/CT

- i. description of suboptimal or limited studies (e.g., artifacts, dose infiltration, poor count density, patient motion, metal, urine contamination, excessive muscle uptake or misregistration);
- ii. deviation from facility’s protocol, if any;
- iii. description of the image results including:
- pertinent positive findings (e.g., intensity/size/location, inhomogeneity, pattern, change over time);
 - pertinent negative findings;
 - quantitative data with reference values (e.g., SUV compared with liver activity and/or mediastinal activity; size measurement of nodules/masses; and density measurements from CT);
 - correlative imaging results, if applicable (e.g., CT portion of PET/CT).
- iv. comparison to previous and/or other imaging or non-imaging studies (e.g., x-ray, ultrasound, laboratory results), as appropriate. It is preferable that “no previous studies” be stated to document that there was none.

3.4.10A a succinct impression, which clearly communicates the results of the study and answers the clinical question that was the indication for the examination. This must include an interpretation of significant abnormalities and/or indicate when results are normal. This must also include a clear summary of any significant changes from prior studies. This also includes recommendations for additional studies based on results of the procedure being reported, as appropriate.

3.4.10.1A Nuclear Cardiology Myocardial Perfusion Imaging (including SPECT and PET)

- i. summary of perfusion (e.g., normal, equivocal, abnormal: ischemia or infarction);
- ii. summary of function (e.g., normal, equivocal, abnormal).

Comment: Impression should resolve any inconsistencies or discrepancies (e.g., abnormal stress test with normal myocardial perfusion images).

3.4.10.2A General Nuclear Medicine

- i. diagnosis or summary list of differential diagnoses with likelihood.

3.4.10.3A PET or PET/CT

- i. diagnosis or summary list of differential diagnoses with likelihood;
- ii. for oncologic studies, response assessment (e.g., complete response, partial response, stable disease, progressive disease). Both the metabolic response and anatomic response may be reported.

3.4.11A Report finalization to include:

3.4.11.1A identification and manual or electronic signature (password protected) of the interpreting physician as described in Standard 3.2.4A;

3.4.11.2A date report finalized and signed by the interpreting physician;

3.4.11.3A if the report is amended, the original report content, author and date of signature must be retained. The content of the amendment, author and date of amendment must be clearly recorded.

(See Guidelines on Page 23 for further recommendations.)

Section 3A: Examination Reports and Records

Guidelines

3.1A *It is strongly recommended that raw digital image data be retained for a minimum of three years.*

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 (e.g., SMPTE or similar patterns).

3.2.1A *Although static images may be interpreted from film or other hard copy, it is preferable that they be interpreted on the computer.*

3.4.9.1A *The description should use standard nomenclature such as the 17-segment cardiac model for myocardial perfusion imaging.*

Reporting of normal values for left ventricular ejection fraction is strongly recommended.

3.4A *The final report should include:*

- *Unique patient identifier (e.g., unique identification number or sufficient demographic information to identify patient)¹⁶*

For nuclear cardiology studies, a standardized report is recommended (e.g., The American Society of Nuclear Cardiology Guidelines on Standardized Reporting of Radionuclide Myocardial Perfusion and Function).

Section 4A: Facility Safety

STANDARD – Patient and Facility Safety

4.1A Patient and employee safety is ensured by written protocols. Written protocols must be in place for the following:

Comment: 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.

- 4.1.1A **Patient Identification Policy** – For all clinical procedures there must be a process that assures accurate patient identification immediately prior to administration of radiopharmaceutical, pharmaceuticals and/or initiating the test.
- 4.1.1.1A The identification procedure must reliably identify the individual as the correct person for whom the scan or therapy is intended and to match the correct scan or therapy to that individual.
- 4.1.1.2A Two independent patient-specific identifiers must be used. Examples of patient-specific identifiers include the patient’s identification bracelet, hospital identification card, driver’s license or asking the patient to state his or her full name or birth date, avoiding procedures in which the patient can answer “yes” or “no.”
- 4.1.1.3A When a test requires the collection and/or administration of blood or blood products, two independent patient specific identifiers must be used to label the collection containers.
- 4.1.1.4A For therapy procedures, immediately prior to dosing, two members of the medical and/or technical staff must verify the patient’s identity with two identifiers (see Standard 4.1.1.2A).
- 4.1.2A **Pregnancy Screening Policy** – For all clinical procedures there must be a process that assures that patients who could be pregnant are identified. This must be documented and 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 ¹³¹I-sodium iodide for thyroid carcinoma, the pregnancy screening protocol must assure that patients who are pregnant are not administered the radiopharmaceutical.
- 4.1.2.1A 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.
- 4.1.2.2A If it is determined that the study will not be performed, then the patient must receive options for alternative care.
- 4.1.2.3A 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.
- 4.1.2.4A 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.

- 4.1.2.5A **Warning signage must be present to help prevent inadvertent administration of radiopharmaceuticals to patients who are pregnant. At a minimum, these must be easily seen by the patient (and in language(s) understandable to most patients) in the area(s) where initial radiopharmaceutical administration is performed.**
- 4.1.3A Breast-feeding Screening Policy – For all clinical procedures there must be a process that assures that patients who are breast-feeding are identified. This must be documented and must 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.
- 4.1.3.1A For nuclear medicine therapies or diagnostic procedures for thyroid carcinoma using 131I-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 must also be given the opportunity to stop lactating for an appropriate time (usually at least three weeks) prior to receiving 131I therapy to reduce the radiation to the breasts.
- 4.1.3.2A Warning signage must be present to help prevent inadvertent administration of radiopharmaceuticals to patients who are 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.
- 4.1.4A Informed Consent Policy – 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.
- 4.1.5A Request for Services Policy – 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.
- 4.1.6A Infection Control/Communicable Diseases Policy – There must be a policy to ensure appropriate precautions to protect both patients and facility personnel are taken, in accordance with universal precautions, when handling toxic, 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.
- 4.1.7A Hazardous Materials Policy – There must be a policy to ensure appropriate precautions to be taken when using and storing flammable and/or toxic materials.
- 4.1.8A Medical Emergencies Policy – There must be written plan **for responding to patient medical emergencies, which includes an outline of staff responsibilities. Each staff member must be familiar with his/her role in the plan. The plan should be appropriate for the risks of the procedures performed by the facility.**
- 4.1.9A Handling of Non-Radioactive Pharmaceuticals Policy
- 4.1.9.1A Pharmaceuticals must be properly stored. Controlled substances kept on-site (e.g., such as in a crash cart) must be secured to **limit access only to authorized personnel.**

- 4.1.9.2A Pharmaceuticals must be properly prepared.
- 4.1.9.3A Patient dosages must be determined using standardized protocols (approved by the Medical Director or appropriate designee [see Standard 2.4.1.3B]) or by individually written prescriptions. For each patient dose, the prescribing physician must be clearly identifiable.
- 4.1.9.4A Patient identity must be verified prior to pharmaceutical administration (see Standard 4.1.1.1A).
- 4.1.9.5A The identity and dosage of each pharmaceutical must be verified immediately prior to administration by the prescribed route.
- 4.1.9.6A The expiration date of the pharmaceutical must be checked and the dosage administered prior to the expiration.
- 4.1.9.7A There must be clear documentation of the administration of pharmaceuticals (substance, amount, route, site, time and identity of person administering).
- 4.1.10A Drug Administration Errors Policy – Records of medication (non-radioactive) administration errors must be maintained. Events must be reported as required. Documentation of actions taken in response to identified problems must be available.
- 4.1.11A Adverse Drug Reactions Policy – There must be a procedure for documenting and reporting adverse reactions (e.g., unexpected, unintended, undesired or excessive response) to medications.

(See Guidelines on Page 31 for further recommendations.)

STANDARD – Radiation Safety and Radioactive Materials Handling Protocols

- 4.2A There must be written radiation safety and radioactive materials handling protocols.
 - 4.2.1A The Radiation Protection Program content and implementation must be reviewed at least annually.
 - 4.2.1.1A The annual review must include protocol evaluation to minimize the effective radiation dose while producing interpretable, diagnostic quality images.
 - 4.2.1.2A Records of this review must include program changes, noted deficiencies and actions taken (or a statement that none is needed). This must be signed/initialed and dated by the Medical Director or an appropriate designee.

