CMD 25-H113 - CNSC Staff Submission

Request to increase the total activity limits of Nuclear Substances and Radiation Devices Licence No. 01495-19-26 issued to McMaster University

Classification	UNCLASSIFIED
Type of CMD	Original
CMD Number	25-H113
Reference CMD(s)	N/A
Type of audience	Hearing in writing based solely on written submissions
Public hearing date	Click or tap to enter a date.
Word e-DOC #	7552212 - EN
PDF e-DOC #	7562018 - EN
Attachments	References
Summary	This CMD presents CNSC staff evaluation of the request made by McMaster University for a temporary exemption from the application of total activity limits until the Commission makes a decision on the application for a Class 1B licence
Actions required	CNSC request the Commission to render a decision on allowing McMaster University to process or use more than 10^{15} Bq of nuclear substances per calendar year under a Nuclear Substances and Radiation Devices licence while applying for a Class IB facility licence.

CMD 25-H113

Request to increase the total activity limits of Nuclear Substances and Radiation Devices Licence No. 01495-19-26 issued to McMaster University

Signed by:

X OwenWhitred, Karen

Digitally signed by OwenWhitred, Karen
DN: C=CA, O=GC, OU=CNSC-CCSN, CN="OwenWhitred, Karen"
Reason: I am approving this document
Location: Karen Owen-Whitred
Date: 2025.08.15 14:45:58-04'00'
Foxit PDF Editor Version: 13.0.1

Karen Owen-Whitred
Director General, Directorate of Nuclear Substance Regulation

Request to increase the total activity limits of Nuclear Substances and Radiation Devices Licence No. 01495-19-26 issued to McMaster University

Canadian Nuclear Safety Commission

Table of contents

Land acknowledgement **1**

Plain language summary **1**

1. Overview **3**

1.1. Background 3

2. Regulatory Requirements **4**

3. Matters for Consideration **5**

3.1 Class 1B Licence Application 5

3.2 Global Supply Chain 6

3.3 Human performance management 6

3.4 Radiation Protection 7

3.5 Environmental Protection 7

3.6 Emergency management and fire protection 8

4. Conclusions and Recommendations **8**

References **10**

Land acknowledgement

The Canadian Nuclear Safety Commission acknowledges that McMaster University is located in the traditional territory of the Haudenosaunee and Anishnaabe Nations.

Plain language summary

McMaster University (McMaster) has applied for an exemption from the definition of a Class I facility as defined in Section 1 of the Class I Nuclear Facilities Regulations.

McMaster is currently supporting the Lutetium-177 (Lu-177) global supply chain by using a Nuclear Substances and Radiation Devices Licence to perform activities at their Centre for Advanced Nuclear Systems (CANS) facility (separate from the research reactor). The process involves receipt of the irradiated targets, removal of the targets from the aluminum target holder and placing the targets back into a shipping container. Removal of the target holder reduces the total activity in the package to permit air transport of raw materials to Germany for processing into a therapeutic radiopharmaceutical.

The *Class I Nuclear Facilities Regulations* indicate that a plant processing or using greater than 10^{15} Bq of a nuclear substance in a calendar year other than uranium, thorium, or plutonium would be considered a Class IB facility for licensing . The exemption, if granted, would permit McMaster to increase their annual throughput beyond 10^{15} Bq using the NSRD licence by being exempted from the regulatory requirements normally imposed by the *Class I Nuclear Facilities Regulations* while McMaster prepares and submits an application for a Class IB licence to the Commission.

The Commission may grant an exemption under section 7 of the *Nuclear Safey and Control Act* provided it meets the criteria in Section 11 of the General *Nuclear Safety and Control Regulations,* i.e. that the licensee's activities will not

- (a) pose an unreasonable risk to the environment or the health and safety of persons;
- (b) pose an unreasonable risk to national security; or
- (c) result in a failure to achieve conformity with measures of control and international obligations to which Canada has agreed.

The additional risk associated with increasing the annual throughput would be minimal as there is no handling of unsealed isotopes, the CANS Facility provides adequate protection for workers and the environment, and the need to immediately ship the product for processing prevents accumulation of an inventory of product at McMaster. In addition, the exemption would not

pose unreasonable risk to national security or result in a failure to achieve conformity with measures of control and international obligations to which Canada has agreed.

This exemption would only apply to the activities covered under licence 01495-19, and the exemption would be in place until the Commission renders a decision on the application from McMaster for a Class IB licence.

Referenced documents in this CMD are available to the public upon request, subject to confidentiality considerations.

1. Overview

1.1. Background

McMaster University is located in Hamilton, Ontario and currently holds 7 licences for various activities regulated by the CNSC. CNSC licence No. 01495-19 [1] was issued by a Designated Officer in the Nuclear Substances and Radiation Devices program on December 4, 2024 for the processing of Lutetium-177 (Lu-177) at the Centre for Advanced Nuclear Systems (CANS) Facility that is separate from the research reactor. Licence 01495-19 will expire on December 31, 2026. Lu-177 processing was previously covered under CNSC licence 01495-2.

Figure 1: Centre for Advanced Nuclear Systems (CANS) at McMaster University

Since August 2023, McMaster University has been supporting the Lu-177 global supply chain by using a Nuclear Substances and Radiation Devices licence to perform activities that facilitate air transport of raw materials to Germany for processing into a therapeutic radiopharmaceutical. Removal of the target holder and repackaging of the Lu-177 targets reduces the total activity in the package to permit air transport of raw materials to Germany. Due to the relatively short half-life of Lu-177, the material is immediately sent to Toronto airport at the conclusion of the process; McMaster does not maintain an inventory of Lu-177 on site through this activity. As the production of Lu-177 has increased, the activity performed by McMaster University has reached the current annual activity limit of 10^{15} Bq. The processing and use of activity above this annual limit requires a Class 1B licence.

Therefore, McMaster University (McMaster) has applied for a temporary exemption from the *Class I Nuclear Facilities Regulations*, to allow them to continue the removal of the aluminum cladding under their NSRD licence.

