STANDARDS FOR DIAGNOSTIC IMAGING

NUCLEAR MEDICINE

STANDARDS FOR NUCLEAR MEDICINE

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1. INTRODUCTION AND DEFINITION

Nuclear medicine is a medical specialty that involves the use of radioactive isotopes in the diagnosis and treatment of disease. Nuclear medicine uses very small amounts of radioactive materials (radiopharmaceuticals) to diagnose and treat disease. The radiopharmaceuticals used in nuclear medicine emit gamma rays that can be detected externally by special types of cameras: gamma or positron emission tomography (PET) cameras. These cameras work in conjunction with computers used to form images that provide data and information about the area of body being imaged. In treatment or therapy, the radiopharmaceuticals go directly to the organ being treated.

These standards were developed with permission and based upon the 2007 edition of the "Accreditation Standards for Nuclear Medicine" from the Diagnostic Accreditation Program (DAP); a Standing Committee of the College of Physicians & Surgeons of British Columbia.

2. QUALIFICATION OF PERSONNEL

See Bylaw 25.1.

3. EXAMINATION REQUEST

3.1 Examination requests should be standardized to ensure that accurate, comprehensive and appropriate information is clearly relayed.

3.2 Policies and procedures should be in place to ensure that examination requests meet the needs of the patients/clients and service.

Note: Requests may be verbal, written or electronic.

- Request format is clear and easy to follow.
- Requesting users of the service provide input for examination requests.
- Examination request guidelines are available to users of the service, *e.g.* examination protocols, patient preparation, etc.
- Examinations are only performed when requested by authorized individuals. (Note: In this context "authorized individuals" includes medical physicians and other designated health professionals as permitted by governing legislation, rules and bylaws.)

- There is a system for uniquely identifying patients and records. Discrepancies noted in previously held patient records are resolved prior to requests for new examinations being performed.
- There are processes that address situations where requests lack the necessary information or contain errors. (Intent: It is the responsibility of the requestor to provide the relevant clinical information and for the nuclear medicine service to have processes to deal with incomplete requests.)
- There is a policy for handling verbal requests.
- Examination requestors are notified of cancelled examinations.
- There are processes for expediting urgent and non-routine examinations.
- There is a process for substituting and/or requesting additional examinations at the discretion of the qualified physician and technologist, where appropriate.
- Requests are reviewed by a qualified physician or delegate for appropriateness, priority and protocol assignment, prior to booking the examination.

3.3 Examination requests need to contain appropriate information.

- Examination requests need to include relevant clinical and other information:
    - Patient name
    - Provincial health number
    - Date of birth
    - Gender
    - Examination requestor
    - If an urgent/stat report is required the requestor contact information is indicated
    - Examination type(s) and any specific instructions
    - Pertinent patient history
    - Additional copy(s), where appropriate
    - Indication of relevant prior examinations
    - Known or suspected communicable infectious disease, *e.g.* active Tuberculosis, Methicillin Resistant Staphylococcus Aureus (MRSA), Vancomycin Resistant Enterococcus (VRE), etc.
    - Medications
    - Patient weight
- The date the request is received is indicated.
- There is a standardized and unambiguous method to indicate urgency.

4 PATIENT PREPARATION

4.1 Patients are appropriately prepared for the examination being performed.

4.2 Patient preparation instructions are clearly communicated.

- Patients and/or supporting individuals are advised of patient instructions prior to the examination, as needed.
- Patient instructions are available in a variety of languages considering the population served.
- There are processes to identify and work with patients who do not speak English.
- Multi-lingual staff members are identified and available where practical and in accordance with nuclear medicine service policy.

4.3 Examination preparation is delivered in a manner that meets the needs of the patient.

- Positive patient identification is confirmed using at least two patient identifiers.
- There are processes in place to ensure that patients have followed the preparation instructions and to address situations where patients are inappropriately prepared.
- Prior to procedures, there are processes to identify possible communicable diseases.
- Any factors that may affect the examination are documented and considered.
- Contraindications are assessed, *e.g.* pregnancy, breastfeeding, medications, etc.
- A qualified physician is involved in assessing any contraindications.
- When required, informed consent is documented in accordance with hospital or nuclear medicine service policy and provincial legislation.

5 EXAMINATION PROTOCOLS

5.1 The nuclear medicine department should have a comprehensive process in place for protocol adoption and development.

- Protocols should be developed and reviewed on a regular basis by qualified individual(s).