Comment: Records must also include justification of any administered radiopharmaceutical dose exceeding standard protocol for adults.
 - 4.2.2A There must be written designation of a Radiation Safety Officer. This is generally found on the radioactive materials license.
 - 4.2.3A Designation of who may handle/administer radionuclides (i.e., list of authorized user physicians, nuclear medicine technologists, trained nurses and/or others who are properly trained and approved, as appropriate).
- 4.3A Facility operations must comply 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.

4.4A Radiation safety protocols must address the following topics:

4.4.1A General Radioactive Materials Handling and Radiation Safety (i.e., Safe Use and Handling of Radioactive Materials)

4.4.1.1A Provision for a safe working environment, including an ALARA (as low as reasonably achievable) radiation exposure policy (for workers and general public).

4.4.1.2A The use of signage for radioactive materials use and storage areas, as required by applicable regulations.

4.4.1.3A Monitoring and reporting of excessive radiation levels to the general public. Including method of monitoring, method of calculation, trigger levels and reporting requirements.

4.4.1.4A 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.

Comment: Individuals who become authorized users during their tenure on staff must receive initial and annual training.

4.4.1.5A 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.

- i. Personnel dosimeters that require processing must be processed by a **National Voluntary Laboratory Accreditation Program (NVLAP)**-approved and accredited dosimetry processor.
- ii. **Employees who are monitored must be advised of their dose annually if their occupational dose exceeds one millisievert (100 millirem) TEDE or one millisievert to any organ or tissue.**
- iii. Exposure records must be easily retrievable and made available to the employee.
- iv. 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 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).

4.4.1.6A Information for employees, who are or may become pregnant, regarding their responsibility to voluntarily declare the pregnancy to management and the facility’s plan for addressing the employee’s radiation safety needs.

4.4.1.7A Proper use of shielding, radiation protection devices (e.g., syringe shields, glass shields, etc.) and protective clothing (e.g., facility coats) as well as refraining from eating or drinking in radiation use areas.

4.4.1.8A Each syringe and vial that contains a radiopharmaceutical must be labeled to identify the radionuclide and quantity of radioactivity at a specified date and time. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

- 4.4.1.9A Spill confinement/decontamination procedures include guidelines posted in the facility (with the radiation safety officer's phone number for work and after hours contact) and documentation requirements for reporting spills/decontamination. The procedures must include instructions for the reporting, documentation and possible investigation of all spills.
- 4.4.1.10A Proper use of radiation monitoring devices.
- 4.4.1.11A Periodic area surveys (particularly dose preparation areas) and wipe tests including tolerance limits and response to trigger levels.
- Comment: 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 (e.g., training sites), more frequent monitoring may be appropriate. The facility protocol must document the chosen frequency.
- i. For sites performing nuclear medicine procedures requiring a written directive (therapies or procedures using dosages greater than 30 microcuries of ¹³¹I-sodium iodide), area surveys must be performed daily in areas of dosage preparation and administration.
- 4.4.1.12A Sealed source inventory and wipe/leak testing protocol and documentation including:
- i. frequency;
- ii. radionuclide identity;
- iii. model and serial number, if assigned;
- iv. activity, date and name of the person performing the inventory;
- v. wipe/leak test.
- The location of the source at the time of the inventory and the results of the wipe/leak test must be documented.
 - The frequency of the sealed source wipe/leak test is a minimum of every six months.
- 4.4.1.13A Protocol for reporting theft or loss of radioactive materials based on types and amounts of materials and the risk to the public. This should include instruction for notification of the proper agencies or individuals as well as the information to be reported.
- 4.4.1.14A 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).
- 4.4.1.15A As needed, instruction of patients, family members and hospital staff (e.g., nursing personnel) regarding radiation precautions for all therapeutic procedures and/or when appropriate for diagnostic procedures.
- 4.4.1.16A 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 ¹³¹I-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 must be identified.

4.4.2A Receipt of Radioactive Materials

- 4.4.2.1A designation of a specific secured area for placing shipments of radionuclides;
- 4.4.2.2A recording of receipt of all shipments of radionuclides;
- 4.4.2.3A survey of shipments of radionuclides, prior to opening, including tolerance limits and response to triggers (including proper notification if damage or leak).

4.4.3A All facilities compounding radiopharmaceuticals must be aware of and in compliance with the guidelines of the United States Pharmacopeia (USP) Chapter 797.

4.4.4A Preparation of Radiopharmaceuticals (as applicable)

Comment: If only unit doses are used, no protocols are needed since this is done by supplier.

- 4.4.4.1A assay of generator eluate for total activity;
- 4.4.4.2A assay of generator eluate for breakthrough of parent radionuclide;
- 4.4.4.3A preparation of radiopharmaceuticals according to product insert or other written protocol;
- 4.4.4.4A verification of radiochemical purity of radiopharmaceuticals;
- 4.4.4.5A documentation of lot or batch numbers of components used in radiopharmaceutical preparation;
- 4.4.4.6A verification of pH of radiopharmaceutical preparations when appropriate;
- 4.4.4.7A performance of sterility testing on radiopharmaceuticals prepared using non-commercial kits;
- 4.4.4.8A performance of endotoxin testing on radiopharmaceuticals prepared using non-commercial kits;
- 4.4.4.9A proper storage of kits and prepared radiopharmaceuticals.

4.4.5A Administration of Radiopharmaceuticals to Patients

- 4.4.5.1A Patient dosages must be determined using standardized protocols (approved by the Medical Director or an appropriate designee [see Standard 2.4.1.3B]) or by individually written prescriptions. For each patient dose, the prescribing physician must be an authorized user for the specific radioisotope and amount.
 - i. Administered radiopharmaceuticals must use the lowest radiation dose necessary to acquire a diagnostic quality image.
 - ii. The system for adjusting radiopharmaceutical dosages by weight or appropriate adjustment in imaging acquisition parameters to compensate for patient size/weight must be documented. If adjusting radiopharmaceutical dosages, this must be signed by the Medical Director or a designated authorized user. An onsite dose calibrator may be helpful for dose adjustment based on the patient's weight.
 - iii. There must be 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).

- 4.4.5.2A Assay of patient dosages of radiopharmaceuticals (using a dose calibrator) on-site prior to administration.
 - i. Alternatively, for sites using unit doses, where permitted, the dosages may be determined based on decay correction of the unit dose.
 - ii. 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).
- 4.4.5.3A Recording of specific patient dosages (as determined by methods noted in Standard 4.4.5.1A) prior to administration.
- 4.4.5.4A Verification of patient identity prior to radiopharmaceutical administration as well as pregnancy/breast-feeding status, as described in Standard 4.1.3A.
- 4.4.5.5A Verification of the radiopharmaceutical identity and dosage immediately prior to administration by the prescribed route.
- 4.4.5.6A Verification of the expiration date/time of the radiopharmaceutical and assurance it is administered prior to expiration.
- 4.4.5.7A Clear documentation of the administration of radiopharmaceuticals (substance, amount, route, site, date, time, identity of person administering).
- 4.4.6A Records of radioactive materials administration errors must be maintained for both reportable and non-reportable errors. Events must be reported as required. Actions taken in response to identified problems must be available.
- 4.4.7A Adverse Radiopharmaceutical Reactions – There must be a procedure for documentation and reporting adverse reactions (e.g., unexpected, unintended, undesired or excessive response) to radiopharmaceuticals.
- 4.5A Radioactive Materials Storage and Disposal
 - 4.5.1A Radioactive trash (wipes, syringes, alcohol swabs, etc.) is kept separate from normal trash, stored and appropriately discarded.
 - 4.5.2A Security (e.g., locking) of areas containing radioactive materials (including hot laboratory, other radioactive use and storage/decay areas) when not under direct supervision of clinic personnel must ensure that non-authorized personnel (including visitors, patients and non-authorized staff) cannot access any radioactive materials.
 - 4.5.3A 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 4A: Facility Safety *Guidelines*

4.1A *Written protocols should be in place for the following:*

Safety/Security for Staff and Patients – There should 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.

Special Needs Patient Care – Personnel should be trained to deal with patients with language barriers, physical disabilities, serious illness or those unable to cooperate.

Sample documents for policies and protocols listed in Section 4A are available on the IAC Nuclear/PET website at intersocietal.org/nuclear/seeking/sample_documents.htm.

Section 5A: Administrative

STANDARD – Patient Confidentiality

- 5.1A All patient records are maintained confidentially. Responsibility for patient confidentiality extends to all staff including trainees and must be HIPAA compliant.