2. Regulatory Requirements

McMaster currently holds a licence issued in accordance with Subsection 24(4) of the *Nuclear Safety and Control Act,* which authorizes the activity in question. The application for this licence was reviewed using the DNSR procedure titled *Determine the Regulatory Approach for Non-standard Nuclear Substances and Waste Nuclear Substance Activities* [2]. This process requires CNSC staff to evaluate the application against each Safety and Control Area (SCA) to determine if the SCA is applicable to the application and where specialist input is required for the SCA.

Under their current licence, McMaster University are limited in the amount of activity (throughput) that can be processed in a year as a Class 1B licence is required for processing more than 10^{15} Bq in accordance with the *Class I Nuclear Facilities Regulations*. McMaster University is aware of this requirement and is in the process of developing an application for a Class 1B licence. In the meantime, McMaster University is seeking an exemption from the Commission to allow continued processing of the Lu-177 under Licence No. 01495-19 while making an application for a Class 1B licence.

In section 1 of the *Class I Nuclear Facilities Regulations*, a Class IB nuclear facility is defined as:

"a plant, other than a Class II nuclear facility as defined in section 1 of the *Class II Nuclear Facilities and Prescribed Equipment Regulations*, for the processing or use, in a quantity greater than 10^{15} Bq per calendar year, of nuclear substances other than uranium, thorium or plutonium" (paragraph (d)).

In section 7 of the *Nuclear Safety and Control Act*, the ability of the Commission to grant a regulatory exemption is defined:

The Commission may, in accordance with the regulations, exempt any activity, person, class of person or quantity of a nuclear substance, temporarily or permanently, from the application of this Act or the regulations or any provision thereof.

Section 11 of the *General Nuclear Safety and Control Regulations* includes the criteria to be met for an exemption under Section 7 of the Act.

For the purpose of section 7 of the Act, the Commission may grant an exemption if doing so will not

- (a) pose an unreasonable risk to the environment or the health and safety of persons;
- (b) pose an unreasonable risk to national security; or
- (c) result in a failure to achieve conformity with measures of control and international obligations to which Canada has agreed.

3. Matters for Consideration

Section 3.1 to 3.6 includes CNSC staff evaluation of McMaster's application for exemption and includes the relevant areas from the CNSC's 14 Safety and Control Areas – namely Human performance management, Radiation protection, Environmental protection, and Emergency management and fire protection . CNSC staff assessment confirmed that the activities performed under the licence are safe. The increase in the total activity to be processed does not change CNSC staff conclusions. Based on CNSC staff assessment of McMaster's submission, CNSC staff confirm that the time limited exemption approach taken by McMaster for this request will not

- (a) pose an unreasonable risk to the environment or the health and safety of persons;
- (b) pose an unreasonable risk to national security; or
- (c) result in a failure to achieve conformity with measures of control and international obligations to which Canada has agreed.

3.1 Class 1B Licence Application

As per the definition of a Class 1B facility under the *Class 1 Nuclear Facilities Regulations*, CNSC licence No. 01495-19, issued to McMaster University under the *Nuclear Substances and Radiation Devices Regulations* allows the processing or use of up to 10^{15} Bq per year at the CANS Facility. Due to the high activity of the material being repackaged, and the increase in the amount of Lu-177 produced, the CANS Facility can only be utilized for approximately five months of the year under the current limits.

In its application McMaster stated that they are in the process of developing an application for a Class IB licence for the CANS Facility that will include the licensed activities covered under CNSC Licence No. 01495-19. CNSC staff recommend that the Commission exempt McMaster for the duration of Licence No. 01495-19, until its expiry on December 31, 2026. Should additional time be required at that point for the Commission to render a decision on the application from McMaster for the Class IB licence, CNSC staff would consider renewing Licence No. 01495-19 and assessing the need for an extension of the exemption at that time.

In addition, McMaster is proposing the following maximum throughput limits to be applied to CNSC licence No. 01495-19 should the Commission grant the exemption:

- 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. These limits will be incorporated in CNSC licence No. 01495-19 if the exemption is approved by the Commission.

3.2 Global Supply Chain

Lu-177 has emerged as a key isotope in cancer fighting radiotheranostic protocols. The relatively short half life of the isotope, the type of the radioactive emission during decay, and the chemical properties make the isotope ideal for use in targeted therapies that provide maximum radiation dose to tumors while minimizing dose to healthy tissues.

Currently, McMaster University is one of the only two licensed facilities available to support the supply of Lu-177 in Canada. With the Lu-177 industry growing each year, power reactors are working to increase the global supply of this isotope. With its proximity to power reactors in Ontario, McMaster is well located for repackaging the materials.

McMaster is supporting the Lu-177 global supply chain by using a Nuclear Substances and Radiation Devices Licence to perform activities at their CANS facility (separate from the research reactor). The process involves receipt of the irradiated targets, removal of the targets from the aluminum target holder, and placing the targets back into a shipping container. Due to the relatively short half-life of Lu-177, the material is immediately sent to Toronto airport at the conclusion of the process; McMaster does not maintain an inventory of Lu-177 on site through this activity.

Removal of the target holder reduces the total activity in the package to permit air transport of raw materials to Germany for processing into a therapeutic radiopharmaceutical. The additional risk associated with increasing the number of runs would be minimal as there is no handling of unsealed isotopes, the CANS facility provides adequate protection for workers and the environment, and the need to immediately ship the product for processing prevents accumulation of an inventory of product at McMaster.

3.3 Human performance management

The assessment of this Safety Control Area is focused on the Personnel training specific area.

Lu-177 decanning operations involve operators and support staff employed by McMaster and third-party contractors involved in the supply chain process. McMaster has a comprehensive systematic training program which identifies risks associated with the tasks individuals are involved in and ensures that those individuals are prepared to complete the work.

McMaster’s training program for the Lu-177 decanning process comprises of general McMaster Radiation Protection and Health and Safety training, training specific to the operation of the

CANS facility, and tasks unique to the decanning activities. New employees are supervised by senior staff and McMaster Health Physicists as part of the qualification process.

