IAC Standards and Guidelines for Radiopharmaceutical Therapy Accreditation

Accreditation Standards

APRIL 2025

Introduction

The Intersocietal Accreditation Commission (IAC) accredits facilities specific to radiopharmaceutical therapy. IAC accreditation is a means by which facilities can evaluate and demonstrate the level of patient care they provide.

This program is designed to accredit facilities that perform radiopharmaceutical therapy procedures by ensuring that the facility meets requirements for training and education, performance and documentation of radiopharmaceutical therapy procedures.

A radiopharmaceutical therapy facility is defined as a facility where radiopharmaceutical therapies are administered and is composed of, at a minimum, a qualified Medical Director and Technical Director. Under the supervision of the qualified Medical Director there may be additional medical staff, advanced practice providers, certified nuclear medicine technologists and nurses. All physicians administering radiopharmaceutical therapies must be included in the application for accreditation as part of the medical staff. The facility must meet the organizational requirements defined in this document.

Imaging may or may not be performed at a radiopharmaceutical therapy facility. If imaging is performed as a part of the radiopharmaceutical therapy procedures (pre or post), the facility must meet the imaging equipment requirements as defined in this document.

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

These accreditation Standards and Guidelines are the minimum standards for accreditation of radiopharmaceutical therapy 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.*

New or emerging technologies, protocols and other novel imaging or interventional approaches not included in guidelines published by professional societies must have supporting documentation that demonstrates adherence to manufacturer's training, safety specifications and quality control specifications as applicable. Facilities are encouraged to contact the IAC for guidance related to utilization of new technology not currently addressed in the IAC Standards.

These Standards were published and effective on June 23, 2023. Additional recommendations were published on April 1, 2025 to include an Artificial Intelligence (AI) Guidance Document.

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

Part A: Organization

Section 1A: Personnel and Supervision

STANDARD – Medical Director

1.1A Medical Director(s) must be a licensed physician and be an authorized user of radioisotopes according to NRC, state, provincial or appropriate regulatory agency regulations for radiopharmaceutical therapy.

1.1.1A Medical Director Required Training and Experience

The Medical Director must have appropriate training and clinical experience in the interpretation of nuclear medicine and PET imaging (e.g., SPECT/CT, PET/CT and/or PET/MRI), as it relates to the administration of radiopharmaceutical therapies and meet the following criteria:

1.1.1.1A Board certified by the American Board of Nuclear Medicine (ABNM), American Board of Radiology (ABR) (diagnostic radiology with nuclear medicine training or special competence in nuclear medicine, radiation oncology or interventional radiology), Royal College of Physicians and Surgeons of Canada or Le College des Medicins du Quebec or equivalent certification with specific training in nuclear medicine imaging and therapy recognized by federal, state and provincial regulations.

AND

1.1.1.2A Must have appropriate training and maintain proficiency in the radiopharmaceutical therapies in which they are applying for accreditation and administrations must be documented in a log that includes date, type of radiopharmaceutical therapy and dose administered.

Comment: Must maintain proficiency in interpretation of imaging as related to the administration of radiopharmaceutical therapies. This includes reviewing imaging prior to radiopharmaceutical therapy administration.

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 ensure compliance with all policies/procedures/ protocols and review and update radiopharmaceutical therapy/radiation safety manuals periodically as necessary (minimum every year) or as new protocols are introduced. This review must be documented via signature (or initials) and date on the reviewed document or manual.

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 both nuclear medicine and radiopharmaceutical therapy, every three years.

Comment: If the Medical Director has successfully attained ONE or more of the following within the three years prior to the application submission date, the CME requirement will be considered fulfilled:

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i. completion of an Accreditation Council for Graduate Medical Education (ACGME) approved relevant residency or fellowship;
ii. attaining initial certification by a relevant ABMS recognized board.

1.1.3.2A Documentation of CME credits must be kept on file and available for inspection.

1.1.3.3A A maximum of five of the 15 required credits may come from MR and/or CT education.

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 Must possess and maintain an appropriate credential in nuclear medicine technology [Certified Nuclear Medicine Technologist (CNMT), Nuclear Medicine Advanced Associate, 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].

1.2.1.2A Current Basic Life Support (BLS) certification.

1.2.2A Technical Director Responsibilities

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

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

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

i. The appointed technologist acting as Technical Director:
   - may supervise and assist others in performing examinations;
   - may oversee day-to-day activities; and
   - must communicate at least weekly with the Technical Director to maintain compliance with the IAC Radiopharmaceutical Therapy Standards.

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 radiopharmaceutical therapy every three years. All CE hours must be approved CE (i.e., VOICE, ASRT, ACE, AMA Category I).

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

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

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iii. attainment of advanced technical credential (NCT, PET or Nuclear Medicine Advanced Associate [NMAA]).

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

1.2.3.3A A maximum of five of the 15 required credits may come from MR and/or CT education or attainment of an advanced technical credential in MR and/or CT.

STANDARD – Medical Staff

1.3A All members of the medical staff must be licensed physicians and authorized users of radioisotopes according to NRC or state regulatory agency regulations for the type(s) of radiopharmaceutical therapy submitted for accreditation.

1.3.1A Medical Staff Required Training and Experience

The medical staff members must have appropriate training, clinical experience and meet the following criteria:

1.3.1.1A Board certified by the American Board of Nuclear Medicine (ABNM), American Board of Radiology (ABR) (diagnostic radiology with nuclear medicine training or special competence in nuclear medicine, radiation oncology or interventional radiology), Royal College of Physicians and Surgeons of Canada or Le College des Medicins du Quebec or equivalent certification with specific training in nuclear medicine imaging and therapy as recognized by federal, state and provincial regulations.

AND

1.3.1.2A Must have appropriate training and maintain proficiency in the radiopharmaceutical therapies in which they are applying for accreditation and administrations must be documented in a log that includes date, type of radiopharmaceutical therapy and dose administered.