- Processes should be in place to ensure that protocols meet the needs of requesting physicians.
- Protocols selected for use have been developed by experts in the appropriate fields, cited and published in peer reviewed textbooks, journals and/or websites and/or have been recommended by national, international or regional agencies.
- Before new protocols or those not recognized as standard practice are used, they are validated and referenced by qualified individual(s) to confirm they satisfy intended use.
- Validation results of new protocols should be maintained.
- There should be a process in place to communicate and educate staff in new or revised protocols.

5.2 Examination protocols should contain all the information necessary to perform the examination.

- The documentation of the examination protocol should follow a standardized format.
- The protocol effective date and revision dates are indicated.
- Protocols are readily available to staff performing the examination.
- Handwritten amendments should be clearly marked, dated and initialed.
- All the details necessary to perform the examination are available.
- Protocols should be equipment specific, when appropriate.

5.4 Information in nuclear medicine examination results.

- Examinations are labeled in a standardized way that allows for proper patient identification and annotation including:
    - Patient name
    - Second patient identifier, *e.g.* identifying number and/or date of birth
    - Facility name
    - Date and time of examination
    - Identifying annotation, when appropriate
    - Other examination parameters as per nuclear medicine policy
    - Anatomic markers, when appropriate
- Images should be reviewed for diagnostic quality before the patient is released and includes:
    - Anatomic area of interest
    - The presence of artifacts and motion
    - Count density
    - Attenuation maps are reviews for diagnostic quality and artifacts

    - Single Photon Emission Computed Tomography/Computed Tomography (SPECT/CT) images are reviewed to verify co-registration in all planes
- Deviations from the standard protocol should be recorded particularly when there are reasons for examination limitations.
- There should be a verification process to confirm all images acquired are available for review.

5.5 Exercise and/or pharmacological stress testing is performed according to established protocols.

- Stress testing protocols include a description of graded protocols (*e.g.* speed, incline, workload, if applicable) and/or infusion details that include, but are not limited to:
    - Timing of assessing symptoms, heart rate, blood pressure and ECG tracing
    - Exercise/resting endpoints
    - Radiopharmaceutical injection criteria
    - Post-stress monitoring
    - Treatment of common adverse effects
- Electrocardiogram (ECG) tracing contain standardized identification as outlined in protocols and include:
    - Patient name
    - Second patient identifier, *e.g.* identifying number and/or birth date
    - Date and time of examination
    - ECG tracings are recorded in the patient record and are readily available.

5.6 Radiotherapy procedures.

- Radiotherapy procedures should be performed according to established protocols. Radiotherapy protocols contain all the necessary information to ensure they are safely performed.
- The radiopharmaceutical will be identified along with dosage, timing and route of administration.
- There is a written prescription signed and dated by the authorizing nuclear medicine physician.

- Any other pharmaceuticals used in the procedure are identified along with the dosage, timing, route of administration and any precautions and restrictions.
- Treatment procedures include:
    - Documented consultation by a physician qualified in radiotherapy
    - Informed consent
    - Supervision of the dosage administered
    - Ongoing patient monitoring
    - Medical record documentation
    - Radiation precautions following treatment, as appropriate

6 DOCUMENTATION

6.1 The patient record is current, accurate and contains relevant examination details. There is appropriate and comprehensive examination documentation in the patient record.

- Examination details are recorded that includes:
    - Technologist performing examination
    - Date and time of examination
    - Additional relevant clinical information provided by patient
    - Pre-, peri- and post-examination observations and/or complications
    - Pregnancy status, breast feeding status and known medications, where appropriate
    - Date of Last Menstrual Period (LMP), for women of child-bearing age
    - Allergies, where appropriate
    - Patient preparation, when different than routine procedure
    - Radiopharmaceutical agent is identified including the dosage, time, route of administration and the individual administering
    - Pharmacologic agents are identified including the dosage, time, route of administration, individual administering and any precautions or restrictions

6.1 The nuclear medicine service maintains accurate and controlled documents that clearly define the responsibilities for patient care and the scope of services performed.

Note: Documentation may be paper-based (*e.g.* manuals) or electronic format and includes policy statements, Standard Operating Procedures (SOPs) and examination protocols.

6.2 Operational policies and procedures are current, accurate and authorized.

- Documentation follows a standardized format.
- Access to policies and procedures is available for consultation by all staff.
- Policies and procedures are authorized by the medical leader prior to use.
- Policies and procedures are periodically reviewed.
- New or revised policies and procedures are communicated and available to staff.

6.3 The nuclear medicine service defines and maintains procedures to control documents.

- There are defined authorities, procedures and processes for maintenance and review of documents.
- There is a master list of controlled documents that identifies the current version.
- Documents are well marked and uniquely identified.
- Only current authorized versions of documents are in use.
- Policies and procedures are archived for later reference and retained as per facility requirements.
- Where handwritten amendments are permitted, pending re-issue of document, the amendments are initialed and dated.
- There are established procedures on how to make changes to documents in computerized systems.

