

Revision: 2
Date: May 2020
Page: 1 of 6

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1. Purpose

- 1.1. Canadian Nuclear Safety Commission (CNSC) licences managed by McMaster University establish possession limits for radioactive material. Under the McMaster University Radiation Safety Program, individual project supervisors are granted radioisotope permits that convey permission to possess and use radioactive materials, with specific limits on the quantities to be purchased, used and stored. The acquisition, use, storage and transfer of radioactive materials must be carefully managed to ensure compliance with CNSC licences and internal radioisotope permits. Each permit holder is required to maintain an up to date inventory of all radioactive sources (sealed and unsealed) in their possession. This procedure provides specific guidance on fulfilling these requirements.
- 1.2. Implementation of these requirements provides assurance that radioactive materials will remain within the controls of the Radiation Safety Program and thereby protects staff and members of the public from the potential hazards of radioactive material. In addition, the University and individuals using radioactive material are protected from statutory liabilities which may arise from enforcement action by the CNSC and from civil liabilities which may arise from exposure to members of the public.

2. Scope

- 2.1. This procedure applies to all activities involving the acquisition, possession, use, storage, transfer, shipping, production, import, export, servicing, disposal and abandonment of nuclear substances and radiation devices under CNSC licences managed by McMaster University, except where specifically excluded below.
- 2.2. Those areas and activities that fall under Nuclear Facility licences issued by the CNSC are subject to separately documented Radiation Protection Programs and, as such, are exempt from these requirements.

3. Related Documents

3.1. RMM 700 Radiation Safety Program for University Laboratories

4. Definitions

4.1.	Permit	A permit to use nuclear substances or radiation devices issued by the McMaster University Health Physics Advisory Committee
4.2.	HPAC	The McMaster University Health Physics Advisory Committee
4.3.	CNSC	The Canadian Nuclear Safety Commission
4.4.	Radiation Device	As defined in the Nuclear Substances and Radiation Devices Regulations. The full definition from the regulations is:
		(a) a device that contains more than the exemption quantity of a nuclear substance and that enables the nuclear substance to be used for its radiation properties; and;
		(b) a device that contains a radium luminous compound
4.5.	Exemption Quantity	As defined in the Nuclear Substance and Radiation Devices Regulations. Generally, the quantity of nuclear substance above which activities may require CNSC licensing.

5. Responsibilities

- 5.1. Project Supervisors are responsible for:
 - implementing this procedure in all activities related to their project
 - ensuring and verifying that inventory limits specified on the permit are adhered to
 - assigning trained personnel to carry out this procedure
 - providing all equipment required to carry out this procedure
 - maintaining records as specified



Revision: 2 Date: May 2020 Page: 2 of 6

- 5.2. Authorized Radionuclide Users are responsible for:
 - complying with the requirements of this procedure
- 5.3. The Health Physics Department, under the direction of the Senior Health Physicist, is responsible for:
 - approving acquisitions of radioactive material
 - · maintaining records of all acquisitions of radioactive material
 - auditing laboratories to verify implementation of this procedure
 - training personnel in the safe receipt of shipments of radioactive materials
- 5.4. Financial Affairs personnel are responsible for:
 - placing all orders for nuclear substances and radiation devices according to the restrictions in Section 6.
- 5.5. Receiving personnel are responsible for:
 - safe receipt and delivery of radioactive material delivered to university licensed location.

6. Procedures

6.1. <u>Prepare to Possess Radioactive Material</u>

- 6.1.1. Radioactive material may only be acquired by individuals holding a valid permit issued by the HPAC.
- 6.1.2. Prepare a binder or file to keep inventory information. This should contain the following, appropriately organized into sections:
 - A copy of the current HPAC Permit.
 - A section to hold the forms documenting the current unsealed source inventory. (See Attachment A for an example unsealed inventory form).
 - A copy of a form documenting the current sealed source inventory (see Attachment B for an example sealed source inventory form).
 - A section with several copies of blank forms used in the lab, kept stocked to ensure they are available when needed.
- 6.1.3. Prepare a separate binder or file to keep used forms.
 - A section to hold inventory sheets that have been used and the material disposed of.
 - A section to hold records of material transferred onto the permit (see Attachment C for an example form), if any.