STANDARD – Patient or Other Customer Complaints

- 5.2A There must be a policy in place outlining the process for patients or other customers to issue a complaint/grievance in reference to the care/services they received at the facility and how the facility handles complaints/grievances.

STANDARD – Primary Source Verification

- 5.3A There must be a policy in place identifying how the facility verifies the medical education, training, appropriate licenses and certifications of all physicians as well as, the certification and training of all technical staff members and any other direct patient care providers.

Section 5A: Administrative *Guidelines*

Sample documents are available for each of the required policies listed in Section 5A on the IAC Nuclear/PET website at intersocietal.org/nuclear/seeking/sample_adminprotocols.htm.

Section 6A: Multiple Sites (Fixed and/or Mobile)

STANDARD – Multiple Sites

6.1A When procedures are performed at more than one physical facility, the facility may be eligible to apply for a single accreditation as a multiple site facility if the following criteria are met:

- 6.1.1A All facilities have the same Medical Director and Technical Director.
- 6.1.2A Identical clinical, administrative and radiation safety procedures are used at all sites (with variance only for differences in equipment and physical facilities).
- 6.1.3A The Quality Improvement (QI) Program must include all sites.
- 6.1.4A Staff at all sites must be included in periodic staff meetings (e.g., for education, QI, etc.).
- 6.1.5A The Medical and Technical Director must assure that they have adequate contact and supervision with each site including periodic observation of operations.

Comment: Supervision by the Technical Director may be accomplished by one or more of the following:

- 6.1.5.1A The Technical Director works at each site two days each month.
- 6.1.5.2A Every technical staff member from each multisite(s) works at the main facility two days each month.
- 6.1.5.3A An appropriately credentialed lead technologist is appointed at each multi-site to report to the Technical Director. The lead technologist:
 - i. Supervises and assists others in performing examinations.
 - ii. Oversees day-to-day activities at the multisite.
 - iii. Communicates weekly with the Technical Director to maintain compliance with the testing Standard.

Section 6A: Multiple Sites (Fixed and/or Mobile) *Guidelines*

Facilities needing complete details on adding a multiple site should review the current IAC Policies and Procedures available on the IAC website at intersocietal.org/iac/legal/policies.htm.

Part B:

Examinations and Procedures

Section 1B: Instrumentation and Equipment

STANDARD – Instrumentation

- 1.1B Equipment and instrumentation used in the nuclear medicine facility must be in good working condition and must be routinely inspected for safety and proper functionality and records kept on file.
- 1.1.1B All imaging and non-imaging devices must be FDA-approved or used under an approved research protocol with informed consent by the patient.
- 1.1.2B The facility must maintain records of service and maintenance.
- 1.1.3B Equipment and instrumentation must include at least the following:
- 1.1.3.1B dose calibrator or decay correction calculation system, as applicable;
 - 1.1.3.2B imaging/counting equipment;
 - 1.1.3.3B 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).
 - 1.1.3.4B resuscitation equipment and supplies (appropriate to the types of procedures being performed):
 - i. oxygen;
 - ii. defibrillator/AED;
 - iii. emergency drugs (including a master list; all unexpired).
 - 1.1.3.5B exercise equipment (as applicable);
 - 1.1.3.6B ECG equipment (as applicable);
 - 1.1.3.7B ancillary monitoring equipment (as applicable);
 - 1.1.3.8B infusion pumps/automated injectors (as applicable);
 - 1.1.3.9B glucometers (as applicable);
 - 1.1.3.10B hood for volatile radionuclides or cell handling (as applicable);
 - 1.1.3.11B xenon (or other gas) trap (as applicable).

STANDARD – Equipment Quality Control Protocols

1.2B The facility must have acceptable site-specific written protocols for all routine quality control procedures of imaging and non-imaging equipment.

Comment: Simply stating “following manufacturer’s recommendations” is not sufficient.

1.2.1B The facility must maintain records of all routine quality control of imaging and non-imaging equipment.

1.2.1.1B Protocols for quality control must be step-by-step, camera-specific and include:

- i. frequency of test performance;
- ii. type of source and position (e.g., point, sheet), if applicable;
- iii. equipment setup (e.g., intrinsic, extrinsic, collimator, energy window setting, matrix size, zoom, etc.);
- iv. acquisition instructions including views, time/counts, etc.;
- v. processing instructions, if applicable (e.g., region of interest for quantification, sinogram generation, graphs, etc.);
- vi. evaluation and acceptable range (or tolerance limits) of the results of each procedure;
- vii. instructions for corrective action of out-of-tolerance results;
- viii. instructions for retention and comparison with previous results.

1.2.1.2B The results of QC testing must be reviewed by appropriate staff in a timely manner and action taken if results are not within tolerance limits.

1.2.1.3B Quality control protocols must be reviewed and/or updated as equipment is changed and at least every three years by the Medical Director, physicist or other responsible person.

1.2.2B If frequency of QC testing 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).

1.2.3B Appropriate reference standards (i.e., sealed sources) for QC of imaging and non-imaging equipment must be used with a reference source traceable to the National Institute of Standards and Technology (NIST).

(See Guidelines on Page 40 for further recommendations.)

STANDARD – Imaging Equipment Quality Control

1.3B Site-specific, detailed protocols must be documented and followed for routine inspection and testing of all imaging equipment. Protocols must be in accordance with all applicable federal, state and local requirements.

1.3.1B Gamma Camera (Planar, SPECT, and SPECT/CT)

1.3.1.1B Energy peaking to verify that the photopeak is centered in the set photopeak energy window must be performed, if applicable (documentation not required).
Frequency: Daily (prior to use) or per manufacturer’s recommendation

1.3.1.2B Intrinsic or extrinsic uniformity calculation of integral and/or differential uniformity value must be performed (e.g., 3-5%).
Frequency: Daily (prior to use)

- 1.3.1.3B Spatial resolution/spatial linearity with resolution phantom (e.g., bars) must be performed.
Frequency: Weekly
- 1.3.1.4B Center-of-rotation (COR) must be performed on SPECT cameras to ensure mechanical and electrical alignment of the center of field of view.
Frequency: Monthly
- 1.3.1.5B High-count flood for uniformity correction, performed to correct for residual detector and collimator non-uniformity, must be performed.
Frequency: Per manufacturer's recommendation
- 1.3.1.6B Preventive maintenance (PM) must be performed.
Frequency: Every six months
- 1.3.1.7B For SPECT/CT equipment, daily system tests (as recommended by the manufacturer) must be performed to assess system function/constancy (e.g., calibration scan, CT warm-up, CT calibration, water phantom, coincidence timing, normalization update, etc.). The daily system test procedure must be specifically described.

Comment: Energy peaking and uniformity testing must be appropriate for the energy of the radioisotopes being imaged (e.g., low energy or medium energy).

Comment: 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) the QC tests must be repeated after each move and prior to equipment use.

(See Guidelines on Page 40 for further recommendations.)

1.3.2B PET and PET/CT Scanner

- 1.3.2.1B Daily system tests (as recommended by the manufacturer) must be performed to assess system function/constancy (e.g., calibration scan, blank scan, CT warm-up, CT calibration, water phantom, coincidence timing, normalization update, etc.). The daily system test procedure must be specifically described.
Frequency: Daily (prior to use)
- 1.3.2.2B Tomographic uniformity using a cylinder phantom of uniform radioactivity must be performed.
Frequency: Per manufacturer's recommendation
- 1.3.2.3B Normalization to calibrate the efficiency of all detectors in the system must be performed.
Frequency: Per manufacturer's recommendation and after preventive maintenance and major hardware repair.
- 1.3.2.4B For facilities performing quantitative analysis of images, such as standardized uptake value (SUV) calculation, absolute activity calibration and testing must be performed. Facilities must develop procedures that validate quantitative scanner performance.
Frequency: After a hardware change or per manufacturer's recommendations
- 1.3.2.5B Preventive maintenance of all PET and PET/CT scanners must be performed.
Frequency: Every six months

Comment: If the PET or PET/CT scanner is physically moved from site to site, the daily system test as described in Standard 1.3.2.1B must be performed after each scanner relocation and prior to injection.

(See Guidelines on Page 40 for further recommendations.)

- 1.3.3B CT-Specific Quality Control - Please refer to the [IAC Standards and Guidelines for CT Accreditation](#) for specific quality control requirements for CT scanners.

