Canada's Nuclear Regulator

Class II Nuclear Facilities

Licence Application Guide: Class II Nuclear Facilities and Prescribed Equipment

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Licence Application Guide: Class II Nuclear Facilities and Prescribed Equipment
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Preface

This regulatory document is part of the CNSC's Class II nuclear facilities series of regulatory documents. The full list of regulatory document series is included at the end of this document and can also be found on the CNSC's website.

In accordance with the *Nuclear Safety and Control Act* and regulations made under it, a person must have a licence issued by the CNSC to perform any of the following activities:

- construct, operate or decommission a Class II nuclear facility
- possess, use, process, store, transfer, transport, import, export or abandon nuclear substances
- service Class II prescribed equipment

Regulatory document REGDOC-1.4.1, *Licence Application Guide: Class II Nuclear Facilities and Prescribed Equipment*, sets out requirements and guidance for applying for any Class II facility and/or prescribed equipment licence.

This document also consolidates and will supersede the following licence application guides:

- RD/GD-289, *Licence Application Guide, Class II Isotope Production Accelerators*
- RD/GD-120, *Licence Application Guide, Radiotherapy*
- RD/GD-207, *Licence Application Guide, Service Class II Prescribed Equipment*

While the use of the application form associated with this guide is not a specific requirement for licensing, it is intended to assist applicants in submitting complete and structured information to the Commission so that the request can be processed as quickly as possible. The application form is available on the CNSC's website. CNSC staff can provide additional guidance upon request; contact the CNSC at cnsc.info.ccsn@canada.ca.

For information on the implementation of regulatory documents and on the graded approach, see REGDOC-3.5.3, *Regulatory Fundamentals*.

The words "shall" and "must" are used to express requirements to be satisfied by the licensee or licence applicant. "Should" is used to express guidance or that which is advised. "May" is used to express an option or that which is advised or permissible within the limits of this regulatory document. "Can" is used to express possibility or capability.

Nothing contained in this document is to be construed as relieving any licensee from any other pertinent requirements. It is the licensee's responsibility to identify and comply with all applicable regulations and licence conditions.

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Licence Application Guide:
Class II Nuclear Facilities and Prescribed Equipment

1. Introduction

The licence requirements contained in this guide are based on the *Nuclear Safety and Control Act* (NSCA) and its regulations, which are administered by the Canadian Nuclear Safety Commission (CNSC), the organization that has regulatory authority for all nuclear facilities and uses of radioactive materials in Canada. Appendix A provides regulatory references for the information requested.

The NSCA authorizes the CNSC to issue licences to applicants who, in the opinion of the CNSC:

- are qualified to undertake the proposed licensed activity
- will make adequate provisions for the health and safety of persons, the protection of the environment and the maintenance of national security
- will take measures necessary to implement international obligations to which Canada has agreed

Each application should demonstrate that the applicant is capable of and committed to complying with all requirements under the NSCA, including maintaining an effective radiation safety program as required by the *Radiation Protection Regulations*.

This guide will help the applicant to provide the information the CNSC needs in order to make a determination of whether to issue a licence. The associated application form is tailored to different licensed activities or facility types, and is intended to aid the applicant in preparing and submitting a complete application.

This guide and its associated form may also be used to request the removal of commissioning restrictions in an operating licence ("routine operation amendment").

1.1 Purpose

This guide identifies the information to be provided in support of an application for a licence to:

- construct, operate or decommission a Class II nuclear facility
- operate Class II prescribed equipment not installed in a facility
- service Class II prescribed equipment
- possess, use, store, transfer, import or export a nuclear substance used in manual brachytherapy, incorporated in Class II prescribed equipment, or otherwise associated with the licensed activity

1.2 Scope

This document will be used:

- by applicants to prepare a licence application regarding a Class II nuclear facility and/or Class II prescribed equipment as defined in the *Class II Nuclear Facilities and Prescribed Equipment Regulations* (Class II regulations)
- by CNSC staff to assess the licence application

1.3 Relevant legislation

The following provisions of the NSCA and the regulations made under it are relevant to this document:

- *Nuclear Safety and Control Act*, subsection 24(4) and section 26
- *General Nuclear Safety and Control Regulations*, sections 3, 27, and subsections 29(1), 29(2)
- *Class II Nuclear Facilities and Prescribed Equipment Regulations*, sections 3, 4, 5, 6, 7, 21
- *Nuclear Substances and Radiation Devices Regulations*, section 3
- *Radiation Protection Regulations*, paragraph 4(a) and section 24
- *Packaging and Transport of Nuclear Substances Regulations, 2015*, section 40
- *Canadian Nuclear Safety Commission Cost Recovery Fees Regulations*, Part 2, Part 3, Part 5

2. About This Guide

The guide is divided into seven parts:

- Part A: General Information
- Part B: Activities and Facilities To Be Licensed
- Part C: Facility Construction
- Part D: Commissioning Plan
- Part E: Management System and Radiation Protection Program
- Part F: Routine Operation and Confirmation of Facility Design
- Part G: Decommissioning Plan

The CNSC has created an electronic application form to assist applicants in submitting the required information to the CNSC. The application form is available on the CNSC's regulatory documents web page.

Some parts or sections in this guide are not applicable to all licensed activities and facilities. Submit only the information that is relevant to the proposed activities and facilities. The dynamic nature of the electronic application form should ensure that only the relevant parts/sections are available for a given application type once Part A and B.1 are completed.

This symbol indicates important information that the applicant needs to consider before proceeding.

The CNSC is updating the technical content of the following regulatory guidance referenced in this document:

- GD-52, *Design Guide for Nuclear Substance Laboratories and Nuclear Medicine Rooms* [1]
  - The CNSC expects to post a draft for public consultation in spring 2020 under the title REGDOC-2.5.6, *Design Guide for Rooms where Unsealed Nuclear Substances are Used*.
- G-129, rev. 1, *Keeping Radiation Exposures and Doses "As Low As Reasonably Achievable (ALARA)"*[2]

    - The content has been updated and incorporated into draft regulatory document REGDOC-2.7.1, *Radiation Protection*. The CNSC posted REGDOC-2.7.1 for consultation in March 2019.
- G-91, *Ascertaining and Recording Radiation Doses to Individuals* [3]
    - The content has been updated and incorporated into draft regulatory documents REGDOC-2.7.1, *Radiation Protection* and REGDOC-2.7.2, Dosimetry, Volume I: *Ascertaining Occupational Dose*. The CNSC posted REGDOC-2.7.2 for consultation in April 2019.
- CNSC web pages titled Regulatory Expectations for Calibration of Survey Meters and Radioisotope Safety – Monitoring for Radioactive Contamination
    - The content has been updated and incorporated into draft regulatory document REGDOC-2.7.1, *Radiation Protection*. The web pages will be updated after REGDOC-2.7.1 is published.