NOTE: Maintaining inventory records is a requirement of the Regulations, the licence and the University Radiation Safety Program. Maintaining a well organized, clear and legible set of inventory records is an important indicator of safety and compliance attitudes within the laboratory and will have a significant impact on internal and external compliance audits.

6.2. Purchase of Unsealed Radioactive Material

6.2.1. Determine the quantity of radioactive material that is required.

NOTE: Purchases should be planned to minimize the quantity of material stored in a laboratory to the extent practical. For example, if two uses of 1mCi of ³H are required but they are expected to be several months apart, purchase the material in two lots, close to the time that they will be used.

- 6.2.2. Review the current inventory of the laboratory (including material in storage and in use) and the expected usage between the time of placing the order and the time of delivery. Ensure that adding the intended purchase to your inventory will not cause you to exceed the inventory limits on the permit.
- 6.2.3. For unbound radioiodine purchases, confirm the current bioassay status of all personnel involved in the project. Users should complete the Request to Acquire Unbound Radioiodine form provided in Attachment D.
- 6.2.4. Submit a purchase order for the material for approval of Health Physics. Note the quantity, activity, radionuclide and the Permit Number on the purchase order. Purchase orders must be submitted by the Permit Holder or a person designated in writing as having authority to order on behalf of the Permit Holder.



Revision: 2 Date: May 2020 Page: 3 of 6

6.2.5. Health Physics will:

- Review the purchase to verify activity and radionuclide are within the limits specified on the permit.
- For unbound radioiodine, verify the bioassay status of the personnel involved in the project.
- Maintain a record of the purchase for compliance reporting.
- Verify that the purchase order is submitted by an authorized person.
- Approve the purchase if it meets these requirements.
- 6.2.6. On receipt of a Purchase Order for radioactive material, the Purchasing Officer will:
 - Verify that it has been approved by the Health Physics department.
 - Place the order.
 - Ensure that any changes to the order are first approved by the Health Physics department.
- 6.2.7. Standing orders for radionuclides are discouraged and will only be approved by Health Physics under exceptional circumstances where staff can demonstrate undue hardship and have satisfactorily demonstrated that adequate procedures are in place to control inventories and ensure safe receipt during holiday periods. The maximum period for a standing order is one year or to the expiry date of the permit, whichever is less.
- 6.2.8. Orders may not be placed directly with suppliers. Orders for radioactive materials must be placed through purchasing resources.

6.3. Purchase of Sealed Sources and Radiation Devices

6.3.1. The process for ordering radioactive materials in Section 6.2 shall be followed, but sealed sources and radiation devices must be delivered direct to the Health Physics department for leak testing if required, and inventory. Contact the Health Physics department to make arrangements.

Note: in the case of large radiation devices, delivery to Health Physics may not be practical. Alternate arrangements will be made for leak testing if required and inventory on receipt.

- 6.3.2. All radiation devices purchased or obtained must be certified by the CNSC.
- 6.3.3. For devices that have not been pre-certified, purchasers must be prepared to obtain certification prior to use of the device. Health Physics will assist in obtaining required certifications.

6.4. Other Acquisition of Radioactive Material

- 6.4.1. Radioactive material may also be obtained by means other than purchase from a radioisotope supplier. Possible examples are the receipt of samples from a collaborative researcher, or transfer of material between licences managed by McMaster University.
- 6.4.2. Any acquisition must be approved in advance by Health Physics and is subject to the requirements of this procedure.
- 6.4.3. The Project Supervisor receiving the material shall follow the process outlined in this procedure, replacing the purchase order with a form approved in advance by Health Physics. An example Radioactive Material Acquisition Approval form is shown in Attachment C. The form must contain the following information
 - Isotope and activity to be received
 - The permit onto which the material will be received
 - The name of the project supervisor and the approval of the supervisor or delegate
 - The date on which the material will be received
 - The institution or company and name of contact (if available) from which the material will be received
 - The signature or approval of the Health Physics department