3.4 Radiation protection

In its application, McMaster demonstrated that the removal of the aluminium target holder at the CANS Facility has resulted in very low doses to the workers who are all classified as Nuclear Energy Workers (NEW). Based on data collected since the beginning of the activity in August 2023, McMaster University demonstrated that the maximum individual dose to workers is below 1 mSv per year. For 2025, McMaster demonstrated that the maximum individual dose to workers would conservatively be estimated to 1.124 mSv per year. The estimate is based on assumptions that the same worker is conducting the work each week for the entire year, using the highest dose recorded in the first quarter of 2025. (0.281 mSv x 4).

From McMaster's experience, each ampoule is containing the same approximate activity of Lu-177 and Yb-175 (an impurity generated from Yb-174 during target irradiation). Consequently, the dose to workers is directly proportional to the number of ampoules handled. Through the end of 2025, McMaster estimates that 25 ampoules would be processed per run, which represents the maximum number of ampoules they have received so far. For the following years the number of ampoules per run is up to 58, as that is the maximum number that can currently be irradiated at a time.

McMaster has provided worker dose data for all decanning runs since 2023. The doses are cumulative and reported on an annual basis. Workers wear both passive dosimetry and electronic personal dosimeters.

In accordance with the *Radiation Protection Regulations*, the effective dose limits to Nuclear Energy Workers (NEW) cannot exceed 50 mSv in one year or 100 mSv over a 5-year period. In addition to the regulatory dose limits, McMaster is using Administrative Control Level (ACL) for individual doses to their workers. The ACL is set at 15 mSv per year for NEWs. The data demonstrates that worker doses are well below McMaster action limits and applicable regulatory dose limits. An increase in production runs would not be anticipated to result in dose limits being exceeded.

3.5 Environmental protection

McMaster is performing routine environmental monitoring of the CANS Facility using environmental thermoluminescent dosimeters to monitor the radiation fields in the work areas and publicly accessible areas. CNSC staff reviewed these results and are satisfied that the increase in number of ampoules processed will not significantly increase the doses to the workers and the public.

The Facility also contains 4 continuous air monitors (CAMs) that measure alpha and beta-emitting particles in various locations.

Since Lu-177 processing has been initiated at CANS, McMaster reported one event involving a broken ampoule and spill of target material. The event did not result in any increase in doses to workers involved in the operations nor result in any increase in releases to the environment.

CNSC staff reviewed the air monitoring results which demonstrate that filtration systems within the CANS Facility hot cell and nuclear ventilation system ensured releases were kept below the McMaster airborne contamination monitoring trigger point and at 0.12% of the Derived Air Concentration (DAC) for Lu-177. CNSC staff concluded that the releases have no offsite impact.

3.6 Emergency management and fire protection

McMaster has a well-developed emergency response program. This program provides support for all licensed activities on campus, including the CANS Facility.

A Health Physicist is on-call during Lu-177 decanning operations and is contacted in the event of an incident. The on-call staff can quickly attend the CANS Facility to provide support, instrumentation, and manage any incidents.

In April 2025 the emergency response plan for Lu-177 decanning was activated. During processing, operators noticed that an ampoule was broken, and the irradiated target material was spilled in the hot cell. Operators contacted the on-call Health Physicist as required; clean up of the hot cell and adjacent areas was accomplished with minimal dose to operators and no emissions to the environment. CNSC staff are satisfied with the response and corrective actions McMaster put in place as a result of the incident. CNSC staff conclude that the emergency response program is adequate for the activities conducted on licence 01495-19.

4. Conclusions and Recommendations

The additional risk associated with increasing the annual throughput would be minimal as there is no handling of unsealed isotopes, the CANS Facility provides adequate protection for workers and the environment, and the need to immediately ship the product for processing prevents accumulation of an inventory of product at McMaster.

CNSC staff recommends that the Commission grant the exemption from the ~~*Class I Facilities Regulations*~~ under Section 7 of the ~~*Nuclear Safety and Control Act*~~, to McMaster University for the purposes of Lu-177 processing through December 2029. CNSC staff based their

recommendations on Section 11 of the *General Nuclear Safety and Control Regulations* that McMaster University will not:

- (a) pose an unreasonable risk to the environment or the health and safety of persons;
- (b) pose an unreasonable risk to national security; or
- (c) result in a failure to achieve conformity with measures of control and international obligations to which Canada has agreed.

CNSC staff recommend that the Commission approve the exemption.

Should the Commission approve the exemption to process or use in a quantity greater than 10^{15} Bq of nuclear substances per calendar year under the Nuclear Substances and Radiation Devices licence 01495-19, issued to McMaster University, CNSC staff will revise licence 01495-19 to include the annual activity limits on the licence to reflect the Commission's approval of the annual increased limits. The revised licence will be submitted to a designated officer for review and approval.

References

1. **CNSC Licence** No 01495-19-26.3 (CNSC document No. 7535158), Appendices removed from reference as they are considered prescribed information.
2. **CNSC.** *Determine the Regulatory Approach for Non-standard Nuclear Substances and Waste Nuclear Substance Activities* (CNSC document No. 6061234)

Haralampieva, Nezabravka

From: Doucette, Tracy
Sent: June 13, 2025 12:40 PM
To: 'cmalcol@mcmaster.ca'
Cc: Babcock, Neil; Receivables / Recevables (CNSC/CCSN)
Subject: Licence Issued 01495-19-26.3
Attachments: NSRD Licence 01495-19-26.3 (1).pdf

Dear Licensee:

As requested, please find enclosed a copy of your licence issued pursuant to section 24 of the *Nuclear Safety and Control Act*. The information submitted meets the regulatory requirements, policies and guidance of the Canadian Nuclear Safety Commission (CNSC).

You will require a PDF Reader to view and print this licence. No additional copies of the licence will be sent to you unless you request otherwise.

The following links include relevant CNSC documents that are available electronically:

Licensing: Nuclear substances and radiation devices - Canadian Nuclear Safety Commission

Licensing: Class II licensed facilities - Canadian Nuclear Safety Commission

The format for all licences is comprised of a main body and appendices attached to the licence. All appendices, attachments and documents referenced in the licence form part of the licence and therefore become requirements for the licensed activities and are classified as prescribed information.

