Nova Scotia Health Authority
Central Zone

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Version 5

Radiation Safety Program Manual
Part 3 Cyclotron - Isotope Production

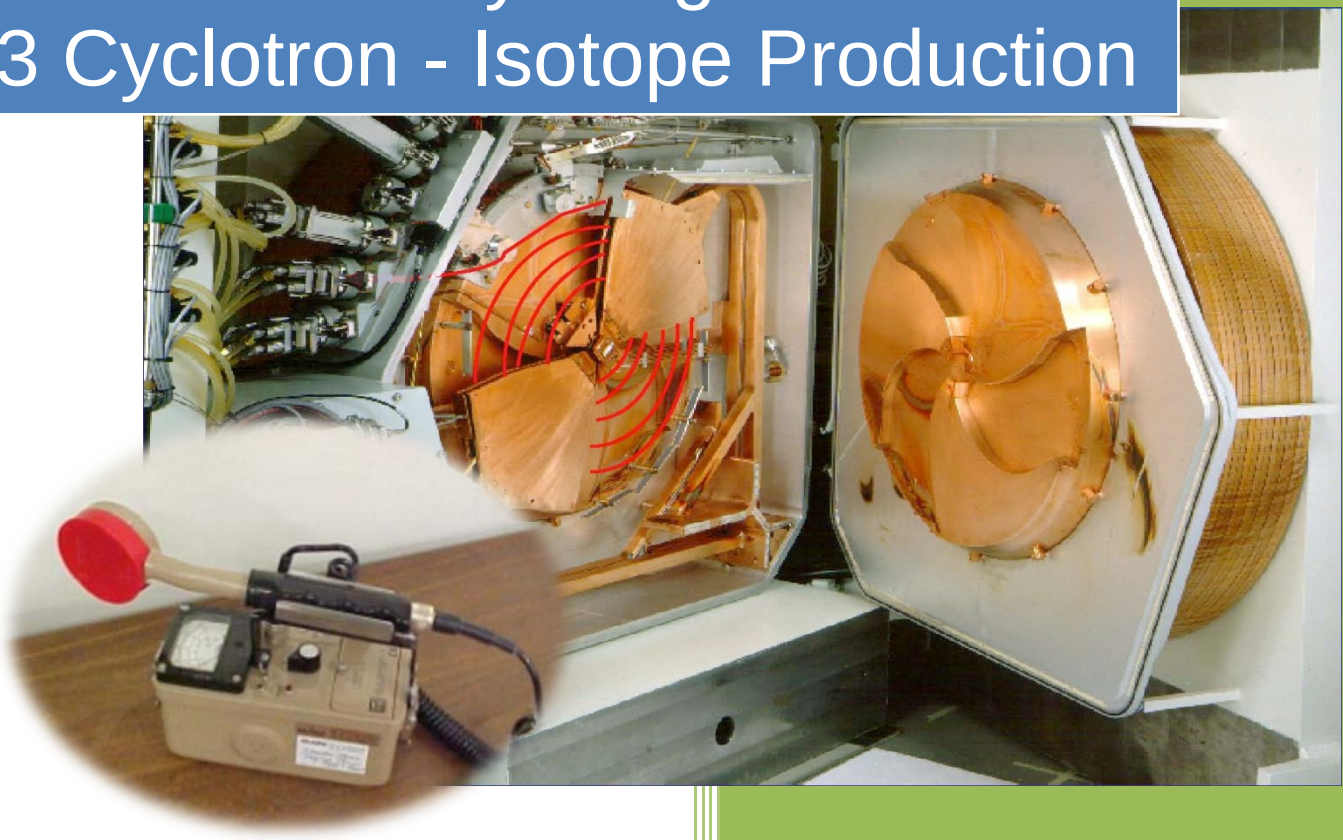

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Table of Contents

INTRODUCTION

As programs will vary depending on the size of the organization, the type of work being performed and regulatory requirements that govern radiation use, this section includes specific radiation safety practices for **Cyclotron Isotope Production Facilities.**

