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Update from CNSC Staff

Mise à jour du personnel de la CCSN

Follow up from April 27 and October 5, 2021 Commission meetings

Suivi à la suite des réunions de la Commission du 27 avril et 5 octobre 2021

Update from CNSC Staff on exceedance of the annual dose limit for a Nuclear Energy Worker at Jubilant DraxImage

Mise à jour du personnel de la CCSN au sujet du dépassement de la limite annuelle pour un travailleur du secteur nucléaire à Jubilant DraxImage

Commission Meeting

Réunion de la Commission

March 24, 2022

Le 24 mars 2022

Canada

Government of Canada / Gouvernement du Canada

MEMORANDUM NOTE DE SERVICE

To / À
D. Saumure
Commission Registrar

cc: Ramzi Jammal, ROB EVP-CROO

From / De
Karen Owen-Whitred
Director General
Directorate of Nuclear Subtances Regulation
Canadian Nuclear Safety Commission

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Subject / Objet Additional update on Event at Jubilant DraxImage Inc. involving high radiation dose to the thyroid of a Nuclear Energy Worker

Summary

During the October 5th Commission meeting, CNSC staff presented an update on the event at Jubilant DraxImage Inc. that occurred on April 19, 2021 as CDM 21-M46.

On November 3, the Commission Secretary shared with CNSC staff the Commission members' concerns regarding the cause related to the EIR. The Commission members indicated that there might be basic issues at stake related to the use of glass vials that, if not corrected, could lead to similar incidents in the future and asked CNSC staff to look into those questions and concerns.

As acknowledged by the Commission, glass is used throughout the industry as the standard material of choice for vials of the type involved in this event. Use of glass vials for containing radiopharmaceuticals is also an international practice. While it is true that there is a risk that the glass vials used for manufacturing and dispensing radiopharmaceuticals could break, CNSC staff believe that the probability of this occurrence is low and does not outweigh the many benefits of using this material. Furthermore, commensurate with the additional risk posed by iodine-131 (I-131), which is a highly volatile material, the CNSC requires licensees handling this isotope to have controls in place to support defense in depth in the event of a broken vial. The effectiveness of these additional safety measures was demonstrated by the event in question: the doses received by the workers cleaning up the spilled I-131 during the April 2021 DraxImage event were below detectable limits. The uptake of I-131 only occurred when the worker disposing of the broken vial removed his personal protective equipment (PPE) during the final step of the disposal process. As explained in the October update to the Commission on this EIR, CNSC staff are satisfied that the licensee has revised its procedures to require PPE for every step of clean-up and disposal in the event of a spill; these corrective measures have also been implemented by other licensees working with I-131.

Based on these considerations, CNSC staff believes that the risk to the health and safety of workers handling these glass vials is minimal, that the April 2021 event related to a broken glass vial was an isolated incident, and that the use of glass in this application does not constitute an inherent design flaw.

Background

As acknowledged by the Commission, glass is used throughout the industry as the standard material of choice for vials of the type involved in this event.

Glass is an inert material and therefore does not cause any modification to the products with which it comes into contact. Glass has a long history of being a safe material to use with pharmaceuticals worldwide: it has no genotoxic impurities and it can sustain extreme temperatures that may be required, such as high heat as part of the cleaning process, and freezing temperature for the storage of the final product. For the licensee, its primary goal and priority is patient safety and glass is the safest material at the present time.

Analysis

Low probability of vial breakage

CNSC staff looked at reported events submitted between January 1st, 2017 and December 2021, to determine the number of events related to broken vials.

DraxImage performs the I-131 process approximately 8 times a week which equates to more than 2000 times over the last 5 years. They reported a total of 7 spills since 2017 (Appendix A). Apart from the April 2021 event, none of these events have resulted in workers receiving a dose above the licensee's internal action levels. Of these broken vial events, one was for a broken vial received in a transport package (Event #5069), one was due to a defective vial (cleaned and dry heat sterilized multiple times) (Event #3109), and the recent event where the vial was broken from the dropped pot lid (Event #5196). Over the last 10 years, CNSC staff have verified the licensee's thyroid monitoring program and with the exception of the April 2021 event, never identified a non-compliance. The licensee has a rigorous program for monitoring workers to determine if an overexposure has occurred. This licensee does not have a history of employees exceeding dose limits.

With this analysis, CNSC staff are satisfied that the April 2021 event at DraxImage was an isolated incident and is not indicative of a systemic issue related to the use of glass vials.

Licensing assessment

Notwithstanding the low probability of a glass vial breaking, there are additional controls in place to support defense in depth in the event of a broken vial and CNSC staff ensures that the licensee's program includes a defense in depth approach for added protection. Bulk I-131 like the one that DraxImage uses at the start of the formulation process to produce radiopharmaceuticals is more volatile than the final product and this is taken into account in the CNSC staff's assessment of the radiation safety programs of licensees using this material. The high volatility aspect of I-131 is of particular interest and consideration as it represents a risk to workers working with this isotope even without a spill. Workers must be trained and qualified on how to use the required personal protective equipment (PPE) appropriately in order to prevent the inhalation of I-131 due to its volatility. As part of the licensee's procedures, all trained workers must use the required PPE, including respirators, at the completion of each process where I-131 is used, including the cleaning of the glovebox and equipment as well as preparing for the next process, as there is usually a small amount of contamination in the glovebox after each use. Some of the critical

facility design elements to address the volatility of the I-131 reviewed as part of the licence assessment are described below.