For security reasons, prescribed information shall be safeguarded pursuant to sections 21 to 23 of the *General Nuclear Safety and Control Regulations*. Pursuant to paragraph 14(1)(b) of the *General Nuclear Safety and Control Regulations*, you may post a notice of licence rather than a copy of the licence itself. Choosing this alternative further reduces the need to print physical copies of the licence. If you choose to post the licence in accordance with paragraph 14(1)(a) of the *General Nuclear Safety and Control Regulations*, only the main body of the licence (sections I through V) should be posted.

Field operations

Pursuant to subsection 14(2) of the *General Nuclear Safety and Control Regulations,* licensees conducting field operations must keep a copy of the current licence at the place where the field operations are being conducted; an electronic version of the licence satisfies this requirement.

Assistance

If you have any questions about the licence, please contact your CNSC representative that is copied on this message.

Please call us at 1 (888) 229-2672 for any licence fee matters (Cost Recovery)

Tracy Doucette
Administrative Assistant / Adjointe administrative
Directorate of Nuclear Substance Regulation / Direction de la réglementation des substances nucléaires
Canadian Nuclear Safety Commission / Commission canadienne de sûreté nucléaire
Government of Canada | Gouvernement du Canada
tracy.doucette@cnsc-ccsn.gc.ca

Mobile: (343) 571-2818

I) LICENCE NUMBER: 01495-19-26.3

II) LICENSEE

Pursuant to section 24 of the Nuclear Safety and Control Act, this licence is issued to:

McMaster University
1280 Main Street West
Hamilton, ON
L8S 4K1
Canada

This licence replaces licence 01495-19-26.2.

III) LICENCE PERIOD

This licence is valid from: June 13, 2025 to December 31, 2026 unless otherwise suspended, amended, revoked or replaced.

IV) LICENSED ACTIVITIES

This licence authorizes the licensee to:

(a) possess, transfer, export, use and store the nuclear substances listed in the Appendix: Nuclear Substances and Radiation Devices of this licence.

(b) conduct licensed activities in the location(s) specified in the Appendix: Locations of Licensed Activities of this licence.

This licence is issued for: consolidated uses of nuclear substances (815).

V) CONDITIONS

The contents of the appendices attached to this licence form part of the licence.

1. Prohibition of Human Use
   This licence does not authorize the use of nuclear substances in or on human beings.
   (2696-0)

2. List of Areas, Rooms and Enclosures
   The licensee shall maintain a list of all areas, rooms and enclosures in which more than one exemption quantity of a nuclear substance is used or stored.
   (2569-2)

3. Posting of Safety Poster(s)
   The licensee shall post and keep posted, in a readily visible location in areas, rooms or enclosures where nuclear substances are handled, a radioisotope safety poster approved by the Commission or a person authorized by the

Commission, which corresponds to the classification of the area, room or enclosure.
(2570-4)

4. Storage
The licensee shall:
(a) ensure that when in storage radioactive nuclear substances or radiation devices are accessible only to persons authorized by the licensee;
(b) ensure that the dose rate at any occupied location outside the storage area, room or enclosure resulting from the substances or devices in storage does not exceed 2.5 microSv/h; and
(c) have measures in place to ensure that the dose limits in the Radiation Protection Regulations are not exceeded as a result of the substances or devices in storage.
(2575-2)

5. Area Classification
The licensee shall classify each room, area or enclosure where more than one exemption quantity of an unsealed nuclear substance is used at a single time as:

(a) basic-level if the quantity does not exceed 5 ALI,
(b) intermediate-level if the quantity used does not exceed 50 ALI,
(c) high-level if the quantity does not exceed 500 ALI; or,
(d) containment-level if the quantity exceeds 500 ALI.

Except for the basic-level classification, the licensee shall not use unsealed nuclear substances in these rooms, areas or enclosures without written approval of the Commission or a person authorized by the Commission.
(2108-4)

6. Contamination Meter Requirements
The licensee shall make available to workers at all times at the site of the licensed activity a properly functioning portable contamination meter.
(2572-1)

7. Survey Meter Requirements
The licensee shall provide at all times where nuclear substances, except for Hydrogen-3 and Nickel-63, are handled or stored a radiation survey meter.
(2058-1)

8. Contamination Criteria
The licensee shall ensure that for nuclear substances listed in the Appendix: Classes of Radionuclides, attached to this licence:
(a) non-fixed contamination in all areas, rooms or enclosures where unsealed nuclear substances are used or stored does not exceed:
  (i) 3 becquerels per square centimetre for all Class A radionuclides;
  (ii) 30 becquerels per square centimetre for all Class B radionuclides; or
  (iii) 300 becquerels per square centimetre for all Class C radionuclides; averaged over an area not exceeding 100 square centimetres; and
(b) non-fixed contamination in all other areas does not exceed:
  (i) 0.3 becquerels per square centimetre for all Class A radionuclides;
  (ii) 3 becquerels per square centimetre for all Class B radionuclides; or
  (iii) 30 becquerels per square centimetre for all Class C radionuclides; averaged over an area not exceeding

100 square centimetres.

(2642-10)

9. Internal Authorization

The licensee shall ensure that:

(a) internal authorizations are issued in accordance with the licensee's internal authorization policies and procedures approved by the Commission or a person authorized by the Commission; and

(b) internal authorization forms are posted in a readily visible location in or near each room, area or enclosure where nuclear substances and radiation devices are used or stored.

(c) the licensed activity is conducted in accordance with the terms and conditions of the internal authorization.

(2215-4)

10. Project Approval

The licensee shall obtain written approval from the Commission or a person authorized by the Commission before starting any work requiring the use of more than 10,000 exemption quantities of a nuclear substance at a single time.

(2214-0)

11. Disposal (General)

When disposing of unsealed nuclear substances set out in column 1 of the Appendix: Disposal Limits to municipal waste, to sewer systems or to atmosphere, the licensee shall ensure that the concentration limit set out for each nuclear substance is not exceeded.