1.3.2A Medical Staff Responsibilities

Medical staff responsibilities include but are not limited to:

1.3.2.1A The planning and administration of radionuclide therapies.

1.3.3A Continuing Medical Education (CME) Requirements

1.3.3.1A The medical staff must obtain at least 15 hours of AMA Category I CME credits, relevant to nuclear medicine and radiopharmaceutical therapy every three years.

Comment: If the medical staff has successfully attained ONE or more of the following within the three years prior to the application submission date, the CME requirement will be considered fulfilled:

i. completion of an Accreditation Council for Graduate Medical Education (ACGME) approved relevant residency or fellowship;
ii. attaining initial certification by a relevant ABMS recognized board; or
iii. re-certification by the American Board of Nuclear Medicine (ABNM), or American Board of Radiology (ABR) with AU eligible status.

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

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1.3.3.3A A maximum of five of the 15 required credits may come from MR and/or CT education.

STANDARD – Technical Staff

1.4A All technical staff must be nuclear medicine technologists with the following qualifications:

1.4.1A Technical Staff Required Training and Experience

The technical staff must meet the following criteria and maintain documented training for the specific therapies submitted for accreditation:

1.4.1.1A Must possess and maintain an appropriate credential in nuclear medicine technology [Nuclear Medicine Advanced Associate (NMAA), Certified Nuclear Medicine Technologist (CNMT) or Registered Technologist (Nuclear) RT(N) credential in the U.S. or Registered Technologist Nuclear Medicine (RTNM) or Medical Radiation Technologist (Nuclear) MRT(N) credential in Canada].

1.4.1.2A Current Basic Life Support (BLS) certification.

1.4.2A Continuing Education (CE) Requirements

1.4.2.1A The technical staff must obtain at least 15 hours of accredited CE relevant to nuclear medicine and radiopharmaceutical therapy, every three years. All CE hours must be approved CE (i.e., VOICE, ASRT, ACE, AMA Category I).

Comment: If the technical staff has successfully attained ONE of the following within the three years prior to the application submission 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 (NCT, PET or Nuclear Medicine Advanced Associate [NMAA]).

1.4.2.2A Documentation of CE credits must be kept on file and available for inspection.

1.4.2.3A A maximum of five of the 15 required credits may come from MR and/or CT education or attainment of an advanced technical credential in MR and/or CT.

STANDARD – Medical Physicist

1.5A All medical physicists must possess the following qualifications:

1.5.1A Medical Physicists Required Training and Experience:

1.5.1.1A Board certified by the American Board of Radiology (ABR), the American Board of Medical Physics (ABMP) or the Canadian College of Physicists in Medicine (CCPM) in a discipline that includes nuclear medical physics.

1.5.1.2A Board Certified by the American Board of Health Physics (ABHP) with training in medical health physics.

1.5.1.3A Board certified by the American Board of Science in Nuclear Medicine in Nuclear Medicine Physics and Instrumentation or General Nuclear Medicine Science.

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1.5.1.4A Listed on a facility license as Radiation Safety Officer (RSO) for radiopharmaceutical therapy use.

1.5.2A Continuing Medical Education (CME) Requirements

1.5.2.1A The medical physicist must obtain at least 15 hours of CME credits, relevant to nuclear medicine and radiopharmaceutical therapy, every three years.

Comment: "Relevant" to nuclear medicine includes content that is directly related to nuclear cardiology, general nuclear medicine, PET or radiopharmaceutical therapy uses of radiopharmaceuticals.

STANDARD – Radiation Safety Officer

1.6A Radiation safety officer responsibilities include but are not limited to:

1.6.1A Responsible for oversight of the radiation safety program relating to therapeutical administration. This may include proper room preparation, staff training or dosimeter review.

1.6.2A Ensuring that the written directives and other required documentation is complete and maintained for all patients.

1.6.3A Ensuring compliance with the radioactive material regulations and licensing conditions specific to therapeutical administrations.

1.6.4A Ensuring proper QC and calibration of all equipment required to support the radiopharmaceutical therapy program.

1.6.5A Review of patient dosimetry program if applicable. This can include patient specific dose calculations, patient specific release calculations or dose manipulation as part of administration.

Comment: The radiation safety officer can be a physician, medical physicist or member of the technical staff.

STANDARD – Nursing Staff

1.7A The nursing staff work under the direction of the Medical Director. The nurse must possess knowledge of radiopharmaceutical therapy procedures and meet the required training and experience pathways.

1.7.1A Nurse(s) Required Training and Experience

The nurse(s) must be licensed and meet one of the following criteria:

1.7.1.1A Registered Nurse (RN)

1.7.1.2A Advanced Practice Nurse (APRN)

1.7.1.3A Advanced health care degree or Bachelor of Science in Nursing (BSN)

AND

Documentation of training for the specific radiopharmaceutical therapies submitted for accreditation must be kept on file.

1.7.1.4A Current Basic Life Support (BLS) certification

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1.7.2A Nursing staff must not administer radiopharmaceutical therapies unless specifically stated on radioactive materials license.

STANDARD – Advanced Practice Provider(s)

1.8A The advanced practice provider(s) works under the direction of the Medical Director or medical staff member. The advanced practice provider(s) must possess knowledge of radiopharmaceutical therapy procedures and must practice within the scope of practice of an advanced practice provider determined by local, provincial, state and/or federal regulations.

1.8.1A Advanced Practice Provider(s) Required Training and Experience:

The advanced practice provider(s) must be licensed and meet one of the following criteria:

1.8.1.1A Physician Assistant (PA)

1.8.1.2A Doctor of Nursing Practice (DNP)

1.8.1.3A Nurse Practitioner (NP)

1.8.1.4A Nuclear Medicine Advanced Associate (NMAA)

AND

1.8.1.5A Documentation of training for the specific radiopharmaceutical therapies submitted for accreditation must be kept on file.