The general radiation safety program that applies to more than one department is covered in the ***Radiation Safety Program Manual Part 1 General Radiation Safety.***

PART 3 CYCLOTRON – ISOTOPE PRODUCTION (Section 300)

Section 301 Cyclotron Radiation Safety Quality Control Procedures

Policy RSP-301 Cyclotron Quality Control Procedures

Manufacturers identify all aspects of the safe operation of radiation devices. Device operators shall conduct all start-up and shut-down procedures as well as preventive maintenance checks according to the manufacturer guidelines.

301.1 Daily Checks – Start-up

The following Daily checks are to be performed before the PETtrace system is started. If any daily check fails, the cyclotron is not started, the operator will attempt to resolve the issue and if not resolved will report the issue for troubleshooting and possible service.

1. No water leakage in the Equipment Room or the Cyclotron Room.
2. Ventilation working in the Equipment Room and the Cyclotron Room.
3. Room Humidity and Temperature are within operational tolerance levels.
4. Electrical power present at Cabinets and Equipment Room Secondary Cooling Unit
5. Accelerator Control Unit (ACU) is up and running.
6. Vacuum level on the VCU display is within operation limits..
7. Gas valves for target gases hydrogen, argon and helium open
8. Radiation Shield is closed.
9. No personnel in the Cyclotron Room.
10. Door to Cyclotron Room closed.
11. Beam Current Set and does not exceed licence conditions
12. Facility Safety System allows beam.
13. Warning Lights (Magnet, RF, Beam) on start up
14. Swedewater: Water conductivity, temperature and pressure within operation limits
15. Shield door has not been opened. IF door was opened (ie to change target or add water) conduct a radiation survey of door seams during bombardment.

301.2 Monthly Checks

The following monthly checks are performed to ensure the safety systems, not checked daily, are functioning.

1. Door Interlock (attempt opening of shield door when cyclotron is operating)
2. Door interlock (Trying to start cyclotron when shield door is open)
3. Emergency Stop Button Console
4. Emergency Stop Button Cyclotron Vault
5. Shield Tank Water Level Switches (rotational basis)
6. Constancy checks on contamination meters.

301.3 Semi-Annual Checks

1. Preventive maintenance as defined by service contract and device manufacturer specifications. (under manufacturer service licence)

301.4 Annual Checks

1. Preventive maintenance as defined by service contract and device manufacturer specifications. (under manufacturer service licence)
2. Annual radiation gamma and neutron survey.
3. Calibration of Radiation Survey/Area Meters (done on a rotational basis throughout the year)
4. Efficiency check of contamination meters.

Section 302 Safety System Checks

Policy RSP-302 Cyclotron Radiation Safety System Checks

Device operators shall conduct radiation safety system checks for their specific device as defined in the Class II Nuclear Facility and Prescribed Equipment Regulations.

INTRODUCTION

The self shielded cyclotron facility is exempt from some safety systems as long as certain dose related criteria are met. **The following are <u>not</u> required if the self shielded device DOES NOT have a radiation dose greater than 200uSv/hour at 30cm from the device AND has a door to the room that can be locked and only accessed by authorized personnel during the operation of the device.** Note: if any emergency systems are part of the facility design, even if they are not required, they must be tested.

1. Room Door Interlocks
2. Last Person Out Button
3. Audible alarm in the cyclotron room prior to start of irradiation
4. Emergency Stop Buttons except at the operating console.

302.1 Door Interlocks

While room door interlocks are not required the device is equipped with shield door interlocks that serve the same purpose and are tested. To verify the cyclotron is not able to start when the shield door is open or stops the cyclotron if the doors get opened.

