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)
- cardiac positron emission tomography (PET)

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

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

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.

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.
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 radiology with at least four months of nuclear cardiology training.

OR

Board certified (or Board eligible but within two years of finishing training) in radiology with special competence in nuclear medicine.

1.1.1.6A Board certified (or Board eligible but within two years of finishing training) in radiology and at least one year (full-time equivalent) of nuclear cardiology practice experience with independent interpretation of at least 800 nuclear cardiology studies.

OR

Board certified (or Board eligible but within two years of finishing training) in radiology with at least four months of nuclear medicine training with interpretation of at least 800 nuclear medicine procedures.

1.1.1.7A 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 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 at least 20 nuclear medicine therapies required.

1.1.1.8A 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 all 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.

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 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, nuclear imaging 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 does not include education primarily concerning echocardiography/ultrasound, MRI, CT, cardiac catheterization, general medicine, or the treatment of diseases unless related to the interpretation of nuclear imaging or radionuclide therapies.

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

1.1.3.2A Documentation of CME credits must be kept on file and available for inspection. 
(See Guidelines on Page 13 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 BLS (Basic Life Support) 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; and
• 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 verify and document proper training and, at least annually, assess 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, ARRT-Category A, ASRT, ACE, AMA Category I).

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

Comment: If the Technical Director has successfully attained ONE of the following within the three years prior to the application date, the CE requirement will be considered fulfilled:

i. completion of an accredited nuclear medicine training program;
ii. attainment of an appropriate technical credential in nuclear medicine; or
iii. attainment of advanced technical credential.

1.2.3.2A  Documentation of CE credits must be kept on file and available for inspection.

(See Guidelines on Page 13 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.

(See Guidelines on Page 13 for further recommendations.)

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 radiology with at least four months of nuclear cardiology training.

OR

Board certified (or Board eligible but within two years of finishing training) in radiology with special competence in nuclear medicine.

1.3.1.6A  Board certified (or Board eligible but within two years of finishing training) in radiology and at least one year (full time equivalent) of nuclear cardiology practice experience with independent interpretation of at least 800 nuclear cardiology studies.

OR

Board certified (or Board eligible but within two years of finishing training) in radiology with at least four months of nuclear medicine training with interpretation of at least 800 nuclear medicine procedures.

1.3.1.7A  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 Medicins 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 at least 20 nuclear medicine therapies required.

1.3.1.8A  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, nuclear imaging 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 does not include education primarily concerning echocardiography/ultrasound, MRI, CT, cardiac catheterization, general medicine, or the treatment of diseases unless related to the interpretation of nuclear imaging or radionuclide therapies.

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

*(See Guidelines on Page 13 for further recommendations.)*

**STANDARD – Nuclear Medicine Technologist(s)**

1.4A All imaging personnel must be nuclear medicine technologists who have the following qualifications:

1.4.1A **Nuclear Medicine Technologist 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 BLS (Basic Life Support) certification

1.4.2A **Nuclear Medicine Technologist Responsibilities**

Nuclear medicine technologist responsibilities include but are not limited to:

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

1.4.3A **Continuing Education (CE) Requirements**

1.4.3.1A The nuclear medicine 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, ARRT Category A, ASRT, ACE, AMA Category I).

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

Comment: If the technical staff member has successfully attained one of the following within the three years prior to the application 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.

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

*(See Guidelines on Page 13 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. (See Bibliography) Comment: See Appendix A for specific training and competence requirements.

1.5.2A At a minimum, at least 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.

1.5.4A Advanced Cardiac Life Support – 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 13 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 13 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 13 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.
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: There should be written descriptions of the duties and responsibilities 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 (i.e., diagnostic and/or therapeutic nuclear medicine).

1.5A Direct Patient Care Personnel – All personnel involved in direct patient care should have current BLS (Basic Life Support) certification.
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 15 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 must be provided for:

2.3.1A the storage of digital data;

2.3.2A the storage must ensure confidentiality of data and should be safe from fire/flood;

2.3.3A patient records, reports and digital data storage areas;

2.3.4A administration records and support areas; and

2.3.5A equipment/supply storage areas.
Section 2A: Facility Guidelines

2.1.1A It is preferable that patients and staff have separate bathrooms.
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. If the only images that are retained are hard copy, then they must be of high quality.

3.1.2A Technical data that are not included as part of the final report must be maintained as part of the facility records. The specific imaging and processing parameters used should be retrievable for each clinical study.