1.8.1.6A Current Basic Life Support certification

1.8.2A Advanced practice provider(s) must not administer radiopharmaceutical therapies unless specifically stated on the radioactive materials license.

Comment: Standard 1.8.2A does not apply to Nuclear Medicine Advanced Associates that are practicing within the scope of practice of an advanced practice provider.

STANDARD – Direct Patient Care Personnel

1.9A All direct patient care personnel must meet the following qualifications:

1.9.1A All personnel directly supervising radiopharmaceutical therapy procedures must have appropriate training/experience. Only authorized users that are specifically listed on the license for the radiopharmaceutical therapy may administer the radiopharmaceutical, all personnel should be properly trained on the procedure.

1.9.2A Basic Life Support – All personnel, including physicians, directly supervising radiopharmaceutical therapy procedures must have appropriate training/experience and must be certified in basic life support.

1.9.3A Advanced Cardiac Life Support (ACLS) – There must be ACLS certified personnel on site and immediately available during radiopharmaceutical therapy administrations.

STANDARD – Physician and Nuclear Medicine Technologist Trainees

1.10A Physicians and nuclear medicine technologists in training must not compromise patient care.

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1.10.1A Physician and Nuclear Medicine Technologist Trainee Supervision

1.10.1.1A 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.

STANDARD – Nuclear Medicine Assistants

1.11A 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.

1.11.1A A nuclear medicine assistant must not perform radiopharmaceutical therapy procedures.

STANDARD – Ancillary Personnel

1.12A Ancillary personnel necessary for safe and effective patient care must be available.

1.12.1A 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.

1.12.1.1A Ancillary personnel may consist of:

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

1.12.1.2A 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.

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Section 2A: Facility

STANDARD – Radiopharmaceutical Therapy 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, patient/ staff bathrooms;

2.1.2A dedicated radioactive bathroom during therapy administration;

2.1.3A appropriate radioactive materials use and storage areas;

2.1.4A pre- and post- radiopharmaceutical therapy 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/treated) into images/measurements from other patients, radioactive materials or radioactive waste;

2.1.5A patient education, consultation and examination areas with accessible handwashing for staff;

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 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.

2.1.8A Adequate designated space must be available for radiopharmaceutical therapy procedures that require a longer stay (i.e., procedures requiring admission to the hospital or taking several hours). This space must include, as appropriate:

2.1.8.1A designated patient therapy room;

2.1.8.2A use of signage; and

2.1.8.3A proper use of shielding and appropriate protection of surfaces from bodily fluids to minimize radiation exposure and contamination.

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Section 3A: Facility Safety

STANDARD – Patient and Facility Safety

3.1A Patient and employee safety is ensured by written protocols. Written protocols must be in place for the following:

(See Guidelines on Page 16 for further recommendations.)

Comment: As required, there also must be documentation for initial and recurrent training (such as for HIPAA, OSHA, etc.) as required by local, state, provincial or federal rules.

3.1.1A Patient Identification Policy – For all radiopharmaceutical therapy procedures there must be a process that assures accurate patient identification immediately prior to administration of the therapeutic radiopharmaceutical and ancillary pharmaceuticals.

3.1.1.1A The identification procedure must reliably identify the individual as the correct person for whom the radiopharmaceutical therapy is intended and to match the correct radiopharmaceutical therapy to that individual.

3.1.1.2A 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."

3.1.2A Pregnancy Screening Policy – For all radiopharmaceutical therapy procedures there must be a process that assures that patients who could be pregnant are identified. The pregnancy screening protocol must include serum testing prior to radiopharmaceutical therapy administration to assure that patients who are pregnant are not administered the radiopharmaceutical.

3.1.2.1A 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.

3.1.2.2A 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.

3.1.2.3A Warning signage must be present to help prevent inadvertent administration of radiopharmaceuticals to patients who are pregnant. At a minimum, these must be easily seen by the patient (and in language(s) understandable to most patients) in the area(s) where initial radiopharmaceutical administration is performed.

3.1.3A Breast-feeding Screening Policy – For all radiopharmaceutical therapy 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 technologist verifying the information. 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.

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3.1.3.1A For radiopharmaceutical therapies the breast-feeding screening protocol must assure that any patient who is breast-feeding is not administered the radiopharmaceutical therapy. A patient who is breast-feeding must also be given the opportunity to stop lactating for an appropriate time prior to receiving radiopharmaceutical therapy to reduce the radiation to the breasts.

3.1.3.2A Warning signage must be present to help prevent inadvertent administration of radiopharmaceutical therapy dose to patients who are breast-feeding. At a minimum, these must be easily seen by the patient (and in a language understandable to most patients) in the area where initial radiopharmaceutical therapy administration is performed.

3.1.4A Informed Consent Policy –Written informed consent must be obtained from the patient or guardian for radiopharmaceutical therapy procedures by an appropriately qualified practitioner.

3.1.5A Infection Control/Communicable Diseases Policy – There must be a policy to ensure appropriate precautions to protect both patients and facility personnel are taken, in accordance with universal precautions, when handling toxic, biologic materials (i.e., used syringes, needles, blood and/or body fluid, etc.) or when in contact with communicable diseases. This includes policies/procedures regarding decreasing the probability of needle stick of staff and what to do if a worker is punctured by a used needle.

3.1.6A Hazardous Materials Policy – There must be a policy to ensure appropriate precautions to be taken when using and storing flammable and/or toxic materials.

3.1.7A Medical Emergencies Policy – There must be written plan for responding to patient medical emergencies, which includes an outline of staff responsibilities. Each staff member must be familiar with his/her role in the plan. The plan should be appropriate for the risks of the procedures performed by the facility.