STANDARD – Non-imaging Equipment Quality Control

- 1.4B Site-specific, detailed protocols must be documented and followed for routine inspection and testing of all non-imaging equipment. Protocols must be in accordance with all applicable federal, state and local requirements.

1.4.1B Survey Meter

- 1.4.1.1B Constancy of response must be checked by measuring the exposure or counting rate of a long-lived reference source. Measurements must be within acceptable tolerance levels (e.g., within 10-20%).

Frequency: Daily or prior to use **or per manufacturer's recommendation**

- 1.4.1.2B The battery must be checked, if applicable, to verify the voltage supplied by the battery is within the acceptable operating range.

Frequency: Daily or prior to use

- 1.4.1.3B The survey meter must be calibrated using suitable long-lived reference sources.

Frequency: Annual or following repair **as per manufacturer's recommendation**

(See Guidelines on Page 40 for further recommendations.)

1.4.2B Dose Calibrator

- 1.4.2.1B **Background exposure must be measured**

Frequency: Daily or before use

Comment: This must include daily quality control as required by the manufacturer's recommendations.

- 1.4.2.2B Constancy of response must be checked by measuring the exposure or counting rate of a long-lived reference source. Measurements must be within acceptable tolerance levels (e.g., within 5-10% **or per manufacturer's recommendation**).

Frequency: Daily or before use

- 1.4.2.3B Linearity that is within tolerance limits must be verified (e.g., within 10%). Method of linearity check (i.e., decay or shield method) including activity, volume, time of measurement, etc., must be specifically defined.

Frequency: Quarterly

- 1.4.2.4B Accuracy that is within tolerance limits must be verified (e.g., within 5-10% **or per manufacturer's recommendation**).

Frequency: Annual

(See Guidelines on Page 40 for further recommendations.)

- 1.4.2.5B Measurement of geometry dependent responses **that affect volume changes of vials and/or syringes** must be performed.

Frequency: At installation and following repair or relocation **as per manufacturer's recommendation**.

1.4.3B Well Counter

- 1.4.3.1B Energy spectrum check, if applicable, to verify that the counter is properly peaked and that the photopeaks of the radionuclides coincide with the preset photopeak energy windows.
Frequency: Daily or per manufacturer recommendation
- 1.4.3.2B Background exposure or counting rate must be measured.
Frequency: Daily (or prior to use)
- 1.4.3.3B Constancy of response must be checked by measuring the exposure or counting rate of a long-lived reference source. Measurements must be within acceptable tolerance levels (e.g., within 5-10% as per manufacturer's recommendation).
Frequency: Daily (or prior to use)
- 1.4.3.4B Chi-square (X²) test, if applicable, to measure reproducibility and random variation must be performed.
Frequency: Quarterly
- 1.4.3.5B Efficiency to determine the ratio of detected counts measured by the system to the actual rate of decay (cpm/mCi or dpm), for a specific nuclide or region of interest must be performed.
Frequency: Annual or per manufacturer's recommendation

1.4.4B Intraoperative Probes

- 1.4.4.1B The battery must be checked to verify the voltage supplied by the battery is within the acceptable operating range.
Frequency: Daily or before use
- 1.4.4.2B Background exposure or counting rate must be measured.
Frequency: Daily or before use
- 1.4.4.3B Bias voltage of primary and back-up battery must be checked, if applicable.
Frequency: Per manufacturer's recommendation
- 1.4.4.4B Constancy of response must be checked by measuring the exposure or counting rate of a long-lived reference source. Measurements must be within acceptable tolerance levels (e.g., within 5-10% or as per manufacturer's recommendation).
Frequency: Daily or before use

1.4.5B Organ Uptake Probes (e.g., thyroid uptake probes)

- 1.4.5.1B System Test/Detector Status/Autocalibration (as recommended by manufacturer) must be performed to assess internal data, full width half-maximum (FWHM), voltage and gain settings.
Frequency: Daily or before use
- 1.4.5.2B Energy spectrum check, if applicable, to verify that the counter is properly peaked and that the photopeaks of the radionuclides coincide with the preset photopeak energy windows.
Frequency: Daily or before use
- 1.4.5.3B Background exposure or counting rate must be measured.
Frequency: Daily or before use
- 1.4.5.4B Constancy of response must be checked by measuring the exposure or counting rate of a long-lived reference source. Measurements must be within acceptable

tolerance levels (e.g., within 5-10% or as per manufacturer's recommendation).
Frequency: Daily or before use

1.4.5.5B If probe is used to perform radioactive contamination wipe tests, efficiency for a specific nuclide or region of interest must be measured to determine the ratio of detected counts measured by the system to the actual rate of decay (cpm/Bq or cpm/mCi) or disintegrations per minute (dpm).

Frequency: Annual or per manufacturer's recommendation

1.4.5.6B Chi-square (X²) test to measure reproducibility and random variation must be performed.

Frequency: Quarterly

STANDARD – Other Equipment Quality Control

1.5B Site-specific, detailed protocols must be documented and be followed for routine inspection and testing of all other medical equipment. Protocols must be in accordance with all federal, state and local requirements.

1.5.1B Emergency Equipment

1.5.1.1B 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 to assure that all expected items are present and none is expired.

Frequency: Monthly

1.5.1.2B Defibrillator/AED device and supplies (e.g., pads, gel) must be checked for functionality (e.g., voltage and battery, expiration date)

Frequency: Daily when patient studies are performed

1.5.1.3B Oxygen sources (wall unit or portable cylinder) must be checked for availability, pressure gauge shows adequate tank filling, proper function and proper tubing/mask.

Frequency: Daily when patient studies are performed

1.5.2B Miscellaneous Equipment

1.5.2.1B Glucometer accuracy must be confirmed.

Frequency: Daily if used

1.5.2.2B Infusion pump accuracy must be confirmed.

Frequency: Per manufacturer's recommendation

1.5.2.3B Xenon trap and nebulizer

i. Nebulizer must be visually inspected for damage and cleaned.

Frequency: As necessary

ii. Xenon trap moisture absorbing crystals must be replaced (e.g., every 3-5 patients).

Frequency: Per manufacturer's recommendation

iii. Xenon trap leak test must be performed.

Frequency: Monthly

iv. Xenon trap/charcoal filters must be replaced.

Frequency: Per manufacturer's recommendation

Section 1B: Instrumentation and Equipment

Guidelines

1.2B *For each quality control test performed, the following information should be recorded:*

- *the test performed;*
- *date and time of the test;*
- *identification of the device tested (e.g., make, model);*
- *the make, model and serial number of any reference sources used, if applicable;*
- *the results of the test;*
- *a notation indicating if the test result was or was not acceptable;*
- *the signature or initials of the individual performing the test or clear delineation of this duty written into a policy.*

Comment: Preferably, the information is recorded on a structured form or documented in a facility management program.

Initial acceptance results for all equipment should be retained and used for comparison. Preferably, acceptance testing should be performed by a party other than the equipment supplier

1.3.1B *Gamma Camera:*

Overall system performance may be evaluated using a fillable phantom containing non-radioactive (cold) inserts of different sizes and visually inspecting the resulting images.

Frequency: Annually

Collimator integrity, comparing the extrinsic and intrinsic uniformity flood along with visual inspection of collimator for damage, should be performed.

Frequency: Annually

1.3.2B *PET and PET/CT Scanners:*

Bed position overlap (e.g., 2-bed test, continuous bed motion, incremental bed overlap) is recommended.

Frequency: Per manufacturer recommendation

Alignment of the PET and CT scans (for PET/CT scanners) should be performed as per manufacturer recommendation.

Frequency: Per manufacturer recommendation

1.4.1.3B *Survey Meter* - *A dated sticker summarizing the calibration results should be affixed to the meter itself.*

The calibration report should specify the reference sources, the measurement procedure and the measured and expected exposure rates.

1.4.2.4B *Dose Calibrator* - *It is preferable that accuracy be measured with at least two reference sources.*

Section 2B: Clinical Protocols

STANDARD – Procedures Volumes

- 2.1B The annual procedure volume must be sufficient to maintain proficiency in examination interpretation and performance.
- 2.1.1B For general nuclear medicine accreditation, a facility must be able to submit the minimum number of cases per area required in the application process. The cases must be performed within one year from the date of submission.

(See Guidelines on Page 47 for further recommendations.)