See the CNSC's regulatory documents web page for more details.

3. Application Process

3.1 Application form

While the use of the application form is not a requirement for licensing, it may assist applicants in submitting complete and structured information to the CNSC so the request can be processed as quickly as possible. Any attachments should have a title and be cross-referenced to the sections of the application they relate to.

The application form is dynamic; the user's input determines which sections are displayed. Once sections A and B are completed, only sections of the form relevant to the user's licence request will be displayed. All of these sections are mandatory unless otherwise noted. Detailed instructions on how to complete the form can be found on the form itself.

3.2 Submitting an application

Before submitting an application to the CNSC for a new licence or renewal of an existing CNSC licence, the applicant must ensure the following:

- The application is complete.
- All supporting documents are attached, clearly identified and cross-referenced.
- Payment is enclosed if subject to the *Canadian Nuclear Safety Commission Cost Recovery Fees Regulations*.
    - To arrange payment by credit card, contact the CNSC Cost Recovery Group at 613-995-5894 or toll free at 1-888-229-2672.

Submit the complete application to the CNSC using the "submit" button embedded in the application form, or by email.

If submitting a paper copy of the completed application, send it to the CNSC at:

Canadian Nuclear Safety Commission
P.O. Box 1046, Station B
280 Slater Street
Ottawa ON K1P 5S9

Applicants should keep a completed copy of the application for their records. Applicants should be aware that all information submitted is subject to the provisions of the *Access to Information Act* and the *Privacy Act*. For more details, please see section A.14.

Some of the information required for licence issuance may be considered prescribed. Prescribed information, as it is defined in section 21 of the *General Nuclear Safety and Control Regulations*, may only be transmitted by secure means such as letter or courier. Guidance for the protection and transmission of prescribed information can be found in REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material* [4]

For additional information, contact the CNSC by:

- telephone (toll free): 1-888-229-2672
- fax: 613-995-5086
- email: cnsc.info.ccsn@canada.ca

3.3 Service standards

The CNSC strives to meet its published standards for licence application processing. The service standards on the CNSC's website specify expected licence processing times for applications with clear, relevant, precise, accurate and complete information. If applications are incomplete or unclear, processing times may exceed published standards.

3.4 Amending a licence

To request a licence amendment other than a routine operating amendment, the applicant must submit the following information, where applicable:

- a list of the changes to the information contained in the current licence
- a description of the effects that the proposed changes may have, or are expected to have, on land, areas, buildings, structures, components, equipment, systems or nuclear substances
- the proposed start date and expected completion date of any modifications described in the request

It is acceptable to request a licence amendment by email.

If information previously submitted to the CNSC has not changed, the applicant can refer to:

- information listed in the current licence appendix
- information previously submitted

Class II licensees must notify the CNSC whenever a change is made to the radiation protection program or to the design of the licensed facilities. The CNSC will review the change and determine if a licence amendment is required.

3.5 Renewing a licence

To request a licence renewal, the applicant must provide the information required by all relevant sections of this guide. As the application form is dynamic, selecting the "licence renewal" option in section B.1 of the form will ensure that only the relevant sections for renewing a licence are displayed.

If information previously submitted to the CNSC has not changed, the applicant can refer to:

- information listed in the current licence appendix
- information previously submitted

References to previously submitted material should, at a minimum, include the licence number under which it was submitted, the document title and date, and page/section numbers where the information can be found. References to the CNSC document number, if available, are preferred; document numbers can be found in the appendix of licence documents on existing licences.

3.6 Revoking a licence

The applicant may request a revocation of an existing licence by sending a request in writing to the CNSC. An email is acceptable. When requesting revocation of a licence to operate a remote brachytherapy afterloader or a decommissioning licence for any facility, licensees must complete a revocation request form. CNSC staff may contact the applicant if additional information is required.

3.7 Licence period

Consolidated operating licences are typically valid for a 10-year period. All other licences are typically valid for 5 years; however, the Commission or a designated officer, at their discretion, may issue a licence for a shorter or longer period. A specific licence period can be requested for long-term projects and may be granted by the Commission or a designated officer.

3.8 Transferring a licence

When requesting the transfer of an existing CNSC licence, the applicant must complete a licence transfer form. The completed form may be submitted to the CNSC by mail or by email at cnsc.forms-formulaires.ccsn@canada.ca.

3.9 Consolidated licences

The CNSC issues several types of consolidated licences, when one or more licensed activities are conducted under a single licence, for example, operation and servicing of a particle accelerator.

Due to the dynamic nature of the form, it is not necessary to explicitly apply for a consolidated licence. Complete sections A and B.1of the form, and the proper licence type will be selected automatically and the appropriate sections of the form will become available.

Licensees who currently hold more than one licence, and who wish to consolidate them, may make an application in writing (email is acceptable) to their licensing officer at the CNSC.

Part A: General Information

In this part of the application the CNSC requires information about the applicant, including complete contact information and proof of legal status.

A.1 Application Type

For organizations that do not currently hold a CNSC licence, select "New licensee".

For existing licensees, select "Existing licensee" and enter the first five digits of your CNSC licence number.

A.2 Language of Licence

Specify the official language(s) preferred for the licence.

A.3 Date Licence Required By

If the licence is required by a particular date, enter it in the provided space; otherwise, leave this blank. Licence applications are subject to service standards. However, whenever possible, the CNSC will endeavour to meet the requested date. For more information on service standards, see section 3.3.

A.4 Number of Bunkers or Rooms

Specify the number of bunkers or rooms affected by this licence application. If Class II prescribed equipment will be operated outside a fixed facility, enter the number of devices affected by the application.

Enter 0 (zero) in this field if the application is for a stand-alone licence to service Class II prescribed equipment throughout Canada.

A.5 Name of Applicant's Authorized Representative

Provide the name and title of the person who is submitting the application on behalf of the applicant. This person should have authority to act on behalf of the applicant. Applicant(s) wishing to notify the CNSC of changes in persons authorized to act for them should submit a Representatives of Applicants and Licensees form. Note: all new applicants must submit this form.

A.6 Applicant's Name and Business Address

Applicant

Submit the legal name of the organization or individual applying for the licence as it appears on the proof of legal status documentation, such as the proof of incorporation or sole proprietorship.

Name an individual as applicant only if that person is a sole proprietor or will be solely responsible for the licence.

Head office address

Provide the legal, physical address of the applicant's head office. The address should include the street name and number, the rural route number, the city, province or territory, and the postal code, as appropriate. A post office box address is not acceptable as a head office address.

Mailing address

Provide the mailing address if it is different from the head office address. The address should include the street name and number, the post office box or rural route number, the city, province, territory or state, the postal code and the country. A post office box is acceptable as a mailing address.

If no mailing address is given, the licence issued in response to the application will be mailed to the head office address.