6.5. Receipt of Radioactive Material



Revision: 2 Date: May 2020 Page: 4 of 6

- 6.5.1. Purchases may be ordered for delivery to the McMaster University West Campus receiving dock, Health Sciences Centre receiving dock or direct delivery to the recipient. All purchases specified as direct delivery must include a cell phone number at which the courier may contact the recipient.
- 6.5.2. The receiver must visually inspect the package to verify that there is no indication of damage or material leaking from within.
- 6.5.3. The receiver must verify the delivery address to ensure the package was delivered to the correct location.
- 6.5.4. If delivered to a receiving dock, receiving staff must deliver the package without delay to the laboratory. The package must be delivered to a member of the staff in the lab.
- 6.5.5. On receiving the package, an Authorized User who is part of the lab personnel must:
 - Always open and inspect packages immediately upon receipt.
 - Wear a lab coat and disposable gloves while handling the package.
 - Place package in the fume hood if possible, or in a designated radioisotope handling area.
 - If an appropriate survey monitor is available, personnel should monitor the radiation fields around the package and compare with the units stated on the package. Report any discrepancies to Health Physics.
 - Inspect the package for evidence of damage or leakage. Wipe test the package if damage or leakage is suspected.
 - Remove packing slip.
 - Open the outer package and check for possible damage to the contents, broken seals or discoloration of packing materials. If the contents appear to be damaged, isolate the package to prevent further contamination and notify Health Physics.
 - If no damage is evident, remove the inner package or primary container and wipe test the container. If contamination is detected, monitor all packaging and if appropriate, all areas coming into contact with the package for contamination. Contact Health Physics, then contain the contamination, decontaminate and dispose of material in accordance with established practices for the lab.
 - Verify the radioisotope, the activity and other details with the information on the packing slip and with the purchase order. Any discrepancies must be reported to the Health Physics department.
 - Place the radioisotope in an appropriate storage container with appropriate shielding.
 - Remove or deface radioactive labels on empty uncontaminated containers before disposing of them.
- 6.5.6. Any anomalies with the shipment must immediately be reported to the supervisor and Health Physics department. Possible anomalies that must be reported include
 - Any observable damage to the package
 - Radiation levels in excess of the package labelling
 - Any detection of contamination or leakage of contents
 - Any shipping or documentation errors
- 6.5.7. Add the material to the laboratory inventory.

6.6. <u>Maintaining an Inventory of Radioactive Material - Unsealed Sources</u>

- 6.6.1. Enter each vial, kit, sample, or item received containing in excess on one exemption quantity of radioactive material into the laboratory inventory. An example Unsealed Radioisotope Inventory Control Form is provided in Attachment A. The following information must be documented for each sample
 - A unique identifier (see next step)
 - Isotope
 - Activity
 - Activity reference date



Revision: 2 Date: May 2020 Page: 5 of 6

- Form (e.g. liquid or solid)
- Location of storage
- 6.6.2. Assign a unique identifier to the sample, generally the lot number.

NOTE: Review the lot numbers of other items in the lab inventory. Lot numbers are not unique to each vial. For long lived radionuclides and in cases where samples are ordered at high frequency, more than one vial may be in possession with the same lot number. If this occurs, make the sample identifier unique by adding a suffix (e.g. "-A" or "-B") to the end of the lot number.

- 6.6.3. If the material is aliquoted into separate vials, on receipt, enter each aliquot into inventory with a unique identifier, as above.
- 6.6.4. If the vial is to be kept in a container (such as a shielded "pig") label the outside of the container with the radionuclide, the original activity, the date of receipt, and the unique identifier assigned above.
- 6.6.5. As material is used from each stock vial, update the inventory. Normally, this should be done just before you remove the material from the vial for use. Record the amount of material being removed and the balance of material remaining, with appropriate units.