7 SAFETY PRACTICES

The nuclear medicine service must perform examinations in a manner that ensures patient and staff safety.

DEFINITIONS:

The term *Transfer of Function* refers to a situation where staff performs any function(s) that are outside of their normal scope of practice. The mechanism for the delegation or Transfer of Function will allow the service to develop roles to meet

specific needs of patients. There must be clearly defined policies and procedures regarding Transfer of Function.

The term *medication reconciliation* refers to the process of comparing a patient's medication orders to all the medications that the patient has been taking. This reconciliation is done to avoid medication errors such as omissions, duplications, dosing errors or drug interactions. It should be done at every transition of care in which medications are ordered or existing orders are rewritten.

7.1 Mechanisms should be in place to ensure patient safety is sustained throughout the examination.

- Emergency call systems are available in patient areas.
- Alternate, latex-free products are available, where appropriate.
- Policies and procedures are in place where Transfer of Function duties are performed.
- Oxygen and suction equipment with the appropriate delivery devices and attachments are readily available.
- The design and layout of the nuclear medicine service are appropriate for the work performed.
- Appropriate space is available for the following functions:
    - "Hot" and "cold" patient waiting areas
    - "Hot" and "cold" patient bathrooms
    - Radiopharmacy lab
    - Cell labeling
    - Injections
- There should be an emergency crash cart immediately accessible (equipped as per facility or hospital policy).
- Procedures will be in place to handle medical emergencies.
- Staff will be familiar with the procedures required to respond to medical emergencies and how to access emergency medical services.
- Medical and technical staff members have appropriate training and current certification, *e.g.* cardio pulmonary resuscitation (CPR) to deal with medical emergencies.

7.2 Policies and procedures must be in place to ensure patient and staff safety and should include, but are not limited to:

- Adequately well-marked "clean" sinks and hand-cleansing materials are available.
- Hazardous materials and waste is handled and disposed of safely, efficiently and in accordance with Workplace Hazardous Materials Information System (WHMIS) regulations.

- Material Safety Data Sheets (MSDS) are posted where toxic and corrosive agents are used.
- Toxic and corrosive agents are labeled and stored in accordance with WHMIS regulations.
- There are policies and procedures for the disinfection and sterilization of supplies and equipment:
    - Disinfection solutions are appropriately used
    - Appropriate disposal of solutions
- There are policies and procedures for glassware and sharps control:
    - Glassware, sharps and needles are discarded into clearly labeled, puncture-resistant containers
    - Procedures are in place for sharps containers to be disposed of safely
    - Procedures are in place to handle puncture wound accidents
- Safe work procedures and practices relating to the use of safety-engineered needles or needle-less systems are implemented.
- The use of glass syringes is discouraged, where possible.
- Adequate personal protective equipment is available and appropriately used, as needed.
- Standard precautions are practiced with every patient and staff members are protected from contact with blood and body fluids.
- Appropriate infection control procedures are used.
- Eyewash stations are conveniently located and flushed, where appropriate
- Gloves are worn during IV therapy.

7.3 Education is provided and safety practices are in place to prevent staff injuries.

- There are mechanisms in place to prevent staff from assuming postures that could result in musculo-skeletal injuries that include:
    - Technologists follow guidelines for equipment adjustment to ensure optimal ergonomics
    - Technologists follow guidelines for proper body mechanics while performing examinations
    - Positioning and immobilizing devices are available
    - There is adequate assistance available when moving heavy patients
    - The availability and use of appropriate patient transfer devices, *e.g.* transavers and slider boards
    - Patient lifts are available where the workload includes the transfer or lift of heavy and/or immobile patients
    - The weight limits of lifting equipment is clearly marked
    - Staff members are trained in the use of lifting equipment

7.4 Emergency drugs and Basic Cardiac Life Support supplies are monitored and maintained.

- There is a system in place to ensure the availability, safety and security of required emergency drugs.
- There is a system in place to ensure the availability, safety and security of the emergency resuscitation and monitoring equipment.
- There is periodic staff training on the use of resuscitation and monitoring equipment.

7.5 There are mechanisms in place that meet provincial legislation requirements to control air quality where toxic chemicals are being used.

- General (*e.g.* dilution) ventilation, where appropriate.
- The use of local exhaust ventilation systems (*e.g.* exhaust hoods or ductless fume hoods), where appropriate.

7.6 Policies and procedures are in place to ensure patient safety when radiopharmaceuticals and/or pharmacologic agents are administered.