(a) The concentration limits set out in column 2 apply to quantities of solid waste of less than three tonnes per building per year. Nuclear substances released to the municipal garbage system must be in solid form and uniformly distributed in the waste with a concentration that is less than the limits in column 2. Where more than one nuclear substance is disposed of at one time, the sum of the quotients obtained by dividing the quantity of each substance by its corresponding limit in column 2 shall not exceed one.

(b) The limits set out in Column 3 apply to the water soluble liquid form of each nuclear substance which may be disposed
of per building per year. Where more than one nuclear substance is disposed of at one time, the sum of the quotients obtained by
dividing the quantity of each substance by its corresponding limit in column 3 shall not exceed one.

(c) The concentration limits set out in Column 4 may be averaged over a one-week period and apply to releases of less than 3 million cubic metres per year. Where more than one nuclear substance is disposed of at one time, the sum of the quotients obtained by dividing the quantity of each substance by its corresponding limit in column 4 shall not exceed one.

(2160-12)

12. Decommissioning

The licensee shall ensure that prior to decommissioning any area, room or enclosure where the licensed activity has been conducted:

(a) the total surface contamination (non-fixed plus fixed) for nuclear substances listed in the table titled "Classes of Nuclear Substances" found in Appendix Y of REGDOC-1.6.1 Licence Application Guide does not exceed:

(i) 0.3 becquerels per square centimetre (0.3 Bq/cm2) for all Class A radionuclides;

(ii) 3 becquerels per square centimetre (3 Bq/cm2) for all Class B radionuclides; and

(iii) 30 becquerels per square centimetre (30 Bq/cm2) for all Class C radionuclides; averaged over an area not exceeding 100 square centimetres;

(b) the release of any area, room or enclosure containing fixed surface contamination in excess of the values listed in paragraph (a), is approved in writing by the Commission or person authorized by the Commission;

(c) all nuclear substances and radiation devices have been transferred in accordance with the conditions of this licence; and

(d) all radiation warning signs have been removed or defaced.
(2571-6)

13. Import and Export Restrictions
This licence does not authorize the licensee to import or export the following items as described in the schedule, Parts A and B, to the Nuclear Non-proliferation Import and Export Control Regulations, subject to any restrictions or exemptions as noted in each paragraph of the schedule:

(1) Special fissionable material, as described in paragraph A.1.1:
(i) Plutonium;
(ii) Uranium 233;
(iii) Uranium enriched in Uranium 233 or Uranium 235.
(2) Source material, as described in paragraph A.1.2:
(i) Uranium, containing the mixture of isotopes that occurs in nature;
(ii) Uranium, depleted in the isotope Uranium 235;
(iii) Thorium.
(3) Deuterium and heavy water, as described in paragraph A.1.3.
(4) Tritium, as described in paragraph A.1.5.
(5) Alpha-emitting nuclear substances, as described in paragraph B.1.1.1, including but not limited to:
(i) Actinium 225, 227;
(ii) Californium 248, 250, 252, 253, 254;
(iii) Curium 240, 241, 242, 243, 244;
(iv) Einsteinium 252, 253, 254, 255;
(v) Fermium 257;
(vi) Gadolinium 148;
(vii) Mendelevium 258, 260;
(viii) Neptunium 235;
(ix) Polonium 208, 209, 210;
(x) Radium 223.
(6) Radium-226, as described in paragraph B.1.1.16.
(2480-11)

14. Annual Compliance Report
The licensee shall, by March 31 of each year, submit to the Commission a written annual compliance report in the form specified at www.nuclearsafety.gc.ca/acr.
(2912-3)

15. Safeguards
The licensee shall implement and maintain a safeguards program in accordance with the requirements set out in REGDOC-2.13.1 Safeguards and Nuclear Material Accountancy.
(2410-1)

16. Financial Guarantee

The licensee shall maintain, at all times, a financial guarantee in respect of the activities authorized by this licence of a value set by the Commission and in a form acceptable to the Commission.
(2020-2)

17. Operation Limitations

Subject to any other condition of this licence and unless otherwise permitted by the prior written approval of the Commission or a person authorized by the Commission, the licensee shall carry out the licensed activities in accordance with the documents or parts thereof referred to in the Appendix: Licence Document(s).
(2917-7)

18. Inaccuracies Notification

The licensee shall report to the Commission or a person authorized by the Commission, as soon as is practicable, the discovery of any inaccuracy or incompleteness in the documents referred to in the Appendix: Licence Document(s).
(2920-6)

Digitally signed by Faille, Sylvain
DN: C=CA, O=GC, OU=CNSC-CCSN, CN="Faille, Sylvain"
Reason: I am approving this document
Foxit PDF Editor Version: 13.0.1

Designated Officer pursuant to paragraph 37(2)(c) of the Nuclear Safety and Control Act

Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

Work Instruction Document

How to:

Determine the Regulatory Approach for Non-standard Nuclear Substance and Waste Nuclear Substance Activities

This document provides instructions to assist in determining the appropriate regulatory approach for non-standard nuclear substance and waste nuclear substance activities

Revision Number: 000
e-Doc Number: **e-Docs Number**
Effective Date: March 9, 2021

Canada

DOCUMENT APPROVAL

Endorsed by: _____ Caroline Ducros, Director, Nuclear Processing Facilities Division, Directorate of Nuclear Cycle and Facilities Regulation	***Date:***

Endorsed by: _____ Nancy Greencorn, Director, Wastes and Decommissioning Division, Directorate of Nuclear Cycle and Facilities Regulation	***Date:***

Endorsed by: _____ Sylvain Faille, Director, Nuclear Substance and Radiation Devices Licensing Division, Directorate of Nuclear Substance Regulation	***Date:***

Endorsed by: _____ Claire Pike, Director, Operations Inspection Division, Directorate of Nuclear Substance Regulation	***Date:***

Approved by: _____ Karen Owen-Whitred, Director General, Directorate of Nuclear Substance Regulation	***Date:***

Approved by: _____ Kavita Murthy, Director General, Directorate of Nuclear Cycle and Facilities Regulation	***Date:***

REVISION HISTORY

The following table identifies the revision history of this document.