3.1.8A Handling of Non-Radioactive Pharmaceuticals Policy

3.1.8.1A Pharmaceuticals must be properly stored. Controlled substances kept on-site (e.g., such as in a crash cart) must be secured to limit access only to authorized personnel.

3.1.8.2A Pharmaceuticals must be properly prepared.

3.1.8.3A Patient dosages must be determined using standardized protocols or by individually written prescriptions. For each patient dose, the prescribing physician must be clearly identifiable.

3.1.8.4A Patient identity must be verified prior to pharmaceutical administration (see Standard 3.1.1.1A).

3.1.8.5A The identity and dosage of each pharmaceutical must be verified immediately prior to administration by the prescribed route.

3.1.8.6A The expiration date of the pharmaceutical must be checked and the dosage administered prior to the expiration.

3.1.8.7A There must be clear documentation of the administration of pharmaceuticals (substance, amount, route, site, time and identity of person administering).

3.1.9A Drug Administration Errors Policy – Records of medication (non-radioactive) administration errors must be maintained. Events must be reported as required. Documentation of actions taken in response to identified problems must be available.

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3.1.10A Adverse Drug Reactions Policy – There must be a procedure for documenting and reporting adverse reactions (e.g., unexpected, unintended, undesired or excessive response) to medications.

STANDARD – Radiation Safety and Radioactive Materials Handling Protocols

3.2A There must be written radiation safety and radioactive materials handling protocols.

3.2.1A 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 is needed). This must be signed/initialed and dated by the Medical Director or an appropriate designee.

Comment: This review must meet state/provincial and local requirements.

3.2.2A There must be written designation of a radiation safety officer. This is generally found on the radioactive materials license.

3.2.3A Designation of who may handle/administer radionuclides (i.e., list of authorized user physicians, nuclear medicine technologists, medical physicists and/or others who are properly trained and approved, as appropriate).

3.3A Facility operations must comply with accepted provincial, 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.

3.4A Radiation safety protocols must address the following topics:

3.4.1A General Radioactive Materials Handling and Radiation Safety (i.e., Safe Use and Handling of Radioactive Materials):

3.4.1.1A Provision for a safe working environment, including an ALARA (as low as reasonably achievable) radiation exposure policy (for workers and general public);

3.4.1.2A The use of signage for radioactive materials use and storage areas, as required by applicable regulations.

3.4.1.3A Monitoring and reporting of excessive radiation levels to the general public. Including method of monitoring, method of calculation, trigger levels and reporting requirements.

3.4.1.4A Radiation safety instruction upon hire and annually thereafter for all personnel in the facility who are handling or are potentially exposed to, radioactive materials, including all authorized users. Records of this training must be retained.

Comment: Individuals who become authorized users during their tenure on staff and nursing staff providing care during radiopharmaceutical therapy procedures must receive initial (prior to first radiopharmaceutical therapy administration) and annual training.

3.4.1.5A Monitoring of all staff for radiation exposure as required by provincial, federal or state guidelines. This includes the use of hand monitoring ("ring badge") of those directly handling radiopharmaceuticals and bioassays of those administering radioiodine.

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i. Personnel dosimeters that require processing must be processed by a National Voluntary Laboratory Accreditation Program (NVLAP)-approved and accredited dosimetry processor.

ii. Employees who are monitored must be advised of their dose annually if their occupational dose exceeds one millisievert (100 millirem) TEDE or one millisievert to any organ or tissue.

iii. Exposure records must be easily retrievable and made available to the employee.

iv. Results of personnel monitoring must be reviewed periodically to assure that exposures are as low as reasonably achievable.

- This must be documented (such as by signature/initials and date by the responsible reviewer) and any excess exposures reported as appropriate.
- Additionally, results of personnel monitoring must also reflect appropriate use of monitoring device (e.g., for a technologist who is preparing radiopharmaceuticals for use, their ring badge exposure result should not routinely be background level).

3.4.1.6A 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.

3.4.1.7A 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.

3.4.1.8A 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.

3.4.1.9A Spill confinement/decontamination procedures include guidelines posted in the facility (with the radiation safety officer's phone number for work and after hours contact) and documentation requirements for reporting spills/decontamination. The procedures must include instructions for the reporting, documentation and possible investigation of all spills.

3.4.1.10A Proper use of radiation monitoring devices.

3.4.1.11A Area surveys (particularly dose preparation areas) and wipe tests including tolerance limits and response to trigger levels.

i. Daily area surveys must be performed in areas of dosage preparation and administration to include hospital room after discharge, if applicable.

3.4.1.12A Sealed source inventory and wipe/leak testing protocol and documentation including:

i. frequency;

ii. radionuclide identity;

iii. model and serial number, if assigned;

iv. activity, date and name of the person performing the inventory;

v. wipe/leak test:

- The location of the source at the time of the inventory and the results of the wipe/leak test must be documented.

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- The frequency of the sealed source wipe/leak test is a minimum of every six months.

3.4.1.13A 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 instructions for notification of the proper agencies or individuals as well as the information to be reported.

3.4.1.14A Procedure for monitoring radiation exposure for visitors to radiation use areas, if needed based on the potential exposure.

3.4.1.15A Protocols establishing, defining and explaining specific procedures for following and adhering to the "written directive" policy for all personnel involved in administration of radiopharmaceutical therapies. When protocols regarding written directives are not followed, the cause of the deviation and the actions to prevent recurrence must be identified.

3.4.2A Receipt of Radioactive Materials

3.4.2.1A designation of a specific secured area for placing shipments of radiopharmaceutical therapies;

3.4.2.2A recording of receipt of all shipments of radiopharmaceutical therapies; and

3.4.2.3A survey of shipments of radiopharmaceutical therapies, prior to opening, including tolerance limits and response to triggers (including proper notification if damage or leak).

3.4.3A All facilities compounding radiopharmaceuticals must be aware of and in compliance with the guidelines of the United States Pharmacopeia (USP) Chapter 825.