- There are policies and procedures in place for the administration of radiopharmaceuticals:
    - Written protocols for the preparation and administration radiopharmaceuticals are readily available
    - Radiopharmaceutical type and dose for each procedure
    - Dose protocols for the pediatric population
    - Radiopharmaceuticals are prepared according to manufacturer's specifications or there is documentation to validate product stability and/or efficacy of the off label preparation
    - Radiopharmaceuticals are administered for indications according to manufacturer's specifications or there is documentation to validate its efficacy of the off-label use
    - Availability of nuclear medicine physician or designated physician
    - Verification of patient identity
    - All relevant radiopharmaceutical information is documented and remains a permanent part of the patient record, *e.g.* radiopharmaceutical, dose, route, site, date, time, identify of person administering, etc.
- There are policies and procedures in place for the administration of pharmacologic agents:
    - Written protocols for the preparation and administration of pharmacologic agents are readily available

    - All pharmacologic agents are prepared and administered as per manufacturer's specifications
    - A physician is readily available to treat any potential reactions or complications that may arise
    - Technologists who administer pharmacologic agents are appropriately trained in pharmacologic administration and documentation procedures
    - Prior to administration the agent is visually inspected for colour, clarity and expiration date
    - Verification of patient identity
    - All relevant pharmacologic information is documented and remains a permanent part of the patient record, *e.g.* pharmacologic agent, dose, route, site, date, time, identify of person administering, etc.
- Storage of pharmacologic agents complies with manufacturer's recommendations.
- Medication reconciliation processes are established to prevent errors.

7.7 Appropriate resources are available when exercise and/or pharmacologic stress testing is performed.

- A physician is readily available to treat any potential reactions or complications that may arise.
- Emergency cardiac drugs, a cardiac defibrillator and equipment and supplies are readily available to deal with reactions/complications.
- Medical and technical staff who have appropriate training and current certification (*e.g.* CPR) are available to deal with medical emergencies.

7.8 There are established processes to continually assess hazards and incidents to improve the safety of the service.

- There is an assessment of radiopharmaceutical administration errors and a process for change where improvements are identified.
- There is an assessment of radioactive contamination reports and a process for change where improvements are identified.

7.9 Patients are appropriately discharged. Post-procedure instructions are communicated to patients and supporting individuals.

- Drugs dispensed to patients at the time of discharge are recorded in the patient record, verbal and written instructions for their use are given to the patient or his/her accompanying adult.

- Outpatients are advised of potential complications that may arise post-examination using an appropriate format.
- Outpatients are given instructions to contact the family physician, nuclear medicine service or emergency department in the event that complications arise after the patient is discharged.
- Documentation is provided to outpatients who are known to be traveling across international borders.

8 INTERPRETATION AND REPORTS

8.1 Examination reports are standardized and provide comprehensive and appropriate information for clinical decision-making. There are policies and procedures in place to ensure the examination report meets the needs of the service, clients and patients.

- There is a policy in place for verbal reports that includes follow-up using either paper-based or electronic format.
- There are policies and procedures for reporting urgent and other non-routine examinations.
- The nuclear medicine service and the examination requestors share responsibility for ensuring that reports are received by the appropriate individuals.
- Processes are in place to ensure no exam goes unreported.
- All dictations are transcribed and disseminated in a timely manner in accordance with established service standards.
- Medical staff responsible for the patient is notified of report delays in variance with established turn-around-times and in cases that may compromise patient care.
- Medical staff responsible for the patient is notified when there is a significant discrepancy between a preliminary or emergency report and the final written report.
- Reports can be promptly retrieved.

8.2 Reports are comprehensive, accurate and contain the appropriate information.

- The report identifies appropriate information including:
    - Name of patient and second patient identifier
    - Facility name
    - Examination performed
    - Examination requestor

    - Report recipient(s)
    - Date of the examination and interpretation
    - The time of examination is recorded in instances of multiple examinations performed on a single day
- The report indicates whether or not the contents of the report have been verified by the author.
- When reports have not been verified by the author, there is a process in place to verify the accuracy of the transcription.
- The contents of the final report are verified by the reporting physician electronically or by handwritten signature.
- A process is in place to ensure standardized report formats. The interpretation of the examination includes but is not limited to:
    - Clinical indications leading to the performance of the examination
    - An adequate description of the procedure performed including the type, amount and route of administration of any radioactive or non-radioactive material administered
    - The type of stress or intervention, if applicable
    - An overview of the results of the examination, including pertinent positive and negative findings
    - The reasons for limited examinations and /or deviation from standard protocols, if applicable
    - Comparative information with previous examinations, whenever appropriate
    - An overall succinct impression
    - Recommendation for follow-up and additional diagnostic studies, whenever appropriate
- Mechanisms are in place to detect and correct examination reporting errors.
- Processes exist to resolve patient identification issues.
- Examination reports from other facilities are available, whenever possible.
- Multiple page reports include patient identifiers on each sequentially numbered page.
- Preliminary reports are clearly labeled as such, distinct from the final report.

