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> Eastern Health

Eastern Health – Radiopharmaceutical Sciences Radiation Safety Public Disclosure Program Report

Timeframe: January 1, 2021 to December 31, 2021

Radiation Safety Office	
Eastern Health	
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Eastern Health – Radiopharmaceutical Sciences Radiation Safety Public Disclosure Program Report - 2021

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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 # 13124-9-26.0	Licence Type Production Accelerator (Cyclotron)		Use Type 616
Radiation Safety Program Organi	zation		
Applicant Authority:	Kenneth Baird	Vice President, Quality, Pr Clinical Supports	ocess Improvement, and
Signing Authority:	Kayla Stokes	Corporate Radiation Safet	y Officer
Class II Radiation Safety Officer:	Julio Panama		
Radiopharmaceutical Sciences Or	ganization		
Director of Medical Imaging:	Julie Larouz		
Manager of Cyclotron:	Julio Panama		
Manager of Production:	Vincent Bouvet		

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 five times in 2021 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.



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, six 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 cyclotron Class II Radiation Safety Officer and consists of employees of the Radiopharmaceutical Sciences team.

In total, one meeting was held and chaired by the Class II Radiation Safety Officer.

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	7
Radiopharmaceutical Sciences Non-Nuclear Energy Workers	1
Infrastructure Support Nuclear Energy Workers	2

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 2021 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 2021.

Incidents Reported to the Regulatory Authorities 2021	
Unplanned power failures	3
Planned power failures	1
Equipment failures	3
Unplanned service outage	1
Action level exceeded	1

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 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:

- 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)

Section 2 – Personnel Dosimetry

Radiation exposures to 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.



	ERHA-F	RPS Whole	Body TLD Re	adings Jai	nuary to D	ecember	2021	
Upper Regulatory Limit:		Nuclear Energy Worker = 50mSv/yr			Non-Nuclear Energy Worker (General Public) = 1mSv/yr			
				Numbers	of Workers	in Each Dos	e Category	
Classification	# of Non- Nuclear Energy Workers	# of Nuclear Energy Workers	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	0	7	2	4	3	-	0.98	0.32
Office	1	-	1	-	-	-	BDL	BDL
Support	0	2	2	-	-	-	BDL	BDL

ERHA-RPS EXTREMITY TLD Readings January to December 2021								
Upper Regulatory Limit:			Nuclear Energy Worker = 500mSv/yr			Non-Nuclear Energy Worker (General Public) = 50mSv/yr		
	# of Non-	# of		Numbers of Workers in Each Dose Category				
Classification	# of Non- Nuclear Energy Workers	# of Nuclear Energy Workers	0 and < 10 (mSv)	10 and < 50 (mSv)	< 50 and < 100 (mSv)	> 100 (mSv)	Maximum Individual Dose (mSv)	Average Dose (MSv)
Production	-	7	6	1	-	-	21.79	5.54
Office	1	-	1	-	-	-	BDL	BDL
Support	-	2	2	-	-	-	BDL	BDL

Section 3 – Cyclotron Facility

Operations

The facility is fully operational and supplies the Nuclear and Molecular Medicine Program with F-18 for the Positron Emission Tomography (PET) Centre.

The cyclotron workload was within the regulated operating parameters for the facility during the calendar year.



Cyclotron Workload

Cyclotron Workload 2021						
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	179.3	19496.4	
¹⁶ Ο (p,α) ¹³ N	$^{13}NH_3$	38	1	0	0	
¹⁴ N (,α) ¹¹ C	CO ₂	120	1	0.667	96	

Annual Compliance Report

The annual compliance report for 2021 was submitted to the CNSC on May 2022. 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.

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	Date
Medical Imaging Program internal memo, re: Nuclear and Molecular Medicine – Cyclotron Preventative Maintenance	2021-07-06
New Medical Imaging Program external website launch, including the new Cyclotron and processing facility webpage	2021-09-16
Medical Imaging Program internal memo, re: Medical Imaging Program	
public website.	2021-09-16
Social media posts in conjunction with new Medical Imaging Program	2021-09-16
external website launch.	2021-09-20
External website update to the Cyclotron and processing facility	
webpage, re: 100th clinical production of 18F-FDG.	2021-10-04
Eastern Health all staff email newsletter (Pulse+) information, re: 100th	
clinical production of 18F-FDG.	2021-10-04
Ongoing external website updates to the Cyclotron and processing	
facility webpage, as required, re: Additional Information section.	2021-12-09 (Ongoing)

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.