A.7 Financial Contact Person

Provide the name and contact information of the person to be contacted for licence fee payments. If the applicant is exempt from payment of fees under the *Canadian Nuclear Safety Commission Cost Recovery Fees Regulations*, the applicant does not need to complete this section.

A.8 Radiation Safety Officer

Applicants who do not currently hold a CNSC licence must provide the name and contact information of the radiation safety officer (RSO). The RSO is normally the person responsible for the management and control of the licensed activities in accordance with paragraph 15(b) of the *General Nuclear Safety and Control Regulations* and is normally considered authorized to act for the applicant or licensee. For more information regarding RSOs, see section E.1.2 of this guide.

The applicant must also complete the Representatives of Applicants and Licensees form. The form should be submitted concurrently with the application if possible.

A.9 Alternate Radiation Safety Officer

For applicants who do not currently hold a CNSC licence, provide the name and contact information of the alternate radiation safety officer, if applicable.

A.10 Signing Authority

For applicants who do not currently hold a CNSC licence, provide the name and contact information of the signing authority.

The "signing authority" is the person who has prepared the application and who has been delegated the authority to apply for this specific licence on behalf of the applicant or licensee. This person certifies that the information submitted is true and correct to the best of the person's knowledge.

Since the signing authority is the only person who can request changes to a licence, it is recommended that the RSO be designated as the signing authority.

The applicant must provide this information using the Representatives of Applicants and Licensees form. This form should be submitted to the CNSC concurrently with the application if possible.

A.11 Applicant Authority

For applicants who do not currently hold a CNSC licence, provide the name and contact information of the applicant authority.

A senior manager must be identified as the applicant authority. The applicant authority must be a duly authorized representative of the applicant and have sufficient authority to direct the human and financial resources required to address any issue of non-compliance identified by the CNSC.

The applicant must provide this information using the Representatives of Applicants and Licensees form. This form should be submitted to the CNSC concurrently with the application if possible.

A.12 Proof of Legal Status

For applicants who do not currently hold a CNSC licence, provide proof of legal status by submitting proof of incorporation or sole proprietorship.

If the applicant is a public institution, specify the title of the enabling legislation (act) under which the institution was created, if applicable.

If the applicant is a corporation, submit proof of incorporation and an official corporation profile report, including:

- the corporation's legal name
- the corporation number
- the date of incorporation
- the registered office address

Federally incorporated companies under the *Canada Business Corporation Act* can obtain an official corporation profile report from Industry Canada. For provincially incorporated corporations, similar profile reports are available from the provincial department where the corporation was registered.

Canadian applicants should submit the business number identifier assigned to them by the Canada Revenue Agency. Applicants from outside of Canada should provide the equivalent information available through their local jurisdiction.

A.13 Financial Guarantees

Subsection 24(5) of the NSCA allows the Commission to request a financial guarantee. If required, provide the value and form of the financial guarantee. Consult the CNSC website for more information about financial guarantees for class II nuclear facilities and prescribed equipment.

A.14 Public Access to Information

Specify whether any part of this application is subject to a request for exemption from public access as described below.

As a federal government institution, the Commission is subject to provisions of the *Access to Information Act* (AIA) and the *Privacy Act*. Pursuant to subsection 4(1) of AIA, every Canadian citizen or permanent resident has access to documents under the control of a government institution. Consequently, all information submitted with a licence application, subject to the exceptions listed in the AIA, can be made available to the public. Requests for exemption should be made in writing to the CNSC, detailing the applicant's reasons for such an exemption. Requests for exemption may be denied if justification is not sufficient.

- If information may be made public, the applicant should check the box "No exemption requested" on the application form.
- If requesting that the information submitted not be disclosed, the applicant should check the "exemption requested" box on the application form and reference the items to be exempted, and provide justification for the request.

Part B: Activities and Facilities to be Licensed

B.1 Licence Type and Phase

Once the user selects the appropriate licence type and phase, the form will only display the sections that are relevant to the licence being requested.

Applicants who wish to licence fixed facilities typically go through the licensing phases in the following order: construction, commissioning, operation and, if applicable, decommissioning.

Applicants wishing to operate Class II prescribed equipment outside of a fixed facility (portable accelerators, geophysical logging accelerators, etc.) are not required to complete the construction or commissioning phases and may apply directly for an operation licence.

Applicants wishing to service Class II prescribed equipment and who do not also hold a CNSC operating licence or do not intend to operate prescribed equipment may apply directly for a licence to service.

For commissioning/operation licence applications, applicants have the option to concurrently apply to include servicing of the prescribed equipment by the operator's staff. This option is selected later in the form.

Modifications to a currently licensed facility may require a construction licence and commissioning activities if the modifications will result in changes to the doses or dose rates surrounding the facility (shielding change, beamline change, etc.). Contact your CNSC licensing officer for more information.

In addition to selecting the licence type/phase, specify whether nuclear substances or activated components will be included or affected by the application (this includes nuclear substances incorporated in Class II prescribed equipment).

Indicate if this application is for renewal of a current CNSC licence; if so, enter the current CNSC licence number.

B.1.1 Construction

Indicate the sector under which the desired facility to be constructed falls and then select one of the resultant facility types. At this time, because the CNSC does not issue consolidated construction licences, it is only possible to make one selection. Applicants who wish to construct multiple facility types concurrently will need to submit a separate application for each.

Although details of the management system and radiation protection program are not required for a construction licence, the CNSC recommends that if this information exists, it be submitted at the construction phase. This information must be submitted before a CNSC operating licence can be issued. If submitting this information with the construction application, select the appropriate checkbox.

B.1.2 Commissioning (with option to service)

Indicate the sector under which the facility to be commissioned falls and then select one of the resultant facility types. In instances where limited research is to be carried out utilizing Class II prescribed equipment that is primarily being used for other applications, the prescribed equipment should be licensed according to its primary intended use.

While it is possible to consolidate commissioning and servicing activities, applicants who wish to commission multiple facility types will need to submit a separate application for each.

Applicants who wish to perform servicing operations on the prescribed equipment while it is being commissioned must either enter the current CNSC licence number that allows servicing of the prescribed equipment or select the checkbox requesting that a consolidated commissioning and servicing licence be issued. Applicants must demonstrate that they meet the requirements for a licence to service by filling in the relevant sections of the form, which will be displayed when the checkbox is selected.

B.1.2.1 Replacing Class II equipment in an existing facility

Licensees wishing to replace Class II prescribed equipment in fixed facilities without otherwise modifying the facility design may bypass the construction licensing phase and apply directly for a commissioning licence, provided that the following conditions are met:

- For isocentric facilities, the isocentre has not moved; it may also be acceptable if the isocentre has moved towards an area adjacent to the room/bunker that is below grade or has

zero occupancy. For such cases, contact your CNSC licensing officer to confirm that it is acceptable to skip the construction phase.
- The maximum field size of the radiation beam is the same or smaller.
- The energy or accelerating potential is the same or lower than that of the equipment that is being replaced.