8.3 There are policies and procedures in place to deal with corrected reports.

- Addendum reports are clearly identified and always include the original report.
- A mechanism exists to ensure there is no ambiguity in determining the original and addendum report.

- The date and time of the change is recorded.
- The identity of the individual making the change is recorded.
- The reasons for corrected reports are recorded and reported, where appropriate.
- Medical staff responsible for the patient is notified when there is clinical significance.
- Addendum report audits or other processes are in place to detect trends and improve the quality of the nuclear medicine service.

8.4 There are policies and procedures in place to deal with unusual, unexpected or urgent findings.

- Appropriate medical staff are notified by direct means, *e.g.* in person or by telephone.
- Direct communication is based upon the immediacy of the clinical situation.
- Contingency plans are available in the event that the medical staff cannot be contacted.
- All actions taken in response to unusual, unexpected or urgent findings are recorded in the report.

8.5 Images are retrievable in a timely manner. Processes are in place to ensure images are readily accessible to the service, clients and patients.

- There is sufficient space for data storage.
- Digital back-up is performed daily.
- A second copy of examination data is securely stored in a separate physical location.
- Raw digital image data is retained for a minimum of three years.

9 EQUIPMENT AND SUPPLIES

Examinations are performed using equipment, instruments and medical device capable of effectively imaging the area of interest.

DEFINITION:

The term *acceptance testing* is a process to verify compliance with the performance specifications of the nuclear medicine cameras as written in the purchase contract and also to verify that the equipment performance meets manufacturer's specifications. Acceptance testing is performed by a medical physicist with in-depth knowledge of the particular type of

camera and the relevant regulations prior to any clinical use of the equipment. The results from the acceptance testing should be used to set baseline values and limits on the operational performance of the equipment. These baseline values and limits are essential to the Quality Assurance program.

9.1 Equipment inventory is effectively managed.

- There is a current equipment inventory which includes, but is not limited to:
  - Name of item, manufacturer, serial number or other identifier
  - Date of installation and condition of equipment at the time it was acquired, *e.g.* new, re-conditioned, etc.
  - Acceptance testing reports
  - Quality control and preventative maintenance records

9.2 Equipment, instruments, medical devices and supplies are operated, maintained and monitored in a safe and appropriate manner.

- New equipment goes through the appropriate acceptance testing process. Equipment, instruments and medical devices are used only as intended by the manufacturer.
- Manufacturer's manuals are readily available as a reference.
- Service manuals are readily available and include the resource contact information, where appropriate.
- Equipment and supplies are stored safely and securely. They are located to maximize efficiency.
- An orientation and training program is provided to those who use the equipment to ensure safe and appropriate operation.
- Equipment and supplies are clearly and appropriately labeled and comply with regulatory requirements, *e.g.* Canadian Standards Association (CSA).
- Electrical safety is assessed, *e.g.* extension cords and surge power bars are assessed for damage and inappropriate use, etc.
- Specialized equipment and instrumentation is operated by competent staff with the necessary education, knowledge, skills and certification and/or legal authority.
- Equipment problems that impact examination quality and/or safety are reported and repaired.

9.3 The nuclear medicine service investigates incidents and problems involving equipment, instruments, supplies and medical devices.

- Roles and responsibilities for incident investigation and prevention are documented and communicated.
- Appropriate staff knows how to obtain repair services.
- Responsible staff members are trained in resolving equipment incidents. Information about incidents is collected, documented, monitored and analyzed.
- Actions to prevent recurrence are identified.
- Defects and recalls are acted upon in a timely manner.
- Equipment, instruments and medical devices that are not functioning as per manufacturer's guidelines and/or poses a safety risk are clearly labeled and removed from service.
- Equipment, instruments and medical devices that exhibit performance limitations, but are deemed safe, are identified to relevant staff.
- Equipment is repaired in a suitable location that provides the necessary staff protection.

9.4 Supplies are monitored in a way that ensures continuity and eliminates shortages and waste.

- Receipt and service entry dates of solutions and supplies are recorded as necessary.
- Storage complies with manufacturer's recommendations.
- Expiration dates are monitored.
- Rejected goods are clearly marked and promptly returned to the supplier.
- Documentation of supply disposal and utilization is routinely reviewed. Inventory control problems and actions taken are documented.