PROCEDURE
To verify the cyclotron cannot start if the shield door is opened
Frequency: Monthly

1. Open left door and leave open with the right door remaining closed)
2. Start a production run on the cyclotron control computer
3. No production should be possible
4. The test is successful if: The cyclotron program should give a message that it cannot start because the shield door is open
5. If the test fails, report to the on-site RSO and for servicing
6. Repeat the above with the right door open and left door closed

PROCEDURE
To verify the shielding door cannot be opened during cyclotron operation
Frequency: Monthly

1. Start a production run on the cyclotron control computer: Magnet ON, RF ON and Ion Source ON;
2. Start the compressed air machine;
3. On the shield door panel turn ON the key of the left shield door: The shield door should not open;
4. Try again to turn ON the key of the right shield door: The shield door should not open;
5. Stop the production.
6. The test is successful if: The shield door is unable to be opened during cyclotron operation
7. If the test fails, report to the on-site RSO and for servicing

302.2 Last Person Out Button

A button that prevents the equipment from being used unless a person activates the button from inside the room and then leaves the room within a preset-time. **Not required for self shielded device.**

302.3 Warning Lights

To verify warning lights are operational.
Frequency: Daily

1. Start a production run on the cyclotron control computer
2. Once the magnet, RF and beam are on the warning lights for each should come on by the operating console as well the door entrance to the cyclotron (equipment room).
3. The test is successful if: The radiation warning light is operational
4. If the test fails, report to the on-site RSO and for servicing

302.4 Pre-Irradiation Alarms

A device that provides a continuous audible signal within the vault for a period of time before irradiation begins. **Not required for self shielded device.**

302.5 Emergency Stop Buttons

For a self shielded device the regulatory requirement is to have an emergency stop button at the console of the device. If any other emergency stop buttons are present, they must be included in any quality assurance testing procedures.

PROCEDURE
To verify if the Emergency Stop Buttons in the control room (Console) and cyclotron room are accurately working.
Frequency: Monthly

1. Start a production run: Magnet, RF and Beam are ON;
2. Push the emergency button in the control room;
3. The Beam and the RF should stop but the magnet and the rest of the equipment still in operation;
4. Repeat the procedure for the second emergency stop button in the cyclotron room;
5. The Beam and the RF should stop but the magnet and the rest of the equipment still in operation.
6. The test is successful if: The Beam and the RF shut off (ie disconnect from main power supply)
7. If the test fails, report to the on-site RSO and for servicing

302.6 Radiation Area Monitors

The room shall be equipped with radiation detectors that continuously monitor radiation dose rates and trigger alarms at dose rates above normal expected operating conditions. Areas that shall have radiation include:

1. Cyclotron room
2. Synthesis (Hot) Cell room
3. Processing (Dispensing) Cell room
4. Ventilation Systems (stack)

PROCEDURE

1. All radiation monitors shall be maintained according to manufacturer specifications.
2. Radiation monitors shall be calibrated annually as part of a regular preventive maintenance schedule. This can be done on a rotational basis as long as all are calibrated annually.

Section-303 Other Radiation Safety Procedures

Policy RSP-303 Other Cyclotron Radiation Safety Procedures

Manufacturers identify all aspects of the safe operation of radiation devices. Device operators shall conduct all start-up and shut-down procedures as well as preventive maintenance checks according to the manufacturer guidelines

303.1 Non-Standard Operation

From time to time it may be necessary to operate the cyclotron in a non-standard mode during service and/or preventive maintenance procedures.

PROCEDURE

To test parts during service or preventive maintenance procedures

Frequency: As required by manufacturer service personnel or cyclotron engineer

1. When a request is made to operate the cyclotron in non-standard mode it must be first cleared with the cyclotron engineer or department head.
2. Non-standard mode operation shall be in the presence of manufacturer service personnel or cyclotron engineer.
3. All non-standard mode operations shall be documented.

303.2 Shielding Test (Water Levels)

The cyclotron, as a self shielding device, should not be able to operate if the water level in the shielding tanks falls below the manufacturer's specifications.

