

Eastern Health – Radiopharmaceutical Sciences Radiation Safety Public Disclosure Program Report

Timeframe: January 1, 2022, to March
17, 2023

Radiation Safety Office

Eastern Health

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www.easternhealth.ca

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Section 1 – General

Cyclotron and Processing Licence

The cyclotron, located at the Health Sciences Centre, Nuclear and Molecular Medicine Facility, is a federally regulated Class II prescribed equipment that produces radioactive isotopes for Eastern Health Medical Imaging. The Canadian Nuclear Safety Commission (CNSC) is a federal regulatory agency that issues licences to those who successfully complete the application process.

Licence Specifics

Licence #	Licence Type	Use Type
13124-9-26.5	Production Accelerator (Cyclotron)	616

Radiation Safety Program Organization

Applicant Authority:	Kenneth Baird	President and CEO (Interim)
Signing Authority:	Julio Panama	Program Radiation Safety Officer
Corporate Radiation Safety Officer:	Melanie Loveless / Kelsey Campbell	
Program Radiation Safety Officer:	Julio Panama	

Radiopharmaceutical Sciences Organization

Director of Medical Imaging:	Tony Poole
Manager, Radiopharmaceutical Sciences And Cyclotron Operations	Julio Panama

Public Disclosure Program

The CNSC requires Eastern Health to have a public information and disclosure program for the operation of the cyclotron and processing facility (Radiopharmaceutical Sciences). The purpose of the program is to provide transparency to stakeholders with regards to radiation safety of staff, the public and the environment.

Corporate Radiation Safety Committee

The Corporate Radiation Safety Committee, CRSC, reports and provides recommendations to Executive Management with respect to the oversight of the Radiation Safety Program for Eastern Health.

The Eastern Health Corporate Radiation Safety Committee met four times in 2022 to discuss radiation safety issues along with approving recommended radiation safety program changes. The committee consists of a variety of stakeholders who work with ionizing radiation from around Eastern Health.

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Radiation Safety Administration and Operations Group

The Radiation Safety Administration and Operations Group consists of the Radiation Safety Officers throughout Eastern Health, who work collaboratively to manage the administration and operations of the Radiation Safety Program.

In total, four meetings were held during the calendar year. The meetings were chaired by the Eastern Health Corporate Radiation Safety Officer.

Cyclotron Radiation Safety Group

The Radiopharmacy Radiation Safety Group was created in December 2021 to improve the radiation safety culture in the department. The workgroup is led by the Program Radiation Safety Officer and consists of employees of the Radiopharmaceutical Sciences team.

In total, four meetings were held and chaired by the Program Radiation Safety Officer during the reporting period.

Authorized Users and Training

Authorized users are those who are required to be registered to use nuclear substances and radiation emitting devices under federal regulations. Authorized users include technologists, managers, scientists, and support staff such as trades-workers who work directly with ionizing radiation.

General Summary of Authorized Users

General Summary of Authorized Users	
Radiopharmaceutical Sciences Nuclear Energy Workers	8
Radiopharmaceutical Sciences Non-Nuclear Energy Workers	1
Infrastructure Support Nuclear Energy Workers	1

Training is available to all authorized users in a variety of formats.

General radiation safety orientation training is available through the Eastern Health *Learn* e-learning system, and specialized training is given as on the job training specific to the tasks being performed. Refresher training is required every three years and is monitored by the Radiation Safety Office and the Radiopharmacy Quality Assurance program. It is the responsibility of the manager to ensure training is completed. All required training for authorized users in the Radiopharmaceutical Sciences was up to date during the 2022 calendar year.

Job duty specific training is provided by standard operating procedures, live demonstrations, presentations, and on-the-job exercises that have been developed by the radiation safety office in conjunction with the managers and subject matter experts.

Classroom and/or e-learning training is provided for those requiring Transport of Dangerous Goods for Shipping and Receiving of Class 7 Radioactive Material.

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Incidents

The following incidents from the cyclotron licence were reported to regulatory authorities in 2021.

Incidents Reported to the Regulatory Authorities 2021	
Unplanned power failures	2
Planned power failures	1
Equipment failures	0
Unplanned service outage	0
Action level exceeded	0

Disclosures

Annual disclosure of the Annual Compliance Report and Cyclotron Public Disclosure Program Report were made available via the Eastern Health website within the targeted disclosure times.

Waste Management

The primary disposal method for radioisotopes is to store them onsite until radioactive decay reaches background levels. Then, the waste may be disposed of through the normal hospital waste systems. There were no amounts released to the environment that exceeded the regulatory limits.