3.1.3A Specific worksheets for non-imaging studies must be maintained as part of the facility records.

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 19 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 19 for further recommendations.)

3.2.2A All diagnostic procedures must be reviewed promptly after the study is completed as appropriate for the risk of clinically significant results at least within one working day. Results of examinations with critical results must be communicated to the referring physician as quickly as clinically indicated. A record of the communication must be maintained.

3.2.3A 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.

3.2.4A The final report must be reviewed, signed and dated manually or electronically by the interpreting qualified member of the medical staff. Electronic signatures must be password protected and indicate they are electronically recorded. Stamped signatures or signing by non-physician staff is unacceptable.

Comment: In unusual circumstances, when the interpreting physician is not available, another qualified member of the medical staff may sign for them, if they choose to take such responsibility.

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 stress (exercise or pharmacologic) or other pharmacologic intervention (including but not limited to symptoms, rest and stress heart rate/blood pressure data, rest and stress ECG findings, etc., as appropriate for the type of stress or pharmacologic intervention). This information must be included in the final report as noted in 3.4A.

3.3.3A Acceptable quality radionuclide images and/or derived quantitative data including acceptable:

3.3.3.1A count density;

3.3.3.2A processing/filtering;

3.3.3.3A 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)]; and

3.3.3.4A lack of artifacts (e.g., patient motion, attenuation, subdiaphragmatic activity).

3.3.4A Other relevant imaging modalities (i.e., echo/ultrasound, CT, MRI, etc.), if available.

3.3.5A Comparison with prior nuclear medicine examinations when available. It is preferable that “no previous studies” be stated to document that there were none.

3.3.6A 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. This includes, but is not limited to:

3.4.1A identification of the name, address and phone number of the facility;

3.4.2A patient’s first and last name, gender and date of birth or age;

3.4.3A requesting health care provider’s name;

3.4.4A interpreting physician name;

3.4.5A date of the examination;

3.4.6A date report signed and approved by interpreting physician;

3.4.7A clinical indications and pertinent history leading to the performance of the examination (e.g., medications, recent contrast, prior administration of radiopharmaceuticals, prior therapy which might affect radiopharmaceutical distribution, results of pertinent imaging studies and facility results);

3.4.8A name of the procedure [type of examination(s)]; and

3.4.9A an adequate description of the procedure performed. The description must include the name of the procedure [type of the examination(s) or protocol]. It must also include the specific name, specific amount, and route of administration of any radioactive or non-radioactive material administered. If applicable, the type of stress, pharmacologic agent, dose and route of administration must be described. If applicable the type and use of attenuation correction must be specified.
3.4.10A a description of the results of the exam including pertinent positive and negative findings including:

3.4.10.1A non-imaging data such as stress test responses and summarized findings (when applicable);

Comment: Stress testing data reported must include patient response to stress (Rest and peak stress HR, rest and peak stress blood pressure, rest and peak stress ECG findings), stress symptoms, stress duration, percent of maximum predicted HR, reason for termination of stress, and timing of administration of radiopharmaceuticals as it relates to pharmaceutical or other stress administration.

3.4.10.2A image description, including location and types of findings (including size/extent and severity/intensity of cardiac defects);

(See Guidelines on Page 19 for further recommendations.)

3.4.10.3A identification of suboptimal or limited examinations and/or deviations from standard protocols. This may include attenuation (general soft tissue, breast, diaphragm), patient/organ motion (limb/body movement, upward creep of the heart), activity in non-target organs (e.g., subdiaphragmatic activity on cardiac studies), or other imaging artifacts.

(See Guidelines on Page 19 for further recommendations.)

3.4.11A an accurate, succinct impression (e.g., normal, abnormal, stable);

Comment: This must clearly communicate the result of the study and, when possible, answer the clinical question that was the cause for the examination. This final conclusion should resolve any inconsistencies or discrepancies (e.g., abnormal stress test with normal myocardial perfusion images) or provide guidance for further studies to do so.

3.4.12A any need for additional studies based on the results of the procedure being reported;

3.4.13A identification of and manual or electronic signature (password protected) of the interpreting physician as described in 3.2A and 3.2.4A.

(See Guidelines on Page 19 for further recommendations.)