PROCEDURE

To verify if the water level switches inside the shield tanks are working.

Frequency: Annual for each water level switch. Testing is conducted monthly on one switch on a rotational basis such that each of the eight switches is tested at least annually.

1. Ensure the magnet is on.
2. Ensure target is filled with 0^{16} water.
3. Safely use a ladder go to the top of the cyclotron;
   For each water level switch tested use the following procedure
4. Open the lid on one of the tanks and check that the water level is about 2 cm under the sealing and that the water level switch is not in its lowest position;
5. Push the water level switch to the lowest position;
6. Hold it in that position;
7. As soon as the water switch is in the lowest position the message "ACS fault at safety interlocks, safety door open", will appear.
8. A second person starts a production on the control system. "ACS warning in target 1, target already full" will appear.
9. The Start Irradiation button will become active.
10. Click on the "Start Irradiation" button.
11. "ACS fault in start beam for target 1, safety door open" will appear and production is stopped
12. Click on "Abort Production"
13. The test is successful if: The cyclotron production should not start with production

303.3 Ventilation Monitoring

All equipment in the facility related to the HVAC system must be monitored daily.

Differential Air Flow

PROCEDURE
To verify pressure differentials and the air flow in laboratory meet Health Canada Guidelines.
Frequency: Daily.

1. Record daily pressure differential readings, between room 1080 and 1079, 1081 and 1081A, 1081A and 1078 from the displays.
2. Record values on P-025-1 Pressure Differential and Air Flow Log.
3. Ensure direction of air flow is recorded by recording whether the pressure differential is positive or negative.
   Acceptable Limits:
   The direction of air flow must be:
   Room 1080 (dispensing room) must be positive to Room 1079 (interlock).
   Room 1081(Production), must be positive to Room 1081A (QC).
   Room 1081A (QC) must be positive to Room 1078 (Gowning).
   Gowning must be positive to Hallway
   Pressure Differentials between rooms must be:
   Room 1080 (dispensing) to Room 1079 (interlock) between +0.04 and +0.06 WC.
   Room 1081 (Production) to 1081A (QC) at least +0.001 WC *
   Room 1081A (QC) to 1078 (Gowning) between +0.04 and +0.06WC.
4. If any results fall outside the acceptable limits do not start production and report to supervisor for assessment and decision.

Stack Flow Monitoring

PROCEDURE
To verify the flow in the exhaust stack is operating according to manufacturer recommendations.
Frequency: Daily

1. Record the current exhaust flow on P-029-1.
2. Open graph on MediSMART system, assess graph flow since last monitored.
3. Record whether or not range has stayed within limits.
   Acceptable Limits:
   Exhaust Stack Flow Limits: 0.3 m3/sec - 1.2 m3/sec
4. If any results fall outside the acceptable limits do not start production and report to supervisor for assessment and decision.

303.4 Radiation Surveys

Survey After Shield Doors Are Opened

A radiation survey of the front of the shield door seam shall be conducted as a check of the radiation dose rate each time the doors are opened. The survey shall include both neutron and gamma measurements and serves as a periodic check between the full survey conducted annually.

PROCEDURE

To verify the efficacy of the cyclotron shield during production.
Frequency: The next time the cyclotron is operated after the shield doors have been opened

1. Using the gamma and neutron detector, monitor points GG, HH and II along the front seam when the cyclotron is operating.
2. The test is successful if the dose rate readings are below the expected readings as indicated in the device specs.
3. If readings are higher than expected or outside of the GE specifications, do not permit anyone in the room during the irradiation and notify the on-site RSO.
4. Attach the survey form to the appropriate Daily Check list where it was indicated the doors had been opened.