Inspections

The cyclotron facility was inspected by regulatory authorities in 2021, where seven non-compliance items were identified and five closed within the calendar year. Eastern Health – Radiopharmaceutical Sciences continues to work with the CNSC to resolve the outstanding items.

The identified items include:

- The frequency in which facility systems are verified and tested.
- Scope of testing for facility safety systems
- Verification and labeling of containers transferred to the Nuclear Medicine Program
- Disclosure and reporting of events where control of the facility is lost. (i.e. power or network outage)

All non-compliance items identified during the CNSC inspection were closed and accepted during the 2022 reporting period.

Section 2 – Personnel Dosimetry

Radiation exposure reports for all workers are kept well below the regulatory limits. Regulatory limits for nuclear energy workers (N.E.W) and the non-nuclear energy workers (general public) can be found in the tables below. Regulatory limits vary between whole body radiation monitoring and extremity (hand) radiation monitoring.

The organization has a policy of setting investigation levels that trigger an investigation if a reading exceeds the normal values expected for the group. These investigation levels are still well below the regulated limits but allow the program to monitor work practices and workload changes that may require revisions.

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ERHA-RPS Whole Body TLD Readings January 2022 to March 2023								
Upper Regulatory Limit:			Nuclear Energy Worker = 50mSv/yr			Non-Nuclear Energy Worker (General Public) = 1mSv/yr		
Classification	# of Non-Nuclear Energy Workers	# of Nuclear Energy Workers	Numbers of Workers in Each Dose Category					
			Below Detectable Limits (BDL)	0.1 and < 0.5 (mSv)	< 0.5 and < 1 (mSv)	> 1.0 and < 5.0 (mSv)	Maximum Individual Dose (mSv)	Average Dose (mSv)
Production	-	8	1	7	1	-	0.56	0.27
Office	1	-	1	-	-	-	BDL	BDL
Support	0	1	1	-	-	-	0.01	0.01

ERHA-RPS EXTREMITY TLD Readings January 2022 to March 2023								
Upper Regulatory Limit:			Nuclear Energy Worker = 500mSv/yr			Non-Nuclear Energy Worker (General Public) = 50mSv/yr		
Classification	# of Non-Nuclear Energy Workers	# of Nuclear Energy Workers	Numbers of Workers in Each Dose Category					
			0 and < 10 (mSv)	10 and < 50 (mSv)	< 50 and < 100 (mSv)	> 100 (mSv)	Maximum Individual Dose (mSv)	Average Dose (MSv)
Production	-	8	8	-	-	-	9.22	3.64
Office	1	-	1	-	-	-	-	-
Support	-	1	1	-	-	-	BDL	BDL

Section 3 – Cyclotron Facility

Operations

- The facility is fully operational and supplies the Nuclear and Molecular Medicine Program with ^{18}F -FDG and ^{68}Ga -DOTATATE for the Positron Emission Tomography (PET) Centre.
- The cyclotron workload was within the regulated operating parameters for the facility during the calendar year.
- The production output of ^{18}F increased by nearly 25% from the previous reporting period.

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Cyclotron Workload

Cyclotron Workload 2022					
Reaction	Product	Typical Yield, EOB (mCi/μA)	Number of Targets used for production	Total Operation (hours)	Total Yield (GBq)
$^{18}\text{O} (p,n) ^{18}\text{F}$	^{18}F	240	2	223.3	25722.6
$^{16}\text{O} (p,\alpha) ^{13}\text{N}$	$^{13}\text{NH}_3$	38	1	0	0
$^{14}\text{N} (\alpha) ^{11}\text{C}$	CO_2	120	1	0	0

Annual Compliance Report

The annual compliance report for 2022 encompassing from January 1st, 2022, to March 17th, 2023, was submitted to the CNSC in May 2023. The details of the annual compliance report in its entirety are located throughout this document.

Facility

In 2021 Eastern Health – Radiopharmaceutical Sciences transitioned from a regulatory licence that permits the operation of a PET cyclotron facility to a licence that permits the operation and service of an isotope production accelerator facility.

In 2022, as noted by the Public Information Disclosure Program and the department website, Radiopharmaceutical Sciences started the preparation of ^{68}Ga -DOTATATE via generator and reconstitution with a cold kit.

Section 4 – Public Disclosure Program

Program Review

All information for the program can be found on the Eastern Health website:

<https://mi.easternhealth.ca/miservices/nuclear-and-molecular-medicine/cyclotron-and-processing-facility/>

A summary of the public disclosure protocol can be found in Appendix A of this report.