STANDARD – General Protocol Guidelines

- 2.2B 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.
- 2.2.1B Complete procedure manuals must be present in the facility and include corresponding references.
- 2.2.2B Protocols must be organized for easy use (such as in notebook or electronic form) with a table of contents with sections/headings such as: clinical imaging protocols, exercise and/or pharmacologic stress protocols, therapeutic protocols, equipment quality control, radiation safety and radioactive materials handling, administrative policies and facility quality assessment and improvement.
- 2.2.2.1B The protocol manual must be readily accessible to appropriate staff members during operational hours.
- 2.2.2.2B Where appropriate, records must be maintained to document compliance with protocols (e.g., radiopharmaceutical receipt/disposal records, spill records, etc.).

(See Guidelines on Page 47 for further recommendations.)

- 2.2.3B Clinical protocols must be reviewed and updated at least annually by the Medical Director or by an appropriate designee. For areas in which the Medical Director does not have education, training and experience, a designee must be appointed to review those protocols. This designee must be a physician whom meets the criteria relevant to the delegated responsibility, as outlined in Standard 1.1A.

- 2.2.3.1B As noted in Standard 4.4.5.1A, protocols should use the lowest radiation dose necessary to acquire a diagnostic-quality image.

- i. Myocardial Perfusion Imaging protocols administered radiopharmaceutical dose must be within the following ranges:

Comment: Large patient is defined as >250 lbs or BMI >35 and (rest) denotes optional rest injection and only performed where clinically warranted.⁷

Comment: There are circumstances in which the administered dose will exceed the ranges listed. Justification must be kept on file. Protocols may include individualized weight based dosing strategies.

Current SPECT Myocardial Perfusion Imaging Protocols: Required Radiopharmaceutical Activities and Their Corresponding Radiation Effective Doses

REFERENCE: ASNC Imaging Guidelines for SPECT Nuclear Cardiology Procedures: Stress, Protocols and Tracers (February 2016)

| | First Injection | | | Second Injection | | | Total | Total Dose If |
|---|-----------------|----------------|------------|------------------|----------------|------------|------------|-------------------|
| | Given at | Activity (mCi) | Dose (mSv) | Given at | Activity (mCi) | Dose (mSv) | Dose (mSv) | Stress-only (mSv) |
| Tc-99m Protocols | | | | | | | | |
| Tc-99m One Day Stress-First/Stress-Only | Stress | 8-12 | 2.0-3.0 | (Rest)** | 24-36 | 7.0-10.5 | 9.0-13.5 | 2.0-3.0 |
| Tc-99m One Day Rest/Stress | Rest | 8-12 | 2.3-3.5 | Stress | 24-36 | 6.1-9.1 | 8.4-12.6 | n/a |
| Tc-99m Two Day Stress/Rest | Stress | 8-12 | 2.0-3.0 | (Rest)** | 8-12 | 2.3-3.5 | 4.3-6.5 | 2.0-3.0 |
| Tc-99m Two Day Stress/Rest - Large Patient* | Stress | 18-30 | 4.5-7.6 | (Rest)** | 18-30 | 5.2-8.7 | 9.8-16.3 | 4.5-7.6 |
| Tc-99m Two Day Rest/Stress | Rest | 8-12 | 2.3-3.5 | Stress | 8-12 | 2.0-3.0 | 4.3-6.5 | n/a |
| Tc-99m Two Day Rest/Stress - Large Patient* | Rest | 18-30 | 5.2-8.7 | Stress | 18-30 | 4.5-7.6 | 9.8-16.3 | n/a |
| TI-201 Protocols | | | | | | | | |
| TI-201 Stress/Redistribution Rest | Stress | 2.5-3.5 | 10.9-15.3 | n/a | n/a | n/a | 10.9-15.3 | 10.9-15.3 |
| TI-201 Stress/Redistribution Rest/Reinjection | Stress | 2.5-3.5 | 10.9-15.3 | Rest | 1-2 | 4.4-8.8 | 15.3-24.1 | n/a |
| TI-201 Rest/Redistribution | Rest | 2.5-3.5 | 1.9-15.3 | n/a | n/a | n/a | 10.9-15.3 | n/a |
| Dual Isotope TI-201 Rest/Tc-99m Stress | Rest | 2.5-3.5 | 10.9-15.3 | Stress | 8-12 | 2.0-3.0 | 13.0-18.3 | n/a |
| Dual Isotope TI-201 Rest/Tc-99m Stress - Large Patient* | Rest | 3.0-3.5 | 13.1-15.3 | Stress | 18-30 | 4.5-7.6 | 17.7-22.9 | n/a |
| I-123 Protocol | | | | | | | | |
| MIBG | Rest | 10 | 4.6 | n/a | n/a | n/a | 4.6 | n/a |
| Newer Technology Reduced-Dose Protocols | | | | | | | | |
| Tc-99m One Day Stress-First/Stress-Only | Stress | 4-6 | 1.0-1.5 | (Rest)** | 12-18 | 3.5-5.2 | 4.5-6.7 | 1.0-1.5 |
| Tc-99m One Day Rest/Stress | Rest | 4-6 | 1.2-1.7 | Stress | 12-18 | 3.0-4.5 | 4.2-6.3 | n/a |
| Tc-99m Two Day Stress/Rest | Stress | 4-6 | 1.0-1.5 | (Rest)** | 4-6 | 1.2-1.7 | 2.2-3.3 | 1.0-1.5 |
| Tc-99m Two Day Stress/Rest - Large Patient* | Stress | 9-15 | 2.3-3.8 | (Rest)** | 9-15 | 2.6-4.4 | 4.9-8.1 | 2.3-3.8 |
| Tc-99m Two Day Rest/Stress | Rest | 4-6 | 1.2-1.7 | Stress | 4-6 | 1.0-1.5 | 2.2-3.3 | n/a |
| Tc-99m Two Day Rest/Stress - Large Patient* | Rest | 9-15 | 2.6-4.4 | Stress | 9-15 | 2.3-3.8 | 4.9-8.1 | n/a |
| TI-201 Stress/Redistribution Rest | Stress | 1.3-1.8 | 5.7-7.9 | n/a | n/a | n/a | 5.7-7.9 | 5.7-7.9 |
| Dual Isotope TI-201 Rest/Tc-99m Stress | Rest | 1.3-1.8 | 5.7-7.9 | Stress | 4-6 | 1.0-1.5 | 6.7-9.4 | n/a |
| Dual Isotope TI-201 Stress/Tc99m Rest | Stress | 1.3-1.8 | 5.7-7.9 | Rest | 4-6 | 1.2-1.7 | 6.9-9.6 | 5.7-7.9 |

[\(See Guidelines on Page 47 for further recommendations.\)](#)

- 2.2.3.2B All protocols and/or revisions must be dated and initialed/signed by the Medical Director or the designated person.

Comment: It is acceptable for the Medical Director to sign a summary page to indicate he/she has approved the entire protocol manual.

Comment: The Radiation Safety Program must also be reviewed annually (see Standard 4.2.1A).

- 2.2.4B 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 training/orientation and annual training records.

- 2.2.5B The protocols and the facility's performance must be in compliance with:

- 2.2.5.1B 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.

- 2.2.5.2B Accepted practices such as those in published guidelines.¹⁻¹⁶

[\(See Guidelines on Page 47 for further recommendations.\)](#)

STANDARD – Clinical Procedure Protocols

- 2.3B The clinical procedure manual must include every clinical procedure performed at the facility, even those performed only occasionally.
- 2.3.1B All procedures that are performed must have detailed, site-specific written instructions.
- 2.3.2B All clinical procedures must be performed under conditions that ensure patient and staff safety.
- 2.3.3B Protocols must be sufficiently detailed to enable recreation of the protocol in the event of staffing or software change.

[\(See Guidelines on Page 47 for further recommendations.\)](#)

- 2.4B 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^{6, 7} (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.

- 2.4.1B Clinical protocols must include, as appropriate:

- 2.4.1.1B clinical indications and contraindications;

- 2.4.1.2B patient preparation and education/instructions such as food/diet restrictions, if any, withholding or non-withholding of medications or other relevant information. If there are no patient preparations or restrictions, the protocol must specifically state this.

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

Comment: For myocardial perfusion imaging protocols, the indications, contraindications and patient preparation for exercise and pharmacologic stress testing must also be listed in the relevant stress protocols, as applicable.

