PERFORM Centre

Standard Operating Procedure

RADIATION EMITTING DEVICES

PC-SOP-IM-007-v02

Revision History

Version	Reason for Revision	Date
01	New SOP	January/30/2015
02	Major changes to simplify Addition of safety screening form to appendix	June/13/2018

Summary

The content of this standard operating procedure (SOP) provides guidelines for all users in meeting the regulatory requirements for radiation emitting devices. Users of radiation emitting devices have a responsibility to protect themselves and other persons from the hazards arising from their use of these devices.

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1. Definition of Terms and Abbreviations

ALARA	As Low As Reasonably Achievable
CAMRT	Canadian Association of Medical Radiation Technologists
Collège des médecins du Québec	Organization overseeing medical practice in the Province of Quebec
DEXA	Dual Energy X-ray Absorptiometry
Radiation Dose	The quantity of energy (radiation) absorbed in a unit mass of material
Dosimeter	A device for measuring the quantity of ionizing radiation to which a person has been exposed
EHS	Concordia University Environmental Health & Safety
Incidental Findings	Incidental findings 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
Ionizing Radiation	Radiation with sufficient energy to cause the removal of electrons from neutral atoms to create ions
OTIMROEPMQ	Ordre des technologues en imagerie médicale, en radio-oncologie et en électrophysiologie médicale du Québec
PET-CT	Positron Emission Tomography - Computed Tomography
Principal Investigator (PI)	Head researcher who is responsible for all aspects of a given research project or program at PERFORM
Responsible User	Technologist or designated user authorized by the Associate Director, Bio-Imaging, to operate the equipment in the imaging suite
RSO	Radiation Safety Officer, responsible for the safe use of radiation and radioactive materials as well as regulatory compliance
RSO-NM	Radiation Safety Officer responsible for the Human Research Studies License
Sievert	Unit for equivalent dose (mSV = millisievert)
SPECT-CT	Single-photon emission computed tomography - Computed Tomography

Technologist	An imaging technologist is a person trained in the technology of Radiology or Nuclear Medicine and is a member in good standing of the CAMRT and/or OTIMROEPMQ
User	Person using space or equipment at the PERFORM Centre who has received adequate technical and safety training
X-rays	A type of ionizing radiation used in medical imaging

2. Introduction

2.1. Background

The imaging facility at PERFORM consists of specialized radiation emitting (and radiation detecting) devices known as PET-CT, SPECT-CT, and DEXA scanners. As the operation of these devices is associated with a risk of exposure to ionizing radiation, there is a need for standard procedures to be followed by users to ensure the safety of all users and research participants.

2.2. Purpose

This SOP provides a set of minimum standards and practices for the safe use of the radiation emitting devices at the PERFORM Centre of Concordia University. It outlines the minimum training requirements and general rules to be adhered to in the different areas of the Bio Imaging suite.

2.3. Scope

This SOP applies to all faculty, staff and students working with and in close proximity to the designated radiation emitting devices.

2.4. Responsibility

2.4.1. All Users

All users of radiation emitting devices are responsible for:

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

2.4.1.2. Reporting any incident, injury, hazard, or damage to equipment or property to the RSO-NM.

2.4.1.3. Using and wearing all relevant personal protective equipment (lead aprons, lab coats, gloves etc.) as required by any study protocol and postings in relevant areas of the imaging suite.
2.4.1.4. Attending all training courses as directed by Perform Administration and EHS.
2.4.1.5. Wearing a radiation dosimeter if they are required to do so as deemed necessary by the RSO-NM.

2.4.2. 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.

2.4.3. PERFORM Associate Director, Biomedical 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. That person evaluates the need for medical supervision during research protocols, and authorizes technologists and other potential responsible users to work in the imaging suite.

2.4.4. PERFORM Nuclear Medicine Supervisor, Radiation Safety Officer (RSO-NM)

The Nuclear Medicine Supervisor has overall 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 CNSC and Concordia's Radiation Protection program for all Bio Imaging studies involving ionizing radiation. As per university requirements, the RSO-NM will maintain a list of all the users who are authorized to access the Bio Imaging suite. They will establish and maintain records including radiation exposure for all research participants, staff and designated project members.

The RSO-NM implements and enforces the Radiation Safety Program. The RSO-NM has the authority to suspend any procedure involving radiation which is considered unsafe or have the potential to cause harm to a person or the environment.

Any incident involving exposure to radiation or otherwise in the Bio Imaging suite must be reported to the RSO-NM and to the principal investigator/ project lead.