3.4.4A Administration of Radiopharmaceutical Therapies to Patients

3.4.4.1A patient dosages must be determined by individually written prescriptions;

3.4.4.2A assay of patient dosage of radiopharmaceutical therapy (using a dose calibrator) on site prior to administration;

Comment: Documentation must be maintained for any activity adjustment performed by the facility prior to administration.

3.4.4.3A recording of specific patient dosages prior to administration;

3.4.4.4A verification of patient identity prior to radiopharmaceutical therapy administration as well as pregnancy/breast-feeding status;

3.4.4.5A verification of the radiopharmaceutical therapy identity an activity immediately prior to administration by the prescribed route;

3.4.4.6A verification of the expiration date/time of the radiopharmaceutical therapy and assurance of administration prior to expiration; and

3.4.4.7A clear documentation of the administration of radiopharmaceutical therapy (substance, activity, route, site, date, time and identity of person administering).

3.4.5A Records of radioactive materials administration errors must be maintained for both reportable and non-reportable errors. Events must be reported as required. Actions taken in response to identified problems must be available.

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3.4.6A Adverse Radiopharmaceutical Reactions – There must be a procedure for documentation and reporting adverse reactions (e.g., unexpected, unintended, undesired or excessive response) to radiopharmaceuticals.

3.5A Radioactive Materials Storage and Disposal

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

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

3.5.3A Adequate shielding of radioactive materials storage areas based on the types and amounts of radiopharmaceutical therapies as well as the types of use of surrounding areas.

Section 3A: Facility Safety *Guidelines*

3.1A Written protocols should be in place for the following:

Safety/Security for Staff and Patients – There should be a written procedure for responding to disasters or other threats to staff or patient safety/security. This includes when staff may be present after normal facility hours.

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

Sample documents for policies and protocols listed in Section 3A are available on the IAC website at www.intersocietal.org/helpful-resources/sample-documents-repository.

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Section 4A: Equipment and Instrumentation

STANDARD – Equipment and Instrumentation

4.1A 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.

4.1.1A All imaging and non-imaging devices must be FDA-approved or used under an approved research protocol with informed consent by the patient.

4.1.2A The facility must maintain records of service and maintenance.

4.1.3A Equipment and instrumentation must include at least the following:

4.1.3.1A dose calibrator or decay correction calculation system, as applicable;

4.1.3.2A imaging/counting equipment;

4.1.3.3A radiation monitoring devices including:

i. portable survey meter (required);
ii. removable contamination counting equipment (as applicable); and
iii. fixed area survey meter for dose preparation/storage areas (as applicable).

4.1.3.4A resuscitation equipment and supplies (appropriate to the types of procedures being performed):

i. oxygen;
ii. suction (as applicable);
iii. defibrillator/AED; and
iv. emergency drugs (including a master list; all unexpired).

4.1.3.5A ECG equipment (as applicable);

4.1.3.6A ancillary monitoring equipment (as applicable);

4.1.3.7A infusion pumps/automated injectors (as applicable);

4.1.3.8A glucometers (as applicable); and

4.1.3.9A hood for volatile radionuclides or cell handling (as applicable).

STANDARD – Equipment Quality Control Protocols

4.2A The facility must have acceptable site-specific written protocols for all routine quality control procedures of imaging and non-imaging equipment.

Comment: Simply stating "following manufacturer's recommendations" is not sufficient.

4.2.1A The facility must maintain records of all routine quality control of imaging and non-imaging equipment.

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4.2.1.1A 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.

4.2.1.2A Quality control protocols must be reviewed and/or updated as equipment is changed and at least every three years by the Medical Director, physicist or other responsible person.

4.2.2A If frequency of QC testing varies from Standards below, 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).

4.2.3A 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).

STANDARD – Imaging Equipment Quality Control

4.3A Site-specific, detailed protocols must be documented and followed for routine inspection and testing of all imaging equipment. Protocols must be in accordance with all applicable federal, state and local requirements.

4.3.1A Gamma Camera (Planar, SPECT, and SPECT/CT)

4.3.1.1A Energy peaking to verify that the photopeak is centered in the set photopeak energy window must be performed, if applicable (documentation not required).
Frequency: Daily (prior to use) or per manufacturer's recommendation

4.3.1.2A Intrinsic or extrinsic uniformity calculation of integral and/or differential uniformity value must be performed (e.g., 3-5%).
Frequency: Daily (prior to use)

4.3.1.3A Spatial resolution/spatial linearity with resolution phantom (e.g., bars) must be performed.
Frequency: Weekly

4.3.1.4A Center-of-rotation (COR) must be performed on SPECT cameras to ensure mechanical and electrical alignment of the center of field of view.
Frequency: Monthly

4.3.1.5A High-count flood for uniformity correction, performed to correct for residual detector and collimator non-uniformity, must be performed.
Frequency: Per manufacturer's recommendation

4.3.1.6A Preventive maintenance (PM) must be performed.
Frequency: Every six months

4.3.1.7A For facilities performing quantitative analysis of images, absolute activity calibration and testing must be performed. Facilities must develop procedures that validate quantitative scanner performance.
Frequency: After a hardware change or per manufacturer's recommendations

4.3.1.8A For SPECT/CT equipment, daily system tests (as recommended by the manufacturer) must be performed to assess system function/constancy (e.g., calibration scan, CT warm-up, CT calibration, water phantom). The daily system test procedure must be specifically described."

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4.3.1.9A 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.

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

4.3.2A PET and PET/CT and PET/MR Scanner

4.3.2.1A Daily system tests (as recommended by the manufacturer) must be performed to assess system function/constancy (e.g., calibration scan, blank scan, CT warm-up, CT calibration, water phantom, coincidence timing, normalization update, etc.). The daily system test procedure must be specifically described.