2.4.1.3B radiopharmaceutical identity, dosage and route of administration (e.g., intravenous, oral, inhaled, subdermal) (See Standard 4.4.5A for additional protocol dosage requirements):

- i. For 131-sodium iodide dosages greater than 30 microcuries, there must be a written directive.
 - The written directive must be dated and signed by an authorized user before administration of dose.
 - Written directive must include: patient's name, radiopharmaceutical identity, radiopharmaceutical dosage for the specific patient, route of administration and signature of an authorized user for that specific agent and date.
 - Protocols for any administration requiring a written directive must include:
 - Immediately prior to dosing, verification of the patient's identity with two identifiers (see Standard 4.1.1.2A) by two members of the medical and/or technical staff.
 - Immediately prior to dosing, verification of the radiopharmaceutical, amount and route of administration by two members of the medical and/or technical staff (see Standard 4.1.1.4A).

(See Guidelines on Page 47 for further recommendations.)

2.4.1.4B non-radioactive drugs (e.g., pharmacologic stress agents, pyrophosphate (PYP), sincalide, cholecystokinin, morphine sulfate, furosemide, captopril, aminophylline, metoclopramide, pentagastrin, Lugol's solution) used in the procedure including dosage, timing, route of administration, patient instruction, patient monitoring and any precautions or restrictions;

2.4.1.5B camera setup (e.g., collimator, energy window setting, orbit and orbit type, acquisition type [static, dynamic, planar, SPECT, SPECT/CT, PET, PET/CT, PET/MR, PEM, step and shoot, continuous], gating, matrix size, zoom, etc.);

2.4.1.6B patient position (e.g., supine, prone, posterior, anterior, head in, head out, arms up, arms down) and camera position (e.g., starting angle, detector configuration, caudal tilt, detector to patient distance);

2.4.1.7B camera/computer specific acquisition instructions including views, timing of views, time/counts per view and number of views as well as SPECT/PET specific parameters, pre-filtering (reconstruction) and attenuation correction if used;

2.4.1.8B camera/computer specific processing protocols including such parameters as filtering, reconstruction parameters, reconstruction algorithms, attenuation correction, motion correction, curve generation, reformatting and quantitative analysis requirements;

2.4.1.9B camera/computer specific instructions regarding the images and data to be displayed for physician interpretation (screen shots and examples are acceptable forms of documentation);

2.4.1.10B instructions for how image will be labeled to include: facility name, patient name, date of birth, patient identifier, date of study, time interval (as appropriate), view or projection, laterality and anatomical markers (as appropriate);

Comment: Screen shots and examples are acceptable forms of documentation.

Comment: If acquisition/processing/display protocols are in the computer software, they must be listed in the protocol manual by the name of the protocol as on the computer. 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).

2.4.1.11B protocols utilizing new (emerging) technologies and other novel imaging approaches not included in guidelines published by the professional societies must have supporting documentation, as directed by IAC Nuclear/PET, based on the specific technology including but not limited to:

- i. patient simulator study to determine defect reproducibility using facility's actual imaging parameters;
- ii. demonstration of adherence to manufacturer's QC specifications;
- iii. documentation of training and clinical competency by technical staff;
- iv. corresponding published references (if available).

2.4.2B Exercise and/or Pharmacologic Stress Testing – All exercise/pharmacologic protocols must follow accepted practices¹⁻⁵ (or have published justification for variance) and include the following:

Comment: Exercise stress is the preferred stress testing protocol in patients who are physically able to exercise to an adequate workload. Exercise protocols differ in the speed and incline and can be varied based on individual patient characteristics.

2.4.2.1B detailed description of graded protocols (e.g., charts showing speed, incline and workload) and/or infusion protocols used;

- i. If low-level exercise is used with any infusion protocol, this must be described in detail (e.g., type of exercise, speed/incline if treadmill used, duration of exercise, and timing of exercise in relation to pharmaceutical and tracer administration).

2.4.2.2B instructions for time of measurement of symptoms, heart rate, blood pressure and electrocardiographic tracings during stress;

2.4.2.3B injection criteria and exercise/testing end points including any specific events that are reasons for stopping the stressing activity (e.g., duration of pharmaceutical administration or specific symptoms at peak exercise).

Comment: Protocol must specifically state when the tracer is injected either by time or other criteria relative to the stress type. Exercise stress tests must be symptom-limited unless indications for stopping the test early are achieved. Achievement of 85% of maximum, age-adjusted, predicted heart rate is not sufficient an indication for termination of the test.

2.4.2.4B reasons for early termination of exercise stress or pharmacologic stress (e.g., moderate to severe angina, marked dyspnea, ST segment depression > 2 mm);

- 2.4.2.5B instructions for post stress monitoring including time of symptoms, measurement of heart rate, blood pressure and electrocardiographic tracings as well as criteria for terminating post stress monitoring (i.e., minimum duration of post stress monitoring and acceptable reasons for stopping);
- 2.4.2.6B identification and treatment of common adverse effects for both exercise and/or pharmaceutical stress (e.g., hypertension, dyspnea, chest pain).

Section 2B: Clinical Protocols

Guidelines

- 2.1B *Procedure Volumes - It is recommended that a facility should perform a minimum of 600 nuclear medicine patient procedures annually.*
- 2.2.2B *Availability of protocols in digital format is desirable.*
- 2.2.5B *Sample protocol information is available on the IAC Nuclear/PET website at intersocietal.org/nuclear. References are listed in the Bibliography.*
- 2.3B *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.*
- 2.2.3.1B *It is strongly recommended against the routine use of a dual isotope protocol for myocardial perfusion imaging except during extraordinary circumstances (i.e., technetium shortage) or for use with Newer Technology combined with the Reduced-Dose Protocols above.*
- It is strongly recommended for obese patients undergoing two-day myocardial perfusion imaging protocols or patients with a low pretest probability should have stress imaging performed first and rest imaging performed only if stress imaging is abnormal.*
- 2.4.1.3B *Radiation dosimetry: Effective dose and critical organ dose for each radiopharmaceutical given should be included. If relevant, pediatric exposures should be included.^{8,9}*

Part C:

Quality Improvement

Section 1C: Quality Improvement (QI) Program

STANDARD – QI Program

1.1C The facility must have a written QI program for all imaging procedures. The performance of all staff physicians and nuclear medicine technologists must be assessed as part of the QI program. The QI program must include the QI measures outlined below but may not be limited to the evaluation and review of:

1.1.1C test appropriateness;

1.1.2C technical quality and safety of the imaging;

1.1.3C interpretive quality review;

1.1.4C report completeness and timeliness; and

1.1.5C correlation.

(See Guidelines on Page 49 for further recommendations.)

1.2C The Medical Director, staff and/or an appointed QI committee must provide oversight to the QI program that includes pre-defined indicators of quality and predefined thresholds that indicate the need for corrective action. The oversight includes but is not limited to review of the reports of QI evaluations and any corrective actions taken to address any deficiencies.

Section 1C: Quality Improvement Program

Guidelines

1.1C Typically, assessments are an ongoing process with monthly or quarterly review of results.

Section 2C: Quality Improvement Measures

STANDARD – QI Measures

2.1C Facilities are required to have a process in place to evaluate the QI measures outlined in sections 2.1.1C through 2.1.4C.

(See Guidelines on Page 52 for further recommendations.)

2.1.1C Test Appropriateness: The facility must evaluate the appropriateness of the test performed and categorized as:

2.1.1.1C appropriate/usually appropriate;

2.1.1.2C may be appropriate;

2.1.1.3C rarely appropriate / usually not appropriate.

Comment: Test appropriateness must be measured in consecutive (e.g., two-three week) time periods so that 5% of the annual volume of patients referred for radionuclide testing are evaluated. For smaller volume facilities, a minimum of 30 patients must be evaluated.

(See Guidelines on Page 52 for further recommendations.)

2.1.2C Technical Quality Review: To assess and improve the technical quality of the images and if applicable the safety of procedures being performed. The review must include, but ~~are~~ is not limited to the evaluation of:

2.1.2.1C the clinical images for clarity of images and/or evaluation for suboptimal images or artifact;

2.1.2.2C reproducibility of processed images and/or quantitative results;

2.1.2.3C image display/labeling;

2.1.2.4C correct patient preparation, as specified in the clinical written procedures, at the time of study;

2.1.2.5C verification of administered radioactive dose to prescribed dose listed in protocol;

2.1.2.6C completeness of the study;

2.1.2.7C adherence to the facility imaging acquisition protocols.

