# Medical Isotope Cyclotron Facility Access Control
## Standard Operating Procedure

**Title:** Medical Isotope Cyclotron Facility Access Control SOP  
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## Document History:

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<thead>
<tr>
<th>Version #</th>
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<th>Approval Date</th>
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<tr>
<td>0</td>
<td>Robert Pawliuk</td>
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<td>Originated from UofA Secure Space Access Control SOP</td>
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<td>Robert Pawliuk</td>
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<td>Robert Pawliuk</td>
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<td>Simplify space classifications and update work clearance procedures.</td>
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1. PURPOSE

1.1. To provide a procedure for visitors to enter the Medical Isotopes and Cyclotron Facility (MICF). These spaces include the following designated areas of the building:

   1.1.1. Restricted Spaces (Research & Production Areas)
   1.1.2. Semi-Restricted Spaces (Service Areas)
   1.1.3. Non-Restricted Spaces (Administration Areas)

2. DEFINITIONS

2.1. **AHS**: Alberta Health Services

2.2. **Aseptic Processing Suites**: Encompasses all clean rooms with classified air backgrounds where radiopharmaceuticals and cold kits are produced. This area includes rooms 1-302 to 1-390.

2.3. **Cyclotron Radiation Safety Officer**: Person responsible for the day-to-day administration and control of radiation protection programs for the cyclotron and processing operations at the MICF.

2.4. **Director Cyclotron Operations & Research**: Person responsible for managing and overseeing the operation of the Cyclotron component of MICF, and liaising with the ERC Director and/or Cyclotron Radiation Safety Officer.

2.5. **EH&S**: University of Alberta Environmental Health & Safety

2.6. **ERB**: Emergency Response Binder – located in the fire alarm panel, this document provides the floor plans of the building showing location of hazardous materials within the facility and other pertinent information.

2.7. **ERC Director**: Person responsible for managing and overseeing the operation of the Edmonton Radiopharmaceutical Centre (ERC), and liaising with the Director Cyclotron Operations & Research and/or Cyclotron Radiation Safety Officer.

2.8. **MICF**: Medical Isotope Cyclotron Facility.

2.9. **MICF Staff**: Individuals that on a daily or regular basis work within the MICF, and they occupy the facility for an unspecified time. They include, but are not limited to employees of the University of Alberta or Alberta Health Services.

2.10. **Medical Isotope Cyclotron Facility Work Decision Matrix**: Flow chart included in Appendix 1 of this document to assist in the determination of the requirements associated with maintenance work in the building.

2.11. **Non-Restricted Space**: Area of the building where Visitors do not require escort from MICF staff.
2.12. **Principle Investigator:** Individual responsible for an area and/or work being conducted in the facility.

2.13. **Restricted Space:** Area of the building where Visitors require escort from MICF staff.

2.14. **Semi-Restricted Space:** Area of the building where Visitors may or may not require escort from MICF staff dependent on the activity being performed by and training levels of the Visitor.

2.15. **UAPS:** University of Alberta Protective Services

2.16. **Visitor:** Individuals that are present in MICF for specific reasons and/or specified times. They include but are not limited to students, University of Alberta Staff, Alberta Health Services Staff, External Auditors and Contractors.

2.17. **Work Clearance:** A written and approved document that authorizes specific work in the radiation areas and service spaces, at a specific location, and at a specific time period. Completed work clearances ensure all required procedures are followed and all hazards have been considered to protect the product, facility and worker.

3. **SPACE DESIGNATIONS**

3.1. Refer to the following drawings for the designation of each area of the building:

   3.1.1. Level One Medical Isotope And Cyclotron Facility
   3.1.2. Level Two Medical Isotope And Cyclotron Facility
   3.1.3. Roof Medical Isotope And Cyclotron Facility

4. **RESPONSIBILITIES**

4.1. It is the responsibility of the University of Alberta and Alberta Health Services to ensure this SOP is followed.

4.2. University of Alberta (UofA) Facilities & Operations (F&O) is responsible for all facility maintenance including electrical, mechanical, architectural, facility alarms, and the heating, ventilation, air conditioning (HVAC) system serving the entire building. This includes services and utilities feeding AHS Aseptic Spaces (Restricted) from central building systems exclusive of those listed as the responsibility of AHS Facilities Maintenance Engineering (FME).