10 QUALITY ASSURANCE

Quality assurance activities ensure procedures and equipment will produce the intended quality examinations.

10.1 Equipment performance is regularly assessed.

- There is a designated person(s) responsible for monitoring and reviewing Quality Control (QC) on a regular basis.
- QC records are retained for a minimum of two years.
- QC tolerance values are established according to manufacturer's recommendations and baseline values.
- A plan is in place when control results exceed tolerances that include:
    - Documentation and notification of appropriate staff

    - Processes are in place to determine the root cause
- For new, relocated or recently repaired equipment, QC results are reviewed and deemed acceptable before patient examinations are performed.
- Staff adheres to manufacturer's guidelines for QC as well as recognized best practices.
- A documented schedule of QC procedures is routinely performed.

Refer to the Nuclear Medicine Equipment Quality Control list at the end of this document.

- Personal protective equipment (*e.g.* lead aprons) and mobile shielding are inspected and tested for defects a minimum of once per year.
- For SPECT/CT hybrid systems, the radiation levels are monitored at critical areas in the imaging room (*e.g.* bedside, doorway, workstation, etc.) at acceptance testing and after CT tube replacement.

10.2 There is a preventative maintenance program in place.

- Documented preventative maintenance is performed at regular intervals by appropriately trained staff according to manufacturer's recommendations.
- Preventative maintenance records are retained for the lifetime of the equipment.

10.3 The nuclear medicine service has defined procedures for quality control of radiopharmaceuticals.

- Radiopharmaceutical QC procedures are routinely performed.
- QC records are retained for a minimum of two years.

**** Refer to the Nuclear Medicine Radiopharmacy Quality Control list at the end of this document.***

11 RADIATION SAFETY

See associated link:

CNSC Radiation Safety Regulations

Appropriate measures are in place to prevent unnecessary radiation exposure to staff and visitors.

11.1 A radiation protection program is in place.

- The nuclear medicine service has a Radiation Safety Officer (RSO) responsible for overseeing radiation protection.
- The RSO reports to a radiation safety committee where appropriate or other mechanisms are in place to identify and review radiation exposures and act on any outlying values.
- There are documented policies and procedures for radiation safety and for handling radioactive materials.
- Radiation warning labels are posted at the entrance of each room that may contain a source of ionizing radiation.
- Exposure of staff is kept As Low As Reasonably Achievable (ALARA).
- Nursing and ancillary staff are aware of the risks of ionizing radiation and manage it appropriately.
- Education is provided on the hazards of radiation and the appropriate means of reducing exposures to all relevant nursing and ancillary staff.
- Radiation safety education is provided upon hire and ongoing continuous education is provided to all staff that handles, or is potentially exposed to radioactive materials.
- The nuclear medicine service operates in compliance with the Canadian Nuclear Safety Commission (CNSC) Regulations for medical diagnostic and/or therapeutic use of radioisotopes.

11.2 Nuclear Medicine staff is aware of the risks of ionizing radiation and manage the risks appropriately.

- Policies and procedures are in place to protect pregnant staff.
- Staff members who are exposed to ionizing radiation that exceeds, or may exceed the action level of 1mSv per year must be provided with and must properly use a personal dosimeter.
- Results of personal dosimeters are reviewed and monitored by a radiation safety officer or designate on a regular basis:
    - An investigation must be initiated when a high reading is reported
    - Results are posted in the nuclear medicine service
    - All staff members are responsible to sign their posted results
- Protection is made available and used appropriately by staff that includes:
    - Personal protection, *e.g.* aprons, etc.

- Lead glass dose drawing station
- Lead syringe shields
- Free standing lead barriers
- Lead bricks for the radiopharmaceutical lab

11.3 Where radioactive materials are present, there are policies and procedures in place to ensure safety.

- Instructions on radiation precautions for therapeutic procedures and/or diagnostic procedures are given to patients, their families, nursing staff and ancillary staff, whenever appropriate.
- Staff is aware of the protocols establishing, defining and explaining specific procedures (*e.g.* monitoring and decontamination) for dealing with radioactive materials.
- Staff refrains from eating or drinking in radiation-use areas. Radioactive materials are stored and disposed of appropriately.
- Staff contamination checks, including daily hand monitoring and bioassay are performed and recorded, when appropriate.
- Area surveys and wipe tests are performed, that include tolerance limits and response to trigger levels.
- There is a sealed source wipe/leak testing protocol for semi-annual testing.
- There is a protocol for reporting the theft or loss of radioactive materials based on types and amounts of materials and any risk to the public.
- There is a protocol for reporting excessive radiation exposures (*e.g.* spills, to staff or public) including trigger levels and reporting requirements.
- Volatile radiopharmaceuticals are stored in a fume hood.

