Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

CMD 18-M65

Date: 2018-12-04
File / dossier : 6.02.04
Edocs: 5726609

Event Initial Report

Rapport initial d'événement

Isologic Innovative Radiopharmaceuticals

Exceedance of the regulatory dose limit for extremities by a Nuclear Energy Worker

Isologic Radiopharmaceutiques Novateurs

Dépassement de la limite de dose réglementaire aux extrémités d'un travailleur du secteur nucléaire

Commission Meeting

Réunion de la Commission

December 13, 2018

Le 13 décembre 2018

Canada

This page was intentionally left blank

Cette page a été intentionnellement laissée en blanc

EVENT INITIAL REPORT (EIR)

E-DOCS-# 5711309 (Word)

EIR: **Exceedance of the regulatory dose limit for extremities by a Nuclear Energy Worker at Isologic Innovative Radiopharmaceuticals Ltd.**

Prepared by: Nuclear Substances and Radiation Devices Licensing Division, Directorate of Nuclear Substance Regulation

Licensee: Isologic Innovative Radiopharmaceuticals Ltd.	**Location:** 5450 Harvester Rd., Burlington, Ontario
Date Event was Discovered: 2018-11-06	**Have Regulatory Reporting Requirements been met?** Yes ☐ No ☒ **Proactive Disclosure:** Licensee: Yes ☐ No ☒ CNSC: Yes ☒ No ☐

Overview

Reporting Criteria: Exposure of a person, organ or tissue to radiation in excess or potential for excess of the applicable radiation dose limits prescribed by the Radiation Protection Regulation.

Description: On November 9, 2018, the CNSC duty officer received a call from the Corporate Radiation Safety Officer (RSO) at Isologic Innovative Radiopharmaceuticals (IIR) Ltd. to advise the CNSC that a nuclear energy worker (NEW) had exceeded the equivalent dose limit to the skin of the hand. Following the notification, CNSC staff planned a reactive compliance inspection on November 16, 2018 to gather additional information related to the event.

On November 6, 2018, a NEW was scheduled to dispense therapeutic I-131 capsules. During the dispensing process, some difficulties were encountered. The NEW performed maintenance tasks within the AseptiBot (a robot used in the manufacturing of the I-131 capsules which automatically dispenses a specific activity of I-131 in gel capsules) in an effort to resume the dispensing of I-131. One of the maintenance tasks includes the change of various needles required for the manufacturing process. In one instance, the worker removed a needle with no protective cap which could potentially contaminate the gloves and sleeve covers.

Following maintenance activities of the I-131 manufacturing system (known as AseptiBot) performed on November 6, 2018, the NEW self-monitored for contamination at the end of the day and contamination was found on his gloves and sleeve covers. He then proceeded to remove the gloves and, with his bare hands, remove the sleeve covers. The NEW then left the facility without re-monitoring himself for contamination and without reporting the contamination found to the site RSO.

The following day, November 7, 2018, the NEW reported to work. When leaving the restricted area later that morning, the worker monitored his hands, revealing contamination remaining on the skin of his hand. The site RSO was then notified, who proceeded to initiate response actions. Direct measurement revealed that the skin contamination was limited to the NEW's left thumb. No other contamination was found on the individual. Subsequent direct measurements of his left thumb were performed daily to calculate the equivalent (extremity) dose received.

The calculated dose to the skin of the left thumb is 1.7 Sv. The regulatory equivalent dose limit is 500 mSv per year.

Cause(s):

The cause of the skin contamination with I-131 remains unclear.

Impact of the Event

On People:

How many workers have been (or may be) affected? 1

How many members of the public have been (or may be) affected by the event? None

How were they affected?

The NEW received an equivalent dose to the skin of the left thumb of 1.7 Sv, in excess of the regulatory equivalent dose limit of 500 mSv per year. To date, no health effects have been noted and no physical effects of the exposure are expected.

On the Environment: None

Other Implications: None

Licensee Actions

Taken or in Progress:

E-DOCS-# 5711309 (Word)

EIR: **Exceedance of the regulatory dose limit for extremities by a Nuclear Energy Worker at Isologic Innovative Radiopharmaceuticals Ltd.**

- On November 9, 2018, IIR removed the NEW from duties that could add to his extremity dose. The NEW is currently removed from radiological work until the end of 2018.
- On November 12, 2018, IIR issued a stop work order that obliges a pre-approval in writing by the Corporate RSO for performing repairs of the AseptiBot requiring direct contact inside the main chamber. All IIR staff at the Burlington site had to sign a record to demonstrate that they understand the stop work order.
- On November 14, 2018, IIR issued a stop work order for all I-131 therapy capsule production in the current I-131 manufacturing system. The stop work order will remain valid until IIR's new I-131 facility is fully functional and has completed testing. The manufacturing of the diagnostic capsules is still authorized in the current I-131 manufacturing system.
- IIR is monitoring for any visible deterministic effects (skin reactions) on his left thumb. As of December 3, 2018, no visible sign of deterministic effects (skin reactions) on the NEW's left thumb was noted.

