McMaster University | Nuclear Operations & Facilities

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May 21, 2025 HP-CORR-CANS-00057

MR. PIERRE TREMBLAY
President and Chief Executive Officer
Canadian Nuclear Safety Commission

Canadian Nuclear Safety Commission
Commission Registry
280 Slater Street
PO Box 1046 Stn B
Ottawa, Ontario
K1P 5S9

Dear Mr. Tremblay:

RE: Centre for Advanced Nuclear Systems NSRD Licence Exemption Request

Reference 1. CNSC Consolidated Uses of Nuclear Substances Licence, N. Ringuette to J. Zic, "Nuclear Substances and Radiation Devices Licence No. 01495-19-26.2", December 23, 2024.

The purpose of this correspondence is to submit a time-limited exemption to the McMaster University Nuclear Substances and Radiation Devices (NSRD) licence possession limits [1] for nuclear activities at the Centre for Advanced Nuclear Systems (CANS) facility. Specifically, McMaster is requesting that the total activity possession limit set for the year is increased above the limit for this licence type (>10^{15} Bq), as defined in the *Class I Nuclear Facilities Regulations*. This time-limited exemption will ensure uninterrupted Canadian supply of Lu-177 while McMaster applies for a Class 1B licence for the CANS facility. This exemption request application has been prepared in accordance with REGDOC-3.4.1 *Guide for Applicants and Intervenors Writing CNSC Commission Member Documents, Version 1.1* and is provided as Attachment 1.

McMaster University has partnered with external customers to perform Lu-177 decanning activities in the CANS facility, since August 2023, becoming part of one of the largest supply chains for this isotope in the world. These activities have been performed under the existing McMaster NSRD Consolidated Uses of Nuclear Substances licence (Use Type 815) [1]. It should be noted that the Lu-177 is only repackaged at CANS and is in McMaster's possession for less than 24 hours. No processing of the Lu-177 takes place at CANS.

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In order to support the continued ability of McMaster University to perform Lu-177 de-canning activities in CANS, we are requesting a time-limited total possession limit of 8,500 TBq of Lu-177, 2,100 TBq of Yb-175 and 2,200 TBq of activated materials.

McMaster has a long history of safe and compliant nuclear activities, and we believe that our experience, qualified staff and strong safety programs positions CANS well to continue to support the current Canadian and global supply chain. The CANS facility at McMaster University is currently the most suitable location available in Ontario to help support the critical supply of Lu-177 to patients with advanced prostate cancer and the continued work will ensure patients maintain access to this life-saving therapy.

If you have any further questions or require clarification on the information in the licence application, please contact me at 647-261-2500.

Regards,

Josip Zic
Chief Nuclear Officer
Nuclear Operations and Facilities
McMaster University

Attachments: 1

cc:
Karen Owen-Whitred – CNSC
Sylvain Faille – CNSC
Neil Babcock – CNSC
Ramzi Jammal – CNSC
Derek Cappon – McMaster
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Martijn Jimmink – McMaster
John Preston – McMaster
Andy Knights - McMaster
David Farrar – McMaster

Original

CNSC Commission Member Document (CMD)

CMD: [CMD Number Provided by CNSC Secretariat]

Date Submitted: [21 May 2025]

Reference CMDs: N/A

Request for an Exemption to Increase the Total Possession Activity Limits of the NSRD License No. 01495-19-26

[Two-Part Public Hearing Part 1/Two-Part Public Hearing Part 2/One-Part Public Hearing/Hearing in Writing/Public Meeting/Closed Session]

Scheduled for:

[Date of Hearing/Meeting]

Request for a Decision:

Regarding:

Regulatory Exemption for Total Activity Possession Under a Nuclear Substances and Radiation Devices Licence

Submitted by:

Josip Zic
Chief Nuclear Officer
McMaster University

Table of Contents

Executive Summary

McMaster University is requesting a time-limited exemption to the Nuclear Substance and Radiation Devices (NSRD) 815 Consolidated licence No. 01495-19-26 for the total activity possession limit set for the year allowing 8500 TBq of Lu-177, 2100 TBq of Yb-175 and 2200 TBq of activated materials at the Centre for Advanced Nuclear Systems (CANS) Facility to ensure uninterrupted Canadian supply of Lu-177. These activity amounts reflect the multiple customers proposing to conduct de-canning work at CANS and to allow for flexibility in production demands, a 25% buffer was added. This exemption request will allow continued support to the Canadian radiopharmaceutical supply chain by removing waste materials from the irradiated ampoules to minimize the decay time required for irradiated Lu-177 to be transported to global radiopharmaceutical companies for further production. Completion of this work is critical for supporting the current global supply chain of this medical isotope and the CANS Facility at McMaster University is uniquely positioned to help this need.

The McMaster CANS Facility is one of two locations currently licenced to extract Lu-177 irradiated ampoules from their irradiation carriers. This step is required to allow for their transfer into CNSC certified Type B packages prior to their international shipment to radiopharmaceutical companies. The ampoules are received under the 01495-19-26 Consolidated Licence and remain on the licence for approximately 14 to 16 hours. The Lu-177 product in powder form remains inside a sealed quartz ampoule and is not subject to any form of processing. The ampoules are only repackaged, so that they can be shipped by air for processing in Europe, as facilities for performing this activity are not currently available in Canada. The McMaster CANS Facility was the first to conduct this activity and has been doing so safely since August of 2023.

McMaster University has conducted a dose analysis for personnel working at CANS and the effects of this process on the environment. A conservative dose projection was conducted for the remainder of 2025 and 2026, which demonstrates that the collective dose received by each monitored dose group would be well below the administrative control levels (ACL) set by McMaster University (15 mSv/y) and far below the regulatory limits set by the Canadian Nuclear Safety Commission (CNSC) (50 mSv/y and annual average effective dose of 20 mSv/y). Assessments of impacts on the environment, both taken from effluent monitoring and environmental Thermoluminescent dosimeter (TLD) results show no impact from Lu-177 activities at CANS, this conclusion remaining valid for the period of the requested exemption.

To support this request, McMaster is currently actively engaged in pre-licensing discussions with CNSC staff with the intent to submit an application for a Class 1B Nuclear Facility licence in accordance with CNSC REGDOC-1.2.2, which would support the on-going repackaging of Lu-177 targets, without an exemption. McMaster University plans to submit a Class IB licence application for the CANS facility by May 31st, 2027. If this exemption is granted, McMaster University would request the exemption to the CANS facility possession limits be extended until December 31st, 2029 or until a Class IB licence is granted to support this licensed activity.

