PERFORM Centre

Standard Operating Procedure

Nuclear Medicine Imaging Safety Procedures at PERFORM

PC- SOP-IM-004-v04

Revision History

Version	Reason for Revision	Date
04	Minor changes New format • Removed table of contents • Revised definition table • Removed appendices to become independent form or document	August 12/2019

I. Overview

1.1 Background

All users of radioactive isotopes are required to follow specific rules and regulations in order to promote safety and security for themselves, for research participants and for the general public.

1.2 Purpose

The objective of the current Standard Operating Procedure (SOP) is to outline the minimum requirements and general rules to be followed in the Nuclear Medicine section of the Bio Imaging suite at PERFORM.

1.3 Scope

This SOP applies to all PERFORM users working with, or in close proximity to, radioisotopes. This includes PERFORM researchers, staff, University auxiliary staff, students and authorized visitors.

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2. Definition of Terms

Benchkote	An absorbent, impermeable material designed to protect laboratory surfaces against hazardous spills
Background radiation	Ionizing radiation that the general population is exposed to, including natural and artificial sources
Bq	Becquerel. One Bq is defined as the activity of a quantity of radioactive material in which one nucleus decays per second
CPM	Counts per minute; a measure of the quantity of radioactive material present in a given localization
Dosimeter	A device for measuring the quantity of ionizing radiation to which a person has been exposed
Hot Lab	A room for working with high-activity radioactive compounds
Ionizing Radiation	Radiation with sufficient energy to cause the removal of electrons from neutral atoms to create ions
MBq	1 MBq = 1.000.000 Bq
mSv	Millisievert. 1/1000th of the SI unit of ionizing radiation effective dose. (sievert)
Nuclear Energy Worker (NEW)	A person who is required, in the course of one's occupation to perform duties in such circumstances that there is a reasonable probability of receiving a dose of radiation that is greater than the prescribed limit for the general public
Radiation dose	Energy released in the form of particle or electromagnetic waves in a unit mass of material
Radiopharmaceutical	A radioactive drug used for diagnostic or therapeutic purposes
Radioisotope	A version of a chemical element that has an unstable nucleus and emits radiation during its decay
Radiation Safety Officer (RSO)	Person responsible for the safe use of radiation and radioactive materials as well as regulatory compliance
Wipe Tests	A test for radioactive contamination in which the suspected surface or area is wiped with a filter paper (or other material)

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3. Responsibilities

3.1 Users

All users are responsible for:

3.1 Following all applicable regulations, safety rules and practices as outlined in this SOP, applicable Concordia policies, and the obligations of any professional bodies/orders they belong to.

3.2 Reporting all potential hazards, unsafe conditions or safety issues to the Nuclear Medicine Supervisor, designate or RSO.

3.3 Using and wearing all relevant personal protective equipment (lead aprons, lab coats, gloves etc.) as required by any study protocols and postings in relevant areas of the imaging suite

3.4 Attending all training courses as directed by Environmental Health & Safety and PERFORM administration.

3.5 Wearing a radiation dosimeter if they are required to do so as deemed necessary by the RSO.

3.2 PERFORM Scientific Director

The PERFORM Scientific Director is responsible for ensuring that a safety program is in place and that reviews are conducted regularly to ensure compliance with Concordia University regulatory requirements.

3.3 PERFORM Associate Director, Bio Imaging

The PERFORM Associate Director, Biomedical Imaging has overall responsibility for the Bio Imaging department. That person ensures proper review of, and guidance for, research protocol development so they meet regulatory requirements for public safety while maintaining integrity of data provided to investigators.

3.4 PERFORM Nuclear Medicine Supervisor & Radiation Safety Officer (RSO)

The Nuclear Medicine Supervisor has the responsibility to ensure that all users of the Bio Imaging Suite have completed the proper training to be able to conduct activities in a safe manner. That person must ensure that all users follow the regulations stipulated by the Canadian Nuclear Safety Commission (CNSC) and Concordia's Radiation Protection program for all Nuclear Medicine studies. As per university regulations, the RSO will maintain a list of all the users who are authorized to access the Bio Imaging suite. Together, they will establish and maintain records including radiation exposure for all research participants, staff and designated project members.