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Program Communications

Communications for the program information, website updates and public disclosures included:

Communication	Audience
The Cyclotron and processing facility webpage continues to be promoted and available via the main page of the external Medical Imaging Program website . (January 1, 2022 to March 17, 2023 and ongoing)	Public
Updated Cyclotron and Processing Facility Public Information Disclosure Protocol (PIDP) (May 18, 2022)	Public
External website updates to the following sections of the Cyclotron and processing facility webpage : <ul style="list-style-type: none"> Facility updates: 200th clinical production of 18F-FDG Additional information: Update to loss of utility occurrence date (August 25, 2022) 	Public
The following reports were added to the external Cyclotron and processing facility webpage : Reports <ul style="list-style-type: none"> Eastern Health – Radiopharmaceutical Sciences Radiation Safety Public Disclosure Program Report (January 1, 2021 to December 31, 2021) (PDF) <ul style="list-style-type: none"> Appendix A: Public Disclosure Protocol (PDF) Appendix B: Public Disclosure Summary 2021 (PDF) Annual Compliance Report (2021) (PDF) (August 25, 2022)	Public
External website updates to the following sections of the Cyclotron and processing facility webpage : <ul style="list-style-type: none"> Cyclotron commissioning: General updates Facility updates: 250th clinical production of 18F-FDG and first clinical preparation of Gallium Dotatate (68Ga-Dotatate) Routine preventative maintenance section: general and update to routine preventative maintenance period (November 7, 2022)	Public
External website update to the Positron emission tomography (PET Scan) webpage , re: PET scan that uses the locally prepared radiopharmaceutical Gallium Dotatate (68Ga-Dotatate). (November 7, 2022)	Public
Medical Imaging Program internal memo , re: Nuclear and Molecular Medicine – Cyclotron Preventative Maintenance. (February 14, 2023)	Eastern Health physicians, directors and management

Public Feedback & Response

The public information and disclosure program is committed to public evaluation and program improvement. Any questions, concerns, views, or suggestions from the public are directed to the Radiation Safety Officer. Any media inquiries are directed to Eastern Health's Media Relations Manager, who works with the appropriate subject matter experts to provide information and/or to facilitate interviews.

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All feedback is used to improve the public disclosure program. All changes to the program will be made with the public's views and interests in mind.

No public feedback or media inquiries (related specifically to items that are communicated via the public disclosure protocol) were received in 2022.

Eastern Health did not receive any media inquiries related to cyclotron operations during this reporting period.

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APPENDIX A – Public Disclosure Protocol

 Radiopharmaceutical Sciences Cyclotron and Processing Facility Public Information Disclosure Protocol (PIDP)	Document ID:	QAS-PT-007
	Revision No:	2

PURPOSE/OBJECTIVES

In keeping with Eastern Health's vision, *Health People, Healthy Communities*, the public information disclosure protocol aims to keep the public, as well as key governmental and community stakeholders, informed about activities of the cyclotron and processing facility that may impact, or be of concern to, the population it serves.

The protocol ensures information related to the health, safety and security of persons, the environment, and issues pertinent to the life cycle of the cyclotron and radiopharmaceutical processing facility, are effectively communicated to the public.

The following items are communicated via the public disclosure protocol:

- CNSC Annual Compliance Report;
- Yearly report of licenced activities via document *SAF-RT-001 – Eastern Health – Radiopharmaceutical Sciences Radiation Safety Public Disclosure Program Report* (template included as appendix one);
- Yearly summary of facility milestones via document *SAF-RT-002 – Eastern Health – Radiopharmaceutical Sciences Annual Radiation Public Disclosure Report Summary*;
- Items of concern (e.g., impact of natural events, unplanned significant interruptions of facility operations); and
- Licensing information.

Objectives of the communications protocol include:


- To review information communicated via the [Cyclotron and processing facility webpage](#) regularly to ensure accuracy and relevance to public interest.
- To provide the public with information in plain language that addresses any perceived risk related to the cyclotron and processing facility.
- To demonstrate Eastern Health's commitment to adhering to all regulatory requirements of the Canadian Nuclear Safety Commission and Health Canada.
- To demonstrate the organization's commitment to providing safe, quality and accessible care.

SCOPE

This protocol defines the type of information to report publicly, the anticipated timeline for disclosure, and the potential communications channels for disclosure. Information is presented in a manner that is easily accessible and understandable by the public.

Public disclosure protocol items are communicated, as required, through internal and external communications channels, such as but not limited to:

- external website;
- social media;
- public service announcements, news releases, media advisories;
- weekly email all staff newsletter;
- corporate intranet;
- memos; and
- additional communications channels, as needed.