Frequency: Daily (prior to use)

4.3.2.2A Tomographic uniformity using a cylinder phantom of uniform radioactivity must be performed.

Frequency: Per manufacturer's recommendation

4.3.2.3A Normalization to calibrate the efficiency of all detectors in the system must be performed.

Frequency: Per manufacturer's recommendation and after preventive maintenance and major hardware repair.

4.3.2.4A For facilities performing quantitative analysis of images, such as standardized uptake value (SUV) calculation, absolute activity calibration and testing must be performed. Facilities must develop procedures that validate quantitative scanner performance.

Frequency: After a hardware change or per manufacturer's recommendations

4.3.2.5A If the PET or PET/CT or PET/MR scanner is physically moved from site to site, the daily system test as described in Standard 1.3.2.1B must be performed after each scanner relocation and prior to injection.

STANDARD – Non-imaging Equipment Quality Control

4.4A Site-specific, detailed protocols must be documented and followed for routine inspection and testing of all non-imaging equipment. Protocols must be in accordance with all applicable federal, state and local requirements.

4.4.1A Survey Meter

4.4.1.1A Constancy of response must be checked by measuring the exposure or counting rate of a long-lived reference source. Measurements must be within acceptable tolerance levels (e.g., within 10-20%).

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

4.4.1.2A 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

4.4.1.3A The survey meter must be calibrated using suitable long-lived reference sources.

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

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4.4.2A Dose Calibrator

4.4.2.1A Background exposure must be measured
Frequency: Daily or before use

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

4.4.2.2A Constancy of response must be checked by measuring the exposure or counting rate of a long-lived reference source. Measurements must be within acceptable tolerance levels (e.g., within 5-10% or per manufacturer's recommendation).
Frequency: Daily or before use

4.4.2.3A 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

4.4.2.4A Accuracy that is within tolerance limits must be verified (e.g., within 5-10% or per manufacturer's recommendation).
Frequency: Annual

4.4.3A Well Counter

4.4.3.1A Energy spectrum check, if applicable, to verify that the counter is properly peaked and that the photopeaks of the radionuclides coincide with the preset photopeak energy windows.
Frequency: Daily or per manufacturer recommendation

4.4.3.2A Background exposure or counting rate must be measured.
Frequency: Daily (or prior to use)

4.4.3.3A Constancy of response must be checked by measuring the exposure or counting rate of a long-lived reference source. Measurements must be within acceptable tolerance levels (e.g., within 5-10% as per manufacturer's recommendation).
Frequency: Daily (or prior to use)

4.4.3.4A Chi-square (X2) test, if applicable, to measure reproducibility and random variation must be performed.
Frequency: Annually

4.4.3.5A Efficiency to determine the ratio of detected counts measured by the system to the actual rate of decay (cpm/mCi or dpm), for a specific nuclide or region of interest must be performed.
Frequency: Annual or per manufacturer's recommendation

4.4.4A Intraoperative Probes

4.4.4.1A The battery must be checked to verify the voltage supplied by the battery is within the acceptable operating range.
Frequency: Daily or before use

4.4.4.2A Background exposure or counting rate must be measured.
Frequency: Daily or before use

4.4.4.3A Bias voltage of primary and back-up battery must be checked, if applicable.

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Frequency: Per manufacturer's recommendation

4.4.4.4A Constancy of response must be checked by measuring the exposure or counting rate of a long-lived reference source. Measurements must be within acceptable tolerance levels (e.g., within 5-10% or as per manufacturer's recommendation).

Frequency: Daily or before use

4.4.5A Organ Uptake Probes (e.g., thyroid uptake probes)

4.4.5.1A System Test/Detector Status/Autocalibration (as recommended by manufacturer) must be performed to assess internal data, full width half-maximum (FWHM), voltage and gain settings.

Frequency: Daily or before use

4.4.5.2A Energy spectrum check, if applicable, to verify that the counter is properly peaked and that the photopeaks of the radionuclides coincide with the preset photopeak energy windows.

Frequency: Daily or before use

4.4.5.3A Background exposure or counting rate must be measured.

Frequency: Daily or before use

4.4.5.4A Constancy of response must be checked by measuring the exposure or counting rate of a long-lived reference source. Measurements must be within acceptable tolerance levels (e.g., within 5-10% or as per manufacturer's recommendation).

Frequency: Daily or before use

4.4.5.5A If probe is used to perform radioactive contamination wipe tests, efficiency for a specific nuclide or region of interest must be measured to determine the ratio of detected counts measured by the system to the actual rate of decay (cpm/Bq or cpm/mCi) or disintegrations per minute (dpm).

Frequency: Annual or per manufacturer's recommendation

4.4.5.6A Chi-square (X2) test to measure reproducibility and random variation must be performed.

Frequency: Annually

STANDARD – Other Equipment Quality Control

4.5A Site-specific, detailed protocols must be documented and be followed for routine inspection and testing of all other medical equipment. Protocols must be in accordance with all federal, state, provincial and local requirements.

4.5.1A Emergency Equipment

4.5.1.1A An emergency response cart or kit, appropriate for the types of procedures being performed, must be present. There must be documentation that it is checked to assure that all expected items are present and none is expired.

Frequency: Monthly

4.5.1.2A Defibrillator/AED device and supplies (e.g., pads, gel) must be checked for functionality (e.g., voltage and battery, expiration date)

Frequency: Daily when patient studies are performed

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4.5.1.3A Oxygen sources (wall unit or portable cylinder) must be checked for availability, pressure gauge shows adequate tank filling, proper function and proper tubing/mask.

Frequency: Daily when patient studies are performed

4.5.1.4A Suction equipment (if applicable)
Frequency: As per facility policy

4.5.2A Miscellaneous Equipment

4.5.2.1A Infusion pump accuracy must be confirmed.

Frequency: Per manufacturer's recommendation

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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.

