25-H113-A - CNSC Staff Submission

Commission Request for Information Regarding a Hearing in Writing (CMD-A)

Classification	Unclassified
Type of CMD	Original
CMD Number	25-H113 A
Reference CMD(s)	25-H113 A
Hearing in Writing OR Closed Hearing in Writing date	August 2025
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Summary	In this CMD, CNSC staff will provide responses in writing to questions from the Commission (CMD 25-H113-A) with respect to the hearing in writing (CMD# 25-H113) concerning the request from McMaster University to increase the total activity limits of Nuclear Substances and Radiation Devices Licence No. 01495-19-26. As part of a Commission proceeding, this document – including any items mentioned in the footnotes – will be part of the public record unless the Commission rules in favour of a request for confidentiality.
Actions required	There are no actions requested of the Commission. This CMD is for information only.

Questions from the Commission directed to CNSC staff, as well as staff responses, can be found in the Staff Response section.

CMD 25-H113-A

CNSC Response to Commission Request for Information

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Staff Response

The Commission's questions, including any quoted text from the original CMD, have been reproduced below in the shaded boxes to provide suitable context for CNSC staff's responses. To facilitate staff responses, clarifying text or annotations may be added if the question has been broken down into multiple parts.

#1	**With respect to the proposed exemption, describe how the CNSC's regulatory requirements differ between the current nuclear substances and radiation devices (NSRD) licence and a licence to operate a Class IB facility. Given those differences, explain how the proposed exemption would not pose an unreasonable risk to the environment or the health and safety of persons.** **What additional regulatory oversight measures would CNSC staff apply to the exempted activity to account for the potential change in risk associated with that activity?**

Comparison of Class IB and Nuclear Substances Licences

The primary difference between licences issued under the Nuclear Substances and Radiation Devices Program and the Class IB Facility Program is the licence application process. While both programs require the Licence Application details outlined in sections 3 through 7 of the *General Nuclear and Safety Control regulations*, the *Class I Nuclear Facilities regulations* and the *Nuclear Substances and Radiation Devices Regulations* define different contents for the supporting material in the licence applications. Class IB licences are typically performance-based and rely on the licensee establishing programs for addressing each of the applicable SCAs, while Nuclear Substances and Radiation Devices licenses are more prescriptive and use a mixture of programs and procedures.

In both regulatory programs CNSC staff review the fourteen Safety and Control Areas (SCAs) during the licence assessment process and take a risk-informed approach to compliance activities. The Nuclear Substances and Radiation Devices licence assessment is focused on specific activities that the licensee has applied to carry out. Accordingly, the technical assessments are scoped to those activities.

Explanation of proposed exemption on risk

Regardless of the differences between the two types of licence, the exemption, if granted, would not change the process that McMaster University is currently using for

conducting the licensed activity. As described in CMD-25-H113 (original CMD), the processing of the Luteitium-177 (Lu-177) at McMaster University is limited to removing the sealed ampoule containing Lu-177 from the aluminum target holder (referred to as *decanning*); there is no handling of the Lu-177 target material outside of the sealed ampoule. The targets are taken out of the transport package in hot cells where the target holders are removed in order to reduce the radiation emitted as the target holders are activated. The sealed ampoules are repackaged in CNSC certified Type B(U) packages, allowing the shipment of the sealed ampoules by air to Germany for processing. The requested exemption would permit McMaster to possess larger quantity of Lu-177 for the purpose of conducting more decanning runs using the same existing process that is currently in place and that was last inspected on May 7, 2025 (note that the only non-compliance found during that inspection was related to record keeping, which is of low risk significance. This non-compliance was subsequently closed to the CNSC's satisfaction)

The proposed increased throughput would not increase the risk posed by the activity itself. Due to the short half life of the isotope being processed (Lu-177, half life of 6.6 days), the de-canned material is immediately repackaged for shipment to Europe, in accordance with requirements laid out in IAEA SSR-6 (Rev. 1) *Regulations for the Safe Transport of Radioactive Material*, Annex 18 to the *Convention on International Civil Aviation —The Safe Transport of Dangerous Goods by Air*, the *Packaging and Transport of Nuclear Substances Regulations,* and the *Transport of Dangerous Goods Regulations* . As such the material is at McMaster's site for less than 24 hours and the additional decanning runs will not cause a long term or permanent accumulation of inventory at the site.