1 INTRODUCTION

1.1 Background

McMaster University is requesting a time limited exemption to the NSRD regulations for the 815 Consolidated License 01495-19-26 to allow for processing of up to 8500 TBq of Lu-177, 2100 TBq of Yb-175 and 2200 TBq of activated materials per year at the CANS Facility to ensure uninterrupted Canadian supply of Lu-177 for use in radionuclide therapy while McMaster applies for a Class IB licence. This exemption is requested until December 31st, 2029. Lu-177 is a medium energy beta emitter having a maximum energy of 0.497 MeV as well as producing two low energy gamma energies at 0.113 MeV and 0.208 MeV. The physical half-life of Lu-177 is 6.6 days. Lu-177 is essential for treating patients with advanced prostate cancer, and the work in CANS will ensure patients maintain access to this life-saving therapy.

The CANS Facility was designed to handle and process high activity work from CANDU facilities and this work has been performed successfully in the past. The regulations set by the NSRD consolidated licence limits the maximum quantity of radionuclides that can be possessed to 1000 TBq per year. Due to the high activities being repackaged, the CANS Facility can only be utilized for approximately five months of the year under the current limits. This exemption and will allow for continued support for repackaging activities within the CANS Facility while McMaster applies for a Class IB licence. To support this request, McMaster University has performed a full dose analysis for personnel working at the CANS facility, based on work conducted in the past and work projected for the future, which demonstrates that no individual would exceed an administrative control level or the regulatory limits.

Lu-177 related activities at the McMaster CANS Facility are divided into three stages: receiving, de-canning, and shipping. Before the shipment arrives on-site, McMaster personnel perform a pre-job inspection and material staging of the Canyon Right Cell, the Microscopy Suite, and the Tandem Accelerator Building (TAB) Hallway.

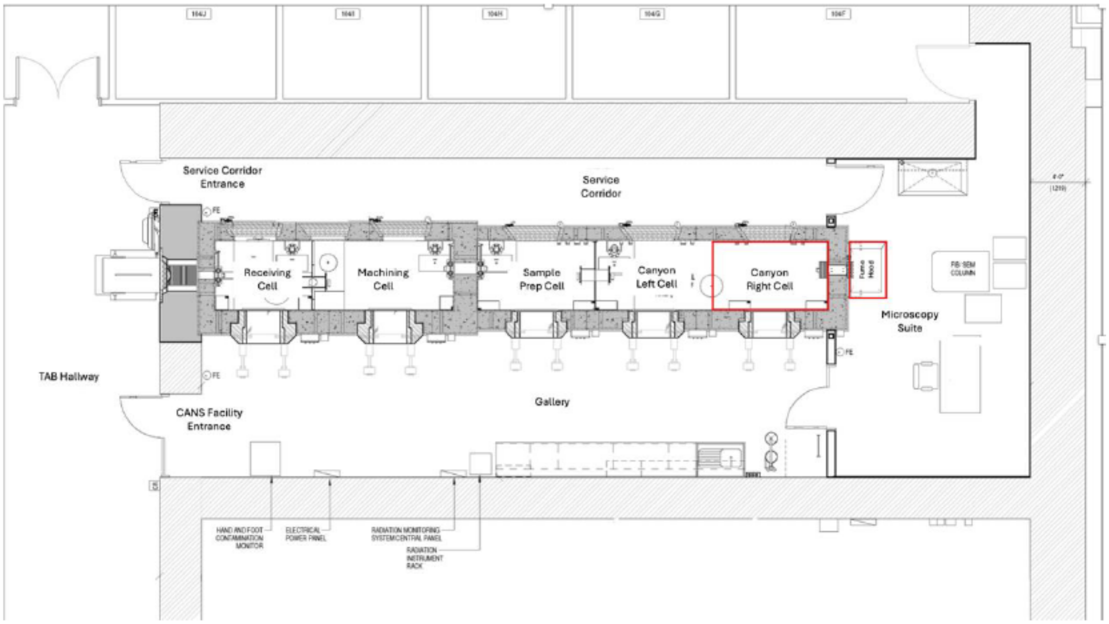

Figure 1: Schematic of the CANS Facility detailing the location of the Canyon Right Cell, the Microscopy Suite and the TAB Hallway. The tungsten insert is placed into a pass through located in the fume hood. The pass through connects to the Canyon Right Cell and work with manipulator arms can be performed.

McMaster has developed a detailed procedure outlining the receiving of shipments [1]. This includes conduct of radiation survey and contamination checks, confirming shipment content and serial numbers with shipping documentation. The exterior CANS Facility is secured with traffic cones and event tape to prevent non-participants from entering the area. Key card access is required for qualified personnel working the de-canning job and ensuring that non-participants are not entering areas where the de-canning is taking place. When shipments of Lu-177 are received, loose contamination checks for each transport package (keg) are performed for the sides and lid. Dose rate surveys of the shipping vehicle and keg are performed at 2 meters from surface of the vehicle, near contact, and the driver seat. All dose rates and contamination checks are recorded per run. Each keg is checked to ensure that the serial number, tag number and activity align with the transport manifest (documentation) provided. The transport indices (TIs) of each keg are measured and compared to the shipping paperwork TIs.

In the Microscopy suite, swipes are performed for the interior of the keg, containment vessel and containment vessel tool. All swipes are counted on the Ludlum 3030 Alpha-Beta Swipe Counter and are recorded. The surface contamination levels are calculated based on the swipe results and recorded within the procedure [1]. A tungsten insert, containing the irradiated ampoules, is removed from the containment vessel utilizing a remote handling tool and placed into the fume hood passthrough – see the location outlined in Figure 1. The insert is moved into the Canyon Right Hot Cell using this passthrough. Once pre-operational checks are complete, work in the hot cell is conducted with the use of manipulator arms to allow for safe work and to keep doses as low as reasonably achievable. Manipulator arms and a cutting tool are used to perform de-canning of ampoules and are then repackaged into a 3D-printed honeycomb with the tungsten insert. All irradiated metal waste is segregated and stored within the hot cell for decay. Continuous air monitors (CAMs) are installed in different locations of CANS to monitor airborne concentrations within the facility and the exhaust during the de-canning work. A detailed procedure for in-cell handling of the ampoules has been created by McMaster for the CANS facility [2].

Once the ampoules are repackaged into the Type B shipping container, they are transferred to a secure storage location within the CANS Facility. The shipping containers are all surveyed and labelled, as per the Packaging and Transportation of Nuclear Substances regulations. A qualified carrier arrives the following morning to transfer the shipment to the airport.

CANS personnel are broken down into three groups: Client Contractors (CCO), Health Physics (HP), and Nuclear Operations and Facilities (NOF). Contractors at CANS move the material and utilize the hot cell and manipulator arms to perform the necessary work required for de-canning. HP personnel are present for radiation protection support and will conduct radiation and contamination surveys throughout the de-canning process. NOF personnel are present for supervising the contractors within the facility, providing facility expertise and procedural guidance, and completing the shipping documentation.

A summary of the repackaging work done at CANS since 2023 and projected activities from May 1st, 2025 to December 31st 2025 is provided in Table 1, based on a maximum of 25 targets expected per week.