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 2021.

Eastern Health responded to three media inquiries that included statements related to cyclotron operations (January 2021):

- Two responses provided information regarding the cost of the "Contract for cyclotron and associated radiopharmaceutical equipment: \$6.6 million."
- One response provided information regarding the frequency of operations of the cyclotron: "As of November 26, 2020, Eastern Health's cyclotron started producing radio-isotopes (FDG) for the PET-CT scanner two days a week which meets the majority of patients' need... The cyclotron is expected to move to producing FDG three days a week by the end of March, further decreasing the reliance on these external sources."



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APPENDIX A – Public Disclosure Protocol

	Radiopharmaceutical Sciences	Document ID:	QAS-PT-007
lth	Radiopharmaceutical Sciences	Revision No:	2
	Processing Facility		
c Informa	ation Disclosure Protocol (PIDP)		
ρυκρο	SE/OBJECTIVES		
protocol	ng with Eastern Health's vision, <i>Health People, Healthy Communi</i> t aims to keep the public, as well as key governmental and commu s of the cyclotron and processing facility that may impact, or be o	unity stakeholders,	informed about
issues pe	ocol ensures information related to the health, safety and securi ertinent to the life cycle of the cyclotron and radiopharmaceutica nicated to the public.		
The follo	wing items are communicated via the public disclosure protocol:		
•	CNSC Annual Compliance <u>Report</u> : Yearly report of licenced activities via document SAF-RT-001 – Ed Sciences Radiation Safety Public Disclosure Program Report (tem Yearly summary of facility milestones via document SAF-RT-002 · Sciences Annual Radiation Public Disclosure Report <u>Summary</u> : Items of concern (e.g., impact of natural events, unplanned signi and Licensing information.	plate included as a – <i>Eastern Health –</i>	ppendix one <u>):</u> Radiopharmaceutical
Objectiv	es of the communications protocol include:		
• •	To review information communicated via the <u>Cyclotron and proc</u> ensure accuracy and relevance to public interest. To provide the public with information in plain language that add cyclotron and processing facility. To demonstrate Eastern Health's commitment to adhering to all Nuclear Safety Commission and Health Canada. To demonstrate the organization's commitment to providing saf	dresses any perceiv regulatory require	ved risk related to the ments of the Canadian
SCOPE			
, potentia	tocol defines the type of information to report publicly, the antici l communications channels for disclosure. Information is present erstandable by the public.		
Public di	sclosure protocol items are communicated, as required, through s, such as but not limited to:	internal and exterr	nal communications
•	external <u>website:</u> social <u>media:</u> public service announcements, news releases, media <u>advisories:</u>		

- weekly email all staff newsletter;
- corporate intranet;
- memos; and
- additional communications channels, as needed.



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Radiopharmaceutical Sciences	Document ID:	QAS-PT-007	
Tealth Radioplial filaceutical Sciences	Revision No:	2	
Cyclotron and Processing Facility			
Public Information Disclosure Protocol (PIDP)			
TARGET AUDIENCES Target audiences include internal and external audiences and can be upda disclosure protocol items that are communicated and as requested by cu			
 Internal Audiences Eastern Health physicians, staff and students, including those of Safety Program and Radiopharmaceutical Sciences team as well 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 ٠ 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).

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.

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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Eastern Health – Radiopharmaceutical Sciences Radiation Safety Public Disclosure Program Report - 2021

