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:

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.

(See Guidelines on Page 18 for further recommendations.)

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.

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.

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, 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.

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.
- 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 instruction 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 dose 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 and dose 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, 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.

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 Nuclear/PET website at www.intersocietal.org/helpful-resources/sample-documents-repository.