Activity Levels at CANS Facility							
Year	**# of Successful Runs**	**Total # of Ampoules**	**Lu-177 Activity (TBq)**	**Yb-175 Activity (TBq)**	**Activated Materials (TBq)**	**Total Activity (TBq)**	**% of Total Activity (TBq)**
2023	[redacted]						
2024							
2025							
Proj. 2025							

Table 1: Summary of de-canning work being performed at the CANS facility starting in 2023 until April 2025. Projections for 2025 were made starting from May 1st, 2025 to December 26th, 2025.

This summary includes the total Lu-177 activity, Yb-175 activity and the activated materials activity for each year along with projected activity amounts for the rest of 2025. These numbers are compared to the annual limit on processing for the licence of 1000 TBqs. The number of successful runs (which occurs once a week) and number of ampoules are also provided along with projections for the rest of 2025. [redacted]

1.2 Highlights

The exemption requested is required to allow the continued safe work supporting Lu-177 production at the McMaster University CANS Facility. With the de-canning runs conducted weekly from January 1 to April 25, 2025, the total activity transferred to McMaster University was 762.2 TBq, 76.2% of the NSRD licence maximum possession limit. Based on an estimated 15 targets per week, it is expected that the last de-canning run at the CANS Facility will occur on May 16, 2025. Before the NSRD limit is reached under the McMaster 01495-19-26 License, de-canning operations will be transferred to another licensed facility authorized to perform this activity; this facility will also reach its licensed limit late summer or early fall 2025 depending on production and demand of Lu-177.

A conservative analysis for the projected amount of activity was performed based on receiving 25 ampoules a week, the highest number of ampoules received in 2025, for the remainder of the year, and assuming all de-canning activities would be performed at the McMaster CANS Facility. The projected total activity for the 2025 year (January 1st to December 31st) at McMaster University in support of this work is 3249.7 TBq, exceeding the total possession limit of 1000 TBq by 324.9 %. The customer has indicated that demand for Lu-177 will increase beginning in 2026, potentially resulting in a maximum of 58 targets per week being handled. This would result in an estimated 5800 TBq of Lu-177 brought onto the CANS Consolidated License for repackaging for 2026.

This exemption will allow the continued supply of medical isotopes and provide meaningful support to those needing Lu-177 for medical treatment. The operation has been demonstrated to be safe to both the operators and to the environment. The CANS personnel at McMaster University have performed de-canning operation safely since 2023. The process does not involve processing of the Lu-177 material itself, and is limited to the removal of the target aluminum carrier and repackaging of the sealed Lu-177 ampoules into a certified Type B transportation package for shipment to an external radiopharmaceutical company for further processing into its final product. The activity is brought on and held on the CANS 01495-19-26 License for approximately 14-16 hours before shipment. The ampoules received are flame-sealed quartz which are never opened in the CANS Facility. The hot cells are well-suited for performing de-canning activities safely, with little to no dose to hot cell operators. The irradiated targets do not contain any volatile radioisotopes and de-canning does not include any abrasive work activities, which would result in particulate emissions from the facility. Projected radiological exposures and environmental releases outlined by McMaster in this report demonstrate that the CANS Facility is well-designed to handle the increased amount of projected radioactivity associated with performing this work until a Class IB licence can be obtained for this purpose.

An ALARA assessment shows that the impact of dose received during the process for each dose group is below the administrative control levels and the regulatory dose limits. McMaster University is confident in its ability to provide high-level support for these operations should an exemption be granted.

2 MATTERS FOR CONSIDERATION

2.1 Class IB Licence Application

McMaster University is currently in the process of establishing a team to prepare the documents required to support a Class IB licence application for the CANS Facility, for submission by May 31st, 2027, in accordance with CNSC REGDOC-1.2.2. McMaster University is working on developing a document submission plan, to ensure application targets are met over this period. If this exemption is granted, McMaster University requests the duration of the exemption to end on December 31st, 2029 to allow for work to continue until the licence application has been reviewed and approved. This period would provide McMaster with 2 years to perform a Safety and Control Area review and work with the CNSC to prepare the documents required to support the application. An additional 2 years would provide the CNSC with time to review the licence documents and provide McMaster with time to address any CNSC comments on the application, make changes to the supporting documents and address any facility changes required to support Class 1B licence requirements.

2.2 Global Supply Chain

The CANS Facility at McMaster University is currently one of two licenced facilities available in Ontario to help support the critical supply of Lu-177 in Canada and world-wide. In Ontario, Lu-177 is typically processed and irradiated at a CANDU Facility for use in radiopharmaceuticals. Irradiated targets are packaged in a certified Type B container and transferred by air to their final processing location. However, the dose rates from the irradiated encapsulated targets are too high to be shipped by commercial airlines due to Transport Index (TI) restrictions for commercial flights. If the irradiation capsules are required to decay before shipment, then the total amount of Lu-177 available for radiopharmaceutical processing decreases. Therefore, removal of the target carrier material is performed to ensure supply and facilitate transport. Due to the high radiation fields involved, this task needs to be performed in a shielded facility. The current CANDU facilities do not have a dedicated shielded hot cell facility required to perform this work, that would allow for minimal cross contamination between the radiopharmaceutical and other radiological processes. The CANS facility at McMaster University has been contracted to perform this work and repackage the Lu-177 ampoules for shipping to their required processing destinations.

McMaster University has been supporting the production of Lu-177 since 2023 and has been instrumental in the global supply chain that provides essential medical treatment to cancer patients. With the Lu-177 industry growing each year, power reactors are working to increase the global supply of this isotope and with its proximity to the power reactors, the CANS Facility is an ideal location for repackaging the materials.

2.3 ALARA Assessment

Subsection 4.1.2 of Section 4 from CNSC REGDOC-2.7.1 states that the CNSC may consider that an ALARA assessment is not required if, during the initial analysis, the licensee can demonstrate that:

- individual occupational doses are unlikely to exceed 1 mSv per year
  or
- doses to individual members of the public are unlikely to exceed 50 μSv per year.

All personnel qualified to conduct de-canning activities at CANS are designated as Nuclear Energy Workers and are issued a thermoluminescent whole body dosimeter (TLD), an extremity dosimeter, and an electronic personal dosimeter (EPD). Electronic personal dosimetry data was collected from August 11th, 2023 to April 25th, 2025 for all personnel involved with a CANS de-canning run. A table summary of personnel doses for each year is shown and demonstrates that no individual occupational dose exceeds 1 mSv per year.