Note: A subset of the information that is normally required at the construction phase will still need to be submitted (workload, dose rate calculations, etc.) concurrently with the commissioning licence application. Selecting the "Replacing Class II equipment in an existing facility" checkbox will ensure that the relevant sections of the form are displayed.

B.1.3 Operation (with option to service)

Indicate the sector under which the desired facility or Class II prescribed equipment to be operated falls, then select one of the resultant facility types. In instances where limited research is to be carried on utilizing prescribed equipment that is primarily being used for other applications, the prescribed equipment should be licensed according to its primary intended use.

While it is possible to perform operation and servicing activities under a single consolidated licence, applicants (other than those in the medical sector) who wish to operate multiple facility types must submit a separate application for each facility type. Medical sector applicants may apply to operate multiple facilities or perform manual brachytherapy in a single application.

Applicants who wish to perform servicing operations on the prescribed equipment as well as operate it must either enter the current CNSC licence number that allows servicing of the prescribed equipment or select the checkbox requesting that a consolidated operation and servicing licence be issued. Applicants must demonstrate that they meet the requirements for a licence to service by filling in the relevant sections of the form, which will be displayed when the checkbox is selected.

B.1.4 Decommissioning

Indicate the sector under which the desired facility to be decommissioned falls, and then select one of the resultant facility types. At this time, because the CNSC does not issue consolidated decommissioning licences, it is only possible to make one selection on the form. Applicants who wish to decommission multiple facility types will need to submit a separate application for each.

Licensees wishing to decommission a brachytherapy remote afterloader do not require a decommissioning licence. However, information regarding the disposal method of any nuclear substance encompassed by the licence, as well as evidence that the facility is safe for uncontrolled occupancy, must be submitted concurrently with the request to revoke the operating licence. See section 3.6 for more information.

Decommissioning implies servicing of Class II prescribed equipment, an activity that requires a CSNC licence. Applicants must either enter the current CNSC licence number that allows servicing of the prescribed equipment or select the checkbox indicating that additional information will be submitted. Applicants must demonstrate that they meet the requirements for a licence to service by filling in the relevant sections if the form, which will be displayed when the checkbox is selected.

B.1.5 Licensed activities for sealed nuclear substances

Select all activities that are applicable to the nuclear substances (including activated components) included in or affected by this application. Note the following definitions:

Activity	Definition
Possess	To have the care and control of a nuclear substance. Possession does not necessarily imply ownership.
Use	To utilize a nuclear substance regularly or frequently for its radioactive properties.
Store	To possess a nuclear substance that is not used on a regular basis, or at all. Not to be used for nuclear substances that are only stored for short periods of time between frequent uses.
Transfer	To change the possession of a nuclear substance from one person or entity to another, where both are located within Canada. Typically both parties must be licensed.
Process	To combine radionuclides with other elements (which may include other radionuclides) to form chemical compounds, typically radiopharmaceuticals. Processing is not permitted during the commissioning phase.
Import	To bring a nuclear substance into Canada from outside Canada's international borders. See note below.
Export	To send a nuclear substance outside of Canada from within Canada's international borders. See note below.
Abandon	(Only available for geophysical logging accelerators) To remove a nuclear substance from regulatory control. The nuclear substance is not transferred to another licensee. Typically the nuclear substance is abandoned in a location where it cannot be accessed (e.g., several hundred metres below ground level).

Notes

- Import and export of tritium or deuterium in any form (e.g., embedded in the targets of neutron generators) requires a separate import/export licence under the *Nuclear Non-proliferation Import and Export Control Regulations*, regardless of the activities selected in this section.
- Export of Category I or II sources requires a separate export licence as per the International Atomic Energy Agency's *Code of Conduct on the Safety and Security of Radioactive Sources* [5]. For categorization of sealed sources, see REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources and Category I, II, and III Nuclear Material* [4].

B.2 Licensed Locations

B.2.1 Fixed facilities: Principal location of use or storage or both

Provide the address of the location where the facility will be constructed, operated or decommissioned. The address should, at a minimum, consist of a room identifier, street name and number, city, province and postal code (a building identifier may also be designated, if applicable/necessary). Use the definitions provided in guidance document GD-52, *Design Guide for Nuclear Substance Laboratories and Nuclear Medicine Rooms* [1] to specify the classification of the rooms where equipment will be constructed, operated or decommissioned. If necessary, additional locations can be added in section B.2.6

All applicants who wish to carry out a licensed activity at a location that is not currently licensed by the CNSC must submit evidence that the applicant is the owner of the site. If the premises are rented or leased, submit a letter from the owner of the site confirming that the applicant has the authority to construct or operate a Class II nuclear facility at the site (as applicable) and that the site owner has no objections to the licensing of this location for the use of prescribed equipment, or use or storage of nuclear substances.

B.2.2 Class II prescribed equipment not in a fixed facility - Principal location of use or storage or both

For the operation of prescribed equipment not installed in a facility, provide the address or location where the equipment will be operated and/or stored. If necessary, additional locations can be added in section B.2.6

All applicants who wish to carry out a licensed activity at a location that is not currently licensed by the CNSC must submit evidence that the applicant is the owner of the site. If the premises are rented or leased, submit a letter from the owner of the site confirming that the applicant has the authority to operate a Class II nuclear facility at the site (as applicable) and that the site owner has no objections to the licensing of this location for the use of prescribed equipment, or use or storage of nuclear substances.

B.2.3 Sealed sources or activated components - Principal location of use or storage or both

Provide the address of the location where sealed sources or activated components will be used or stored. The address should, at a minimum, consist of a room identifier, street name and number, city, province and postal code (a building identifier may also be designated, if applicable). Specify the classification of the rooms where the sources and/or activated components will be used or stored using the definitions provided in GD-52, *Design Guide for Nuclear Substance Laboratories and Nuclear Medicine Rooms* [1]. If necessary, additional locations can be added in section B.2.6.

All applicants who wish to carry out a licensed activity at a location that is not currently licensed by the CNSC must submit evidence that the applicant is the owner of the site. If the premises are rented or leased, submit a letter from the owner of the site confirming that the applicant has the authority to construct or operate a Class II nuclear facility at the site (as applicable) and that the site owner has no objections to the licensing of this location for the use of Class II prescribed equipment, or use or storage of nuclear substances.

B.2.4 Unsealed nuclear substances - Principal location of processing, use or storage

Provide the address of the location where unsealed nuclear substances will be processed, used or stored. The address should, at a minimum, consist of a room identifier, street name and number, city, province and postal code (a building identifier may also be designated, if applicable). Specify the classification of the rooms where the unsealed nuclear substances will be processed, used or stored using the definitions given in GD-52, *Design Guide for Nuclear Substance Laboratories and Nuclear Medicine Rooms* [1]. If necessary, additional locations can be added in section B.2.6.