Planned:

- IIR will provide refresher training to site RSOs and Managers on incident response who will in turn train their employees.
- IIR will submit a return-to-work request to the CNSC before re-introducing the NEW into radiological work.
- IIR will submit a dose change request to have the equivalent dose to the left thumb of 1.7 Sv added to the NEW`s dose record in the National Dose Registry.
- IIR will implement a new end of the day exit monitoring system and practice to include verification by another individual of the contamination monitoring results.
- IIR will modify the operating procedures to include an approved method for allowing the maintenance of the AseptiBot.
- IIR will train all staff on the specific procedure related to personnel contamination on a monthly basis until Q1-2019 and on quarterly basis afterwards.
- IIR will add additional resource to cover all work shifts at Burlington to fully fulfill the responsibilities of the site RSO regarding the Radiation Protection (RP) program.
- IIR will add posters within the Burlington facility detailing actions and contact list for employees when dealing with a variety of RP-related situations.
- IIR will conduct refresher training on the RP program on a quarterly basis.

CNSC Actions

Taken or in Progress: Upon being notified of the skin contamination event on November 9, 2018, CNSC staff reviewed the information provided by IIR and calculated an estimate of the skin dose received by the NEW. CNSC staff independently verified the worker's dose estimate, and have estimated the dose received to the left thumb to be 1.7 Sieverts (or 1700 mSv).

In addition, CNSC conducted a focused inspection at the Burlington site. The scope of the inspection was focused on obtaining supporting information from IIR regarding the circumstances surrounding the I-131 skin contamination incident and the licensee response to the event. CNSC staff carried out:

- A discussion with IIR on their investigation of the event including measures they have taken to date to ensure the safety of workers in the I-131 manufacturing area
- Interviews with the RSOs (Corporate and site), the NEW involved in the event and additional authorized I-131 manufacturing workers.
- An examination of the current I-131 processing facility including the AseptiBot hot cell area (current I-131 manufacturing system) and associated equipment within the facility that are used to produce diagnostic and therapeutic i-131 capsules.
- A review of various prescribed records relating to the reported event and I-131 production activities.

During the inspection, CNSC staff confirmed that the estimated dose to the NEW`s left thumb is 1.7 Sv. Based on the review of the training records for the NEWs currently authorized to work with the AseptiBot, it was noted that the NEW involved in the skin contamination event started production of I-131 therapy capsules in October 2018.

Five (5) items of non-compliance were observed during the compliance inspection. The inspection report was sent to IIR on November 28, 2018 and corrective actions and/or a proposed timeline to restore compliance was received on November 30, 2018. Responses from IIR are currently under review by CNSC staff.

E-DOCS-# 5711309 (Word)

EIR: **Exceedance of the regulatory dose limit for extremities by a Nuclear Energy Worker at Isologic Innovative Radiopharmaceuticals Ltd.**

The following Personal Protective Equipment (PPE) were noted by CNSC staff during the field observations:

- Before entering the restricted area, the NEW has to wear a lab coat, sleeve covers, shoe covers, minimum of one pair of gloves, and an hairnet as shown in picture 1.
- Before entering the current I-131 manufacturing room, the NEW has to add a Tyvek coverall, sleeve covers, boot covers, and gloves as shown in picture 2.

Picture 1: CNSC staff wearing PPE required for entering restricted area

Picture 2, CNSC staff wearing PPE required for entering I-131 area

In addition, a Powered Air Purifying Respirator (PAPR) needs to be worn before handling therapeutic amounts of I-131.

The AseptiBot, shown in Picture 3 and 4, is a robot used in the manufacturing of the I-131 capsules which automatically dispenses a specific activity of I-131 in gel capsules for either diagnostic or therapeutic use. The operation includes the automatic assaying of each capsule in a dose calibrator and then the capsule is placed into a shielded container.

E-DOCS-# 5711309 (Word)

EIR: **Exceedance of the regulatory dose limit for extremities by a Nuclear Energy Worker at Isologic Innovative Radiopharmaceuticals Ltd.**

Picture 3. AseptiBot in use at Isologic for manufacturing the I-131 capsules

Picture 4. Set-up inside the AseptiBot

Planned:

CNSC staff have requested further information and will complete the review of all the information once received. CNSC staff is also considering additional enforcement actions as a result of this event.

In addition, CNSC staff will plan an inspection of the Burlington facility in early 2019 to verify the implementation of the corrective actions made by IIR following the skin contamination event.

Additional reporting to the Commission Members anticipated:

☒ Yes

☐ No

If Yes, provide method of reporting: Information on this event will be included in the 2018 Regulatory Oversight Report to the Commission.

Name and Title	Signature	
Colin Moses Directorate of Nuclear Substance Regulation	Director General	2018-12-04 Date

Appendix 1
Additional information and pictures related to the production of I-131 Capsules

Individual lead container used to shield each capsule – without I-131 capsule

10 lead shield containers setup inside the AseptiBot.

Sample of an empty capsule shell – without I-131