STANDARD – Records

5.4A 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.

5.4.1A Any retained images must be of high quality and reflect the findings described in the final interpretation.

5.4.2A Technical data that are not included as part of the final report (e.g., worksheets, calculations) must be maintained as part of the facility records. The specific imaging and processing parameters used should be retrievable for each clinical study.

5.4.3A Data from non-imaging studies (e.g., thyroid uptake) must be maintained as part of the facility records, if not included in the final report.

5.4.4A The facility must be able to transmit current or archived patient studies to an outside, non affiliated entity in a format of interpretable quality.

Section 5A: Administrative *Guidelines*

Sample documents are available for each of the required policies listed in Section 5A on the IAC website at intersocietal.org/helpful-resources/sample-documents-repository.

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Part B: Process

Section 1B: Radiopharmaceutical Therapy Procedures and Protocols

STANDARD – Radiopharmaceutical Therapy Administration Volumes

1.1B The facility must have performed at least five cases (courses of therapy) per year in therapies in which they are applying for accreditation.

1.1.1B For radiopharmaceutical therapy accreditation, a facility must be able to submit the minimum number of cases required in the application process. The cases must be performed within one year from the date of submission.

STANDARD – General Protocol Guidelines

1.2B 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.

1.2.1B Complete procedure manuals must be present in the facility and include corresponding references.

1.2.2B Protocols must be organized for easy use (such as in notebook or electronic form) with a table of contents with sections/headings such as: clinical imaging protocols, therapeutic protocols, equipment quality control, radiation safety and radioactive materials handling, administrative policies and facility quality assessment and improvement.

1.2.2.1B The protocol manual must be readily accessible to appropriate staff members during operational hours.

1.2.2.2B Where appropriate, records must be maintained to document compliance with protocols (e.g., radiopharmaceutical receipt/disposal records, spill records, etc.).

1.2.3B Radiopharmaceutical therapy protocols must be reviewed and updated at least annually by the Medical Director or qualified designee. For areas in which the Medical Director does not have education, training and experience, a designee must be appointed to review those protocols.

Comment: A qualified designee can be a physician, physicist or other radiation safety staff.

1.2.3.1B All protocols and/or revisions must be dated and initialed/signed by the Medical Director or the designated person.

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

The Radiation Safety Program must also be reviewed annually (see Standard 3.2.1A).

1.2.4B 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.

1.2.5B The protocols and the facility's performance must be in compliance with:

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1.2.5.1B All applicable federal, state, provincial, and local requirements, including Nuclear Regulatory Commission (NRC) regulations or, in Agreement States, with state regulations for medical use of radioisotopes.

1.2.5.2B Accepted practices such as those in published guidelines.

STANDARD – Radiopharmaceutical Therapy Clinical Protocols

1.3B Radiopharmaceutical therapy protocols must describe in detail:

1.3.1B Requirement that the treating physician must be an authorized user for and are on site and immediately available for the administration of the therapeutic radiopharmaceutical. The treating physician or physician designee must be available until patient discharge.

Comment: Virtual oversight is not acceptable for therapeutic administrations

1.3.2B clinical indications and contraindications;

1.3.3B patient preparation and education/instruction such as food/diet restrictions, if any, withholding or non-withholding of medications or other relevant information;

Comment: If there are no patient preparations or restrictions, it must be specifically stated in the protocol.

1.3.4B radiopharmaceutical therapy identity, dosage range or method of calculation and route of administration;

1.3.5B Requirement for a written directive prior to radiopharmaceutical administration which includes:

1.3.5.1B patient's name;

1.3.5.2B radiopharmaceutical identity;

1.3.5.3B radiopharmaceutical dosage for the specific patient;

1.3.5.4B route of administration; and

1.3.5.5B manual signature and printed name or electronic signature of an authorized user, as defined by the Nuclear Regulatory Commission in 10 CFR §35.217, for that specific agent and date.

1.3.6B Requirement for performing a "time out" prior to therapy administration. This must include proper identification of the patient, radioactive therapy identity and dosage for the specific patient.

1.3.7B non-radioactive drugs used in the procedure including identity, dosage, timing of administration, route of administration and any precautions or restrictions;

1.3.8B treatment procedure including:

1.3.8.1B review of relevant clinical history, laboratory/pathology results and imaging data;

1.3.8.2B informed consent with risks, benefits, alternatives and likelihood of success;

1.3.8.3B pregnancy and/or lactation status check;

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1.3.8.4B immediately prior to dosing, verification of the patient's identity with two identifiers by two members of the medical and/or technical staff;

1.3.8.5B immediately prior to dosing, verification of the radiopharmaceutical therapy identity, amount and route of administration by two members of the medical and/or technical staff (refer to Standards 1.1A-1.4A); and

1.3.8.6B immediately prior to dosing, verify patency of access (if applicable).

1.3.9B Radiation precautions following treatment, as appropriate:

Comment: Guidance concerning breast feeding cessation (if relevant) must also be included in radiation precautions following treatment.

1.3.9.1B outpatient instructions, to include, as appropriate:

i. maintaining distance from others, especially children and pregnant women (including during sleep and time in public);
ii. travel (including public transportation and border crossings);
iii. control of body fluids;
iv. handling of potentially radioactive household trash;
v. the duration of these restrictions; and
vi. response to medical emergencies or patient death.

1.3.9.2B in-patient instructions, to include, as appropriate:

i. radiation safety instruction to direct care (e.g., nursing) and housekeeping staff;
ii. hospital room/signage requirements;
iii. radiation monitoring requirements;
iv. visitation policy;
v. handling of materials used by the patient;
vi. release criteria (including travel instructions); and
vii. response to medical emergencies or patient death.

1.3.10B Description of any imaging required in conjunction with the radiopharmaceutical therapy (e.g., I131 post-radiopharmaceutical therapy whole body imaging).