All applicants who wish to carry out a licensed activity at a location that is not currently licensed by the CNSC must submit evidence that the applicant is the owner of the site. If the premises are rented or leased, submit a letter from the owner of the site confirming that the applicant has the

authority to construct or operate a Class II nuclear facility at the site (as applicable) and that the site owner has no objections to the licensing of this location for the use of Class II prescribed equipment, or use or storage of nuclear substances.

B.2.5 Servicing

Servicing licences issued by the CNSC typically allow servicing of Class II prescribed equipment throughout Canada. Check the box to select this option if applicable.

If servicing of Class II prescribed equipment will only be carried out at a single location, provide the address of this location. The address should, at a minimum, consist of a room identifier, street name and number, city, province and postal code (a building identifier may also be designated, if applicable). Additional locations can be added in section B.2.6. Additionally, if applicable, indicate whether nuclear substances and/or activated components will be used or stored at this location.

B.2.6 Additional locations

If Class II prescribed equipment, nuclear substances or activated components included in or affected by this application will be used or stored at locations other than the principal locations listed in sections B.2 through B.2.5, provide the address of these locations. The address should, at a minimum, consist of a room, street name and number, city, province and postal code (a building identifier may also be designated, if applicable). If applicable, specify the classification of the rooms where nuclear substances will be used, processed or stored using the definitions in GD-52, *Design Guide for Nuclear Substance Laboratories and Nuclear Medicine Rooms* [1].

All applicants who wish to carry out a licensed activity at a location that is not currently licensed by the CNSC must submit evidence that the applicant is the owner of the site. If the premises are rented or leased, submit a letter from the owner of the site confirming that the applicant has the authority to construct or operate a Class II nuclear facility at the site (as applicable) and that the site owner has no objections to the licensing of this location for the use of Class II prescribed equipment, or use or storage of nuclear substances.

For each additional location, indicate whether nuclear substances will be processed, used or stored at that location (activated components: used/stored only). Additional locations may be added using the "+" or "-" buttons.

B.3 Class II Prescribed Equipment and Nuclear Substances

B.3.1 Class II prescribed equipment

Section 10 of the *Class II Nuclear Facilities and Prescribed Equipment Regulations*, states: "No person shall use Class II prescribed equipment unless

(a) it is a certified model; or
(b) it is used in accordance with a licence that authorizes its use for development purposes or for scientific research that is not conducted on humans."

For more information about certification of prescribed equipment, the applicant can refer to CNSC regulatory document REGDOC-1.5.1 *Application Guide: Certification of Radiation Devices or Class II Prescribed Equipment* [6].

No person is permitted to use uncertified Class II prescribed equipment unless it is exempt from certification under the Class II regulations.

For each type of Class II prescribed equipment to be licenced, submit the following information:

1. the CNSC certificate number
2. the name of the manufacturer
3. the model name
4. if applicable, the isotope and maximum activity of each source contained in the Class II prescribed equipment
5. for all accelerators, the beam type and maximum energy
6. for medical and veterinary accelerators, the maximum dose rate at isocentre
7. for other accelerators, the maximum beam current
8. the type of servicing or maintenance the applicant intends to perform on the Class II prescribed equipment, for example:
   a. none
   b. preventive maintenance – limited to basic servicing activities and periodic inspections
   c. corrective maintenance – limited to preventive maintenance, plus troubleshooting and limited repairs or adjustments
   d. extensive servicing – corrective maintenance, plus replacement of major components, refurbishment of Class II prescribed equipment, installation or replacement of the prescribed equipment or nuclear substances contained within the prescribed equipment, or dismantling of the prescribed equipment

B.3.2 Nuclear substances – Sealed sources and activated components

Some sealed sources, such as those used for manual brachytherapy treatments, are not incorporated in Class II prescribed equipment. With time, replacement or spent sources will be in the applicant's possession. In addition, other non-exempt sealed sources may also be in the applicant's possession. If these sources are not already covered by an existing CNSC licence, specify the following information for each source:

- the name of the manufacturer
- the model name of the source
- the isotope and maximum (actual) activity of the source

Specify whether activated components from an accelerator or other Class II prescribed equipment will be stored at the site.

B.3.3 Accelerator targets – Isotope production

Specify the targets to be used for isotope production. At a minimum, the information should include:

- if known/applicable, the manufacturer's part or model number
- the nuclear reaction used to produce the desired isotope with each target
- the state of the desired isotope
- the target material

- the maximum beam current and bombardment time per run
- the maximum end of beam (EOB) yields per run

Table 3 illustrates a typical format for submitting this information.

Table 3: Sample isotope production accelerator target table

Target part no.	Nuclear reaction	Product state	Material	Maximum beam current (µA)	Bombardment time (minutes)	Maximum EOB yield (GBq)
Zr-ABC-1	$^{89}Y(p,n)^{89}Zr$	Metal	Rhodium/body, Havar/window, aluminum/body	30	120	2
FGH-212-C11	$^{14}N(p,\alpha)^{11}C$	Gas	Havar/window, aluminum/body	40	60	150
TUV-213-F-20	$^{18}O(p,n)^{18}F$	Liquid	Havar/window, niobium/body	100	45	185

Part C: Facility Construction

This part describes the information the applicant must submit to allow for a technical assessment of an application to construct a Class II nuclear facility. This includes the facility shielding design, proposed workload, design dose targets, instantaneous dose rates, annual dose calculations and facility safety systems. Where applicable, this may also include isotope processing facilities and other special requirements, such as those for pool-type irradiators.

C.1 Facility Design

The applicant must demonstrate that the facility design provides for the adequate protection of workers, members of the public and the environment.

Once the licence to construct is issued, the facility must be built in accordance with the proposed design. Any subsequent changes to the facility design will require a licence amendment subject to Commission or designated officer approval.

C.1.1 Facility plans and drawings

Submit plan and elevation drawings (to scale) of the proposed facility. Those plans and drawings must show:

1. the direction of north
2. the scale of the drawings (e.g., 50:1, 1 cm per m)
3. the location of the facility with respect to nearby occupied or potentially occupied areas
4. the location and purpose of the adjacent areas, such as public areas, offices, laboratories, change rooms, washrooms and storerooms, including the areas above and below the facility; for each room, specify the room number and its name, or give its description (this information will be used to determine the occupancy factors of each area or room as required in section C.1.2)

5. the position and orientation of Class II prescribed equipment and associated devices within the boundary of the facility
6. the location, type, thickness and density of the shielding materials used on all sides of the facility, including floor and ceiling
7. the location and dimensions of access ways, exits, service ducts, and other penetrations and voids in the shielding
8. if applicable, the direction of the primary beam
9. for isocentric units, the plane of beam rotation
10. if a shielded entrance door is proposed, the type, thickness and arrangement of the shielding materials incorporated into the door

The plans and drawings must contain sufficient information to allow CNSC staff to evaluate the proposed facility. CNSC staff require drawings showing the vertical and two orthogonal lateral cross sections of the facility. The drawings must be to scale in order to allow CNSC staff to perform independent verifications of applicants' shielding calculations. If possible, submit these drawings in electronic format, provided there is sufficient resolution to magnify areas of interest and the scale is maintained.