Annual Survey

An annual radiation survey shall be conducted around the self shielded device to determine if the manufacturer dose rates and CNSC requirements for self shielded devices, as submitted with the licence application, continue to be met. The survey shall include both neutron and gamma measurements

PROCEDURE

To verify the efficacy of the cyclotron shield during production.
Frequency: Annually

1. Using the gamma and neutron detector monitor all points indicated on the Annual Survey form when the cyclotron is operating.
2. The test is successful if the dose rate readings are below the expected readings as indicated in the device specs.
3. If readings are higher than expected or outside of the GE specifications, do not permit anyone in the room during the irradiation and notify the on-site RSO.

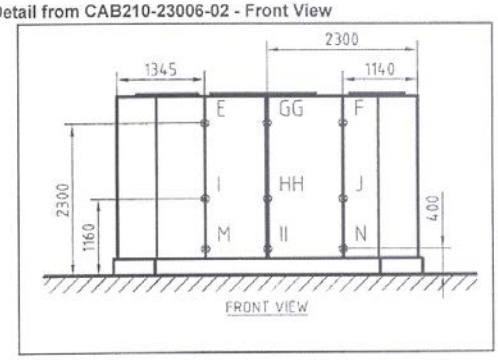
Molecular Imaging and Research Centre of Nova Scotia Shield Door Seam Radiation Survey PETtrace Gamma and Neutron Dose Rate Measurements				
Date			**Performed By:**	
Irradiation	**16 MeV protons at 40 µA for 120min**		**Target Body**	**Niobium**
Target Position	**#1**		**Target Material**	**>97% ^{18}O-water: 2.0 ml**
Gamma Instrument	**Make: Victoreen**	**Model: 451P-DE-SI-RYR**		**Serial Number: 2530**
	Calibrated:		**Background:**	
Neutron Instrument	**Make: Fluke Biomedical** **Probe: Fluke Biomedical**	**Model 190N-S1** **Model: RP-N**		**Serial Number: 107721** **Serial Number: 106197**
	Calibrated:		**Background:**	
Start of Beam (hh:mm)			**End of Beam (hh:mm)**	
Area Monitor - Room 1086 Dose Rate During Bombardment in µSv/hr				

SHIELD DOOR SEAM SURVEY

Location	[A] Measured Gamma Dose Rates µSv/h	Max. Gamma Dose Rate GE SPEC µSv/h		[B] Measured Neutron Integr. Dose (30s) nSv	[C] = [B x (1/30s) x (3600s/h) x (x.xx#) x 1µSv/1000nSv)] Calculated Neutron Dose Rate µSv/h#	Max. Neutron Dose Rate GE SPEC µSv/h	Σ = [B+C] Total Measured Dose Rate µSv/h
GG		**25**				**3**	
HH		**80**				**3**	
II		**140**				**10**	

GE Dose Rate SPEC from Document 2169053-100 Rev 5 (Appendix I-2.2 of CDHA Application to Operate)
 # Ambient dose rate equivalent according to latest ICRU Report (x.xx) x digital meter dose rate reading. NRC Report No. IRS-2010-1384

Detail from CAB210-23006-02 - Front View



Molecular Imaging and Research Centre of Nova Scotia
Annual Radiation Survey
PETtrace Gamma and Neutron Dose Rate Measurements

Date		**Performed By:**	
Irradiation	**16 MeV protons at 40 μA for 120min**	**Target Body**	**Niobium**
Target Position	**#1**	**Target Material**	**>97% ^{18}O-water: 2.0 ml**
Gamma Instrument	**Make: Victoreen** **Model: 451P-DE-SI-RYR** **Serial Number: 2530**		
	Calibrated:	**Background:**	
Neutron Instrument	**Make: Fluke Biomedical** **Model 190N-S1** **Serial Number: 107721** **Probe: Fluke Biomedical** **Model: RP-N** **Serial Number: 106197**		
	Calibrated:	**Background:**	
Start of Beam (hh:mm)		**End of Beam (hh:mm)**	
Area Monitor - Room 1086 Dose Rate During Bombardment in μSv/hr			