11.4 Hazardous and radioactive materials are transported appropriately.

See associated link:
Transportation of Dangerous Goods Regulations

- Biohazardous and radioactive materials are handled appropriately. Staff that handle biohazardous or radioactive materials must be properly trained.
- Biohazardous and radioactive materials are transported appropriately. A nuclear medicine service that ships or receives biohazardous or radioactive materials must have staff certified in the Transportation of Dangerous Goods (TDG) Class 7. Staff members are knowledgeable about:
    - Classification, shipping names, all the use of schedules 1, 2, and 3

- Documentation, safety marks, certification safety marks and safety standards
- Emergency response assistance plan and reporting requirements
- Safe handling, nature and characteristics
- Proper equipment use
- Emergency measures

11.5 The nuclear medicine service appropriately manages patient radiation dose. Processes are in place to manage patient radiation dose.

- There is signage in all patient areas that is clearly visible, alerting women who may be pregnant or breast feeding to notify the technologist.
- Doses do not exceed the established facility protocols.
- Processes are in place for calculating pediatric patient doses based on weight.

There are policies and procedures in place to deal with female patients of childbearing age.

- Patients are asked prior to examination if they may be pregnant.
- There is a procedure for managing patients who have a delayed LMP or where a patient is uncertain of pregnancy status.
- If an examination is requested on a pregnant or potentially pregnant patient, there is a process on how to proceed with the examination request.

MANDATORY REQUIREMENTS FOR NUCLEAR MEDICINE EQUIPMENT QUALITY CONTROL:

Minimum Camera QC Parameter	Frequency	Testing by	Method
☐ Multi-window registration	Acceptance	Physicist	
☐ Maximum count rate	Acceptance	Physicist	
☐ 20% loss count rate	Acceptance	Physicist	
☐ System sensitivity for each collimator	Acceptance	Physicist	
☐ Pixel size calibration	Acceptance	Physicist	
☐ Camera performance at high count rate	Acceptance	Physicist	
☐ Flood uniformity for 10% energy window	Acceptance	Physicist	
☐ Room Background (for intrinsic floods)	Daily	Technologist	Camera acquisition
☐ Tc99m peak position/calibration	Daily	Technologist	Visual / camera calibration
☐ Uniformity flood intrinsic with ^{99m}Tc point source; extrinsic with ^{57}Co sheet source	Daily	Technologist	5-10 million counts; intrinsic with ^{99m}Tc point source; extrinsic with ^{57}Co sheet
☐ Center of rotation protocol	Monthly	Technologist	Per manufacturer protocol
☐ Bar phantoms extrinsic	Monthly	Technologist	5 million counts, extrinsic
☐ Intrinsic uniformity for other radionuclides	Quarterly	Technologist	5-10 million counts; intrinsic with point source for other
☐ Extrinsic uniformity	Quarterly	Technologist	30 million counts on all collimators routinely used to check collimator integrity
☐ Uniformity phantom reconstruction	Quarterly	Technologist	Bleach bottle acquired using clinical parameters
☐ Whole body scan mode check	Quarterly	Technologist	Perform scan with ^{57}Co sheet source and bar
☐ High count intrinsic uniformity flood	Annually	Technologist	^{99m}Tc, 30 million counts. Compare to acceptance
☐ Jaszczak phantom	Annually	Technologist	High count phantom
☐ Tomographic resolution	Annually	Technologist	SPECT acquisition of capillary tubes
☐ Energy resolution	Annually	Technologist	Use manufacturer algorithm
☐ Spatial resolution	Annually	Technologist	Intrinsic bar phantoms
☐ Attenuation Correction Check	According to manufactur	Technologist	Phantom measurements

Well Counter QC Parameter	Frequency	Testing by	Method
☐ Crystal energy resolution	Acceptance	Technologist	Measurement
☐ Linear geometry and sensitivity	Acceptance	Technologist	Measurement
☐ Minimum/Maximum detectable levels	Acceptance	Technologist	Measurement
☐ Background Activity	Per run	Technologist	Measurement
☐ Reference standard calibration (^{57}Co, ^{137}Cs)	Daily	Technologist	Measurement
☐ Chi square reproducibility test	Quarterly	Technologist	Measurement