NOTE: It is generally preferable to track material inventory in units of activity. Units of volume may be used, provided the original activity and volume of the solution or sample is recorded in the inventory. Lab personnel must be able to estimate the current activity at any time from the information recorded in the inventory. Transfers to waste must be recorded in units of activity.

- 6.6.6. Once work is complete, indicate the disposition of the material (solid and/or liquid waste).
- 6.6.7. Normally, samples prepared from stock radioactive material do not need to be inventoried separately unless they will be stored in the lab for longer than one week.
 - NOTE: Regardless of inventory requirements, samples must be appropriately labeled.
- 6.6.8. When work with a stock solution is complete, dispose of the remaining material and record the disposal in the inventory. If paper forms are used, transfer the inventory record from the 'current inventory' binder to the 'used forms' binder.

6.7. Maintaining an Inventory of Radioactive Material - Sealed Sources

- 6.7.1. Enter each sealed source received into the laboratory sealed source inventory. The following information must be recorded for each source
 - Isotope
 - Activity
 - Activity reference date
 - Source model number
 - Serial number
 - Location of storage

6.8. **Storage of Radioactive Material**

- 6.8.1. All radioactive material must be kept securely stored such that it is only accessible to authorized users.
- 6.8.2. The radioactive material must be kept locked when not attended. This may be achieved as follows
 - ensuring that the laboratory is always locked when unattended
 - keeping material within a locked refrigerator, freezer or cabinet
 - keeping the material within a locked box
 - Note: if the laboratory is also used by unauthorized personnel, a lockbox or locked fridge/cabinet is required
- 6.8.3. All areas, fridges, freezers, cabinets etcetera in which radioactive material is stored must be posted with a radiation warning sign.



Revision: Date: Page:

May 2020 6 of 6

6.9. **Transfer of Radioactive Materials Within the University**

- 6.9.1. Transfer of radioactive material between Permit Holders is allowed, subject to prior approval by Health Physics.
- 6.9.2. The Permit Holder receiving the material shall follow the process outlined in this procedure, replacing the purchase order with a form approved in advance by Health Physics. An example Radioactive Material Acquisition Approval form is provided in Attachment C. The form must contain the following information
 - Isotope and activity to be transferred
 - The permit from which the material is originating
 - The permit onto which the material will be received
 - The name of both the originating and destination project supervisor(s) and their approval
 - The date on which the material will be transferred
 - The signature or approval of the Health Physics department
- 6.9.3. The supplying laboratory must record the transfer in their inventory records. If an aliquot has been provided, show the usage as normal on the inventory and write in "transferred to project XXX" as the disposition method. Retain a copy of the completed transfer form in the inventory records.

6.10. **External Transfer of Radioactive Material**

- 6.10.1. Any transfer of radioactive material outside of the University must be approved in advance by Health Physics.
- 6.10.2. The Health Physics will make all packaging, monitoring and shipping arrangements to ensure compliance with the Transport of Dangerous Goods Regulations, the Transport and Packaging of Nuclear Substances Regulations and export restrictions on the applicable licence.
 - Note: in certain circumstances, users who have completed the appropriate Transport of Dangerous Goods Class 7 training may be approved by the Health Physics department to ship radioactive materials. Each shipment must be approved individually by the Health Physics department.
- 6.10.3. Receiving agencies will be required to provide their licence and confirmation from their RSO or delegate approving the acceptance of the material prior to shipment.

6.11. Records

- 6.11.1. The following records are to be retained by the Project Supervisor until disposal is authorized by Health Physics.
 - All inventory control forms

7. EXCEPTIONS

All exceptions to this procedure require the approval of the Senior Health Physicist.

Attachments:

- Unsealed Radioisotope Inventory Control Form
- Sealed Source Inventory Form
- Radioactive Material Acquisition Approval Form
- Request to Acquire Unbound Radioiodine



UNSEALED RADIOISOTOPE INVENTORY CONTROL FORM

LOCATION	RADIOISOTOPE	SHIPMENT
Permit Number:	Isotope:	Date received:
Permit Holder:	Product:	Received by:
Lab room number:	Supplier: Total activity:	Package information verified on receipt: (initials)
Radioisotope location:	Volume:	Package checked for Contamination: (initials)
1 Vial/Kit or sample set per control sheet	I.D. #:	Record and report any anomalies to the Project Supervisor and Health Physics.