2.4.5. Responsible Users: DEXA

Access to the DEXA suite and equipment will be provided to those who have completed Concordia's EHS Radiation Safety – Sealed Sources and X-Ray Devices safety training and the DEXA user training provided by the RSO-NM.

The Responsible User must:

2.4.5.1. Provide signed copies of the CCER approved consent form for all human participants to the platform supervisor.
2.4.5.2. Save, store and transfer the acquired data as appropriate.
2.4.5.3. Properly clean the equipment and room prior to leaving the area.
2.4.5.4. Signal any broken equipment or missing stock to the Platform Supervisor as soon as possible.
2.4.5.5. Be able to identify all evacuation routes and understand procedures for emergency response.

2.4.6. Principal Investigator/Project Lead

The Principal Investigator/Project Lead is responsible for ensuring all their team members (students and staff) and any other users in their protocols/projects have completed the proper training as directed by PERFORM Administration and EHS.

2.5. Relevant Documents

- VPS-40 Environmental Health and Safety Policy
- VPS-42 Policy on Injury/Incident Reporting and Investigation
- VPS-46 Radiation Safety Policy
- PC-SOP-GA-007: General Access to PERFORM Centre
- PC-SOP-IM-004: Nuclear Medicine Imaging Safety Procedures at PERFORM Centre
- Radiation Safety Manual
- Health Canada Safety Code 35: Safety Procedures for the Installation, Use and Control of X-ray Equipment in Large Medical Radiological Facilities

Note: This SOP defers to Concordia policies at all times

3. Procedure

3.1. Radiation Exposure

Radiation emitting devices all require a mechanism to allow the user to know when it is emitting radiation to limit the user's exposure and to prevent accidental exposure. Time, distance and shielding are the fundamental approaches to keeping radiation exposure ALARA. When the doors are closed to these rooms there is no chance of exposure to someone in the adjacent hallway. To understand how x-ray radiation is generated see appendix III.

3.1.1. DEXA

The DEXA has signal lights on its arm to alert the user that radiation is being emitted as well as when the shutter is open. It is expected that the user will return to the console, once the participant has been placed, in order to start and stop the acquisition so they may be the furthest possible from the DEXA table when radiation is being emitted. The user is expected to restrict access to the room when it is in operation. Expected exposure rates to the operator can be found in the DEXA user manual.

3.1.2. CT

The CT rooms have a lighted sign above the entrance that indicates "X-ray in use" when the CT is in operation. The majority of protocols will be run from the console once the user has positioned the participant. The user is expected to keep anyone from entering the room when the device is emitting radiation.

3.2. Occupational Exposure Monitoring

Dosimeters are worn to record cumulative radiation doses received from occupational exposure to ionizing radiation from working around and near radiation emitting devices and participants. They are worn between the waist and the neck level to record whole body exposure. The dosimeters have Al_2O_3 chips which record the exposure to ionizing radiation. 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 by the general public, 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 badge 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 left near a radiation source).

3.3. Radiation Emitting Device Malfunction or Error

In the event the radiation emitting device has a malfunction, produces an unexpected error or is operating abnormally it is important to remove the participant from the room while the system is reset and the quality control procedures are performed again. If the user has confirmed/started a protocol on the console, the assumption is that the participant was exposed to radiation; therefore, it is not acceptable to simply keep running a protocol after an error or malfunction possibly exposing the participant multiple times to radiation without first resetting the system and running a quality control check.

The following table lists some possible health effects at certain exposure levels, none of which are expected to occur with responsible use of the devices.

Dose	Limit or Health Effect
More than 5,000 mSv	**Dose which may lead to death when received all at once**
1,000 mSv	**Dose which may cause symptoms of radiation sickness (e.g. tiredness and nausea) if received within 24 hours**
100 mSv	**Lowest acute dose known to cause cancer**
30-100 mSv	Radiation dose from a full body computed axial tomography (CAT) scan
50 mSv	Annual radiation dose limit for nuclear energy workers
1.8 mSv	Average annual Canadian background dose
1 mSv	Annual public radiation dose limit
0.1-0.12 mSv	Dose from lung X-ray
0.01 mSv	Dose from dental X-ray
0.01 mSv	Average annual dose due to air travel

CNSC Table: Epidemiological Evidence
http://nuclearsafety.gc.ca/eng/resources/radiation/introduction-to-radiation/radiation-health-effects.cfm

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3.4. Infection Control

The scanning room table and any other surface that has come in contact with the research participant must be cleaned and the linen/table paper changed before placing another research participant on the scanning table.
Gloves must be removed and disposed of properly before touching common areas such as scanner keyboard, log books, light switches, counter surfaces and other objects.