Uptake Probe QC Parameter	Frequency	Testing by	Method
☐ Crystal energy resolution	Acceptance	Technologist	Measurement
☐ Background Activity	Daily	Technologist	Measurement
☐ Reference standard calibration (^{57}Co, ^{137}Cs)	Daily	Technologist	Measurement
☐ Confirm proper window settings on radionuclides	Daily	Technologist	Visual Check
☐ Chi square reproducibility test	Quarterly	Technologist	Measurement
☐ Counting efficiency	Annually	Technologist	Measurement

Dose Calibrator QC Parameter	Frequency	Testing by	Method
☐ Instrument linearity	Quarterly	Technologist	Measurement
☐ Geometrical sensitivity	Acceptance	Technologist	Measurement
☐ Zero and background	Daily	Technologist	Measurement
☐ Instrument function test (battery test)	Daily	Technologist	Measurement
☐ Reference source check (accuracy)	Annually	Technologist	Measurement using calibrated standards
☐ Precision other nuclides (constancy)	Daily	Technologist	Measurement for nuclides routinely used

Radiation Survey Meters	Frequency	Testing by	Method
☐ Survey meter calibration	Annually	Outside agency	Calibration

QUALITY CONTROL OF RADIOISOTOPE DOSE CALIBRATORS:

Linearity Test: This test is designed to prove that the dose calibrator readout is linear for sources varying from the µCi range through the mCi range. A high activity ^{99m}Tc source (50-300 mCi) is measured at T_0 and at predetermined time intervals up to 48 hours. Expected and actual measurements are compared (and may be analyzed graphically) to determine if the instrument is linear throughout the activity range one is likely to encounter.

Geometry Test: This test is designed to show that correct readings can be obtained regardless of the sample size or geometry. One ml of ^{99m}Tc in a 10 ml syringe (activity 25 mCi) is measured in the dose calibrator and the value obtained is recorded. The activity is then diluted with water to 2 ml, 3 ml, 5 ml and 10 ml. At each of these points a reading is taken and the value recorded. Data are then evaluated to determine the effect of sample geometry on the dose calibrator reading. If instrument is geometry-dependent, it may be necessary to routinely correct readings obtained when using calibrator. GEOMETRY TEST MUST ALSO BE PERFORMED AFTER REPAIR, RECALIBRATION OR AFTER MOVING INSTRUMENT.

Accuracy Test: This test is designed to show that the calibrator is giving correct readings throughout the entire energy scale that one is likely to encounter. Low, medium, and high energy standards (usually ^{57}Co, ^{133}Ba or ^{137}Cs and ^{60}Co, respectively), are measured in the dose calibrator using appropriate settings. Standard and measured values are compared.

Constancy Test: This test measures precision and is designed to show that using a long-lived source, usually ^{137}Cs (30 year half-life), reproducible readings are obtained day after day on all the various isotope settings one is likely to use. The long-lived source is placed in the dose calibrator. Activity is then measured on the ^{137}Cs setting and all other routinely used settings on a daily basis. Values are recorded in the appropriate logbook and are compared with recent values to determine if instrument is maintaining constancy on a day-to-day basis.

NUCLEAR MEDICINE RADIOPHARMACY QUALITY CONTROL:

Generator QC

- The following QC is performed on each $^{99m}Tc0_4^-$ eluate:
  - ^{99}Mo breakthrough
  - Aluminum breakthrough
  - Clarity and volume
  - Eluate assay

Radiopharmaceutical Kit QC

- The following QC is performed on every prepared radiopharmacy kit:
  - Check for clarity
  - Radiochemical purity checked prior to injection
  - Particle size determination always carried out for ^{99m}TcMAA
- There is a protocol for adjusting ^{99m}TcMAA particle size for compromised patients.
- pH is checked for sulphur colloid preparations.

Record keeping for ^{99m} Tc Radiopharmaceuticals

- The following are recorded:
  - Kit and generator lot number
  - Diluents used
  - Quality control test results for eluates and in-house prepared kits
  - Patient identification
  - Doses dispensed to patients
  - Identification of personnel who prepared and tested kits
  - Storage and disposal of waste material
- There is a mechanism in place to report adverse reactions.
- There is a mechanism in place to report misadministrations.
- Radiopharmaceuticals are prepared according to manufacturer's specifications or there is documentation to validate product stability and/or efficacy of the off-label preparation.

QC for other Radionuclides

- Records are kept for the receipt of other radionuclides, *e.g.* ^{67}Ga, ^{201}T1, ^{131}I, etc.
- Commercial radiopharmaceuticals are assayed in a dose calibrator.
- A visual check is performed.

- Radiopharmaceuticals are labeled for:
    - Total Volume
    - Total Activity
    - Assay time and expiry
- Records are kept for the storage and disposal of waste material.