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Section 2B: Reporting

STANDARD – Radiopharmaceutical Therapy Reporting

2.1B The report of the radiopharmaceutical therapy must be typed or computer-generated and must accurately reflect the treatment performed. This must include:

- 2.1.1B identification of the name, address and phone number of the facility;
- 2.1.2B name of the treatment (type of treatment);
- 2.1.3B patient information:
  - 2.1.3.1B patient's first and last name;
  - 2.1.3.2B gender;
  - 2.1.3.3B date of birth or age; and
  - 2.1.3.4B weight (if applicable).
- 2.1.4B treating physician's name;
- 2.1.5B date of the radiopharmaceutical therapy;
- 2.1.6B the specific radiopharmaceutical administered including:
  - 2.1.6.1B specific identity – radionuclide and chemical form;
  - 2.1.6.2B exact amount administered (XX.X mCi); and
  - 2.1.6.3B route of administration.
- 2.1.7B the following information must be included in the consult, written directive or final report:
  - 2.1.7.1B requesting health care provider's name;
  - 2.1.7.2B patient's diagnosis and justification for radiopharmaceutical therapy including a summary of relevant clinical history, physical findings, laboratory/pathology results and imaging data;
  - 2.1.7.3B a statement that benefits, alternatives, risks (including side effects) and expected outcomes (including likelihood of success) were discussed with the patient and /or decision maker, and consent was given and documented in writing for the initial administration and acknowledged for subsequent administrations.
  - 2.1.7.4B statement that the patient was informed of the information above and written consent was obtained for the initial administration and acknowledged for subsequent administrations;
  - 2.1.7.5B when applicable, evidence that the patient is not pregnant; and
  - 2.1.7.6B when applicable, that the patient is not lactating and/or has been given appropriate breast feeding counseling.
- 2.1.8B any other relevant procedures that were part of the radiopharmaceutical therapy;

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2.1.9B Interpretation of post therapy images (i.e., indication that the administered radiopharmaceutical therapy has the expected bio distribution), if performed;

2.1.10B immediate adverse effects of treatment;

2.1.11B any unusual occurrences or variations from clinic protocols; and

2.1.12B report finalization must include:

2.1.12.1B identification and manual or electronic signature (password protected) of the treating, qualified physician;

2.1.12.2B date report finalized and signed by treating physician; and

2.1.12.3B if the report is amended, the original report content, author and date of signature must be retained. The content of the amendment, author and date of amendment must be clearly recorded.

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Part C: Quality Improvement

Section 1C: Quality Improvement Program

STANDARD – QI Program

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

1.1.1C radiopharmaceutical therapy appropriateness;

1.1.2C quality and safety review of the radiopharmaceutical therapy administration; and

1.1.3C final report and documentation completeness and timeliness.

(See Guidelines below for further recommendations.)

1.2C The Medical Director, staff and/or an appointed QI committee must provide oversight to the QI program. The oversight includes but is not limited to review of the reports of QI evaluations and any corrective actions taken to address any deficiencies.

Section 1C: Quality Improvement Program *Guidelines*

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

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Section 2C: Quality Improvement Measures

STANDARD – QI Measures

2.1C Facilities are required to have a process in place to evaluate the QI measures outlined in sections 2.1.1C through 2.1.3C.

(See Guidelines below for further recommendations.)

2.1.1C Radiopharmaceutical Therapy Appropriateness – The facility must evaluate the appropriateness of the therapy performed and categorized as:

2.1.1.1C indicated; and

2.1.1.2C contraindicated

2.1.2C Quality and Safety Review of the Radiopharmaceutical Therapy Administration – To assess and improve the safety of therapy procedures being performed. The review must include, but is not limited to the evaluation of:

2.1.2.1C correct patient preparation, as specified in the clinical written procedures, at the time of study (labs, etc.);

2.1.2.2C verification of written directive completeness and compliance;

2.1.2.3C adherence to facility radiopharmaceutical therapy protocols;

2.1.2.4C verification of appropriate post therapy care.

2.1.3C Final Report and Documentation Completeness and Timeliness – The facility must evaluate the final report for completeness and timeliness as required in the Standards.

Section 2C: Quality Improvement Measures *Guidelines*

2.1C Administrative Quality – To assess and improve the administrative quality of the facility's operation. Areas that may be assessed include, but are not limited to: scheduling back logs; patient wait times; accuracy of patient information during scheduling; completeness of documentation; time from completion of procedure to distribution of final report; patient satisfaction; referring physician satisfaction.

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Section 3C: Quality Improvement Meetings

STANDARD – QI Meetings

3.1C The facility must have a minimum of two QI meetings per year.

3.1.1C The content of at least one meeting per year is to review the results of the QI analyses and any additional QI-related topics.

3.1.2C All staff must participate in at least one meeting per year.

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Section 4C: Quality Improvement Documentation

STANDARD – QI Documentation and Record Retention

4.1C The facility QI documentation must include, but is not limited to:

4.1.1C the data for all of the QI measures above;

4.1.2C a description of how the QI information is used to improve Nuclear/PET quality;

4.1.3C minutes from the QI meetings; and

4.1.4C participant list (may include remote participation and/or review of minutes).

4.2C The QI documentation must be maintained and available for all appropriate personnel to review.

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Artificial Intelligence (AI) Guidance Document

To assure the quality and safety of care delivery when using AI applications for direct-patient care (clinical*) purposes, each facility should create and follow policies and procedures that address:

1. Training for personnel who use AI;
2. Security of AI software, updates, HIPAA considerations, etc.;
3. AI for Quality Improvement (if applicable);
4. Appropriate use for each AI application; and
5. Governance (authority to make decisions regarding AI implementation).

*Clinical use of AI includes image acquisition, image processing/enhancement, image interpretation, report generation, risk assessment of prognosis, patient history, identification of critical values/results and equipment quality control.

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