STANDARD – Therapy Reporting Protocols

3.5A The report of the therapy must be typed or computer generated and must accurately reflect the treatment performed. This must include, but is not limited to:

3.5.1A identification of the name, address and phone number of the facility;

3.5.2A patient’s last and first name, gender and date of birth;

3.5.3A requesting health care provider’s name;

3.5.4A interpreting/treating physician’s name;

3.5.5A date of the therapy;

3.5.6A date report signed and approved by interpreting physician;

3.5.7A patient’s diagnosis including a summary of relevant history, physical findings, facility and imaging data to confirm the diagnosis;
3.5.8A justification for therapy including alternatives, risks (including side effects), benefits and expected outcomes (including likelihood of success);

3.5.9A that the patient was informed of the requirements of 3.5.8A above and consent obtained;

3.5.10A evidence that the patient is not pregnant (when applicable);

3.5.11A when applicable, that the patient is not breast-feeding or has been properly counseled regarding risks of breast-feeding (if any);

3.5.12A the specific radiopharmaceutical administered including identity, amount, and route and any other relevant procedures that were part of the therapy;

3.5.13A post-therapy instructions given to the patient including planned follow-up (with whom, when, and where or how to arrange the appointment);

3.5.14A any unusual occurrences or variations from clinic protocols; and

3.5.15A the final report must be reviewed and signed manually or electronically by the interpreting qualified member of the medical staff. Electronic signatures must be password protected and indicate they are electronically recorded. Stamped signatures or signing by non-physician staff is unacceptable.

*(See Guidelines on Page 19 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.

3.4.13.2A The description should use standard nomenclature such as the 17-segment cardiac model for myocardial perfusion imaging.

*If quantitative data is used, normal values should be reported*

3.4A The final report should include:

- Unique patient identifier (e.g., unique identification number or sufficient demographic information to identify patient)8
- Date of the transcription
- Date of the interpretation

3.5A The report of therapy should include:

- Unique patient identifier (e.g., unique identification number or sufficient demographic information to identify patient)8
- Date of the transcription
- Date of the interpretation
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 and/or initiating the procedure.

4.1.1.1A The 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 Whenever 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.

4.1.2A 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.

4.1.3A 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 $^{131}$I-sodium iodide, the breast-feeding screening protocol must assure that any patient who is breast-feeding is not administered the radiopharmaceutical. A patient who is breast-feeding must also be given the opportunity to stop lactating for an appropriate time (usually at least three weeks) prior to receiving $^{131}$I therapy to reduce the radiation to the breasts.

4.1.3.2A Warning signs must be present to help prevent inadvertent administration of radiopharmaceuticals to patients who are pregnant or breast-feeding. At a minimum, these must be easily seen by the patient (and in a language understandable to most patients) in the area where initial radiopharmaceutical administration is performed.

4.1.4A 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.

4.1.5A 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.

4.1.6A Investigational Radiopharmaceuticals Policy – These are used only in accordance with research protocols.

4.1.7A Infection Control/Communicable Diseases Policy – 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.

4.1.8A Hazardous Materials Policy – Appropriate precautions are taken when using and storing flammable and/or toxic materials.

4.1.9A Medical Emergencies Policy – There must be written plan for responding to medical emergencies. All staff and trainees must be familiar with their role in the plan.

4.1.10A Handling of Non-Radioactive Pharmaceuticals Policy

4.1.10.1A Pharmaceuticals are properly stored. If controlled substances are kept on-site (e.g., such as in a crash cart) they must be locked with controlled access.

4.1.10.2A Pharmaceuticals are properly prepared.

4.1.10.3A Patient dosages are determined using standard protocols approved by the Medical Director, or individually written prescriptions. For pediatric patients, dosages are determined individually.

4.1.10.4A The health care provider responsible for prescribing the pharmaceutical must be clearly identified for each patient dose (via prescription or protocol) and properly recorded.
4.1.10.5A Patient identity is verified prior to pharmaceutical administration.

4.1.10.6A The identity and dosage of each pharmaceutical are verified immediately prior to administration by the prescribed route.

4.1.10.7A The expiration date of the pharmaceutical is checked and the dosage is administered prior to the expiration.

4.1.10.8A There must be clear documentation of the administration of pharmaceuticals (substance, amount, route, site, time and identity of person administering).

4.1.11A Adverse Drug Events Policy – There must be a procedure for reporting and maintaining the reports of adverse effects of radiopharmaceuticals and other medications.

4.1.12A Drug Administration Errors Policy – Records of medication (non-radioactive) administration errors must be maintained. Events must be reported as required and records must be maintained. Actions taken in response to identified problems must be available.