Revision Number	e-Docs Version	Change	Reason for Change	Approved by	Date
000	Published	Original.	N/A	Kavita Murthy and Karen Owen-Whitred	March 9, 2021
001					
002					

These activities and the associated process are subject to continuous improvement. The most recent version of this document is available on the CNSC intranet site.

If you have any comments or suggestions as to how this activity and/or its documentation can be improved, please contact *jonathan.schmidt@canada.ca*.

Version française: N/A

TABLE OF CONTENTS

1.0 Introduction 1
1.1 Principal Users of this Document 1
1.2 Purpose of this Process 1
1.3 Scope of this Process 1
1.4 Background 1
2.0 Instructions 2
Activity A: Conduct Safety and Control Area Analysis 2
Activity B: Develop Recommendation for Regulatory Approach 4
Activity C: Decide on Regulatory Approach 5
3.0 Tools and References 7
3.1 Tools 7
3.2 References 7
APPENDIX A – Definitions 8
APPENDIX B – Guidance for Determining Regulatory Approach 9

This page has been intentionally left blank.

1.0 INTRODUCTION

1.1 Principal Users of this Document

Principal users of this document are staff and management within the Directorate of Nuclear Cycle and Facilities Regulation (DNCFR), the Directorate of Nuclear Substance Regulation (DNSR) and the Technical Support Branch that are involved in licensing and compliance of nuclear substance and waste nuclear substance activities.

1.2 Purpose of this Process

The purpose of this process is to ensure a systematic and consistent application of a risk-informed methodology when determining a regulatory approach for non-standard nuclear substance and waste nuclear substance activities.

1.3 Scope of this Process

This process is triggered when a licence application submission (for a new licence, an amendment or renewal) is identified as a “non-standard nuclear substance activity” or a “waste nuclear substance activity” as defined below.

A **waste nuclear substance activity** is an activity in relation to waste nuclear substances that are not located at a Class I or Class II nuclear facility or a mine or mill.

A **non-standard nuclear substance activity** is an activity in relation to:

- Using, processing or managing unsealed nuclear substances in a containment level laboratory at quantities below 10^{15} Bq resident inventory and annual throughput (excludes nuclear medicine rooms and veterinary nuclear medicine as defined in APPENDIX A), or
- A novel use of a nuclear substance that has not been assessed under the *DNSR Risk-Informed Regulatory Program* [1]

The scope of this process includes the following:

- Conduct Safety and Control Area Analysis
- Develop Recommendation for Regulatory Approach
- Decide on Regulatory Approach

This process does not include:

- Licensing processes covered under *NSRDLD Licensing Actions Process Document* [2] and *Designated Officer Document Process Document* [3]

1.4 Background

This process was developed to ensure a systematic and consistent application of a risk-informed methodology when determining the regulatory approach for non-standard and waste nuclear substance activities. For more background information, please refer to the document *DNSR/DNCFR Working Group Recommendations with respect to the Regulatory Approach for Non-standard Complex NSRD Licensed Activities and Waste Nuclear Substance Licences* [4].

2.0 INSTRUCTIONS

Activity A: Conduct Safety and Control Area Analysis

Input: Licence application for nuclear substance activities or waste nuclear substance activities

Output: Safety and Control Area Analysis

Step #	Action
Responsibility: Licensing Officer	
A.1	Notify your Director that the regulatory approach for the licence application does not seem appropriate or is unknown for the proposed activities. Specific examples are: • applicant applied for a WNSL but it likely should have applied for a NSRD licence or vice versa • licensee applied for an amendment to its existing licence that seems outside the scope of the licence type • applicant inquired to the CNSC about what type of licence to apply for, for the proposed activities • applicant applied to use, process or manage an unsealed nuclear substance under 10^{15} Bq per year for a new isotope or with a novel process that has not been licensed previously by the CNSC
A.2	Communicate to the applicant/licensee that CNSC staff have received the application but are assessing if an alternative regulatory approach for the proposed activities is more appropriate.
Responsibility: Lead Director	
A.3	Assign project lead to recommend the appropriate regulatory approach for the requested activities. *Note: The project lead may not be assigned as the licensing officer once the regulatory approach is determined.*
Responsibility: Project Lead	
A.4	Review the licence application.
A.5	Provide a brief summary of the applicant/licensee's background in section 1 of the *Regulatory Approach Report* [5].
A.6	Provide a summary of the proposed licensed activities from the licence application in section 2 of the *Regulatory Approach Report* [5].

<table>
<tr><td>A.7</td><td>Answer the questions for each Safety and Control Area (SCA) and other matters of regulatory interest in section 3 of the Regulatory Approach Report [5] using the information in the licence application.
<table>
<tr><th>IF the answer is…</th><th>Then…</th></tr>
<tr><td>Not in the licence application</td><td>1) Ask the applicant/licensee the question(s) for the missing information.
2) Populate the answers in section 3 of the report.</td></tr>
<tr><td>In the licence application</td><td>1) Populate the answers in section 3 of the report.</td></tr>
</table></td></tr>
<tr><td>A.8</td><td>Based on the answers for each SCA, recommend the following:
a. Is the Safety and Control Area applicable? Yes or No
b. Should the Subject Matter Expert (SME) be involved in the initial application assessment? Yes or No
c. Should the SME be assigned as a Facility Assessment and Compliance Team (FACT) member? If yes, should the SME be assigned as a core or occasional member?
Note: the SME assigned to the FACT may not be the SME that assisted in determining the applicability of the SCA.</td></tr>
<tr><td>A.9</td><td>Send the report to the SMEs in the dedicated assessment team for review and comment.
The current dedicated team is outlined in the Dedicated Assessment Team Terms of Reference [6].</td></tr>
<tr><td colspan="2">Responsibility: Subject Matter Expert</td></tr>
<tr><td>A.10</td><td>Review the answers and recommendations for the relevant SCA or other matter of regulatory interest within section 3 of the report.
<table>
<tr><th>IF the SME does…</th><th>Then…</th></tr>
<tr><td>Not agree with the recommendations</td><td>1) Discuss concerns with the project lead and decide on changes to the recommendations together.
2) Revise the recommendations, if required.
3) Proceed to step A.11.</td></tr>
<tr><td>Agree with the recommendations</td><td>Proceed to step A.11.</td></tr>
</table></td></tr>
<tr><td>A.11</td><td>Respond to the project lead with approval of the recommendations.</td></tr>
<tr><td colspan="2">Responsibility: Project Lead</td></tr>
<tr><td>A.12</td><td>Summarize the outcome of the SCA analysis in table 1 within section 4 of the report.</td></tr>
</table>