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TARGET AUDIENCES

Target audiences include internal and external audiences and can be updated, as needed, based on the public disclosure protocol items that are communicated and as requested by current or potential audiences.

Internal Audiences

- Eastern Health physicians, staff and students, including those of the Medical Imaging Program, Radiation Safety Program and Radiopharmaceutical Sciences team as well as those working at the Health Sciences Centre.
- Executive Team.
- Board of Trustees.
- Foundations and volunteers.

External Audiences

- Eastern Health patients, including patients of the Nuclear and Molecular Medicine facility.
- Regulatory/Government stakeholders/departments: Canadian Nuclear Safety Commission (CNSC), Health Canada, Department of Health and Community Services, City of St. John's, targeted stakeholders as required (e.g. elected officials).
- Other Provincial Regional Health Authorities: Western Health, Central Health, Labrador-Grenfell Health.
- Professional associations (e.g. Newfoundland and Labrador Medical Association, NLMA).
- Memorial University staff and students.
- Public, including those living in the vicinity of the cyclotron and processing facility.
- Media (via Eastern Health's media contact list).

PUBLIC AND MEDIA OPINION

The public information and disclosure program is committed to public feedback, evaluation and program improvement. Contact information is available via the [Cyclotron and processing facility webpage](#) and any questions, concerns, views or suggestions from the public are directed to the Radiation Safety Officer. Media inquiries are directed to Eastern Health's Media Relations Manager, who works with the appropriate subject matter experts to provide information and/or to facilitate interviews.

Media monitoring, including monitoring of social media, is conducted daily. Any references to the operations of the cyclotron and processing facility and/or information provided via the protocol would be noted for any action, as appropriate.

All feedback is used to improve the public disclosure program. All changes to the program will be made with the public's views and interests in mind.

Additional information is included in the program evaluation section.

PROGRAM STRATEGY

In order to assess the performance of the Radiation Safety Program and to implement measures to improve effectiveness, an annual evaluation report of the Radiopharmaceutical Sciences Radiation Safety Program is produced by the Program Radiation Safety Officer. Within the report the following major items are discussed:

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- Licence Type, Radiation Safety Program Organization & Committees, Radiopharmaceutical Sciences Organization, Contact Information.
- Analysis of incidents to licenced activities, disclosures, and inspections
- Evaluation of Radiopharmaceutical Sciences staff dosimetry
- Cyclotron workload summary, and production facility updates
- Public Disclosure Program review, summary of communications, summary of public feedback and response, website traffic and engagement metrics (re: communications tactics), as outlined in the *Table 1*.

Communications tactics available to Eastern Health which may be utilized to communicate relevant activities of the cyclotron and processing facility to target audiences, as required, include the following:

Table 1. Communication Tactics

External	Internal
Appointment letter inserts Consultation sessions Client and Family Advisory Council meetings Corporate blog: StoryLine Corporate website PIDP website (Cyclotron and processing facility) Newsletters Digital signage network Events Information booths Information sessions, focus groups and forums Media: News conferences, news releases, media advisories, media availability, media statements, public service announcements (PSAs) Meetings Photography and videography Print materials (posters, booklets, brochures, factsheets, backgrounders) Resident and Family Council meetings Social media channels: Facebook, Twitter, LinkedIn, YouTube Speeches Stakeholder letter Surveys	All management/staff call with CEO Bulletin boards / posted notices and reminders Corporate Intranet Educational events (symposiums, webinars) Email (distribution lists) Events Executive and management team initiatives (greetings, speeches) Information sessions, focus groups and forums Key message document for management to use with staff Meetings (face-to-face; committees; team; huddles) Memos Newsletters – departments/programs, professional associations Photography and videography Print materials (posters, booklets, brochures, factsheets, nursing station drop cards, tent cards) The Pulse+ (weekly all staff e-mail newsletter)

Communication needs are assessed and communications tactics are recommended to address strategic objectives. Relevant tactics are recommended based on the information being communicated and the corresponding target audiences.

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PROGRAM EVALUATION

Program evaluation is completed on an ongoing basis and through annual reports to assess internal and external communication channels and approaches to inform target audiences about activities of the cyclotron and processing facility, as needed.