Individual Occupational EPD Dose 2023	
Person	**EPD Dose (mSv)**
(HP1)	0.143
(HP2)	0.005
(HP3)	0.028
(HP4)	0.004
(NOF1)	0.062
(NOF2)	0.004
(NOF3)	0.040
(NOF4)	0.007
(NOF5)	0.015
(NOF6)	0.006
(CCO1)	0.080
(CCO2)	0.076
(CCO3)	0.017
(CCO4)	0.000
(CCO5)	0.006
(CCO6)	0.000
(CCO7)	0.093
(CCO8)	0.094
(CCO9)	0.098
(CCO10)	0.101
(CCO11)	0.002
(CCO12)	0.002
(CCO13)	0.000

Table 2: Summary of all individual personal EPD data (measured in mSv) collected from August 11th, 2023 to December 22nd, 2023. Contractors are designated as Nuclear Energy Workers (NEW). Some Contract Operators were management members only present for the initial de-canning runs, not participating in the radiological aspects of the work, and therefore, were not issued a TLD or extremity dosimetry. They were provided with an EPD and signed in as a visitor.

Individual Occupation TLD Dose 2023		
Person	**Whole Body (mSv)**	**Extremity (mSv)**
(HP1)	0.580	0.000
(HP2)	0.000	0.000
(HP3)	0.150	0.000
(HP4)	0.000	0.000
(NOF1)	0.000	0.000
(NOF2)	0.000	0.000
(NOF3)	0.000	0.000
(NOF4)	0.000	0.000
(NOF5)	0.000	0.000
(NOF6)	2.630	0.000
(CCO1)	0.000	0.000
(CCO2)	0.000	0.000
(CCO3)	0.000	0.000
(CCO4)	-	-
(CCO5)	-	-
(CCO6)	-	-
(CCO7)	0.000	0.000
(CCO8)	0.000	0.000
(CCO9)	0.000	0.000
(CCO10)	0.000	0.000
(CCO11)	-	-
(CCO12)	-	-
(CCO13)	-	-

Table 3: Summary of all individual personal TLD data (measured in mSv) collected from August 11th, 2023 to December 22nd, 2023. Contractors are designated as Nuclear Energy Workers (NEW). Some Contract Operators were management members only present for the initial de-canning runs, not participating in the radiological aspects of the work, and therefore, were not issued a TLD or extremity dosimetry. They were provided with an EPD and signed in as a visitor.

The 2023 dose data depicted in Tables 2 and 3 showed no individual occupational dose exceeding the 1 mSv per year limit as outlined in CNSC REGDOC-2.7.1, subsection 4.1.2 The maximum EPD dose received by an individual, as outlined in Table 2, was 0.143 mSv, 0.95% of the McMaster Administrative Control Level (ACL) for individual dose. The TLD and extremity data provided for HP and NOF personnel in Table 3 cannot solely be contributed to work being conducted at CANS since these individuals perform work in different facilities and across different licenses at McMaster. The EPD data for HP and NOF personnel shown in Table 4 can be attributed to this work, as all personnel doses are recorded at start and end of the shift. The TLD, extremity, and EPD data provided for individual contractors can be contributed solely to CANS work.

Individual Occupational EPD Dose 2024	
Person	**EPD Dose (mSv)**
(HP1)	0.630
(HP2)	0.057
(HP3)	0.059
(HP4)	0.017
(HP5)	0.001
(NOF1)	0.031
(NOF2)	0.000
(NOF3)	0.026
(NOF4)	0.051
(NOF5)	0.302
(NOF6)	0.004
(CCO1)	0.075
(CCO2)	0.155
(CCO3)	0.001
(CCO4)	0.172
(CCO5)	0.060
(CCO6)	0.030
(CCO7)	0.201
(CCO8)	0.001
(CCO9)	0.081
(CCO10)	0.201
(CCO11)	0.250
(CCO12)	0.001

Table 4: Summary of all individual personal EPD data (measured in mSv) collected from January 5th, 2024 to December 27th, 2024. Contractors are designated as Nuclear Energy Workers (NEW).

Individual Occupation TLD Dose 2024		
Person	**WB TLD (mSv)**	**Ext (mSv)**
(HP1)	0.920	0.000
(HP2)	0.300	0.000
(HP3)	0.550	0.000
(HP4)	0.150	0.000
(HP5)	0.000	0.000
(NOF1)	0.31	0.000
(NOF2)	0.000	0.000
(NOF3)	0.000	0.000
(NOF4)	0.000	0.000
(NOF5)	0.230	0.000
(NOF6)	2.770	0.000
(CCO1)	0.000	0.000
(CCO2)	0.000	0.000
(CCO3)	0.000	0.000
(CCO4)	0.120	0.000
(CCO5)	0.110	0.000
(CCO6)	0.000	0.000
(CCO7)	0.120	0.000
(CCO8)	0.000	0.000
(CCO9)	0.000	0.000
(CCO10)	0.000	0.000
(CCO11)	0.240	0.000
(CCO12)	0.000	0.000

Table 5: Summary of all individual personal TLD data (measured in mSv) collected from January 5th, 2024 to December 27th, 2024. Contractors are designated as Nuclear Energy Workers (NEW).

For 2024, the dose data depicted in Tables 4 and 5 showed no individual occupational dose exceeding the 1 mSv per year limit as outlined in CNSC REGDOC-2.7.1, subsection 4.1.2. The maximum EPD dose an individual received, as outlined in Table 4, was 0.63 mSv in 2024, which was 4.2% of the ACL. As with the 2023 results, the TLD and extremity data provided for HP and NOF personnel depicted in Table 5 cannot solely be attributed to work being conducted at CANS since these individuals perform work in different facilities at McMaster. The EPD data for HP and NOF personnel shown in Table 4 can be attributed to this work, as all personnel doses are recorded at start and end of the shift. The TLD, EPD, and extremity data provided for individual contractors can be attributed solely to CANS work.

Individual Occupation Dose 2025			
Person	**Contractor (mSv)**	**HP (mSv)**	**NOF (mSv)**
(HP1)	-	0.471	-
(HP2)	-	0.018	-
(NOF1)	-	-	0.021
(NOF2)	-	-	0.005
(NOF3)	-	-	0.003
(NOF4)	-	-	0.225
(CCO1)	0.030	-	-
(CCO2)	0.068	-	-
(CCO3)	0.175	-	-
(CCO4)	0.168	-	-
(CCO5)	0.083	-	-
(CCO5)	0.110	-	-

Table 6: Summary of all individual personal EPD data (measured in mSv) collected from January 3rd, 2025 to April 25th, 2025. Contractors are designated as Nuclear Energy Workers (NEW).

For 2025, the EPD dose data shown in Table 6 was collected from January 3rd, 2025 to April 25th, 2025 and showed no individual occupational dose exceeding the 1 mSv per year limit as outlined in CNSC REGDOC-2.7.1, subsection 4.1.2. The TLD and extremity dose data were not available from the dosimetry provider at the time of the report for the period between January 1st to March 31st, so the EPD data was utilized to conduct the ALARA assessment for 2025. The maximum EPD dose an individual received for the period between January 1st and March 31st, as shown in Table 6, was 0.281 mSv and currently has received 0.471 mSv from January 1st to April 25th, which is 1.9% and 3.1% of the ACL for annual whole body dose, respectively.