The RSO implements and enforces the Radiation Safety Program. The RSO has the

authority to suspend any procedure involving radiation which is considered unsafe or has the potential to cause harm to a person or the environment.

Any incident involving radioactivity or otherwise in the Bio Imaging suite will need to be reported to the RSO and to the principal investigator/ project lead.

3.5 Principal investigator/Project Lead

The Principal Investor/Project Lead is responsible for ensuring all their team members (staff and students) and any other users in their protocols/projects have completed the proper training as directed by the Nuclear Medicine Supervisor, RSO, PERFORM Administration and Environmental Health & Safety.

4. Relevant Documents

- VPS-40 Environmental Health and Safety Policy
- VPS-48 Hazardous material spill response policy
- VPS-46 Radiation Safety Policy
- Radiation Safety Manuel

Note: This SOP defers to Concordia policies at all times

5. Procedure

The following must be adhered to when working in the Nuclear Medicine section of the Bio Imaging suite at PERFORM.

5.1 General Rules

All users are responsible for:

5.1.1 Respecting their legal responsibility to protect themselves and their colleagues from radiation hazards arising from their work.

5.1.2 Keeping radiation exposures to members of staff, researchers, students, and visitors at a level which is "as low as reasonably achievable" (ALARA principle).

5.1.3 Ensuring that radioisotope are handled only by authorized members of staff, researchers and students who have received training in radiation safety.

5.1.4 Ensuring that visitors and research participants entering laboratories where radioisotope are used are accompanied by an authorized member of staff.

5.1.5 Ensuring that no eating, drinking, smoking or application of cosmetics takes place in the Bio Imaging Suite.

5.1.6 Wearing protective clothing when manipulating radioisotopes.
- Laboratory coat (fastened at the front).
- Disposable gloves.

5.1.7 Making sure that protective clothing is removed at the end of the procedure. Before commencing work, cuts and breaks in the skin of hands should be covered with an adhesive bandage.

5.1.8 Performing personal contamination monitoring of the hands on leaving the Hot Lab.

5.1.9 Performing contamination monitoring for background, work surface, floor area, disposal sink, and equipment before and after work.

5.1.10 Performing personal contamination monitoring of the body following a contamination incident. Results of monitoring must be recorded on the sheet provided for this purpose. If contamination is detected, decontamination procedures are to be followed.

5.1.11 Dosimeters are worn to record cumulative radiation doses received from occupational exposure to ionizing radiation, including x-rays, received from working around and near radiation emitting devices and participants. They are worn between the waist and the neck to record whole body exposure. . Exposure monitoring with personal dosimeters is done to determine the radiation levels an individual has been exposed to and to prevent an over-exposure by ongoing monitoring. Information obtained from exposure reports is useful to evaluate the effectiveness of the radiation safety program. All monitoring results are maintained and evaluated by the Radiation Safety Officer.

Dosimeters are assigned to individuals who have the potential to be exposed to more radiation than permissible for the general public, i.e. 1mSv. They are not to be shared or transferred to another individual. Care should be taken that the dose recorded by the dosimeter is representative of the true dose for the individual. The dosimeter must not be left in an area where it could receive a radiation exposure when not worn by the individual (e.g. on a lab coat or near a radiation source).

5.1.12 Verifying, when manipulating unsealed radioisotopes, that a suitable contamination monitor is at hand and regularly used to check for personal and laboratory contamination. Particular attention is to be given to the hands, clothing, bench surfaces and floor around the work area. The thyroid must be monitored 24 hours after any procedures involving manipulation of an unsealed radioiodine source having an activity greater than 1MBq or when intake of radioactive iodine is suspected. The result must be recorded in writing. Any sealed source should be treated as an unsealed source unless satisfactorily wipe tested.