(See Guidelines on Page 25 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. Records of this review must include program changes, noted deficiencies, and actions taken (or a statement that none are needed). This must be signed/initialed and dated by the Medical Director or an appropriate designee.

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

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.

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 an approved and accredited dosimetry processor.
ii. Employees who are monitored must be advised of their dose annually if likely to exceed 10% of the occupational limit.
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 indicated by the responsible reviewer) and any excess exposures reported as appropriate. Additionally, results of personnel monitoring must also reflect appropriate use of monitoring device (e.g., for a technologist who is preparing radiopharmaceuticals for use, their ring badge exposure result should not routinely be background level).

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 investigation and documentation 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 [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 sources wipe/leak testing protocol and documentation including frequency, identity, activity, and location of all sources, name of person conducting the inventory and leak testing, and results of wipe/leak testing. 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 Instruction of patients, family members and, as needed, hospital staff (e.g., nursing personnel) regarding radiation precautions for all therapeutic procedures and/or when appropriate for diagnostic procedures.

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; and
4.4.4.9A proper storage of kits and prepared radiopharmaceuticals.

4.4.5A Administration of Radiopharmaceuticals to Patients

4.4.5.1A Determination of patient dosages using standardized protocols (approved by the Medical Director) or by individually written prescriptions (only by authorized users). The authorized user responsible for prescribing the radiopharmaceuticals must be clearly identified for each patient dose (via prescription or protocol signed by an authorized user).

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

ii. 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. Alternatively, for sites using unit doses, where permitted, the dosages may be determined based on decay correction of the unit dose. For sites using other than unit doses, the dosages being administered may be determined using a combination of measurement and mathematical calculations or a combination of volumetric measurements and mathematical calculations based on measurements done by an appropriate preparer (radiopharmacy/supplier).

4.4.5.3A Recording of specific patient dosages (as determined by methods noted in 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 2.3B.

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 its expiration date.

4.4.5.7A Clear documentation of the administration of radiopharmaceuticals (substance, amount, route, site, date, time, identity of person administering).

4.4.6A Clear instruction for the investigation and documentation of any errors in the administration of radioactive material, both reportable and non-reportable.

4.5A Radioactive Materials Storage and Disposal

4.5.1.1A Radioactive trash (wipes, syringes, alcohol swabs, etc.) is kept separate from normal trash, stored and appropriately discarded.

4.5.1.2A Security (e.g., locking) of areas containing radioactive materials (including hot facility, other radioactive use, and storage/decay areas) when not under supervision of clinic personnel must ensure that non-authorized personnel (including visitors, patients, and non-authorized staff) cannot access any radioactive materials.

4.5.1.3A 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 who are unable to cooperate.

Sample documents for policies and protocols listed in Section 4A are available on the IAC Nuclear/PET website at www.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 www.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, QA, 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 www.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. Equipment and instrumentation must include at least the following:

1.1.1B dose calibrator or decay correction calculation system, as applicable;
1.1.2B imaging/counting equipment;
1.1.3B radiation monitoring devices including:
   1.1.3.1B portable survey meter (required);
   1.1.3.2B removable contamination counting equipment (as applicable); and
   1.1.3.3B fixed area survey meter for dose preparation/storage areas (as applicable).
1.1.4B resuscitation equipment and supplies (appropriate to the types of procedures being performed):
   1.1.4.1B oxygen;
   1.1.4.2B defibrillator/AED; and
   1.1.4.3B emergency drugs (including a master list; all unexpired).
1.1.5B exercise equipment (as applicable);
1.1.6B ECG equipment (as applicable);
1.1.7B ancillary monitoring equipment (as applicable);
1.1.8B infusion pumps/automated injectors (as applicable);
1.1.9B glucometers (as applicable);
1.1.10B hood for volatile radionuclides or cell handling (as applicable); and
1.1.11B xenon (or other gas) trap (as applicable).

STANDARD – Equipment Quality Control Protocols

1.2B All imaging and non-imaging devices must be FDA approved or used under an approved research protocol with informed consent by the patient.

1.2.1B Imaging equipment must be in good working condition and safety features should be regularly inspected.
1.2.2B The facility must maintain records of service and maintenance.

1.2.3B The facility must have acceptable site-specific written protocols for and maintain records of all routine quality control (QC) of imaging and non-imaging equipment.