McMaster has provided dosimetry data from the Lu-177 decanning process that demonstrate doses to workers are kept well below regulatory limits and that additional decanning runs would not significantly increase worker dose. McMaster has also provided environmental monitoring data to demonstrate that ambient dose rates are low and emissions to the environment are well below clearance levels associated with the isotope. In addition, McMaster has proposed a maximum annual activity limit that would be processed in the facility as part of their exemption request, which allows staff to assess the modeled upper limit of dose to workers and emissions to the environment. As described in CMD-25-H113, should the exemption be granted, CNSC staff would work with McMaster via the DO process to amend licence 01495-19-26 to reflect this maximum annual activity.

In summary, the requested exemption would not change the nature of the current licensed activity, nor would it lead to an accumulation of inventory on site – in other words, the proposed increased throughput would not increase the risk associated with the decanning process. CNSC staff are of the opinion that McMaster is currently operating the process in a safe and controlled manner and that granting the exemption

to permit McMaster to carry out more decanning runs will not pose an unreasonable risk to the environment or the health and safety of persons.

Compliance Oversight

With respect to oversight measures, the current compliance and oversight program addresses the 14 SCAs. In addition to the routine oversight program for a Nuclear Substances and Radiation Devices licence, staff members from DNSR and DNCFR who are assigned to McMaster licences routinely meet with McMaster representatives through a standing meeting. The Lu-177 decanning activities will be added as an item on this meeting agenda and will address both the processing work under the current licence as well as the status of the Class IB licence application McMaster has committed to submit as part of the exemption request.

In working with McMaster to amend the current licence via the DO process, staff will include in the amended licence a commitment from McMaster to provide a quarterly report on the decanning activities. This quarterly report would include doses to workers and monitoring of the emissions to the environment, to ensure that estimates submitted by McMaster with the exemption request are below regulatory limits and keeping doses As Low As Reasonably Achievable. McMaster in its RP program has established administrative limits as indicators to maintain control over the decanning process.

As part of the Nuclear Substances and Radiation Devices baseline inspection program planning process, McMaster will undergo a follow-up inspection in the 2026/27 fiscal year, and staff from DNCFR will be participating in anticipation of the McMaster Class IB licence application.

#2	**CNSC staff recommend that the temporary exemption expire at the same time as McMaster's current NSRD licence: on December 31, 2026. On the other hand, McMaster has asked for the temporary exemption to extend to December 31, 2029. The shorter duration could result in McMaster needing to make a second exemption request (depending on when its application for a Class IB licence is made and decided).** **Provide additional rationale and regulatory considerations for CNSC staff's recommendation on the duration of the exemption.**

CNSC staff's recommendation to have the exemption expire along with the licence on December 31, 2026, was based on the opinion that granting an exemption of this nature for more than four years was excessive. Aligning the exemption to the expiry date of the current licence would encourage McMaster to make their application submission in a timely manner and ensure the transition to Class IB licensing continues to progress.

CNSC staff acknowledge that the application for a second exemption would create an unnecessary regulatory burden for the licensee, considering there would be no change in the licensed activity. Therefore, staff recommend an exemption through September 30, 2027. In keeping with this recommendation, should the exemption be granted, staff would work with McMaster via the DO process to amend the expiry date of licence 01495-19-26 to September 30, 2027.

Conclusion

CNSC staff's conclusion presented in CMD 25-H113 regarding the exemption request remains unchanged. CNSC staff recommend that the Commission grant McMaster University an exemption from the maximum activity limits applied to a Nuclear Substances and Radiation Devices licence as requested by the licensee.

CNSC staff's conclusion has been amended to reflect the Commission's question regarding the difference between the expiry date of the exemption requested by McMaster University (December 31, 2029) and the date recommended by staff (December 31, 2026). Staff now recommend that the exemption be granted through September 30, 2027. Should the exemption be granted through September 30, 2027, CNSC staff will work with McMaster to amend licence 01495-19-26 via the DO process, to revise the expiry date of the licence so that it is coincident with the proposed duration of the exemption.