The individual doses for the remainder of 2025 can be projected based on the previous de-canning runs. Conservatively assuming the same individuals are conducting the work each week, this would result in HP1 (the maximum dose individual) receiving an occupational dose of 1.124 mSv (0.281 mSv x 4), which is 7.49% of the ACL and 2.2% of the regulatory annual whole-body dose limit. It should be noted that this is a conservative approach which assumes that the same individual is working each week and receiving the same dose regardless of the number of ampoule targets and activity per de-canning run. In practice not every contractor, HP employee and NOF employee is working each CANS run for the whole year. The information demonstrates that the individual occupational dose does not exceed 1 mSv per year.

2.4 Regulatory and Administrative Limits

A projected dose analysis was conducted for the full 2025 year and the following 2026 year. The projection was based on the number of ampoules a shipment may receive as the dose an individual gets is related to the total time spent during the de-canning run (i.e. the number of ampoules present in each keg). Each ampoule is weighed and contains the same amount of target material. The ampoules are irradiated in the same flux for the same length of time within the reactor, and therefore, each ampoule contains approximately the same activity of Lu-177 and Yb-175. Consequently, the number of ampoules handled during each run is directly proportional to the individual dose received. A conservative analysis was performed using the collective effective dose for each group. The approach chosen will demonstrate that the collective dose per group is far below the ACL and regulatory limit proving that the systems built for CANS are effective and efficient for keeping doses low. As well, this approach will therefore prove that the individual doses are kept well below the ACL and regulatory limits. The number of ampoules per run projected for the rest of the year was taken to be 25 per week which is currently the maximum number of ampoules received for a de-canning run. This is taken to be a conservative approach due to most of the past de-canning runs having 12-18 ampoules. A projection of 25 ampoules will account for increases to meet demand for 2025. McMaster has also provided projected doses for each group for 2026 based on a maximum number of 58 ampoules per week from January 2nd, 2026 to December 25th, 2026, as 58 targets is the maximum the customer's system can irradiate at one time. It is expected that with more targets being handled, the activity will increase and by extension, the dose received will also increase. The projected collective doses were performed using a linear extrapolation based on the activity and number of ampoules.

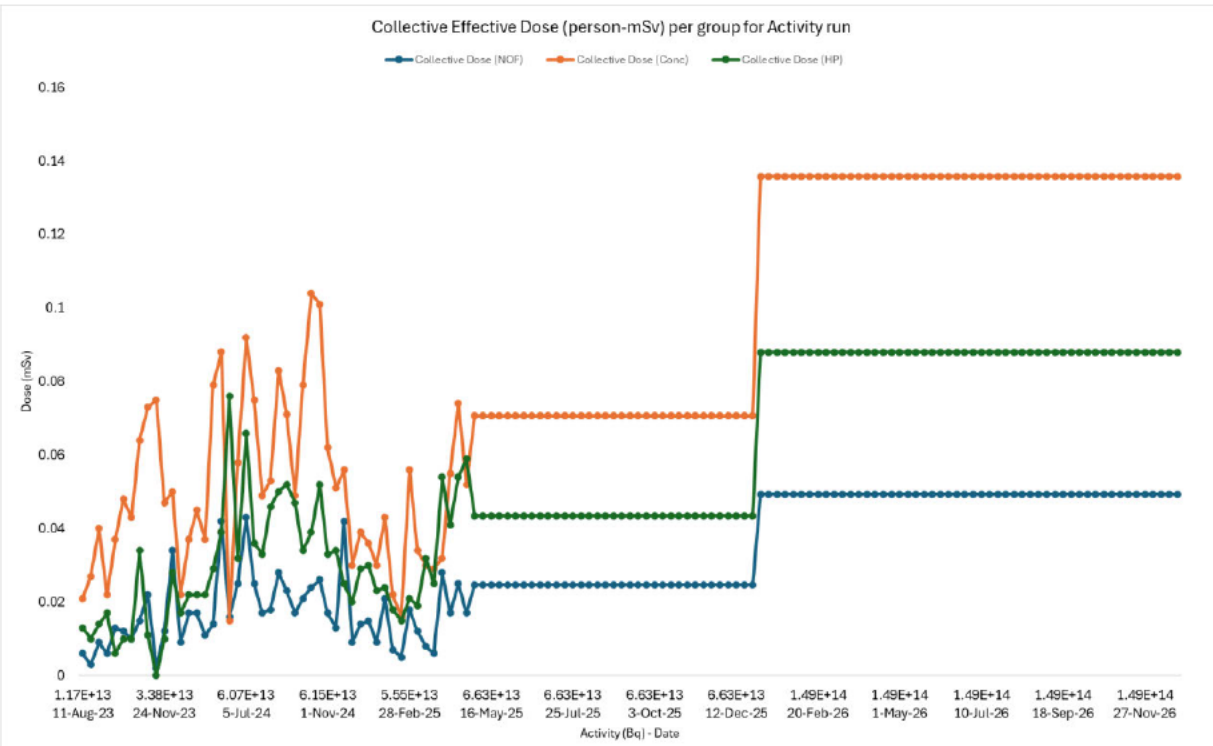

Figure 2: A linear extrapolation performed to project the collective dose for the three dose groups (Contractors, HP and NOF) based on the amount of projected activity for 25 ampoule targets. The projected range spans from May 2nd, 2025 to December 26th, 2025. A projection for 2026 was performed for each group based on the amount of projected activity for 58 ampoule targets a week.

The collective doses for each group were summed for the year and compared to the ACL and the regulatory limit. This conservative approach overestimates the ACL percentage and the regulatory limit percentage since the comparison is made using the collective effective dose instead of the individual dose. No dose group was found to exceed the ACL and regulatory limit, with the largest percentage coming from the contractor dose group (47.1 % and 14.1 % respectively from 2026).

Collective Effective Dose per Group									
Year	**Contractor (mSv)**	**%ACL**	**%Reg**	**HP (mSv)**	**%ACL**	**%Reg**	**NOF (mSv)**	**%ACL**	**%Reg**
2023	0.569	3.8	1.1	0.180	1.2	0.4	0.153	1.0	0.3
2024	1.228	8.2	2.5	0.764	5.1	1.5	0.414	2.8	0.8
2025	3.107	20.7	6.2	2.012	13.4	4.0	1.116	7.4	2.2
2026	7.058	47.1	14.1	4.571	30.5	9.1	2.566	17.1	5.1

Table 7: Summary of the collective effective dose (person-mSv) for each group per year. The collective effective dose per group is compared to the ACL (15 mSv per year) and the regulatory limit (50 mSv per year). Dose values were provided from January 1st, 2025 to April 25th, 2025, and projections were performed for each group from May 2nd, 2025 to December 31st, 2025. Projected doses for each group from January 2nd, 2026 to December 25th, 2026 were also performed.