Activity B: Develop Recommendation for Regulatory Approach

Input: Safety and Control Area Analysis

Output: Draft Regulatory Approach Report

Step #	Action
Responsibility: Project Lead	
B.1	Recommend the appropriate regulatory approach for the proposed activities using the guidance provided in APPENDIX B.
B.2	Document the recommended regulatory approach in section 4 of the report as instructed.
B.3	Provide an executive summary on page 4 of the report.

Activity C: Decide on Regulatory Approach

Input: Draft Regulatory Approach Report

Output: Approved Regulatory Approach Report

<table>
<tr><th>Step #</th><th>Action</th></tr>
<tr><td colspan="2">Responsibility: Project Lead</td></tr>
<tr><td>C.1</td><td>Send licensing and compliance director (if applicable) the draft regulatory approach report for review.</td></tr>
<tr><td colspan="2">Responsibility: Lead Director</td></tr>
<tr><td>C.2</td><td>Review proposed regulatory approach and determine whether they endorse the approach.
<table>
<tr><th>IF the Director…</th><th>Then…</th></tr>
<tr><td>Endorses the regulatory approach</td><td>1) Sign page 1 as the endorser.
2) Send to project lead</td></tr>
<tr><td>Does not endorse the regulatory approach</td><td>Provide feedback to project lead until project lead and Director agree.</td></tr>
</table></td></tr>
<tr><td colspan="2">Responsibility: Project Lead</td></tr>
<tr><td>C.3</td><td>Send the regulatory approach to the Director General of their Directorate.</td></tr>
<tr><td colspan="2">Responsibility: Director General</td></tr>
<tr><td>C.4</td><td>Review proposed regulatory approach.
<table>
<tr><th>IF the Director General…</th><th>Then…</th></tr>
<tr><td>Agrees with the regulatory approach
<u>AND</u>
The regulatory approach is to transfer the file to a division within a different directorate</td><td>Proceed to step C.5.</td></tr>
<tr><td>Agrees with the regulatory approach
<u>AND</u>
The regulatory approach is to keep the file within the directorate</td><td>1) Sign page 1 as approver.
2) Send approved report to the project lead.
3) Notify DNCFR/DNSR DG of Decision.
4) Proceed to step C.8.</td></tr>
<tr><td>Does not agree with the regulatory approach</td><td>Discuss with project lead and Director until everyone agrees on the regulatory approach.</td></tr>
</table></td></tr>
</table>

<table>
<tr><td colspan="2">Responsibility: DG of DNCFR and DNSR</td></tr>
<tr><td>C.5</td><td>Decide whether the proposed regulatory approach is appropriate.
<table>
<tr><th>IF the Director Generals do …</th><th>Then…</th></tr>
<tr><td>Not agree with the regulatory approach</td><td>1) Determine an alternative regulatory approach.
2) Revise section 4 of the report with the alternative regulatory approach.
3) Proceed to step C.6.</td></tr>
<tr><td>Agree with the regulatory approach</td><td>Proceed to step C.6.</td></tr>
</table></td></tr>
<tr><td>C.6</td><td>Sign page 1 of the report as approvers.</td></tr>
<tr><td colspan="2">Responsibility: Project Lead</td></tr>
<tr><td>C.7</td><td>Send the approved Regulatory Approach Report to the new licensing Division and notify the licensee/applicant of the results of the review.</td></tr>
<tr><td colspan="2">Responsibility: Licensing Director</td></tr>
<tr><td>C.8</td><td>Assign a licensing officer to the applicant/licensee.</td></tr>
</table>

3.0 TOOLS AND REFERENCES

3.1 Tools

The following tools have been developed to assist in carrying out this activity:

Item #	Tools	Associated Activity	Reference/Link
[5]	Regulatory Approach Report Template	All activities	e-Doc 6068746

3.2 References

Additional or related information is available in the following reference material:

Item #	Reference	Associated Activity	Reference/Link
[1]	N-7001 Risk Ranking of Use Types Under the DNSR Risk-Informed Regulatory Program	N/A	e-Doc 5874956
[2]	NSRDLD Licensing Actions Process Document	N/A	e-Doc 5346598
[3]	Designated Officer Document Process	N/A	e-Doc 5910579
[4]	DNSR/DNCFR Working Group Recommendations with respect to the Regulatory Approach for Non-standard Complex NSRD Licensed Activities and Waste Nuclear Substance Licences	N/A	e-Doc 6240851
[6]	Dedicated Initial Application Review Team Terms of Reference	Activity A	e-Doc 6337632
[7]	REGDOC-1.6.1, Licence Application Guide: Nuclear Substances and Radiation Devices	N/A	Link
[8]	Facility Assessment and Compliance Team – Terms of Reference	Activity B.1	e-Doc 5525909
[9]	Applicability of Standard licence conditions for Class I Facilities	Activity B.1	e-Doc 4658014
[10]	How to write an Licence Conditions Handbook	Activity B.1	e-Doc 4967591
[11]	How to Develop a Baseline and Facility Specific Compliance Plans	Activity B.1	e-Doc 5607066
[12]	Management of Nuclear Substances and Radiation Devices Performance Verification Program	Activity B.1	e-Doc 5975383