5.1.13 Performing contamination monitoring of surfaces and apparatus before

and after any procedure involving unsealed radioactive material. The result of monitoring must be recorded. The only exception to this rule is that it can be disregarded when the delay linked to performing a thorough contamination monitoring check could adversely affect a research participant's investigation or safety, or the user's safety. In those circumstances only, the user may leave without monitoring for contamination provided that arrangements are made with staff to monitor for them immediately after the manipulation. If staff are not available the user must perform the contamination monitoring as soon as they are available to do so and prior to ending their day.

5.1.14 Ensuring that radioactive material is at all times clearly identified with radioactive material hazard warning tape, and marked with information on the nature of the radioisotope, date, approximate activity, and name of member of staff or group responsible for it.

5.1.15 Using the radioactive materials tracking database on the Hot Lab computer.

5.1.16 Working with radioactive material over a containment tray lined with absorbent wipes laid over plastic-backed absorbent paper (e.g. Benchkote).

5.1.17 Reporting all accidents (including spills) involving radioactivity to the Nuclear Medicine Supervisor or designate.

5.1.18 Ensuring that unused radioactive material is always stored in a secure location, taking special care to minimize the possibility of accidental contamination during storage. In particular, radioactive material stored in a refrigerator is to be double-contained and separated from non-active materials.

5.1.19 Making sure the laboratories in which radioactive material is used or stored are locked when unoccupied.

5.2 Restricted Access Area

Certain areas such as the Single-Photon Emission Computed Tomography (SPECT-CT), Positron Emission Tomography (PET-CT) and the tracer preparation laboratory (Hot Lab) in the Bio Imaging Suite will be inaccessible in the absence of a Technologist or Nuclear Energy Worker as per university, provincial and/or federal regulations. Any access to such area will need to be approved by PERFORM's Nuclear Medicine Supervisor/RSO on a daily basis. The Bio Imaging Suite is identified as a restricted area to which access is permitted to authorized persons only. Those authorized to work within the restricted area must have completed appropriate safety training and must comply with all approved SOPs.

Bio Imaging Suite highlighted in yellow

5.3 Nuclear Medicine Technologist

5.3.1 All Nuclear Medicine Technologists will be trained as evidenced by signed documentation and will be accredited by the national or provincial association for Nuclear Medicine Technologists: Canadian Association of Medical Radiation Technologists (CAMRT) and/or Ordres des technologies en imagerie médicale, en radio-oncologie et en électrophysiologie médicale du Québec (OTIMROEPMQ).

5.3.2 The Nuclear Medicine Technologist must be certain that any female participant is not pregnant before radiopharmaceutical injection. In a case where this is not clearly established, the Nuclear Medicine Technologist can demand a pregnancy test before proceeding, and can decide to cancel a study if she/he remains uncertain about the participant's status.

5.3.3 The Nuclear Medicine Technologist must be present at all times and will verbally monitor the participant throughout the procedure.

5.3.4 The Nuclear Medicine Technologist has the authority to stop procedures when he/she considers them to be unsafe.

5.5 Infection Control

5.5.1 The scanning room table and any other surface that has come in contact with a

research participant must be cleaned and the linen/table paper changed before placing another research participant on the scanning table.

5.5.2 Gloves must be removed and disposed of properly before touching common areas such as scanner key board, log books, light switches, counter surface and other objects.

5.5.3 Surfaces touched with gloves must be cleaned properly before leaving the area.

5.5.4 All biohazard material must be disposed according to Environmental Health and Safety procedures. Link to the Biosafety Manual

5.6 Nuclear Medicine Emergency Procedures

Refer to Concordia's Radiation Safety Manual, Appendix X: Link to radiation safety manual

5.7 Incidental Findings

Incidental findings (IFs) are unexpected discoveries or observations of potential clinical significance detected during the course of a study/activity that are outside the scope, or unrelated to the purpose or variables of the study/activity. They must be dealt with in accordance with PC-SOP-GA-011.

5.8 Dose Limits for Occupational Ionizing Radiation Exposures

Individuals may be classified in one of two categories: (1) nuclear energy workers, individuals who are occupationally exposed to radiation and (2) members of the public. The dose limits are given for both categories in the table. Those dose limits are based on the latest recommendations from the International Commission on Radiological Protection (ICRP) as specified in ICRP Publication 60 (ICRP, 1991).
Dose limits for radiation technologists apply only to irradiation resulting directly from their occupation and do not include radiation exposure from other sources, such as medical diagnosis and background radiation.