Thermoluminescent dosimeter (TLD) data was examined as well and showed no individual exceeding the regulatory limits for skin, eyes and whole body. It should also be noted that McMaster personnel (HP and NOF) on the TLD report conduct work in other areas and their total dose shown cannot solely be contributed to CANS work. The data collected from the EPD doses are the most accurate information that can tie directly to the work being performed at CANS for all personnel groups.

2.5 Environmental Assessment

McMaster University performs routine environmental monitoring of the CANS Facility using environmental TLDs to monitor radiation fields in laboratory/work areas and publicly accessible areas, as shown in Figure 3. The environmental TLDs provide results for dose trends to be assessed and monitored. This results in a long-term assessment of radiological conditions associated with work at the CANS Facility.

CANS Locations for Environmental TLDs – Main Floor	
1	Wall Opposite Horizontal Flask Loading Port
2	Face of Machining Hot Cell
3	Face of Sample Preparation Hot Cell
4	Microscopy Control Desk
5	SEM/FIB Microscope
6	Emergency Exit Door
7	Service Corridor Wall Opposite Waste/Machining Cell Door
8	Office Opposite Waste/Machining Cell Door
9	SEM/FIB Exhaust Filter Bank (Mezzanine)
10	Shielding Stepdown (Mezzanine)

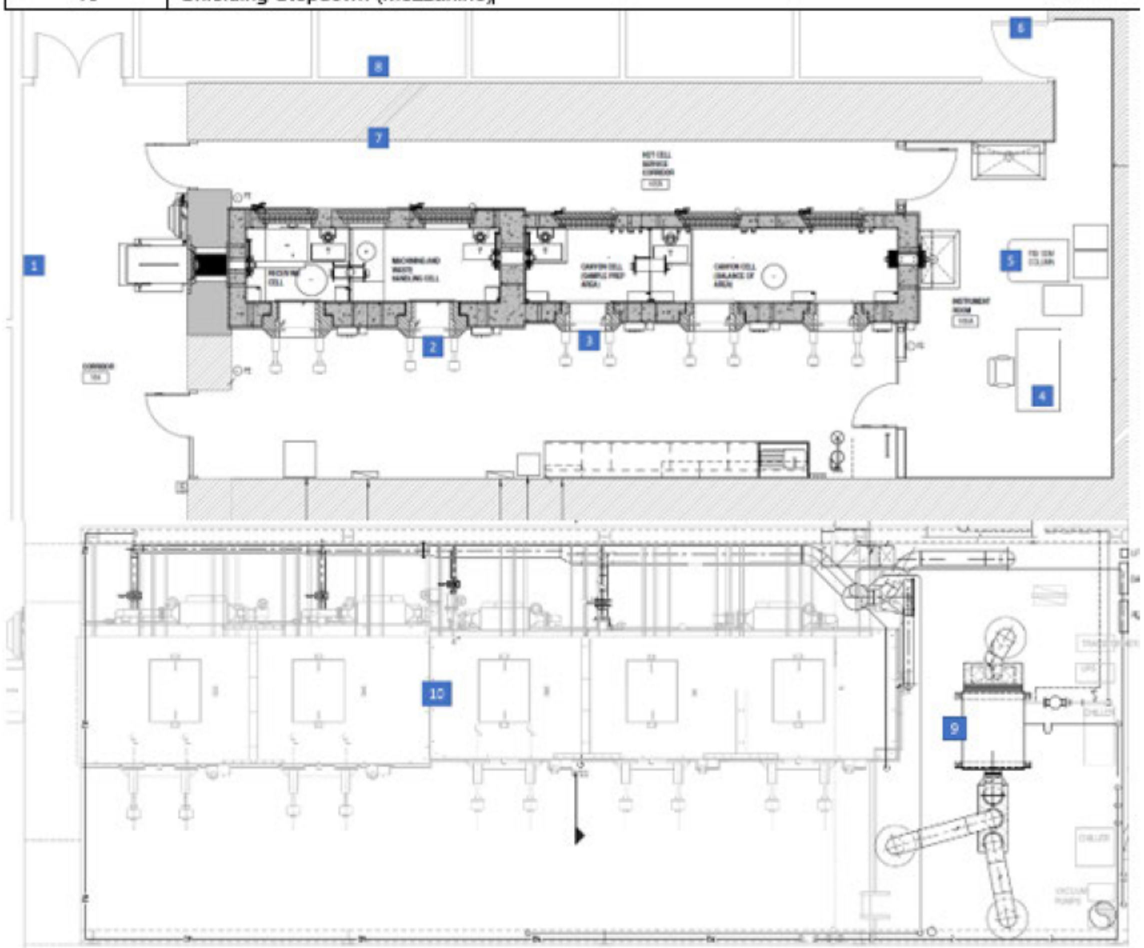

Figure 3: Locations of environmental TLDs for CANS Facility

McMaster University has created a procedure for preparing and changing the various environmental TLDs located throughout CANS [3]. Shown in the following table are the results of the collected environmental TLDs spanning the years 2023-2024. The TLDs are collected every quarter. TLD data for Q1 – 2025 was not available from the dosimetry provider at the time of this report.

These results provided in Table 8 indicate that there is no impact from this work on the environment or the health and safety of the public.

CANS Location	2023			2024		
	HP(0.07) Dose (mSv)	HP(3) Dose (mSv)	HP(10) Dose (mSv)	HP(0.07) Dose (mSv)	HP(3) Dose (mSv)	HP(10) Dose (mSv)
1	0.0	-	0.0	0.0	-	0.0
2	0.0	-	0.0	0.0	-	0.0
3	0.0	-	0.0	0.0	-	0.0
4	0.0	-	0.0	0.0	-	0.0
5	0.0	-	0.0	0.1	-	0.1
6	0.0	-	0.0	0.0	-	0.0
7	0.0	-	0.0	0.0	-	0.0
8	0.0	-	0.0	0.0	-	0.0
9	0.0	-	0.0	0.0	-	0.0
10	0.0	-	0.0	0.0	-	0.0

Table 8: Summary of the environmental TLDs located throughout the CANS facility (10 in total). One location (CANS 5) in 2024 resulted in a dose of 0.1 mSv. All other TLD locations at CANS resulted in no detectable dose.

The CANS Facility contains four continuous air monitors (CAMs) that measure the alpha and beta-emitting particulate concentrations in various locations of the facility: Service Corridor, Gallery, Microscopy Lab, and Exhaust. Refer to Figure 1 for the locations – the Exhaust CAM location is not listed in Figure 1 as it monitors for releases from the facility. These filters are collected and counted weekly by McMaster Health Physics personnel and are measured using a low background automatic alpha/beta counting system. McMaster utilizes a Canberra 6LB counting system to count the filters for alpha and beta particulate. Data has been collected from January 2021 and plotted to analyze trends that may be of concern.