4.3. Alberta Health Services (AHS) is responsible for operation and maintenance associated with the high pressure steam boiler, reverse osmosis (RO) water system, pure steam system, water for injection (WFI) system, laboratory equipment located in AHS Aseptic Space (Restricted), building equipment located in AHS Aseptic Space (Restricted), and any process equipment used by AHS.

4.4. It is the responsibility of the Director Cyclotron Operations & Research (or Designate) and/or ERC Director (or Designate) and the Cyclotron Radiation Safety Officer to determine if Visitors can enter MICF spaces at any time.
5. **REQUIRED / ASSOCIATED DOCUMENTS**

5.1. Medical Isotope Cyclotron Facility Decision Matrix – Appendix 1

5.2. Work Clearance - Medical Isotope Cyclotron Facility Appendix 2

5.3. Gowning for Aseptic Areas at MICF – Appendix 3

6. **TRAINING REQUIREMENTS FOR MAINTENANCE AND CLEANING PERSONNEL**

6.1. For entry into the University of Alberta spaces within the Medical Isotope Cyclotron Facility all maintenance and cleaning personnel must have specific training for the Facility.

6.2. All maintenance and cleaning personnel must be trained in the following Standard Operating Procedures (SOP’s) prior to being given security access and entering the facility unescorted:

   6.2.1. B - Basic Orientation
   6.2.2. RSnU – Radiation Safety of non-Users
   6.2.3. AASO – Area Access Specific Orientation dependant on the space designation and type of activity being performed
   6.2.4. GMP Suite Orientation (GMP documentation, gowning procedures, aseptic suite access and procedures)
   6.2.5. For detail description of the levels of training required for each area of the building refer to the Medical Isotope and Cyclotron Facility Service Catalogue - Section 7 Access Control & Security.

7. **VISITOR SIGN IN AND SIGN OUT PROCESS**

7.1. On entry to MICF, all Visitors shall sign in at one of the two sign in binders located at the reception desk or mechanical room. On exit of MICF visitors must sign out at the respective binder that they signed in at.

8. **PLANNED WORK PROCEDURE**

8.1. No access for the purpose of maintenance will be granted to Restricted Spaces without a completed and approved work clearance.

   8.1.1. AHS Aseptic Space (GMP)

      8.1.1.1. During business hours, ERC staff and / or Cyclotron RSO will determine if it's safe for maintenance work to be completed concurrently with routine production.

      8.1.1.2. The room and equipment must be shown to be free of contamination through swipe test counting before work can be completed in AHS Aseptic Space.
8.2. When there is any kind of planned work to be performed in the Medical Isotope Cyclotron Facility the person who is going to perform the work must first refer to the Medical Isotope Cyclotron Facility Work Decision Matrix (Appendix 1) to determine the requirements for access to the space.

8.3. If the results from the Work Decision Matrix determine that the work can be performed without a Work Clearance, then the subsequent procedures shall be followed:

8.3.1. Proceed to the building.
8.3.2. Sign in and out at the Reception Desk as per the Visitor Sign In and Sign Out Process.
8.3.3. Perform the work.

8.4. If the results from the Work Decision Matrix determine that the work to be performed requires a Work Clearance, then the subsequent procedure shall be followed:

8.4.1. Follow the directions on the Work Clearance form to complete Parts 1 to 3 and obtain the approvals by the required stakeholders (Director Cyclotron Operations & Research, ERC Director, MICF Staff, Principle Investigator, and/or MICF Radiation Safety Officer).
8.4.2. Proceed to building (coordinate your access into any restricted areas with the appropriate MICF Staff in advance of arriving at the facility).
8.4.3. Sign in and out at the Reception Desk as per the Visitor Sign In and Sign Out Process.
8.4.4. Perform work following all requirements outlined in the approved Work Clearance form.
8.4.5. When work is complete, fill out Part 4 of the Work Clearance form and file the completed Work Clearance Form in the Work Clearance binder at the Reception Desk.