- Annual Public Disclosure Program review, including a summary of communications, summary of public feedback and response.
- Daily monitoring of traditional media and social media channels for references to the operations of the cyclotron and processing facility and any action, as appropriate.
- Questions/Inquiries/feedback received from staff or the public via the cyclotron.safety@easternhealth.ca email address or directed to members of the Radiation Safety Program and Radiopharmaceutical Sciences team.
- Number of media inquiries/responses related to the operations of the cyclotron and processing facility.
- Website traffic/analytics to the [Cyclotron and processing facility webpage](#).
- The collection of statistics and analysis of content to internal and external communication channels used to communicate items via the public disclosure protocol, as required.

Based on the results of the program evaluation, internal and external communications approaches are updated to support objectives.

CONTACT INFORMATION

Questions and concerns about the contents of the public information disclosure protocol, or about the cyclotron and processing facility, can be sent to the following email: cyclotron.safety@easternhealth.ca.

Further contact information can be found within the *Radiopharmaceutical Sciences Radiation Safety Public Disclosure Program Report* posted on the ml.easternhealth.ca website where key members of the Radiation Safety Program and Radiopharmaceutical Sciences team are listed.

DISCLOSURE GUIDELINES

Events, incidents, and information included in the *Table 2* will be disclosed according to the timeframe indicated. Eastern Health aims to publish information in a timely manner for the benefit of the public. This information is released as soon as Eastern Health staff can complete initial investigation steps to ensure that the information released is as accurate as possible. All information is published according to Eastern Health established protocols.

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Table 2. Disclosure Rubric

Information for Disclosure	Target Disclosure Timeframe
CNSC Licence information	Within 2 weeks of an update.
CNSC Annual Compliance Report (ACR)	Within 2 weeks of CNSC submission.
Annual Radiation Safety Public Disclosure Report Summary	Within 1 month of end of calendar year.
Notification of planned and unplanned significant interruption	Within 2 weeks of the event.
Important operational developments or events (e.g., labour disputes, expansions, facility changes)	Within 2 weeks of confirmation of the event.
Natural events with potential to have significant impact on protection and safety (e.g., lightning strike, floods, power outage)	Within 2 weeks of the event.
Serious incidents or accidents: <ul style="list-style-type: none"> Fire impacting the facility Lost or stolen nuclear substances Unplanned events exceeding regulatory limits Unplanned environmental release Any facility event resulting in the death or injury of an employee, visitor, or member of the public 	Within 1 week of the event.
Any other event that may have, or is perceived to have, an effect on the safety of the staff, public, or the environment	Within 2 weeks of the event.
Any other event where a disclosure is deemed necessary by Eastern Health	Within 2 weeks of the event.

APPENDIX B – Public Disclosure Summary 2022

EASTERN REGIONAL HEALTH AUTHORITY



2022 Radiation Safety – Annual Radiation Safety Public Disclosure Report Summary

Summary Report

The ERHA Radiation Safety Program provides information to the public about radiation safety in the Eastern Health - Radiopharmaceutical Sciences cyclotron department, located in the Nuclear and Molecular Medicine Facility of the Health Sciences Centre, as a requirement of the organization's licence.

Section 1 - General

- There were 3 reportable radiation safety incidents in 2022 none-of which presented any risk to the public or staff.

Section 2 – Personnel Dosimetry

- All staff members operated within the organizational and federal exposure limits.

Section 3 – Cyclotron Facility

- The facility is operating within the licenced parameters.
- Facility started the preparation of 68Ga-DOTATATE via generator and reconstitution with a cold kit.
- Radiation monitoring surveys were completed with no issues identified.
- The annual compliance report was submitted and accepted to the Canadian Nuclear Safety Commission (CNSC).

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APPENDIX C – Additional Resources

Topic	Resource
Introduction to Radiation	Canadian Nuclear Safety Commission http://nuclearsafety.gc.ca/eng/resources/radiation/index.cfm
Radiation Doses	Canadian Nuclear Safety Commission http://nuclearsafety.gc.ca/eng/resources/radiation/introduction-to-radiation/radiation-doses.cfm
Isotope Disposal Limits	Canadian Nuclear Safety Commission REGDOC 1.6.1 Appendix R http://www.nuclearsafety.gc.ca/pubs_catalogue/uploads/REGDOC-1-6-1-Licence-Application-Guide-Nuclear-substances-and-Radiation-Devices-version2-eng.pdf
Public Information Program	Canadian Nuclear Safety Commission REGDOG 3.2.1 https://nuclearsafety.gc.ca/eng/acts-and-regulations/regulatory-documents/published/html/regdoc3-2-1/index.cfm
Federal Radiation Safety Oversight	Canadian Nuclear Safety Commission Oversight Report http://www.nuclearsafety.gc.ca/eng/the-commission/meetings/cmd/pdf/CMD18/CMD18-M32.pdf