C.1.2 Classification of adjacent areas

Submit occupancy types and occupancy factors of all areas adjacent to the facility.

The purpose of each area adjacent to a Class II nuclear facility, its occupancy type and its occupancy factor are used to determine the facility shielding requirements.

Specify the intended use (such as office space, corridors and consoles) of all areas adjacent to the facility, including areas above and below the facility. Based on the planned use of each area and an evaluation of the shielding, classify each area as follows:

- **Non-controlled**: Access is not restricted.
- **Controlled**: Access is restricted to trained and authorized personnel only.
  - For each controlled area, describe the proposed access control measures, which should be commensurate with the radiation doses that may be incurred in that area (allowed dose levels will be based on whether or not the applicant declares their workers to be NEWs– see section E.2.2).
- **Exclusion**: An exclusion area must have access controls interlocked to the Class II prescribed equipment so that no one can gain access to the area when the equipment is in operation; the interlock systems required are described in section C.2.1.

Designation of an "exclusion area" is only acceptable for completely enclosed spaces with entrances interlocked with the equipment to terminate irradiation if anyone attempts to access the area.

The occupancy factor for each area is the fraction of the facility's normal operating day during which a person might reasonably be expected to occupy a given area. Occupancy factors are usually selected from standard reference values such as those in table B1 in the National Council on Radiation Protection's NCRP Report No.151, *Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities* [7]. Such values are generally conservative. If the applicant elects to use a lower value for a particular area such as for the roof above a treatment room, the applicant must provide the rationale for using that occupancy factor.

In general, use of very low occupancy factors requires some form of physical barrier that restricts access to the area.

Occupancy types and occupancy factors of areas adjacent to the facility may be incorporated directly into a table of annual doses, provided they are clearly identified in the table. Ensure that those areas can be identified on the submitted plans and drawings.

C.1.3 Workload

Submit an estimate or a calculation of the anticipated maximum annual workload of all Class II prescribed equipment at the facility.

The workload represents the anticipated amount of use of the Class II prescribed equipment over a defined period, usually one year, in a manner that can be related directly to the radiation doses incurred by persons occupying adjacent areas over that period. In general, this requires an estimate of the total time the prescribed equipment will be on, or the source exposed, combined with some measurement or estimate of the radiation dose rates at defined reference locations under typical operating conditions.

The workload is used to verify the adequacy of the facility's shielding design; hence, a workload calculation must take into account all operating activities, namely:

- the equipment's intended use (radiography, radiotherapy, etc.)
- research/development
- quality assurance
- post-servicing verification

The applicant should describe any assumptions made and specify the value of any parameter used.

The maximum anticipated workload submitted by the applicant will become the upper limit allowed once a licence is issued. Exceedance of this annual workload must only occur with the prior approval of the CNSC.

C.1.3.1 Particle accelerators

Medical or veterinary accelerators

The workload of medical or veterinary accelerators and teletherapy machines should clearly distinguish between:

- operation at different photon energies
- operation using electrons
- operation in different modes ("flattening-filter-free", etc.)

The number of monitor units (MUs) required to deliver the dose for each of the above scenarios must also be provided.

If intensity-modulated radiation therapy (IMRT), stereotactic, or extended distance treatments are planned, also specify:

- the energy used
- the fraction of the total primary beam workload delivered using these techniques
- the expected average IMRT factor (ratio of MUs delivered to primary beam dose at isocentre)

Industrial accelerators

For electron accelerators such as those used for industrial radiography, material processing or sterilization, the dose rate (in Gy/min or equivalent) at a fixed location within the beam (e.g., at 1 m beyond the X-ray target), multiplied by the total hours per year of each operating activity listed in section C.1.3, will generally allow the applicant to characterize the workload in a manner that enables dose estimates.

Research accelerators

In research facilities, the radiation types, energies and dose rates produced by an accelerator will vary greatly depending on the design and configuration of the accelerator, the types of charged particles being accelerated, the accelerating potential and beam current, the target design, and the materials of the target and of its housing. In such cases, the applicant should perform a detailed analysis of the intended use of the accelerator and of activities listed in section C.1.3 to characterize the workload in a manner that enables dose estimates. Depending on the type of accelerator, the methods described above may be most appropriate.

C.1.3.2 Class II prescribed equipment containing sealed sources

An estimate of the workload can be obtained based on the total time the sources would typically be exposed, and the sources' activity. For the purpose of shielding design, this estimate must be converted into an equivalent dosimetric quantity, denoted in gray (Gy) at 1 m from the source over one year.

In addition to the type of operations listed in section C.1.3, the workload for irradiators and brachytherapy remote afterloaders must also take into account the periodic calibration of the equipment.

C.1.3.3 Isotope production accelerators

For each isotope to be produced, list the maximum total quantity that will be possessed under the licence at any one time and the maximum total quantity for each isotope produced in one calendar year. The determination of the maximum quantity that may be produced should be based on:

- the maximum end-of-beam (EOB) quantity that can be produced using any target
- the number of targets used and the number of production runs per day
- the time between production and shipment of the product to the end user
- the amounts that will be kept in the facility for quality control or as waste
- the isotope's half-life

In the workload table, specify the nuclear reaction that yields the desired product and the beam/target combinations used. Specify the maximum EOB quantity produced per run, as well as annual quantities produced and total annual bombardment time. Include in the workload the time used in carrying on the applicable activities listed in section C.1.3.

C.1.4 Instantaneous dose rates and annual dose calculations

Submit detailed calculations showing the maximum instantaneous dose rate and annual dose expected in each area listed in section C.1.2. Provide the equations, describe the assumptions and specify the value of each parameter used in the calculations. If applicable, include both neutron and gamma doses.

For occupied areas, CNSC regulatory guide G-129, rev. 1*Keeping Radiation Exposures and Doses "As Low As Reasonably Achievable (ALARA)"* [2], recommends that doses be at or below:

- 1 mSv/yr for NEWs
- 0.05 mSv/yr for non-NEW staff and members of the public

If any annual dose is calculated to be higher than that recommended in G-129, submit justification explaining why it is not socially/economically feasible to reduce the dose.

The CNSC will not accept dose calculations that are greater than the dose limits set out in section 13 of the *Radiation Protection Regulations*.