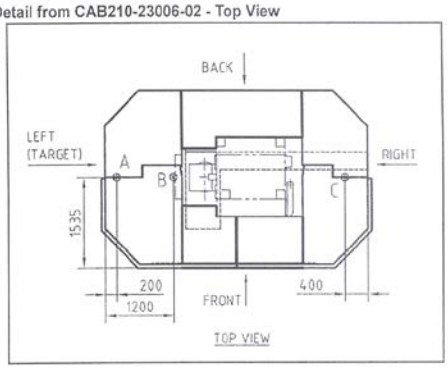
ANNUAL SURVEY

Location (see back)	[A] Measured Gamma Dose Rates μSv/h	Max. Gamma Dose Rate GE SPEC μSv/h	[B] Measured Neutron Integr. Dose (30s) nSv	[C] = [B x (1/30s) x (3600s/h) x (x.xx#) x 1μSv/1000nSv)] Calculated Neutron Dose Rate μSv/h#	Max. Neutron Dose Rate GE SPEC μSv/h	Σ = [B+C] Total Measured Dose Rate μSv/h
A		**20**			**5**	
B		**170**			**20**	
C		**25**			**2**	
D		**12**			**2**	
E		**15**			**2**	
F		**20**			**2**	
G		**6**			**1**	
H		**25**			**6**	
I		**40**			**3**	
J		**30**			**2**	
K		**12**			**1**	
L		**50**			**10**	
M		**150**			**10**	
N		**30**			**2**	
O		**20**			**3**	
P		**30**			**2**	
Q		**30**			**2**	
R		**12**			**1**	
S		**50**			**12**	
GG		**25**			**3**	
HH		**80**			**3**	
II		**140**			**10**	
Measured Dose Rate at 30 cm						
A†						
B†						
L†*						
M†*						
S†*						
HH†*						
II†*						
C†						

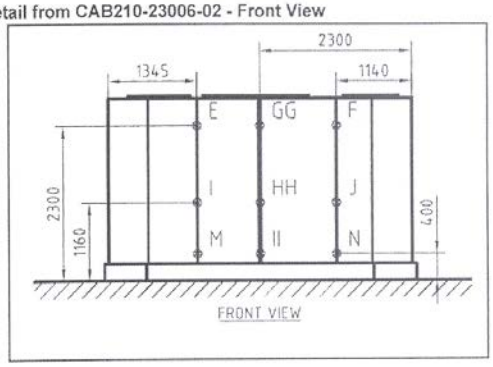
GE Dose Rate SPEC from Document 2169053-100 Rev 5 (Appendix I-2.2 of CDHA Application to Operate)
 # Ambient dose rate equivalent according to latest ICRU Report (x.xx) x digital meter dose rate reading. NRC Report No. IRS-2010-1384 † = 30 cm of the shield surface * = 90 cm off the floor

Molecular Imaging and Research Centre of Nova Scotia
Radiation Survey
PETtrace Gamma and Neutron Dose Rate Measurements
Survey Measurement Locations

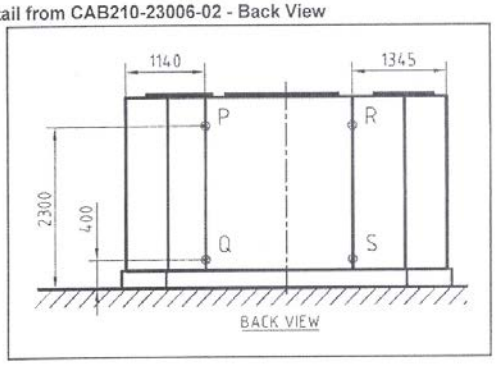
Detail from CAB210-23006-02 - Top View



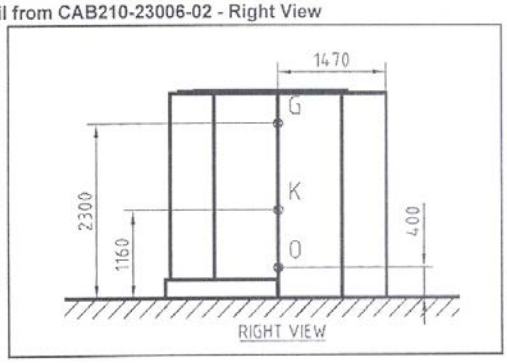
Detail from CAB210-23006-02 - Front View