Radiopharmaceutical S	ciences	Document ID:	QAS-PT-007
	ciences	Revision No:	2
tron and Processing Facility			
Information Disclosure Protocol (PIDP)			
 Licence Type, Radiation Safety Program O Organization, Contact Information. Analysis of incidents to licenced activities, Evaluation of Radiopharmaceutical Science Cyclotron workload summary, and produce Public Disclosure Program review, summa response, website traffic and engagement Table 1. 	disclosures, and ir es staff dosimetry tion facility update ry of communicati	nspections es ions, summary of p	ublic feedback and
Communications tactics available to Eastern Health whi cyclotron and processing facility to target audiences, as <i>able 1. Communication Tactics</i>	,		elevant activities of t
External		Internal	
Appointment letter inserts	All management/	staff call with CEO	
Consultation sessions	· ·	posted notices and	
Client and Family Advisory Council meetings	Corporate Intrane	•	
Corporate blog: StoryLine	Educational even	ts (symposiums, w	ebinars)
Corporate website	Email (distributio	n lists)	
PIDP website (Cyclotron and processing facility)	Events		
PIDP website (Cyclotron and processing facility) Newsletters		nagement team in	itiatives
		0	itiatives
Newsletters	Executive and ma (greetings, speecl	0	
N <u>ewsletters</u> Digital signage network	Executive and ma (greetings, speech Information session	hes)	and forums
N <u>ewsletters</u> Digital signage network Events	Executive and ma (greetings, speech Information session	hes) ons, focus groups a	and forums
N <u>ewsletters</u> Digital signage network Events Information booths	Executive and ma (greetings, speech Information session Key message door with staff	hes) ons, focus groups a	and forums ment to use
N <u>ewsletters</u> Digital signage network Events Information booths Information sessions, focus groups and forums	Executive and ma (greetings, speech Information session Key message door with staff	hes) ons, focus groups a ument for manage	and forums ment to use
Newsletters Digital signage network Events Information booths Information sessions, focus groups and forums Media: News conferences, news releases, media	Executive and ma (greetings, speech Information sessi Key message door with staff Meetings (face-to	hes) ons, focus groups a ument for manage	and forums ment to use
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Communication needs are <u>assessed</u> and communications tactics are recommended to address strategic objectives. Relevant tactics are recommended based on the information being communicated and the corresponding target audiences.



Revision No: 2			
Ith Revision No: 2 tron and Processing Facility	Radiopharmaceutical Sciences	Document ID:	QAS-PT-007
 c Information Disclosure Protocol (PIDP) 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 <i>Radiopharmaceutical Sciences Radiation Safety Public Disclosure Program Report</i> 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 informa	lth	Revision No:	2
 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	otron and Processing Facility		
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Radiopharmaceutical Sciences	Document ID:	QAS-PT-007
h Radiopriarmaceutical Sciences	Revision No:	2
ron and Processing Facility Information Disclosure Protocol (PIDP)		
able 2. Disclosure Rubric		
Information for Disclosure	Target Disc	osure Timeframe
CNSC Licence information	Within 2 we	eks of an update.
CNSC Annual Compliance Report (ACR)	Within 2 weeks	of CNSC submission.
Annual Radiation Safety Public Disclosure Report Summary	Within 1 mont	h of end of calendar year.
Notification of planned and unplanned significant interruption	Within 2 we	eeks of the event.
Important operational developments or events (e.g., <u>labour</u> disputes, expansions, facility changes)		s of confirmation of event.
Natural events with potential to have significant impact on protection and safety (e.g., lightning strike, floods, power outage)	Within 2 we	eeks of the event.
 Serious incidents or accidents: 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 w	eek 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	e Within 2 we	eeks of the event.
Any other event where a disclosure is deemed necessary by Eastern Health	Within 2 we	eeks of the event.



Eastern Health - Radiopharmaceutical Sciences Radiation Safety Public Disclosure Program Report - 2021

Document ID:	SAF-RT-001.1
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on No:	1

APPENDIX B – Public Disclosure Summary 2021

EASTERN REGIONAL HEALTH AUTHORITY



2021 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 10 reportable radiation safety incidents in 2021 none-of which presented any risk to the public or staff.

Section 2 – Personnel Dosimetry

One Staff member reached an extremity radiation dose exposure limit.

Section 3 – Cyclotron Facility

- The facility is operating within the licenced parameters.
- Through an application process the facility was granted permission to service the cyclotron. 0
- Radiation monitoring surveys were completed with no issues identified. 0
- The annual compliance report was submitted and accepted to the Canadian Nuclear Safety 0 Commission (CNSC).

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

Control Document SAF-RT-002.1



Eastern Health – Radiopharmaceutical Sciences Radiation Safety Public Disclosure Program Report - 2021

Document ID:	SAF-RT-001.1
Revision No:	1

APPENDIX C – Additional Resources

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