APPENDIX A – Definitions

Term	Definition
Waste Nuclear Substance Activity	Activities in relation to waste nuclear substances that are not located at a Class I or Class II nuclear facility or a mine or mill.
Non-Standard Nuclear Substance Activity	Activities in relation to: • Using, processing or managing unsealed nuclear substances in a containment level laboratory at quantities below 10^{15} Bq resident inventory and annual throughput (excludes nuclear medicine rooms and veterinary nuclear medicine), or • A novel use of a nuclear substance that has not been assessed under the *DNSR Risk-Informed Regulatory Program* [1]
Containment Level Laboratory	The quantity of unsealed nuclear substance used at a single time exceeds 500 times its corresponding annual limit intake (ALI) (refer to Appendix R of *REGDOC 1.6.1 Licence Application Guide: Nuclear Substances and Radiation Devices* [7] for a list of ALI).
Nuclear Medicine Room	Any area or enclosure where nuclear substances are prepared for, or administered to a person (via injection, inhalation or ingestion) for the purpose of diagnosing or treating disease and for human research studies (excluding medical diagnostic x-rays or the medical use of sealed sources for brachytherapy or teletherapy treatments).
Veterinary Nuclear Medicine	Administration of unsealed nuclear substances to animals for diagnosis or therapy.

APPENDIX B – Guidance for Determining Regulatory Approach

The following table provides guidance on choosing the regulatory approach options for each category within Table 2 of the Regulatory Report.

	Category	Factor	Guidance
Communication	CNSC Contact with Licensee:	Organizational Complexity	Does the licensee have a complex organization? Considerations include: large size of organization, many different licensed activities and locations, activities that are novel or with hazards that are changing over time, the number of interactions required to oversee the licensee's programs (one RSO vs. a licensee SPOC supported by managers in various departments) If the organization is complex, this licensee would benefit from having a single point of contact (SPOC) and clear roles and responsibilities for licensing and compliance verification.
	Use of a CNSC FACT	Subject Matter Experts	If there are more than 3 SMEs involved (refer to Table 1 of the Regulatory Report), consider selecting a FAC Team approach. For more information on a FAC Team approach, refer to *Facility Assessment and Compliance Team – Terms of Reference* [8]
Licensing	Type of Licence	Description of Licensed Activity	Review the proposed licensed activities and select the most suitable licence type. A NSRD licence is suitable when the proposed licensed activities are related to nuclear substances (as defined in section 2 of the *Nuclear Safety and Control Act)* below a resident inventory and annual throughput of 10^{15} Bq and/or a radiation device (as defined in the *Nuclear Substances and Radiation Devices Regulations)*. If a NSRD licence is suitable, select the use type that best applies to the licensed activities. For a list of use types refer to Appendix B of REGDOC-1.6.1, *Licence Application Guide: Nuclear Substances and Radiation Devices, Version 2* [7]. A WNSL may be suitable when the proposed licensed activities are related to waste nuclear substances. WDD should be consulted to confirm the WNS licence type.

		Licence consolidation	Does the licensee have several CNSC licences? If so, consider consolidating them into one licence as this could reduce the regulatory burden on the applicant and increase efficiency and effectiveness in regulating one consolidated high-level program. This may have the benefit of allowing a licensee to make frequent changes to their program without having to come to the CNSC for approval, as long as these changes are made within their approved high-level programs. Transitioning to a consolidated licence may require a phased approach in order to align the licensing and compliance programs of different licence types (Class I, Class II, NSRD, and WNSL). However, beware that consolidating NSRD and Class II licences into a single Class I licence or WNSL could increase the cost recovery fees for the licensee. CNSC staff can recommend licensees consolidate their licences but it is ultimately the licensee's decision.
	Licence Conditions	Complexity and Licence Type	Licence conditions need to be appropriate for the licence type and the complexity of the licensed activities: If a NSRD licence type is chosen, typically the licence conditions for the usetype should be selected. However, if the licensee is significantly complex that they would need a management system (i.e. a SME is required for the management system SCA) or the licensed activities requires a program for a SCA, consider using standard Class I Facility licence conditions. If a WNSL licence type is chosen, the standard Class I Facility licence conditions should be selected. For the list of LCs associated with each usetype, refer to LOUIS licence condition sets. For a list of standard Class I Facility LCs, refer to *Applicability of Standard licence conditions for Class I Facilities* [9].

	Licensing Basis	Type of Licence conditions	If standard Class I Facility licence conditions were chosen, consider using a Licence Conditions Handbook to document the licensing basis documents. Refer to *How to write a Licence Conditions Handbook* [10] for more information on a LCH. If usetype conditions were chosen, consider using the appendix to list all the licensing basis documents.
Compliance	Inspection Criteria	Licensing Basis	If a LCH was chosen, consider selecting a compliance matrix approach. A unique compliance matrix is developed for each inspection. It uses criteria from the applicable Regulations, the LCH and the licensee's programs and procedures. If a LCH was not chosen, consider selecting the worksheet approach. The same worksheet is used on each inspection. The worksheet contains criteria from the applicable Regulations and the licensee's procedures.
	Planning	SMEs	If a FACT approach was chosen, consider selecting a baseline and facility specific plan approach as a SCA focused inspection is potentially required. Refer to work instructions *How to Develop a Baseline and Facility Specific Compliance Plans* [11] for more information. If a FACT approach was not chosen, consider selecting the frequency approach. The frequency of baseline inspections is selected based on the usetype's risk profile and complexity of the licensed activities. Refer to Appendix A of *Management of Nuclear Substances and Radiation Devices Performance Verification Program* [12] for the list of baseline inspection frequencies for usetypes.
Divisions	Licensing and Compliance Divisions	Directorate Structure and Resources	Attention should be given to the organizational structure within a directorate and its available resources to carry out the licensing and compliance programs associated with the proposed licensed activities while considering the licensee's compliance history, if applicable, and the associated CNSC regulatory effort. This consideration should be reviewed with management input when deciding which division to recommend assigning the file.

		Technical Expertise	Where does the expertise and knowledge of the regulated activity reside? Are there similar activities regulated by the CNSC or is this a novel application? Select the directorate/division that would have the expertise to implement the regulatory approach. Areas of expertise could include: waste management practices, fuel cycle activities, isotope production, Nuclear Power Plant R&D, etc.