In the submission:

1. each calculation point should be associated with a location identified on the facility plans and drawings
2. at least one calculation point must be located just outside the entrance barrier to the facility, such as a door or light curtain
3. each calculation should take into account:
   a. the facility design workload as per section C.1.3
   b. the composition and shielding properties or transmission factors of barriers (including shielded doors, where applicable) for the types and energies of the radiation produced by the Class II prescribed equipment
   c. the distribution of the workload between the different beam orientations, the use factor where applicable
   d. the distribution of the workload between the different operating modes (energies, beam particle types, with/without filters/targets, etc.) where applicable
   e. the maximum instantaneous dose rate that the equipment is capable of for each operating mode
   f. the occupancy type (controlled/uncontrolled/exclusion) and occupancy factor for each of those areas
   g. the radiation dose limit (for NEWs or the public) in effect at each calculation point
   h. the contribution from different components of the radiation fields produced by the equipment, including the primary beam, head leakage, scatter and neutrons (Note: Neutron dose rate and annual dose calculations are not required for electron accelerator facilities operating at photon energies less than 10 MV or any high-energy (≥10 MV) electron accelerator facilities that are being retrofitted for low energy (<10 MV) use)
   i. the contribution from all sources of radiation, such as the maximum dose rate at a point in a common hallway between two facilities
   j. radiation scatter down entrance mazes, ducts and other penetrations in the shielding
4. calculation parameters should be based on standard reference values for factors such as shielding tenth-value layers, equipment head leakage rates, scatter factors and occupancy factors. If these are unavailable, for example, because of variations in the composition and

density of heavy concrete, or non-standard parameters such as occupancy factors less than 1/40th are used, the applicant should justify the values used

5. instantaneous dose rate at each calculation point should be calculated using the most conservative (i.e., worst-case) operating conditions such as maximum energy, maximum instantaneous dose rate or current, minimum attenuation by shielding, and maximum source activity; these calculations must:
   a. provide reference values for comparison with the measured dose rates that will be obtained during a radiation survey
   b. identify areas where posting of a radiation warning sign may be required pursuant to the requirements of section 21(b) of the *Radiation Protection Regulations*
6. if Monte Carlo simulations or other commercial shielding calculation software are used, the applicant should:
   a. identify the code, such as MCNPX, and other software packages used, such as Alice 91, as well as the key input parameters used in the simulation or calculations
   b. submit a brief description of the simulation such as geometry, materials, source definition, tallies, doses, graphics
   c. submit copies of input and output files
   d. specify shielding techniques employed, such as importance and weight windows
   e. include mesh tally graphics

C.1.5 Additional requirements for isotope production facilities

C.1.5.1 Instantaneous dose rates and annual dose calculations – Accelerator

In addition to the information required under section C.1.4, the calculations must take into account the source term. The source term is a calculation or an estimate of the prompt gamma, X-ray and neutron radiation produced during bombardment for each beam/target/reaction combination.

For isotope production facilities, the calculated dose rate and annual dose estimates to facility staff should explicitly include an estimate of:

1. whole-body (effective) annual doses in mSv/year from:
   a. operation of the Class II prescribed equipment, including commissioning
   b. routine rebuild of accelerator targets or maintenance of activated components
   c. if applicable, transfer of product from the accelerator to the isotope processing facilities
   d. any processing activity carried out under the licence
   e. packaging of isotopes for shipment
   f. if applicable, routine and potential accidental environmental releases, such as stack releases
2. annual extremity (equivalent) doses in mSv/year from:
   a. routine rebuild or replacing of accelerator targets or maintenance of activated components such as dees and stripping foils
   b. processing of isotopes, quality control, packaging and contamination cleaning activities

The following parameters should also be used in calculating the dose from the transfer of product from the accelerators to the isotope processing facilities, the processing activities and the packaging of isotopes for shipment:

- type and activity of the products
- proximity to source

- shielding in hot cells, lead glass shield, and storage or packaging containers
- duration of each procedure
- number of procedures per year

C.1.5.2 Description of the isotope production targets

Submit the following information:

- the drawings and the technical specifications of the isotope production targets
- an evaluation of the potential release of radioactivity following the failure of a target

If developing experimental targets, also submit:

- the quality assurance program for the design and testing of the targets to ensure that they are fully compatible with the intended irradiation conditions
- any additional safety procedure to accommodate all anticipated experimental configurations

C.1.5.3 Description of the isotope processing facilities

The sections of this guide pertaining to the processing of isotopes are only applicable when the accelerator and the associated processing facilities are integrated into a single radiopharmaceutical production site. If the radioisotopes produced by the accelerator are shipped to and processed at a site other than the accelerator facility, then processing should be licensed separately under the *Nuclear Substances and Radiation Devices Regulations*.

Submit drawings illustrating the layout of the processing facilities, including:

- the scale
- the direction of north
- the location of all key components of the processing system, including hot cells
- the location of the processing facility with respect to the accelerator and other nearby occupied or potentially occupied areas
- if applicable, the location of the transfer lines used for delivering isotopes from the accelerator to the processing facility, including details of any shielding, radiation warning indicators or signs installed along the length of the transfer lines

If possible, submit those plans and drawings in electronic format, provided there is sufficient resolution to magnify areas of interest and the scale is maintained.

In addition, submit a description of:

- the tubing, valves and fittings connecting the target to the processing stations external to the accelerator, including the manufacturer's specifications showing that the tubing and connectors are compatible with the chemicals conveyed, the pressures used and the radiation doses expected; include in the description the specifications for gas regulators and other critical components of the transfer system
- the chemical processes used, including the methods and equipment for handling the radioisotopes at each stage of production; the applicant must demonstrate that components are physically and chemically compatible with the substances handled

- the ventilation system of the radiochemical fume hoods and hot cells, including details of their filter media

The applicant should also submit a completed Design Assessment Form for Nuclear Substance Laboratories and Nuclear Medicine Rooms as detailed in CNSC guidance document GD-52, *Design Guide for Nuclear Substance Laboratories and Nuclear Medicine Rooms* [1].

C.1.5.4 Description of radiochemical hot cells and processing stations

Submit a description of the hot cells or other shielded containers used for hot chemistry.

In addition to the description, also submit calculations or the results of the measurements taken to demonstrate that the shielding incorporated in the hot cells or containers is adequate to ensure that doses to staff and the public will be ALARA. Include a description of any remote handling tool, portable shielding or shielded container used to further reduce doses.