(See Guidelines on Page 52 for further recommendations.)

2.1.3C Interpretive Quality Review: The facility must evaluate the quality and accuracy of the interpretation based on the acquired images. Areas that may be assessed include but are not limited to:

2.1.3.1C interobserver agreement (peer review);

2.1.3.2C intra-observer variability;

2.1.3.3C correlation of interpretation with other diagnostic studies, pathology/surgical results and/or patient outcomes;

2.1.3.4C correlation of intended therapeutic effects with patient response to therapy.

(See Guidelines on Page 52 for further recommendations.)

2.1.4C Final Report Completeness and Timeliness – The facility must evaluate the final report for completeness and timeliness as required in the Standards.

Section 2C: Quality Improvement Measures

Guidelines

- 2.1C *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: scheduling back logs; patient wait times; accuracy of patient information during scheduling; completeness of documentation; time from completion of procedure to distribution of final report; patient satisfaction; referring physician satisfaction*
- 2.1.1C *All other areas of nuclear medicine are encouraged to measure appropriate use as AUC are published by professional medical organizations.*
- 2.1.2C and 2.1.3C *Annual participation in a relevant inter-facility patient simulator exercise (phantom program) may be used to fulfill the annual QI requirement for both the technical and physician performance measurements.*

Section 3C: Quality Improvement Meetings

STANDARD – QI Meetings

- 3.1C The facility must have a minimum of two QI meetings per year.
 - 3.1.1C The content of at least one meeting per year is to review the results of the QI analyses and any additional QI-related topics.
 - 3.1.2C All staff must participate in at least one meeting per year.

Section 4C: Quality Improvement Documentation

STANDARD – QI Documentation

4.1C QI Documentation and Record Retention

4.1.1C The facility QI documentation must include, but is not limited to:

4.1.1.1C the data for all of the QI measures above;

4.1.1.2C a description of how the QI information is used to improve Nuclear/PET quality;
and

4.1.1.3C minutes from the QI meetings.

- i. Participant list which may include remote participation and/or review of minutes.

4.1.2C The QI documentation must be maintained and available for all appropriate personnel to review.

Part D:

Therapy Procedures

Section 1D: Therapy Protocols and Performance

STANDARD – Therapy Reporting Protocols

- 1.1D The report of the therapy must be typed or computer-generated and must accurately reflect the treatment performed. This must include:
- 1.1.1D identification of the name, address and phone number of the facility;
 - 1.1.2D name of the treatment (type of treatment);
 - 1.1.3D **patient information:**
 - 1.1.3.1D patient's **first and last** name;
 - 1.1.3.2D gender;
 - 1.1.3.3D date of birth or age;
 - 1.1.3.4D **height and weight.**
 - 1.1.4D requesting health care provider's name;
 - 1.1.5D treating physician's name;
 - 1.1.6D date of the therapy;
 - 1.1.7D patient's diagnosis and **justification for therapy** including a summary of **clinical** history, physical findings, **laboratory/pathology results** and imaging data;
 - 1.1.8D **benefits, alternatives,** risks (including side effects) and expected outcomes (including likelihood of success);
 - 1.1.9D that the patient was informed of the information above and written consent was obtained;
 - 1.1.10D when applicable, evidence that the patient is not pregnant;
 - 1.1.11D when applicable, that the patient is not lactating;
 - 1.1.12D the specific radiopharmaceutical administered including:
 - 1.1.12.1D **specific** identity – **radionuclide and chemical form;**
 - 1.1.12.2D **exact** amount (**XX.X mCi**);
 - 1.1.12.3D route of **administration (e.g., oral, intravenous).**
 - 1.1.13D any other relevant procedures that were part of the therapy;
 - 1.1.14D **immediate adverse effects of treatment;**

- 1.1.15D post-therapy instructions given to the patient including planned follow-up (with whom, when and where or how to arrange the appointment);
- 1.1.16D any unusual occurrences or variations from clinic protocols;
- 1.1.17D report finalization to include:
 - 1.1.17.1D identification and manual or electronic signature (password protected) of the treating, qualified physician;
 - 1.1.17.2D date report finalized and signed by treating physician;
 - 1.1.17.3D if the report is amended, the original report content, author and date of signature must be retained. The content of the amendment, author and date of amendment must be clearly recorded.

(See Guidelines on Page 59 for further recommendations.)

STANDARD – Therapy Clinical Protocols

- 1.2D Therapy protocols must describe in detail:
 - 1.2.1D requirement that the treating physician must be an authorized user for and must personally supervise the administration of the therapeutic radiopharmaceutical;
 - 1.2.2D clinical indications and contraindications;
 - 1.2.3D patient preparation and education/instruction such as food/diet restrictions, if any, withholding or non-withholding of medications or other relevant information;

Comment: If there are no patient preparations or restrictions, the protocol must specifically state this.
 - 1.2.4D radiopharmaceutical identity, dosage range or method of calculation and route of administration;
 - 1.2.5D the requirement for a written directive prior to radiopharmaceutical administration which includes:
 - 1.2.5.1D patient's name;
 - 1.2.5.2D radiopharmaceutical identity;
 - 1.2.5.3D radiopharmaceutical dosage for the specific patient;
 - 1.2.5.4D route of administration;
 - 1.2.5.5D signature of an authorized user, as defined by the Nuclear Regulatory Commission in 10 CFR §35.2¹⁷, for that specific agent and date.
 - 1.2.6D non-radioactive drugs used in the procedure including identity, dosage, timing of administration, route of administration and any precautions or restrictions;
 - 1.2.7D Treatment procedure including:
 - 1.2.7.1D Review of relevant clinical history, laboratory/pathology results and imaging data.
 - 1.2.7.2D Informed consent with risks, benefits, alternatives and likelihood of success.

- 1.2.7.3D Pregnancy and/or lactation status check. Additionally, if relevant, guidance concerning breast-feeding cessation must also be included.
- 1.2.7.4D Immediately prior to dosing, verification of the patient's identity with two identifiers (see Standard 4.1.1.2A) by two members of the medical and/or technical staff.
- 1.2.7.5D Immediately prior to dosing, verification of the radiopharmaceutical, amount and route of administration (see Standard 4.1.1.4A) by two members of the medical and/or technical staff (see Standards 1.1A - 1.4A).
- 1.2.8D radiation precautions following treatment, as appropriate.
 - 1.2.8.1D out-patient instructions, to include:
 - i. maintaining distance from others, especially children and pregnant women (including during sleep and time in public);
 - ii. travel (including public transportation and border crossings);
 - iii. control of body fluids;
 - iv. handling of potentially radioactive household trash;
 - v. the duration of these restrictions.
 - 1.2.8.2D in-patient instructions, to include:
 - i. radiation safety instruction to direct care (e.g., nursing) and housekeeping staff;
 - ii. hospital room/signage requirements;
 - iii. radiation monitoring requirements;
 - iv. visitation policy;
 - v. handling of materials used by the patient;
 - vi. release criteria;
 - vii. response to medical emergencies or patient death.
 - 1.2.8.3D A description of any imaging required in conjunction with the therapy (e.g., I131 post-therapy whole body imaging). If nuclear imaging is needed as part of a therapy protocol, see Standard 2.4.1B for components of imaging protocols.

STANDARD – Therapy Performance

- 1.3D A qualified member of the medical staff (as defined in Standard 1.1.1A and 1.3.1A) must perform all therapies and provide the final written report. The treating physician must be an authorized user for the radiopharmaceutical administered.
 - 1.3.1D The treating physician must review the pertinent elements of the patient's clinical history, physical findings, laboratory/pathology results and imaging data to confirm the patient's diagnosis and determine the appropriate treatment. The treating physician must take responsibility for the proper administration of the therapy and treatment of side effects.
 - 1.3.2D The written directive must be in accordance with the treatment plan and include all required elements (see Standard 2.4.1.3B).