1.2.3.1B QC protocols must be reviewed and/or updated at least annually by the Medical Director, physicist or other responsible person.

1.2.3.2B Protocols for QC must include acceptable range (or tolerance limits) of the results of each procedure and the corrective action for an out-of-tolerance result.

1.2.3.3B The protocols must contain instructions for record retention and comparison with previous results.

1.2.3.4B 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.

1.2.4B 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 35 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 federal, state and local requirements.

1.3.1B Gamma Camera

(See Guidelines on Page 35 for further recommendations.)

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)

1.3.1.2B Intrinsic or extrinsic uniformity calculation of integral and/or differential uniformity value must be performed on all gamma cameras (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 on all gamma cameras. Frequency: Weekly

1.3.1.4B Center-of-rotation (COR) must be performed 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) of all gamma cameras must be performed. Frequency: Every six months
Comment: Energy peaking and uniformity testing must be appropriate for the energy of the radioisotopes being imaged (e.g., low energy and 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.

1.3.2B PET Scanner

1.3.2.1B A blank scan, performed by uniform irradiation of the detector elements to assess detector response, must be performed.
Frequency: Daily

1.3.2.2B Tomographic uniformity using a cylinder phantom (as applicable for procedures performed per regulations)
Frequency: Per manufacturer’s recommendation

1.3.2.3B Bed position alignment (as applicable for procedures performed per regulations)
Frequency: Per manufacturer’s recommendation

1.3.2.4B Normalization calibration to measure the efficiency of all the detector projections in the system must be performed.
Frequency: After a hardware change or per manufacturer’s recommendations

1.3.2.5B Absolute activity calibration (as applicable for procedures performed per regulations)
Frequency: After a hardware change or per manufacturer’s recommendations

1.3.2.6B Preventive maintenance of all PET and PET/CT scanners must be performed.
Frequency: Every six months

Comment: If imaging equipment is physically moved from site to site, the QC tests must be repeated after each move and prior to equipment use.

1.3.3B SPECT/CT and PET/CT Scanner

1.3.3.1B Accuracy of image registration (as applicable for procedures performed per regulations)
Frequency: Monthly or per manufacturer’s recommendation

1.3.3.2B Accuracy of CT-based attenuation correction (as applicable for procedures performed per regulations)
Frequency: Monthly or per manufacturer’s recommendation

1.3.4B CT-Specific Quality Control

1.3.4.1B CT system acceptance testing must be performed.
Frequency: Installation and following major upgrade

1.3.4.2B Measurement and assessment of patient radiation dose for representative examinations must be performed by a medical physicist or qualified expert.
Frequency: Annually

1.3.4.3B Routine (daily and periodic) QC tests must be conducted as outlined by the manufacturer. Federal standards require CT manufacturers provide QC testing instructions, recommended testing frequency, a QC test phantom appropriate for the scanner and acceptable variations in parameter measurements.

Daily QC tests (as applicable for procedures performed per regulations):
i. Mean CT number for water and other reference material
   Frequency: Daily or per manufacturer’s recommendation
ii. Image noise
    Frequency: Daily or per manufacturer’s recommendation
iii. Artifact assessment
     Frequency: Daily or per manufacturer’s recommendation
iv. Proper function of audible and visual patient safety equipment
    Frequency: Daily or per manufacturer’s recommendation
v. Spatial resolution for high and low contrast objects
    Frequency: Per manufacturer’s recommendation
vi. Image uniformity
    Frequency: Per manufacturer’s recommendation
vii. Slice thickness
     Frequency: Per manufacturer’s recommendation
viii. Alignment of light accuracy
     Frequency: Per manufacturer’s recommendation
ix. Image display and storage devices
    Frequency: Per manufacturer’s recommendation
x. Air calibration, if applicable
    Frequency: Per manufacturer’s recommendation

1.3.4.4B Annual system performance by a medical physicist or qualified expert must be evaluated
using an appropriate phantom(s) (as applicable for procedures performed per regulations):

i. Contrast scale
   Frequency: Annual or per manufacturer’s recommendation
ii. Mean CT number of water and reference material
    Frequency: Annual or per manufacturer’s recommendation
iii. Linearity
     Frequency: Annual or per manufacturer’s recommendation
iv. Internal and external laser light alignment
    Frequency: Annual or per manufacturer’s recommendation
v. Gantry tilt (tilt gantry systems only)
   Frequency: Annual or per manufacturer’s recommendation
vi. Slice localization
    Frequency: Annual or per manufacturer’s recommendation
vii. Table incrementation accuracy
     Frequency: Annual or per manufacturer’s recommendation
viii. Slice thickness
     Frequency: Annual or per manufacturer’s recommendation
ix. Image quality
    Frequency: Annual or per manufacturer’s recommendation
x. Image display and storage devices
    Frequency: Annual or per manufacturer’s recommendation

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 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
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 that might affect calibration

(See Guidelines on Page 35 for further recommendations.)