Annual Dose Limits

Applicable Body Organ or Tissue	NEW (mSv)	Members of the Public (mSv)
Whole Body	20	1
Lens of the eye	50*	15
Skin	500	50
Hands	500	50
All other organs	500	50

5.8.1 It is emphasized that from a regulatory perspective any irradiation involves some degree of risk and that the levels suggested are maximum values. All doses must be kept as low as reasonably achievable and any unnecessary radiation exposure must be avoided.

5.8.2 The ICRP does not recommend discrimination in the dose limits between men and women of reproductive capacity, if the dose is received at an approximately regular rate.

5.8.3 For occupationally exposed women, once pregnancy has been declared, the fetus must be protected from ionizing radiation exposure for the remainder of the pregnancy. For women who are also occupationally exposed, an effective dose limit of 4 mSv must be applied, for the remainder of the pregnancy, from all sources of radiation. This is considered to ensure that the fetus is not exposed to more than 1 mSv (i.e., the dose limit for the general population). Under the scope of this document, occupational exposure to pregnant technologists arises mainly from scattered X-radiation. In this case, the most effective method of monitoring exposures to the fetus, is to measure the equivalent dose to the surface of the abdomen using a thermoluminescent dosimeter.

5.8.4 For technologists-in-training and students, the recommended dose limits for members of the public should apply.

5.8.5 ICRP does not recommend different limits for individual organs. For occupationally exposed technologists, ICRP believes that deterministic effects will be prevented by applying an equivalent dose limit of 500 mSv in a year to all tissues except the lens of the eye, for which it recommends a limit of 50 mSv in a year.

5.8.6 For the skin, the equivalent dose is averaged over its whole area. In situations where deterministic effects are possible, the recommended equivalent dose limit for the skin is 500 mSv and is averaged over areas of no more than 1 cm^2. This limit applies to the skin of the face and hands.

5.8.7 Some provincial or territorial jurisdictions may have different dose limits for some technologists. The appropriate agency should be consulted to determine the dose limits in effect in a particular jurisdiction.

5.9 Action Levels

The use of action levels plays an important part in a radiation management program. Action levels are designed to alert radiation safety personnel before regulatory limits are reached.

Action levels are defined as "a specific dose of radiation or other parameter that, if reached, may indicate a loss of control of part of a Permit Holder's radiation protection program, and triggers a requirement for a specific action to be taken". The primary goal of the action to be taken is to prevent a re-occurrence of the event. The table below lists the action level for the corresponding activity.

Action levels have been identified as required for the following activities:

Activity	Initial Responsibility	Action Level	Action Taken
Personnel Dosimetry for			
NEW wholebody	RSO	>3mSv in a one year dosimetry period	Notification in writing
NEW wholebody	RSO	>1mSv in a quarterly dosimetry period	Investigation
NEW extremity	RSO	>30mSv[3] in a one month period	Investigation
Pregnant NEW	RSO	>0.1 mSv/month	
Radiation user wholebody	RSO	>0.2 mSv in a quarterly dosimetry period	Investigation
Radiation user extremity	RSO	>3 mSv in a quarterly dosimetry period	Investigation
Public	RSO	Not applicable	
Thyroid Bioassay	RSO	>1000 Bq[4] (investigation Level) > 10,000 Bq (Reporting Level)	Investigate and report to CNSC
Radioactive Surface Contamination (i.e. wipe tests)	RSO & Permit Holder	>0.3 Bq/cm^2	Investigate cause and decontaminate
Decommissioning	RSO	>3 Bq/cm^2 for all emitters except for alphas >0.3 Bq/cm^2 for alphas emitters	Investigate cause of contamination and decontaminate in both cases
Package Receipt	Receiving Staff or users	Damaged package or radiation level > than package designation	Reinforce CNSC guidelines: CNSC INFO-0744 "Receiving Radioactive Packages" "Packaging and Transport of Nuclear Substances Regulations"