8.5. If after hours maintenance is approved, workers must contact University of Alberta Controls Centre prior to accessing the area, and again upon completion of the work.

9. **UNPLANNED AFTERHOURS EMERGENCY WORK PROCEDURE**

9.1. Unplanned afterhours emergency work in non-restricted and semi-restricted areas and/or work that will not affect any processes in the building that would not normally require an approved work clearance can be conducted as per the standard operating procedures described in this document. The person who is responding to perform the emergency work shall contact the University of Alberta Control Centre at 780-492-5555 prior to entering the building and upon completion of the work.

9.2. Unplanned afterhours emergency work in restricted areas and/or work that may affect any processes in the building and/or would normally require an approved work clearance will only be granted in an emergency situation (burst pipe, power failure, flooding, etc.).

9.2.1. Refer to the Building Drawings located at reception to determine the location of stored radioactive isotopes and their maximum quantity.

9.3. The person who is responding to perform the emergency work shall contact the University of Alberta Control Centre at 780-492-5555 who will contact the Environment, Health and Safety (EH&S) On-Call Manager to determine which portions of the building are safe to enter.
9.4. The EH&S On-Call Manager will contact the appropriate individuals from the UofA and/or AHS.

9.5. If afterhours emergency maintenance is approved by the EH&S On-Call Manager, workers must contact University of Alberta Controls Centre prior to accessing the approved areas, and upon completion of the work.

9.6. If MICF staff are in the building after normal hours, they may also escort maintenance staff into restricted areas to respond to emergency maintenance situations at the mutual discretion of the MICF Staff member and the maintenance worker.

10. EMERGENCY RESPONSE (FIRE, AMBULANCE, POLICE, ETC.) PROCEDURE

10.1. Emergency response personnel must understand the radiation risks prior to entering the various areas (Restricted, Semi-Restricted, Non-Restricted) of the facility. Floor plans indicating where hazardous materials may be present as well as identifying the various areas are included in the ERB.

10.2. Trained UAPS personnel and Emergency Responders may access all MICF non-restricted and semi-restricted areas during and after occupied hours. If entering the facility afterhours contact the University of Alberta Control Centre at 780-492-5555 prior to entering and when leaving the facility.

10.3. During occupied hours of operation first responders, normally a member of UAPS will consult with the Building Warden and/or MICF Staff about safe entry into the restricted areas of the facility. Where required, MICF Staff will provide the appropriate escort and safety precautions to Emergency Response providers should entry into the specific restricted areas of the facility be required.

10.4. During unoccupied hours first responders, normally a member of UAPS will contact the University of Alberta Control Centre, who in turn will contact the Environment, Health and Safety (EH&S) On-Call Manager to determine which portions of the building are safe to enter. Emergency responders shall enter the specific restricted areas of the facility based on the authorization provided by the EH&S On-Call Manager.

10.4.1. Refer to the building floor plans located in the Emergency Response Binder to determine the location of stored radioactive isotopes and their maximum quantity.

11. VISITOR ACCESS

11.1. Visitors without the required training may enter the Restricted and Semi-restricted areas of the facility only if they are provided with a personal dosimeter and are accompanied by a fully trained MICF Staff Member at all times.

11.2. It is the responsibility of the escorting MICF Staff Member to ensure the visitor follows all procedures to minimize the risk to product, facility or of accidental radiation exposure.
12. **MAINTENANCE RECORDS**

12.1. Maintenance records will be kept by UofA F&O, and will provide a copy of all maintenance records as required by providing a hard copy or an electronic copy to required parties.

12.2. Where a work clearance is required to perform a maintenance task, after the work is completed, the worker shall file the completed Work Clearance Form in the Work Clearance binder at the Reception Desk.
Appendix 1 – Medical Isotope Cyclotron Facility Work Decision Matrix

*** Insert latest version of the Decision Matrix ***
Appendix 2 – Work Clearance – Medical Isotope Cyclotron Facility

*** Insert latest version of the Work Clearance Form ***