1.4.2B  Dose Calibrator

1.4.2.1B  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 5-10%). Frequency: Daily or before use

1.4.2.2B  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

1.4.2.3B  Accuracy that is within tolerance limits must be verified (e.g., within 10%). Frequency: Annual

(See Guidelines on Page 35 for further recommendations.)

1.4.2.4B  Measurement of geometry (position and volume) dependent response must be performed. Frequency: At installation, following repair or relocation

1.4.3B  Well Counter

1.4.3.1B  Energy spectrum check 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 10%). Frequency: Daily (or prior to use)

1.4.3.4B  Chi-square (X²) test to measure reproducibility and random variation must be performed. X² values in the range of 0.05 - 0.95 are generally considered acceptable. Frequency: Quarterly

1.4.3.5B  Efficiency to detect radioactive disintegrations (cpm/Bq or cpm/mCi) 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 if used
1.4.4.2B  Background exposure or counting rate must be measured.  
Frequency: Daily if used

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 10%).  
Frequency: Daily if used

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

1.4.5.1B  Energy spectrum check, if applicable, to verify that the counter is properly peaked and that  
the photopeaks of the radionuclides coincide with the preset photopake energy windows.  
Frequency: Daily if used

1.4.5.2B  Background exposure or counting rate must be measured.  
Frequency: Daily if used

1.4.5.3B  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 10%).  
Frequency: Daily if used

1.4.5.4B  If probe is used to perform radioactive contamination wipe tests, efficiency to detect  
radioactive disintegrations (cpm/Bq or cpm/mCi) must be performed. Frequency:  
Annual or per manufacturer’s recommendation

STANDARD – Other Equipment Quality Control

1.5B  Site specific, detailed protocols must document 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 are expired.  
Frequency: Monthly

1.5.1.2B  Defibrillator/AED device must be checked for functionality (e.g., voltage and battery)  
Frequency: Monthly

1.5.1.3B  Oxygen sources (wall unit or portable cylinder) must be checked for availability,  
proper function and proper tubing/mask.  
Frequency: Monthly

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: As 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

1.6B 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).

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; and
- 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

1.4.1.3B 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.

1.4.2.3B 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.

(See Guidelines on Page 41 for further recommendations.)

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.

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/heads 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. The protocol manual must be readily accessible to appropriate staff members during operational hours. Where appropriate, records must be maintained to document compliance with protocols. (e.g., radiopharmaceutical receipt/disposal records, spill records, etc.).

(See Guidelines on Page 41 for further recommendations.)

2.2.3B Clinical protocols must be reviewed and updated at least annually by the Medical Director or an appropriate designee. All procedures and/or revisions must be dated and initialed/signed by the supervisor or an appropriate designated person.

Comment: The Radiation Safety Program must also be reviewed annually; see Section 4.2A

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 guidelines1,2,3,4,5,6,7,8.

(See Guidelines on Page 41 for further recommendations.)
STANDARD – Clinical Procedure Protocols

2.3B There must be a clinical procedure manual that includes 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 specifically detailed to enable recreation of the protocol in the event of staffing or software change.

(See Guidelines on Page 41 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\(^4,5\) (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 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.

Comment: Other patient instruction/preparation may include skin preparation, wound care, changing or removal of dressings or casts. If there are no patient preparations or restrictions, the protocol must specifically state this.

2.4.1.3B radiopharmaceutical identity, dosage, and route of administration. (See also 4.3.1.4A for additional dosage protocol requirements);

i. For 131-sodium iodide dosages greater than 30 microcuries or therapeutic doses of any other radiopharmaceutical, there must be a written directive.

- The written directive must be dated and signed by an authorized user before administration of therapeutic dose. Written directive must include the patient’s name, dosage, radioactive drug and route of administration.
- Protocols for any administration requiring a written directive must verify the identity of the individual and that the administration is in accordance with the written directive.