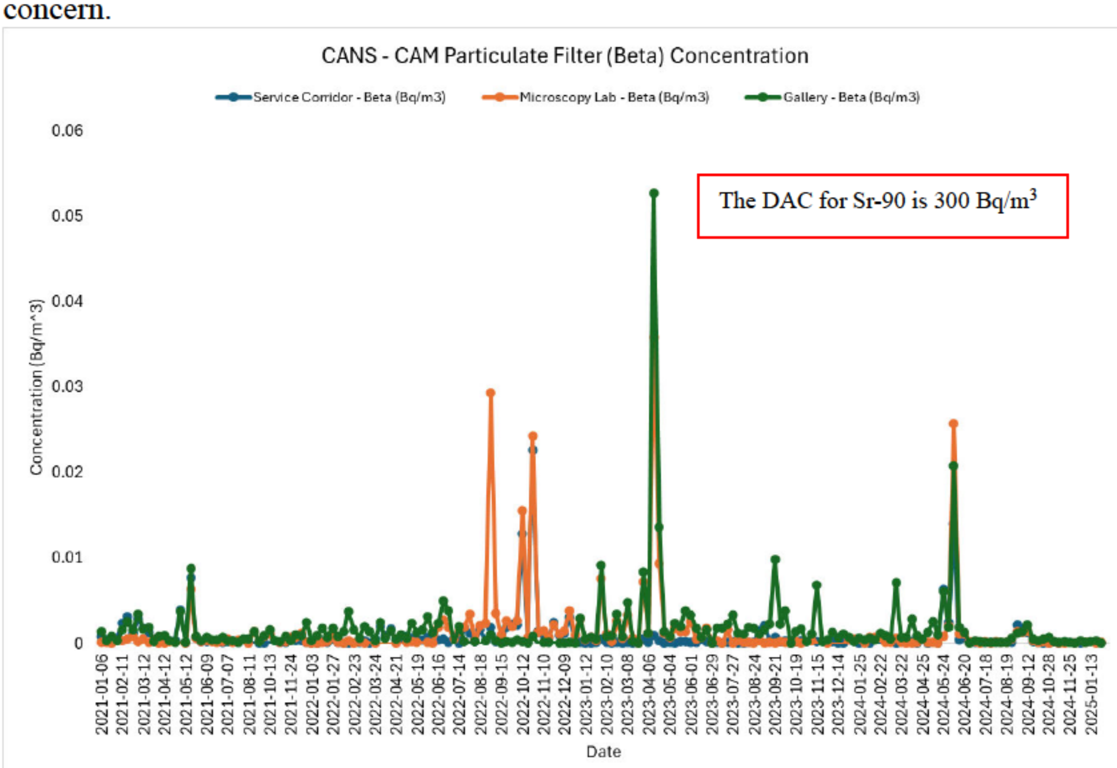

Figure 4: Air borne concentration of beta-emitting particulate contamination for the three CAM filters. Data taken from January 6th, 2021 to January 27th, 2025.

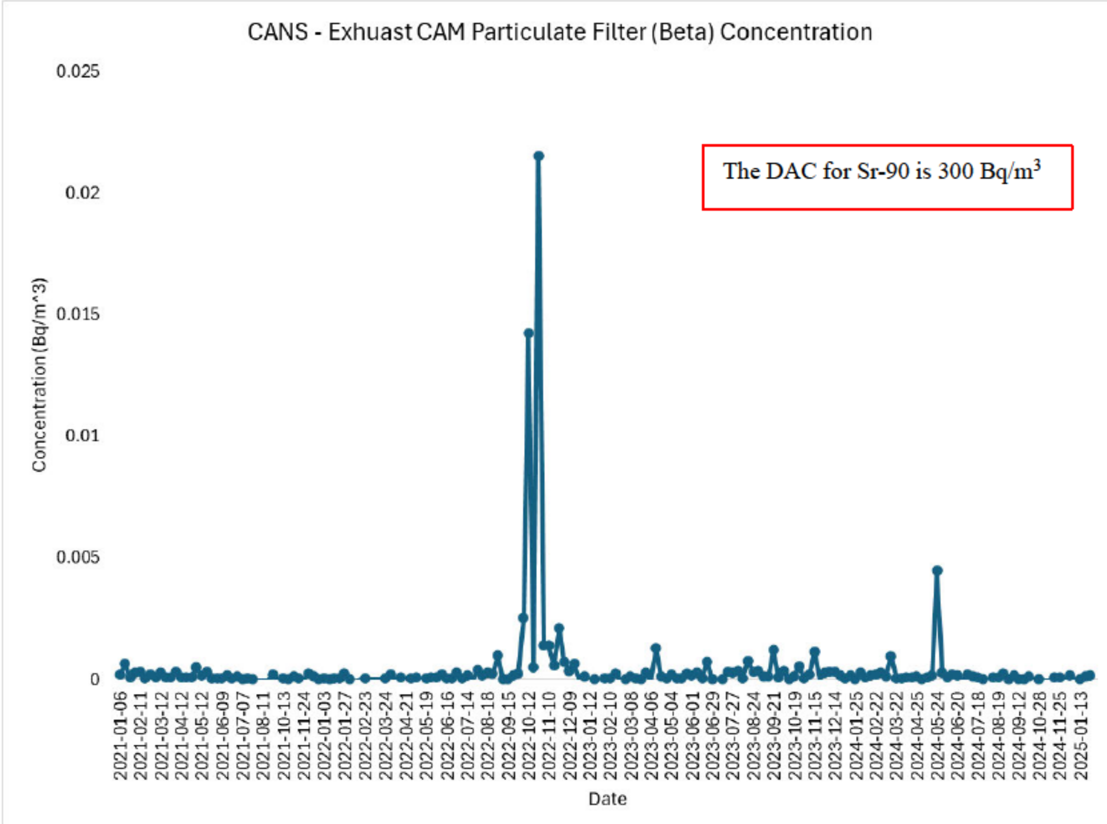

Figure 5: Air borne concentration of beta-emitting particulate contamination for the Exhaust CAM filter. Data taken from January 6th, 2021 to January 27th, 2025.

McMaster University has developed a procedure for environmental releases and the action levels put in place for the CANS facility [4]. The procedure provides trigger levels for the four CAMs which allows for an early intervention point to verify alpha and beta/gamma airborne contamination. These trigger levels were established based on the most limiting radionuclides found in CANDU facilities, as the facility was designed to handle CANDU pressure tubes, which contains high energy beta-gamma nuclides and actinides. For beta and gamma concentrations, the isotope of concern for the establishment of the airborne exhaust trigger levels is Sr-90, which has a Derived Air Concentration (DAC) of 300 Bq/m^3. McMaster had provided a conservative estimate of the general alpha to beta/gamma ratio at CANS being 1:200 [4], but it should not noted that there are no alpha hazards associated with the Lu-177 decanning activities. All CAMs, including the Exhaust, at the CANS Facility have an alarm point set to 29.2 Bq/m^3, 10% of the DAC of Sr-90. These trigger levels have not been exceeded as a result of any of the work conducted at the CANS facility, especially the de-canning work which started in August 2023 as shown in Figure 5. The DAC concentration for Lu-177 is 8000 Bq/m^3 and the DAC for Yb-175 is 10000 Bq/m^3, significantly higher than the conservatively established trigger levels. McMaster has provided trigger levels for the CANS Facility well below the concentrations of two beta nuclides present in the targets to ensure any abnormal airborne incident can be assessed and diagnosed for the safety of personnel working.