	Quantity used Units	Quantity remaining Units	Disp	User's	
Date			Solid (μCi or KBq)	Liquid (μCi or KBq)	Initials

Product holder (i.e. lead/plastic) checked for radio	oactive contamination and provided to Health Physics.
Final date of disposal:	Initials:



SEALED SOURCE INVENTORY

Location:				
Project Supervisor				
Permit Number				
	Sealed Source	Inventory		
Radioisotope	Manufacturer / Lot Number	Reference Date	Activity	Physical Form of Source

□ No Sealed sources are in the possession of this laboratory

Radiation Devices

Isotope	Manufacturer	Model Serial Number		Activity	

□ No radiation devices are incorporated in devices in possession of this laboratory



Radionuclide

Radioactive Material Transfer Form

Activity

Receiving Lab's Possession Limit

			1					
		In	stitutio	n (External):				
From:	Permit Number (McMaster):							
rioiii.	Permit Holder (McMaster)		Name:					
			Signature					
	Institution & Licence Number (External)			er (External):				
To:	Permit Number (McMaster):							
10.	Permit Holder (McMaster) or RSO/Delegate (External)			Name:				
				Signature:				
Date Of Transfer:								
HP Approval Signature:				Date:				
Co	nditions:							



Request to Acquire Unbound Radioiodine

The CNSC licence conditions are stated below and apply to any workers using more than 2 Mbq (0.05 mCi) of radioiodine. Failure to undergo screening and bioassay as required by licence conditions can lead to suspension of radioiodine use.

Confirmation of Compliance	CNSC Licence Conditions
•	
I certify that I am in compliance with the licence conditions stated here, and that I will not knowingly provide unbound radioiodine to another user.	(a) Every person who in any 24-hour period uses a total quantity of Iodine 124, Iodine-125 or Iodine-131 exceeding: i) 2 MBq in an open room; ii) 200 MBq in a fume hood; iii) 20 000 MBq in a glove box; or iv) any approved quantity in any room, area or enclosure authorized in writing by the CNSC
User's signature	shall undergo thyroid screening within a period more than 24 hours after the last use that resulted in any of the above limits being exceeded and less than 5 days after the limit was exceeded.
User's signature	(b) Every person who in any 24-hour period uses a total quantity of Iodine 123 exceeding:i) 200 MBq in an open room;ii) 20 000 MBq in a fume hood;
User's signature	iii) 2 000 000 MBq in a glove box; or iv) any approved quantity in any room, area or enclosure authorized in writing by the CNSC shall undergo thyroid screening within a period more than 8
Date:	hours after the last use that resulted in any of the above limits being exceeded and less than 48 hours after the limit was exceeded.
Isotope:	(c) Every person who is involved in a spill of greater than 2 MBq of Iodine 124, Iodine 125 or Iodine 131 or on whom external contamination is detected, shall undergo thyroid screening
Amount:	within a period more than 24 hours after the spill and less than 5 days after the spill or contamination.
As the Project Supervisor, I certify that the radioiodine to be acquired will be used solely at McMaster University by the persons listed above until it is in a bound form.	(d) Every person who is involved in a spill of greater than 200 MBq of Iodine 123 or on whom external contamination is detected, shall undergo thyroid screening within a period more than 8 hours after the spill and less than 48 hours after the spill or contamination
Signature:	Thyroid Screening Screening for internal Iodine 123, Iodine 124, Iodine 125 and Iodine 131 shall be performed using:
Health Physics	a) a direct measurement of the thyroid with an instrument that can detect 1 kBq of Iodine 124, Iodine-125 or Iodine-131, or 10 kBq of Iodine 123; or b) a bioassay procedure approved by the Commission or a person authorized by the Commission.