- 1.3.3D The written directive must be retained according to state or federal regulations
- 1.3.4D The treating physician must assure that the facility's radionuclide therapy (see Standard 1.2D) and radiation safety protocols (see Standard 4.2A) are followed. Any deviations from the protocol must be justified and documented in the patient's medical record.
- 1.3.5D Prior to administration of the therapeutic dosage, the treating physician must assure:
 - 1.3.5.1D the patient is fully informed regarding the benefits, risks (including side effects), alternatives and expected outcome (including likelihood of success) of the therapy;
 - 1.3.5.2D written consent is obtained;
 - 1.3.5.3D the patient is not pregnant;
 - 1.3.5.4D the patient is not lactating (see Standard 4.1.3.1A);
 - 1.3.5.5D the vial or syringe is labeled with the desired radiopharmaceutical and dosage and is not expired.
- 1.3.6D The treating physician must personally supervise the administration of the therapeutic radiopharmaceutical and assure:
 - 1.3.6.1D the radiopharmaceutical administration is in accordance with the treatment plan and written directive;
 - 1.3.6.2D immediately prior to dosing, confirmation of the proper patient, radiopharmaceutical identity, dosage and route of administration (see Standards 4.1.1.2A and 1.2.7D).
- 1.3.7D The treating physician is responsible for post-therapy care including:
 - 1.3.7.1D post-therapy instructions;
 - 1.3.7.2D follow-up appointment(s) [with whom (physician or office) and when];
 - 1.3.7.3D transition of care to the referring or other provider, if appropriate
- 1.3.8D When nuclear medicine therapy patients are released rather than being hospitalized (e.g., 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 basis for the release and instructions provided must be maintained.

Section 1D: Therapy Protocols and Performance *Guidelines*

1.1D *The report of therapy should include:*

Unique patient identifier (e.g., unique identification number or sufficient demographic information to identify patient)¹⁶

Selected Bibliography

1. Exercise Testing: ACC/AHA 2002 Guideline Update for Exercise Testing: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Exercise Testing). *J Am Coll Cardiol*, 2002 Oct 16;40(8):1531-40. my.americanheart.org/idc/groups/ahaacc-internal/@wcm/@sop/documents/downloadable/ucm_423807.pdf
2. Exercise Standards for Testing and Training: A Scientific Statement from the American Heart Association. *Circulation*, 2013; 128:873-934. circ.ahajournals.org/content/128/8/873.full
3. Recommendations for Clinical Exercise Facilities: A Scientific Statement from the American Heart Association. *Circulation*, 2009; 119:3144-3161. circ.ahajournals.org/content/119/24/3144.full.pdf
4. American College of Cardiology/American Heart Association Clinical Competence Statement on Stress Testing: A Report of the American College of Cardiology/American Heart Association/American College of Physicians-American Society of Internal Medicine Task Force on Clinical Competence. *Circulation*, 2000;102:1726-1738. circ.ahajournals.org/cgi/content/full/102/14/1726
5. Supervision of Exercise Testing by Nonphysicians – A Scientific Statement from the American Heart Association. *Circulation*, 2014;130:1014-1027. circ.ahajournals.org/content/130/12/1014.full
6. SNMMI Procedure Standards. www.snmmi.org/ClinicalPractice/content.aspx?ItemNumber=6414
7. ASNC Imaging Guidelines for SPECT Nuclear Cardiology Procedures: Stress, Protocols, and Tracers. Milena J. Henzlova, W. Lane Duvall, Andrew J. Einstein, Mark I. Travin, Hein J. Verberne, 2016. asn.org/files/Guidelines%20and%20Quality/ASNC%20SPECT%20ProtocolsTracers%20Guidelines2016.pdf
8. Guide for Diagnostic Nuclear Medicine and Radiopharmaceutical Therapy, Jeffrey A. Siegel, 2004. Society of Nuclear Medicine.
9. SNMMI Nuclear Medicine Radiation Dose Tool. snmmi.org/ClinicalPractice/doseTool.aspx?ItemNumber=11216&navItemNumber=11218
10. Recommendations for Reducing Radiation Exposure in Myocardial Perfusion Imaging. Cerqueira, Manuel D., et al, *J Nucl Cardiol*, 2010; 17:709-18. asn.org/files/Rec%20for%20Reducing%20Radiation%20Expo%20in%20MPI.pdf
11. ASNC Preferred Practice Statement: Patient Centered Imaging. Depuey, G., et al., *J Nucl Cardiol*. 2012;19(2):185-215. asn.org/files/PCI%202012.pdf
12. Patient-Centered Imaging: Shared Decision Making for Cardiac Imaging Procedures with Exposure to Ionizing Radiation. Einstein AJ, et al., *J Am Coll Cardiol*. 2014;63(15):1480-1489. content.onlinejacc.org/article.aspx?articleid=1831421
13. ACC/AHA/ASE/ASNC/HRS/IAC/Mended Hearts/NASCI/RSNA/SAIP/SCAI/SCCT/SCMR/SNMMI 2014 Health Policy Statement on Use of Noninvasive Cardiovascular Imaging. Mark DB, et al., *J Am Coll Cardiol*. 2014;63(7):699-721.
14. ACCF/ASNC/ACR/AHA/ASE/SCCT/SCMR/SNM Appropriate Use Criteria - 2009 Appropriate Use Criteria for Cardiac Radionuclide Imaging. content.onlinejacc.org/article.aspx?articleid=1139755
15. ACCF/AHA/ASE/ASNC/HFSA/HRS/SCAI/STS 2013 Multimodality Appropriate Use Criteria for Detection and Risk Assessment of Stable Ischemia Heart Disease. *J Am Coll Cardiol*, 2014;63(4):380-406. content.onlinejacc.org/article.aspx?articleid=1789799
16. ACCF/ACR/AHA/ASE/ASNC/HRS/NASCI/RSNA/SAIP/SCAI/SCCT/SCMR 2008 Health Policy Statement on Structured Reporting in Cardiovascular Imaging. circ.ahajournals.org/content/119/1/187.full
17. NRC:10 CFR Part 35 – Medical Use of Byproduct Material. www.nrc.gov/reading-rm/doc-collections/cfr/part035

Appendix A

Stress Test Supervision by Non-Physician Training and Competency Requirements:

- 1.5.1.1A If a non-physician (e.g., properly trained nurse, physician assistant, nurse practitioner, exercise physiologist) practicing under the physician's license is supervising the stress test, the facility or medical director must document appropriate training and competence as outlined in the American College of Cardiology/American Heart Association Clinical Competence Statement on Stress Testing (See Bibliography)

Supervision Exercise Stress Testing:

- a. Knowledge of appropriate indications for exercise testing.
- b. Knowledge of alternative physiological cardiovascular tests.
- c. Knowledge of appropriate contraindications, risks and risk assessment of testing (not limited to Bayes' theorem and sensitivity/specificity, including concepts of absolute and relative risk).
- d. Knowledge to promptly recognize and treat complications of exercise testing.
- e. Competence in cardiopulmonary resuscitation and successful completion of an AHA-sponsored course in advanced cardiovascular life support and renewal on a regular basis.
- f. Knowledge of various exercise protocols and indications for each.
- g. Knowledge of basic cardiovascular and exercise physiology, including hemodynamic response to exercise.
- h. Knowledge of cardiac arrhythmias and the ability to recognize and treat serious arrhythmias
- i. Knowledge of cardiovascular drugs and how they can affect exercise performance, hemodynamics and the ECG.
- j. Knowledge of the effects of age and disease on hemodynamic and ECG responses to exercise.
- k. Knowledge of principles and details of exercise testing, including proper lead placement and skin preparation.
- l. Knowledge of end points of exercise testing and indications to terminate exercise testing.

Supervision of Vasodilator or Adrenergic-Stimulating Agent Stress:

- a. Knowledge of appropriate indications.
- b. Knowledge of appropriate contraindications.
- c. Knowledge of advantages and disadvantages of different exercise and pharmacological stress for radionuclide cardiac imaging.
- d. Knowledge of complications and ability to recognize and appropriately treat complications, including use of adenosine/dipyridamole antagonists such as theophylline and aminophylline.
- e. Competence in cardiopulmonary resuscitation and successful completion of an AHA-sponsored course in advanced cardiovascular life support and renewal on a regular basis.
- f. Knowledge of various vasodilator, adrenergic stress protocols.
- g. Knowledge of the pharmacokinetics of vasodilator and adrenergic drugs.
- h. Knowledge of basic cardiovascular physiology, including heart rate and blood pressure response to vasodilators and adrenergic-stimulating agents.
- i. Knowledge of electrocardiography and changes that may occur in response to vasodilators or adrenergic-stimulating agents.
- j. Knowledge of cardiac arrhythmias and their treatment, including high-grade ventricular arrhythmia and heart block.
- k. Knowledge of cardiovascular drugs (and other agents [e.g., caffeine]) and their effects on vasodilator and adrenergic drugs