The levels shown in Figures 4 and 5 are well below the levels set at CANS for beta airborne concentrations.

2.6 Contingency Planning

Contingency plans have been developed in the case that an ampoule is broken or damaged during the de-canning process. A procedure has been developed outlining the steps for handling a broken or damaged ampoule, which include containing the broken ampoule and storing it to allow for sufficient decay. In this case, a cell entry cannot be conducted to the Canyon Cell due to the contamination and dose rate levels. The plan allows for containment of the source, and work in the cell may only continue at the discretion of Health Physics.

Contingency plans are also in place in case of mechanical failures of the primary cutting tool, or issues with access to the fume hood passthrough. A member of the CANS supervision team is on-call to handle mechanical failures of a manipulator arm. A secondary cutting tool is stored in a work tray in the Canyon Left Cell, allowing de-canning activities to continue should an error occur with the primary cutting tool. If a failure were to occur with the fume hood passthrough, the material can be transferred to the Sample Prep Cell through the Sample Prep Passthrough, and a cell entry conducted under the supervision of Health Physics to the Sample Prep cell to access the materials.

To account for mechanical failures of the Canyon Cell manipulators, a qualified Hot Cell Supervisor is on-call for all de-canning shifts. This individual is a subject matter expert and would be available to attend campus to provide direction or repairs on the manipulators. Access to the material would be available through the adjacent cell by conducting a cell entry if the arm could not repaired.

2.7 Personnel Qualification and Training

McMaster University requires personnel performing work at CANS to be trained through testing and work observations by qualified individuals. McMaster has created a training outline detailing the required training modules and work observations an individual would need to perform work at the CANS Facility [5]. All training records are kept securely for future reference.

An individual conducting radiological work at the CANS facility is categorized as a partially qualified individual or a fully qualified individual. A partially qualified individual must complete sections 1 and 2 of the CANS personnel training form which includes modules on radiation safety and instrumentation. Section 1 of CANS training includes module HPT-001: *Initial Radiation Safety Training* and HPT-202: *Handling of Radioactive Materials at the Basic and Intermediate Level*. Section 2 of CANS training includes module CANS-101: *CANS Radiation Safety Training and Radiation Safety Quiz*. Personnel are tested on the materials learned through on-the-job training records. All individuals that complete sections 1 and 2 may perform radiological work under supervision of a fully qualified individual [5].

A fully qualified individual can perform radiological work unsupervised. Fully qualified individuals must further complete additional training needs as assessed by Health

Physics. These modules include HPT-201: *Radiation Detection and Instrumentation,* HPT-203: *Working with Radioactive Materials at the High/Containment* Level, CANS-HP-PROC-9105: *Routine Contamination Monitoring at CANS,* HP 9315: *Direct Contamination Monitoring,* HP 9316: *Indirect Contamination Monitoring*, HP 9321: *PAS Operation*, HP 9322: *ICAM Filter Change,* HP 9323: *Alpha Direct Check Measurement*, HP 9324: *Operation of the Ludlum 2929 and Ludlum 3030 Sample Counters*, HP 9406: *Donning and Doffing*, TS 1001: *Use of Continuous Flow Airline Respirator*, TS 1051: *Use of the 3M Versaflo Powered Air Purifying Respirator* and *Operation and Maintenance of Area Radiation Monitors, Continuous Air Monitors and the Integrated Monitoring System*. They must also perform work observations, based on the required training, and conduct a qualification interview with the Senior Health Physicist and CANS manager or the Director of Reactor Operations and Maintenance [5]. An individual is considered fully qualified once all these conditions have been satisfactorily met.

3 CONCLUSIONS

McMaster University has performed a detailed ALARA assessment and environmental assessment of the potential concerns for personnel working at CANS and concludes that any additional risks to personnel and the environment due to this exemption are well understood and shown to be negligible. McMaster has demonstrated under CNSC REGDOC-2.7.1 subsection 4.1.2, that individual occupational doses are unlikely to exceed 1 mSv per year. McMaster has demonstrated that if an exemption would be granted, the doses will remain well below the ACL and regulatory limits. Personnel working in the CANS facility are provided with comprehensive safety training.

McMaster University is committed to applying for a Class IB license for the CANS facility, in accordance with CNSC REGDOC 1.2.2. This request for an exemption is critical for the continued support of the global supply chain for patients to receive Lu-177 in Canada and worldwide. The CANS facility is currently one of two suitable locations available in Ontario and McMaster is confident in their qualified staff, strong radiation safety program and their long history of nuclear safety and compliance that the continual work at CANS can be performed with this required exemption, until a Class 1B licence can be obtained for the facility.

4 REFERENCES

1. McMaster CANS Facility, "CANS-F01-SOP-101 Receiving Fume Hood Entry and Exit Revision 3", November 2, 2023.
2. McMaster CANS Facility, "CANS-F01-SOP-103 In Cell Handling Procedures Revision 1", November 2, 2023.
3. McMaster University Health Physics, "*Environmental Monitoring at CANS, Document CANS-HP-PROC-9201 P0",* January 21, 2019.
4. McMaster University Health Physics, "*Action Levels for Environmental Releases at CANS, Document CANS-HP-REP-00007"*, May 28, 2020.
5. McMaster University Health Physics, "*CANS Personnel Health Physics Training Requirements Form, Document HP-FORM-CANS-9004",* January 10, 2025.

5 GLOSSARY

NSRD	Nuclear Substance and Radiation Devices
CANS	Centre for Advanced Nuclear Systems
CANDU	Canada Deuterium Uranium
TAB	Tandem Accelerator Building
TI	Transport Index
ALARA	As Low As Reasonably Achievable
CNSC	Canadian Nuclear Safety Commission
ACL	Administrative Control Level
EPD	Electronic Personal Dosimeter
NEW	Nuclear Energy Worker
HP	Health Physics
NOF	Nuclear Operations and Facilities
TLD	Thermal Luminescence Dosimeters
CAM	Continuous Air Monitor
DAC	Derived Air Concentration

Addendum A: BASIS FOR RECOMMENDATION

The regulatory basis for the recommendation presented in this CMD is as follows:

- *Consolidated Nuclear Substance and Radiation Devices (NSRD) license No. 01495-19-26.2*
- *CNSC REGDOC-2.7.1, Section 4 and Subsection 4.1.1*
- *CNSC REGDOC-1.2.*