(See Guidelines on Page 40 for further recommendations.)

2.4.1.4B non-radioactive drugs (e.g., pharmacologic stress agents, pyrophosphate (PYP), sinalide, acetazolamide, cholecystokinin, morphine sulfate, furosemide, captopril, aminophylline, metaclopramide, pentagastrin) 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, step and shoot, continuous), gating, matrix size, zoom, etc.);

(See Guidelines on Page 40 for further recommendations.)
2.4.1.6B patient position (e.g., supine, prone, PET/CT, 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; and

iv. corresponding published references (if available).

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

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

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

2.4.2.3B injection criteria and exercise/testing end points including any specific events that are reasons for stopping the stressing activity (such as 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); and

2.4.2.6B identification and treatment of common adverse effects for both exercise and/or pharmaceutical stress (e.g., hypertension, dyspnea, chest pain).

2.4.3B Therapy protocols must describe in detail:

2.4.3.1B clinical indications and contraindications;

2.4.3.2B patient 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.

2.4.3.3B radiopharmaceutical identity, dosage and route of administration;

Comment: There must be a written directive signed and dated by the treating physician who is an authorized user. The written directives must be retained for at least three years or as required by NRC and/or state regulations.

2.4.3.4B the treating physician must directly supervise the administration of the therapeutic radiopharmaceutical;

2.4.3.5B non-radioactive drugs used in the procedure including dosage timing, route of administration and any precautions or restrictions;

2.4.3.6B treatment procedure including counseling, informed consent, pregnancy and/or breast-feeding status check, supervision of dosage administration, medical record documentation;

Comment: If nuclear imaging is needed as part of a therapy protocol, see 2.4B for components of imaging protocols.

2.4.3.7B radiation precautions following treatment, as appropriate (none required for pure beta emitters or 153 Sm):

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

ii. When nuclear medicine therapy patients are released rather than being hospitalized [when exposure to others is likely to exceed 0.1 rem (1 mSv) but not likely to exceed 0.5 rem (5 mSv)], a record of the basis for the release and instructions provided must be maintained.
iii. When patients must be hospitalized due to radiation exposure restrictions, protocols must address radiation safety instruction to direct care (e.g., nursing) and housekeeping staff, hospital room/signage requirements, radiation monitoring requirements, visitation policy, handling of materials used by the patient, and response to medical emergencies or patient death.

**STANDARD – Therapy Performance**

2.5B  Nuclear medicine therapies are performed and a final report provided by the Medical Director or members of the medical staff who are qualified as defined in 1.1.1A and 1.3.1A. The treating physician must be an authorized user for the radioisotope administered if it is controlled under the radioactive materials license.

2.5.1B  The treating physician must review the pertinent elements of the patient’s history, physical findings, facility and imaging data to determine that the proposed treatment is appropriate. The treating physician must take responsibility for the proper administration of the therapy and its potential side effects.

2.5.2B  The treating physician is responsible for assuring that the facility’s therapy protocol is followed as well as radiation safety protocols specifically relevant to radionuclide therapies (4.2A). If deviations from the protocols are made, these must be documented in the patient’s medical record and/or the final report.

2.5.3B  Prior to administration of the therapeutic dosage, the treating physician must assure that the patient is fully informed regarding the risks (including side effects), benefits, alternatives, and expected outcome (including likelihood of success) of the therapy; written consent is obtained; the patient is not pregnant; and the patient is not lactating or is specifically counseled about the risks of breast-feeding (if any) based on the specific treatment.

2.5.4B  The treating physician must assure that the patient is properly identified prior to radionuclide therapy dosage administration and that the administration is in accordance with the written directive including confirmation of the dosage and checking the labeled vial or syringe.

2.5.5B  The treating physician must assure that the patient is given appropriate post-therapy instructions and specific information concerning his/her follow-up appointment(s) [with whom, when, and where].

2.5.6B  The treating physician is responsible for post-therapy care unless coordinated with and transitioned to the referring physician or other health care provider (including providing any specific subject-area information needed for proper care following the therapy).

2.5.7B  Written directive must be dated and signed by an authorized user before administration of therapeutic dose. Written directive must include: the patient's name, dosage, specific radiopharmaceutical, route of administration. Protocols for any administration requiring a written directive must verify the identity of the individual and that the administration is in accordance with the written directive.

2.5.8B  Record of the written directive must be retained according to state or federal regulation.
Section 2B: 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.