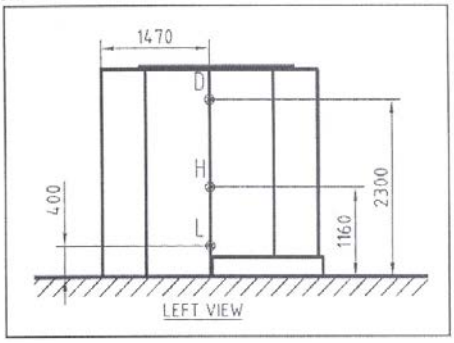
Detail from CAB210-23006-02 - Back View



Detail from CAB210-23006-02 - Right View



Detail from CAB210-23006-02 - Left View



NOTES/COMMENTS:

Section-304 Emergency Procedures

Policy RSP-304 Cyclotron Emergency Procedures

Manufacturers identify all aspects of the safe operation of radiation devices. Device operators shall conduct all start-up and shut-down procedures as well as preventive maintenance checks according to the manufacturer guidelines

The following procedures are in addition to the general emergency procedures listed in the Radiation Safety Program Manual Part 1. In general, most emergencies involving the cyclotron require the same procedures to be enacted.

304.1 Malfunction of Cyclotron

Warning of Malfunction at Control Panel
Target Window Rupture - Transfer Line Leak
Synthesis (Hot) Cell Gas Containment Leak
Loss of Electrical Power

PROCEDURE

1. Immediately shut down the cyclotron using the software, if possible, or press the emergency stop button.
   Note: if electrical power is lost the cyclotron will shut down completely.
2. Ensure no personnel are in the cyclotron room or other affected rooms and shut the doors.
3. Inform all workers in the facility about the accident and evacuate the affected areas.
4. Inform the site-RSO about the incident.
5. Close off areas and identify access points with radiation warning signs.
6. Inform the service provider

Section-305 Maintenance

Policy RSP-305 Cyclotron Maintenance Procedures

Procedures listed in the PETtrace Operator Guide can be conducted by authorized in-house personnel, recognizing that some procedures may be deemed "service" by the Canadian Nuclear Safety Commission and require additional documented training.

The Canadian Nuclear Safety Commission defines servicing Class II devices as:

> any maintenance of the equipment, including installation, repair or dismantling, ***other than*** any installation, repair or dismantling that constitutes routine operating procedures as indicated in the manufacturer's operating manual for the equipment.

The periodic maintenance procedures as well as the target rebuild require additional training. Training is generally provided by the manufacturer or trained service personnel during scheduled preventive maintenance.

305.1 Periodic Maintenance Procedures

PROCEDURE

1. Only authorized personnel with documented "periodic maintenance procedure" training can conduct these procedures.
2. Authorized personnel must follow the PETtrace operator guide for the maintenance procedures they are conducting.
3. Ensure the radiation device maintenance is consistent with the training provided and the manufacturers documented procedures and do not conduct any maintenance outside the scope of training
4. Review procedures and plan work before any work is started and refer to the manufacturer's manual for parts and procedure references as needed.
5. Wear appropriate personal protective equipment, radiation monitors and work behind lead shielding as appropriate.
6. Before starting the work, ensure all tools and equipment required are available.
7. Dispose of any radioactive waste according to radiation safety waste disposal procedures in *Radiation Safety Program Manual Part 1 General.*
8. Following maintenance, all daily operational checks shall be conducted before the device is used.

