# Provincial Health Authority (PHA) – NL Health Services – Radiopharmaceutical Sciences Radiation Safety Public Disclosure Program Report

## Timeframe: March 17, 2023, to December 31, 2023

**Radiation Safety Office**
**Eastern Health**
**300 Prince Phillip Dr**
**St. Johns, NL, A1B3V6**

NL Health Services

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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 Newfoundland and Labrador (NL) Health Services' Medical Imaging department. 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** |
|---|---|---|
| **13124-9-26.6** | **Production Accelerator (Cyclotron)** | **616** |

**Radiation Safety Program Organization**

| | | |
|---|---|---|
| Applicant Authority: | Kenneth Baird | Vice President - Transition |
| Signing Authority: | Julio Panama | Program Radiation Safety Officer |
| Corporate Radiation Safety Officer: | Kayla Stokes | |
| 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 NL Health Services 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 NL Health Services.

The Corporate Radiation Safety Committee met four times in 2023 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 NL Health Services.

## *Radiation Safety Administration and Operations Group*

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

In total, three meetings were held during the calendar year. The meetings were chaired by the NL Health Services 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, three 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 | 10 |
| 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 NL Health Services *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 2023 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.

### *Incidents*

The following incidents from the cyclotron licence were reported to regulatory authorities in 2023.

| Incidents Reported to the Regulatory Authorities 2023 | |
|---|---|
| Unplanned power failures | 1 |
| 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 not inspected by regulatory authorities in 2023, however one standard internal audit was performed in May 2023.

All findings identified during the internal audit have been corrected.

## 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.

| PHA-RPS **Whole Body TLD Readings March 2023 to December 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 | - | 10 | - | 6 | 4 | - | 1.42 | 0.6 |
| Office | 1 | - | 1 | - | - | - | BDL | BDL |
| Support | - | 1 | - | 1 | - | - | 0.11 | 0.11 |

| PHA-RPS **EXTREMITY TLD Readings March 2023 to December 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 | - | 10 | 8 | 2 | - | - | 11.73 | 5.2 |
| 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 decreased by nearly 3% from the previous reporting period.
- The preparation of $^{68}$Ga increased by nearly 138% from the previous reporting period.
- The cyclotron, and facility was shut down for preventive maintenance from July 24 to August 6, 2023.

### *Cyclotron Workload*

| Cyclotron Workload 2023 | | | | | |
|---|---|---|---|---|---|
| Reaction | Product | Typical Yield, EOB (mCi/µA) | Number of Targets used for production | Total Operation (hours) | Total Yield (GBq) |
| $^{18}O$ (p,n) $^{18}F$ | $^{18}F$ | 240 | 2 | 165 | 17834 |
| $^{16}O$ (p,α) $^{13}N$ | $^{13}NH_3$ | 38 | 1 | 0 | 0 |
| $^{14}N$ (,α) $^{11}C$ | $CO_2$ | 120 | 1 | 0 | 0 |

### Annual Compliance Report

The annual compliance report for 2023 encompassing from March 17, 2023, to December 31, 2023, was submitted to the CNSC in May 2024. The details of the annual compliance report in its entirety are located throughout this document.

### Facility

On April 1, 2023, the four former regional health authorities, including Eastern Health and the Newfoundland and Labrador Centre for Health Information were amalgamated to become NL Health Services, a single provincial health authority (PHA). During the transition, information regarding the cyclotron and processing facility and public disclosure protocol continues to be available via the Eastern Health website.

## 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.

## 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**. (March 17, 2023 to December 31, 2023 and ongoing) | Public |
| **External website updates** to the following sections of the Cyclotron and processing facility webpage:<br>• Public disclosure protocol: Reports that are communicated via the public disclosure protocol.<br>• Additional information: Routine preventative maintenance period and loss of utility occurrence date (2023).<br>(September 7, 2023) | Public |
| The **reports** and **resources** sections were updated via the **external Cyclotron and processing facility webpage**:<br>**Reports**<br>• Eastern Health – Radiopharmaceutical Sciences Radiation Safety Public Disclosure Program Report (January 1, 2022 to March 17, 2023) (PDF)<br>○ Appendix A: Public Disclosure Protocol (PDF)<br>○ Appendix B: Public Disclosure Summary 2022 (PDF)<br>(August 4, 2023) | Public |
| **External website updates** to the following sections of the Cyclotron and processing facility webpage:<br>• Facility updates section: 300th clinical production of 18F-FDG.<br>• Routine preventative maintenance section: General and update to routine preventative maintenance period (2023).<br>(March 28, 2023) | Public |
| **Internal Communications:**<br>• FDG Program – August 29, 2023<br>• FDG Program Update – September 1, 2023<br>• FDG Program Update – September 5, 2023<br>• FDG Program Update - September 13, 2023<br>• FDG Program Update – September 21, 2023<br>• Scheduled Interruption of PET/CT Service – December 12, 2023 | Internal |

## 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 NL Health Services' Media Relations Manager, who works with the appropriate subject matter experts to provide information and/or to facilitate interviews.

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 2023.

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

## APPENDIX A – Public Disclosure Protocol

| Eastern Health Radiopharmaceutical Sciences | Document ID: | QAS-PT-007 |
|---|---|---|
| | Revision No: | 2 |
| Cyclotron and Processing Facility<br>Public Information Disclosure Protocol (PIDP) | | |

### 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:

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

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 mi.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:<br>• Fire impacting the facility<br>• Lost or stolen nuclear substances<br>• Unplanned events exceeding regulatory limits<br>• Unplanned environmental release<br>• 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 2023

# PROVINCIAL HEALTH AUTHORITY - NL HEALTH SERVICES

NL Health Services

## 2023 Radiation Safety – Annual Radiation Safety Public Disclosure Report Summary

**Summary Report**

The Provincial Health Authority (PHA) – Newfoundland & Labrador Health Services Radiation Safety Program provides information to the public about radiation safety in the 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 was one reportable radiation safety incident in 2023 which did not present 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.
- Radiation monitoring surveys were completed with no issues identified.
- The annual compliance report was submitted and accepted to the Canadian Nuclear Safety Commission (CNSC).

*Radiation Safety Office*
*NL Health Services – Health Sciences Centre*
*300 Prince Phillip Dr*
*St John's, Newfoundland and Labrador*
*A1B 3V6*
***cyclotron.safety@easternhealth.ca***

NLHealthServices.ca

## APPENDIX C – Additional Resources

| Topic | Resource |
|---|---|
| Introduction to Radiation | Canadian Nuclear Safety Commission<br><br>http://nuclearsafety.gc.ca/eng/resources/radiation/index.cfm |
| Radiation Doses | Canadian Nuclear Safety Commission<br><br>http://nuclearsafety.gc.ca/eng/resources/radiation/introduction-to-radiation/radiation-doses.cfm |
| Isotope Disposal Limits | Canadian Nuclear Safety Commission<br><br>REGDOC 1.6.1 Appendix R<br><br>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<br><br>REGDOG 3.2.1<br><br>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<br><br>http://www.nuclearsafety.gc.ca/eng/the-commission/meetings/cmd/pdf/CMD18/CMD18-M32.pdf |