2.2.5.2B Sample protocol information is available on the IAC Nuclear/PET website at www.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.

2.4.1.3 Radiation dosimetry: Effective dose and critical organ dose for each radiopharmaceutical given should be included. If relevant, pediatric exposures should be included.7
Part C:
Quality Improvement

Section 1C: Quality Improvement Program

STANDARD – QI Program

1.1C The facility must conduct internal Quality Improvement (QI) at regular intervals that are appropriate for the facility’s stated purpose.

(See Guidelines on Page 42 for further recommendations).

1.1.1C The Medical Director and appropriate staff must review and maintain minutes or reports of QI evaluations and document, as applicable, corrective measures taken.

1.1.2C The performance of all staff physicians and nuclear medicine technologists must be assessed as part of the QI Program.

1.1.3C The program must show evidence of improvement activities or, if an assessment confirms acceptable quality of a measure, the program must demonstrate improvement by selecting a new or an additional area for assessment. Measures must be selected based on areas of potential improvement.

1.1.4C The program must have pre-defined indicators of quality and pre-defined thresholds that indicate the need for corrective action.

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 The QI Program must include at least one measure from each of the following three areas: administrative quality, technical quality and physician performance. There must be at least one measurement from each area annually.

2.1.1C 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:

2.1.1.1C scheduling back logs;
2.1.1.2C patient wait times;
2.1.1.3C accuracy of patient information during scheduling;
2.1.1.4C completeness of documentation;
2.1.1.5C time from completion of procedure to distribution of final report;
2.1.1.6C patient satisfaction;
2.1.1.7C referring physician satisfaction; and
2.1.1.8C Appropriate Use Study.

2.1.2C Technical Quality – To assess and improve the technical quality of the images and procedures being performed. Areas that may be assessed include, but are not limited to:

2.1.2.1C image quality;
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; and
2.1.2.6C physiologic patient simulator study.

(See Guidelines on Page 44 for further recommendations.)

2.1.3C Physician Performance – To assess and improve the performance of physicians regarding the quality of medical practice (such as report accuracy, appropriateness of care, effectiveness of radionuclide therapies) and physician behaviors (communication and professionalism). Areas that may be assessed include but are not limited to:

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;
2.1.3.5C physiologic patient simulator study; and
2.1.3.6C Appropriate Use Study.

*(See Guidelines on Page 44 for further recommendations.)*

2.2C As part of the ongoing QI Program, facilities providing nuclear cardiology and cardiac PET imaging must incorporate the measurement of the appropriate use of radionuclide testing based on criteria published and/or endorsed by professional medical organization(s).

*(See Guidelines on Page 44 for further recommendations.)*

2.2.1C Appropriate use 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.

2.2.2C Overall results must be documented. The percentage of appropriate, inappropriate and uncertain indications for testing must be measured.

2.2.3C A program for education and reporting must be developed and include:

2.2.3.1C patterns of adherence to Appropriate Use Criteria (AUC);
2.2.3.2C baseline rates of adherence;
2.2.3.3C goals for improvement of adherence to AUC;
2.2.3.4C measurement of improvement rate; and
2.2.3.5C confidential comparison reports on patterns of adherence in aggregate by ordering physician, ordering practice and interpreting practice.

2.2.4C The appropriate use must be tracked and reported using tools as endorsed by professional medical organizations or using an independent method utilizing criteria published by professional medical organizations.

Section 2C: Quality Improvement Measures

*Guidelines*

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.

2.2C All other areas of nuclear medicine are encouraged to measure appropriate use as AUC are published by professional medical organizations.

Annual participation in an appropriate use measurement program may be used to fulfill the annual QI requirement for both the administrative and physician performance measurements.
Section 3C: Quality Improvement Meetings

STANDARD – QI Meetings

3.1C A minimum of two nuclear cardiology/nuclear medicine/PET QI meetings per year must be held to review the findings of the QI measures and determine actions for improvement of performance. Each member of the medical and technical staff must attend at least one meeting per year. Minutes of the meeting and attendance must be recorded.

3.2C A minimum of four departmental meetings per year, in conjunction with or in addition to QI meetings, must be held to discuss in-service education, safety procedures, technical information and improvements. Each member of the medical, technical and appropriate ancillary personnel involved in nuclear cardiology/nuclear medicine/PET must attend at least 50% of the meetings. Minutes of the meeting and attendance must be recorded.
Selected Bibliography


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