305.2 Rebuilding Target

PROCEDURE

Target Removal and Storage

1. Remove current 'hot' target assembly and place in designated radioactive decay storage area.
2. Let the assembly undergo radioactive decay until the next scheduled maintenance, generally six months.
3. Remove the target assembly from the previous maintenance period and use it for the rebuilding procedure. This assembly will still be radioactive.

4. Conduct the target rebuild behind a radiation shield.

Target Disassembly

1. Remove the bolts that secure the target pieces.
2. Separate the rear flange from the helium coaling flange.
3. Remove the niobium body and VTiMton 0-ring.
4. Remove the larger Havar foil from the helium cooling flange and store the foil as radioactive waste.
5. Pull the helium cooling flange from the front flange.
6. Remove the smaller Havar foil and the aluminum Helicoflex seal and store the foil as radioactive waste.
7. Remove gold seal assembly from the niobium body and proceed to gold seal removal.

Gold Seal Removal

1. Great care should be taken when removing the seal.
2. Lightly knock the niobium insert against a table or gently manipulate the seal with the removal tool supplied with the target.
3. When the seal has been loosened all the way around, lift the seal out of the groove.
4. Remove the four O-rings from the helium cooling flange and proceed to target cleaning

Target Cleaning

1. Conduct the target cleaning behind a radiation shield.
2. Monitor all waste, such as the lint free paper, for radioactivity and dispose appropriately.
3. Using lint-free paper and isopropanol or ethanol, clean the front flange, the helium cooling flange and the rear flange.
4. Wipe off all tightening surfaces for 0-rings and foils.
5. Thoroughly rub out the niobium target volume using lint-free paper moistened with isopropanol or ethanol. Repeat twice using new paper each time.
6. Inspect and, if necessary, clean the gas inlet (upper) and water inlet (lower) holes in the niobium body.
7. Rinse the holes with isopropanol.
8. Rinse the niobium body with distilled or deionized water.
9. Clean and rinse the niobium body with an ultrasonic cleaner.
10. Dry the niobium body with lint free paper and leave to air dry.
11. Visually inspect the niobium body for scratches and contamination.
12. Inspect the connection holes and sealing surfaces of the remaining target parts.
13. Once all cleaning and inspection is complete proceed to target reassembly

Target Reassembly and Mounting

1. Install the Helicoflex seal and the foil and centre the foil if needed.
2. Mount the thinner of the two larger diameter O-rings on the outer edge of the front flange.
3. Mount the smaller 0-ring over the inner edge of the front piece.
4. Place the helium flange on top of the front flange.
5. Install the four O-rings and Havar foil in the cooling flange
6. Mount the gold seal by hand in the groove of the niobium body.
7. Carefully install the niobium insert in the cooling flange.
8. Place the thicker of the large diameter O-rings in the groove of the rear flange.
9. Place the rear flange on top of the niobium insert and cooling flange and ensure the gap is closed, insert bolts and torque to manufacturers specifications.

10. Mount the target by placing it in its correct position and attach the connection plate and lock everything in place.

APPENDIX A – Policy & Procedure Revisions

Policy and Procedure Revisions
Source: Radiation Safety Office **Approval: Radiation Safety Committee**

RSP Number	Revision	Name	Approved Date	Revised Date	Changes
301	0	Cyclotron Quality Control Procedures	2014-09-19		
302	0	Cyclotron Radiation Safety System Checks	2014-09-19		
303	0	Other Cyclotron Radiation Safety Procedures	2014-09-19		
304	0	Cyclotron Emergency Procedures	2014-09-19		
302	1	Cyclotron Radiation Safety System Checks 302.5 Emergency Stop Buttons		2015-08-01	Removed total stop button. Keep console emergency stop check required by regulations.
	version4	Service Procedures 305		2016-12-22	added section 305 relating to procedures to rebuild the target.
	version 5	Service Procedure		2017-mm-dd	changes based on CNSC feedback and clarification of service procedures.