The glovebox used meets the CNSC design requirements for the amount of nuclear substances being used inside (containment lab requirements) as specified in the CNSC guidance document *GD-52, Design Guide for Nuclear Substance Laboratories and Nuclear Medicine Rooms* (new version currently under final review as REGDOC 2.5.6). The glovebox is shielded and therefore designed to protect workers from the spills of I-131 within the glovebox. In addition, CNSC staff assessed the ventilation systems in place, designed to prevent volatile I-131 from escaping the glovebox. The ventilation system has filters to remove the I-131 from the air venting out of the stack. The licensee also has a secondary back up bank of filters. In extreme cases, the filters may be replaced to increase the efficiency of the filters to prevent releases to the environment. The glovebox, ventilation system, and area monitors ensure that there are limited risks to qualified personnel when the appropriate PPE is used.

Based on the above, the current licence assessment process for the medical and commercial sectors licensees handling I-131 adequately addresses the potential exposures to workers, the public and the environment which are the primary concerns in the event of a spill.

Packages Used for the Transport of Bulk Quantity of I-131

In addition to the issue of the glass vial design, the Commission also asked staff the following question: "Among the 14 safety and control areas (SCAs), one is devoted to transport and packaging. Shouldn't the packaging include the design and handling of the packages in all sectors (including the pharmaceutical and medical sectors)?".

All packages containing nuclear substances are required to be designed and transported in accordance with the CNSC's *Packaging and Transport of Nuclear Substances Regulations, 2015*. The design includes all aspects of packaging including the outer package where the identification labels are applied, the inner glass vial that contains the nuclear substance as well as the preparation of the package for transport. A certified package may only be shipped in the configuration of the design that it was certified for.

Figure 1: Certified Package

The raw I-131 material is received at DraxImage in a package that is certified by the CNSC and presented in Figure 1, due to the high activity of the material. As part of the certification process, the preparation for shipment procedure is reviewed by CNSC staff and each user must register the use of the package with the CNSC and confirm that they have the proper instructions for the use of the package. In this case, the I-131 is contained in a glass vial inserted into an inner container of the package that is designed to prevent any leakage in case of accidents during transport.

Conclusion

Glass vials are used internationally due to their unique properties and long history of safety for containing radiopharmaceuticals. The use of glass vials remains the most practical options for licensees and CNSC staff are of the opinion that their use in the current process is safe. This position is based primarily on two factors: first, the probability of glass vials breaking during handling is extremely low, as evidenced by the low rate of reported events involving broken vials compared to the frequent usage of these vials. Second, the CNSC requires licensees to implement an effective radiation safety program, comprised of a combination of engineering controls, barriers for added protection and worker qualifications, such that licensees are able to control environmental releases and doses to workers from spills when they occur, particularly when dealing with I-131. These radiation safety programs require that only trained workers perform the decontamination procedures and this requires the use of PPE to minimize the exposure risk.

In conclusion, CNSC staff are satisfied with the safety measures in place to mitigate the unlikely breakage of a glass vial used in handling radioisotopes. Therefore, we do not see a strong argument for conducting a systems-based review of the use of glass vials for this application.

Appendix A: Jubilant DraxImage Spills Reported

There have been seven reportable events with spill events reported since January 2017 by Jubilant DraxImage Inc. These events are listed below.

Event Number	Date	Summary
3022	2017-03-16	A nuclear medicine isotope (iodine-131) spilled inside a dose calibrator in a hot cell. There was no thyroid update, no environmental releases and no overexposure as a result of this event.
3109	2017-07-19	Iodine-131 spilled inside a shielded manufacturing box. The box was left to decay. There were no thyroid uptakes as a result of this event. There was no overexposure.
3478	2018-10-11	A spill of 1.85 GBq of iodine-131 occurred inside a shielded isolator. No employees were exposed to the spill as the process is automated. No overexposures or personal contamination occurred from this event. Corrective actions have been implemented to prevent recurrence.
4790	2019-10-22	Spill > 100 EQ Iodine-131. No skin contamination. No overexposures. During heating of the vial in a shielded glovebox, the vial was not adequately crimped, and the septum came off of the vial contaminating the cell.
5069	2020-11-04	Receipt of broken vial (inner package) with iodine-131. No contamination.
5196	2021-04-19	Spill of I-131 after the vial was broken when the pot lid fell on the vial. One worker received an unplanned exposure of 29 mSv (effective dose) and a committed equivalent dose to the thyroid of 560 mSv (i.e. below regulatory dose limits). This event was presented as a verbal EIR to the Commission on April 27, with a follow up at the June 8 meeting and another update on Oct. 5.
5261	2021	Spill > 100 EQ Iodine-131. No skin contamination. No overexposures. During heating of the vial in a shielded glovebox, the vial was not adequately crimped, and the septum came off of the vial contaminating the cell.