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

All biohazard material must be disposed according to PERFORM SOP-GA-002 Handling of Biological Materials at PERFORM.

3.5. 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.

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APPENDIX I

DEXA – CT Safety Screening Form

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DEXA - CT Safety Screening Form

Project number: (use as last name) _____

Participant ID: (use as first name) _____

Sex: _____

Height: _____

DOB: _____

Weight: _____

Are you pregnant or think you may be?	Yes	No
Are you less than 18 years old?	Yes	No
Have you under gone any radiological exams with contrast or nuclear medicine exams in the last two weeks?	Yes	No
Have you taken any calcium supplements in the last 24 hours?	Yes	No
Have you under gone any radiological exams or nuclear medicine exams for research in the past 12 months?	Yes	No
If yes, please describe:		

If you have answered yes to any of the above, please speak to the Research Assistant, Technologist or the Principal Investigator.

I have informed the participant about the exam and how it will be performed. I have completed the above questionnaire with the participant and reviewed any possible contraindications to the exams.

Research Assistant/Technologist: _____ Date: _____

Participant Initials: _____

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APPENDIX II

Incident Report Form

Can be completed and submitted at:

https://www.concordia.ca/campus-life/safety/injury.html

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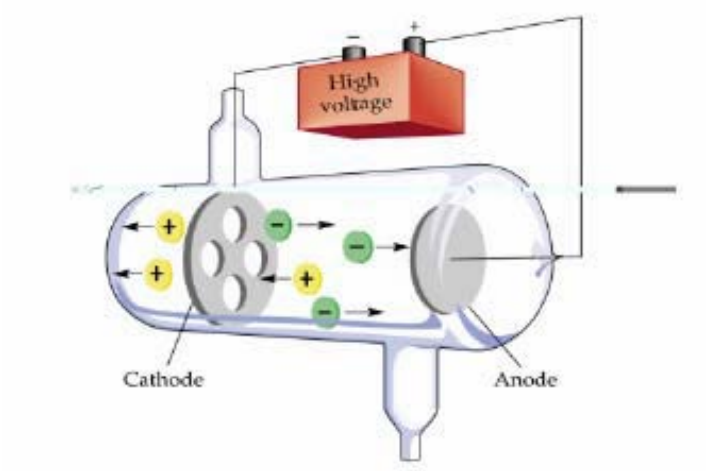
APPENDIX III

X-ray Production

X-rays can be produced by applying a high voltage between 2 electrodes. This allows the electrons to accelerate within a vacuum tube, which allows electrons to be aimed at a target anode. The deflection of the electrons by the orbital electrons or nuclei causes the emission of the x-ray photons.



X-rays are produced by two methods:

a) Characteristic X-rays
Photons are produced when electrons undergo a change in the amount of energy they possess. When a vacancy is created in the inner orbital shell of an atom, the electrons from the higher energy orbitals drop down to fill the inner vacancy. The extra energy from each of the transitions is released in the form of electromagnetic energy (photons), which is "characteristic" of the atom undergoing that rearrangement. The transitions that result in photons with energies in the X-ray range give rise to the characteristic X-rays that are distinct for each element.

b) Bremsstrahlung
X-rays are also produced when high speed electrons from a cathode are directed to hit an anode typically constructed of such metals as tungsten. Because of their high speed, electrons are able to penetrate the target anode electron cloud and interact with the target material's nuclei. Because of the strong attractive forces between the negatively charged electrons and the positively charged nucleus, the electrons slow down in the presence of the nucleus and the electrons give up a portion of their energy in the form of X-rays. This process of X-ray production is also called bremsstrahlung from the German phrase for "braking radiation". X-rays produced in that way have energies that spread over a wide spectrum depending on the degree of braking experienced by the original electrons. The resulting smooth, continuous spectrum of X-ray energies produced does not give rise to the characteristic X-rays discussed earlier. This is the principle behind the operation of x-ray machines.

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APPENDIX IV

SOP Training Record Form

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SOP Title

RADIATION EMITTING DEVICES

SOP Code

Ownership	Document type	Area	SOP Number	Version
PC	SOP	IM	007	V02

Training Record

Full Name	
Institution/PI	
Contact (email or phone number)	

Signature

Sign here and return to SOP custodian

Date