C.1.5.5 Transfer and processing of isotopes

Submit a detailed description of the transfer and processing of isotopes, including:

- the method used to transfer the product from the target to the processing facility
- the duration of the transfer process
- a description of the processing procedures, including the sequence of steps, the locations where the isotopes are handled, the chemical agents and the equipment used, and the estimated duration of each step
- a description of the product quality control activities, including the activity of product used (in Bq), the method used to verify its activity, the sequence of steps, the locations where each isotope is handled and the estimated duration for each step of the quality control activities
- a description of the packaging process prior to transport

C.1.5.6 Other design considerations – Isotope production facilities

For isotope production facilities, submit the following additional information:

- a description of the maintenance program for processing facilities (routine rebuild or replacing accelerator targets, maintenance of activated components such as dees and stripping foils, etc.)
- if applicable, the location of any holding tank or other containment system used to trap isotopes in the event of an accidental release due to a ruptured target window or release inside a hot cell
- if applicable, the location, dimensions and shielding thickness of any radioactive waste storage pit that is an integral part of the facility

C.1.6 Beam limiting

If some sections of the facility walls, ceiling or floor are not designed to adequately shield adjacent areas from the primary beam, it will be necessary to physically restrict aiming the primary beam in these directions. Submit a description of the electrical, mechanical or other physical means used to prevent aiming the beam towards these barriers.

If the restriction of the primary beam direction is through the use of software or firmware "virtual beam stops", as in the case of robotic arm radiotherapy devices, identify in the architectural drawings submitted the areas of the walls, ceiling or floors in the facility that are not primary barriers. For accelerators that use beam stops, such as Faraday cups, submit their description and an evaluation of their adequacy. Include in the description an estimate of the radiation dose rates in areas adjacent to the accelerator when the beam stop is operational.

C.1.7 Evaluation of air activation and ozone production - Industrial electron beam accelerators and pool-type irradiators

Submit an evaluation of the adequacy of the proposed ventilation system, taking into account:

- the concentration of ozone or other toxic gases
- the anticipated radiation doses to staff from nitrogen-13 and oxygen-15

C.1.8 Additional requirements for pool-type irradiators

For pool-type irradiators, submit information demonstrating compliance with the following sections of American National Standards Institute (ANSI) standard N43.10-2001: *Safe Design and Use of Panoramic, Wet Source Storage Gamma Irradiators (Category IV) and Dry Source Storage Gamma Irradiators (Category II)* [8]:

- section 7: Operational safety features
- section 9: Source storage
- section 10: Control identification
- section 11.4: Underwater tools and servicing

C.1.9 Technical security measures – Construction

For medium and high-risk sealed sources (IAEA Categories I-III), the applicant must have technical security measures in place to prevent unauthorized access to these sources and protect against their illegal removal or sabotage.

Applicants must detail the planned technical security measures to be implemented prior to receipt of nuclear substances. The full site security plan is not required for construction licences. However, the details of the intrusion detection system and of the physical barriers that will be put in place must be submitted. See REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources and Category I, II, and III Nuclear Material* [4], for details on:

- physical barrier and intrusion detection requirements
- design of the site security plan
- secure transmission of this information to the CNSC

Details of the technical security measures are considered prescribed information and may only be transmitted by secure means such as mail or courier. Electronic submission of this information to the CNSC is not currently supported.

C.2 Safety Systems – Nuclear Facilities

Submit a description of the facility safety systems.

The systems listed in this section of the document are either explicitly required by the Class II regulations or are industry standards. Use of any substitute system must be justified by demonstrating that it provides an equivalent level of safety.

In addition to the requirements for each individual safety system as described in the following sections, the applicant must also submit:

- a drawing showing the location of each safety system component listed in all subsections below with respect to the physical layout of the Class II prescribed equipment and, if applicable, of the isotope processing facilities
- a flow chart describing the operation of the following:
  - last person out (LPO) button(s)
  - the door or entrance interlocks
  - the emergency stops that are external to the Class II prescribed equipment
  - any other switch, sensor or additional door interlock to be incorporated into the entrance interlock and LPO circuit

The flow chart should describe the conditions/inputs necessary for proper activation of the LPO button, door or entrance interlocks and emergency stops external to the Class II prescribed equipment, and the results/outputs when each system is tripped.

Subsection 15(14) of the Class II regulations provides that the provisions regarding entrance interlocks (subsection (2)), pre-irradiation alarms (subsection (3)); and emergency stop buttons (paragraphs (9)(a) and (c)), do not apply to a particle accelerator if it meets at least one of the following criteria:

- Its radiation dose rate at 30 cm is not greater than 200 µSv/hour with the equipment operating in a manner that produces the maximum dose rate as limited either by its characteristics or interlocks, and it is in a room with a lock and that can be unlocked and entered only by persons authorized by the licensee.
- Its radiation dose rate at 30 cm is not greater than 25 µSv/hour with the equipment operating in a manner that produces the maximum dose rate as limited either by its characteristics or interlocks.

C.2.1 Entrance interlocks

Submit a description of the entrance interlocks and LPO system. The system must adequately protect against unintended exposure to personnel and members of the public. Consequently, the following requirements must be met:

1. There must be an interlock at every entrance to a room where Class II prescribed equipment will be operated (and any other exclusion area) that terminates irradiation if the door is opened while the prescribed equipment is in operation. This interlock must require the last person leaving the area to:
   a. activate the circuit via an actuator (commonly referred to as the LPO switch) inside the area
   b. and then, within a specified time, close the door to transition to the ready-state or “armed” condition
2. The LPO switch should be in a location that allows that person, while activating the switch, to verify that no one else remains inside the area prior to starting the irradiation.

   a. If there is no location within the area that allows for a clear view of the entire area, the applicant must implement additional measures to ensure that the entire area is clear before irradiation commences.
   b. Such measures may include adding other LPO switches at different locations, adding convex mirrors where needed, or taking other measures that provide an equivalent level of safety.
3. The entrance interlock must be designed such that reopening of the door terminates or prevents irradiation until the sequence described above is repeated; furthermore, it should be designed such that any defect or component failure in the system will prevent operation of the Class II prescribed equipment and cause it to "fail safely", that is, to revert to a safe state.
4. Doorless entrances must retain the same operational capability as described above.
   a. However, with doorless entrances, the physical door interlock switch at the entrance to the exclusion area may be replaced by other devices, such as electric eyes, active infrared sensors or motion detectors located at the entrance or within the entrance maze.
   b. Such systems will be evaluated on a case-by-case basis, and the applicant must demonstrate that they provide the operational capability and level of safety equivalent to that of a physical door.

C.2.2 Irradiation state indicators

Submit a description of the irradiation state indicators, such as warning lights, identified in the facility plans. The applicant must demonstrate that the irradiation state warning display clearly indicates the status of the Class II prescribed equipment and whether or not it is safe to enter the room where it is located.

Irradiation state indicators must be:

- installed at each entrance to any room where Class II prescribed equipment will be operated
- clearly visible from the entrance of the facility in all ambient light conditions
- located inside any potentially occupied enclosed area within the facility, such as equipment rooms, and above or beside the entrance leading into the facility
  - if there are multiple entrances, a single warning display at a central location may suffice, provided that it is clearly visible from all points within that area

Irradiation state indicators should:

- flash or illuminate in a clearly visible manner when the Class II prescribed equipment is ON or when radioactive sources are exposed
- be consistent in design, colour, wording, location and operation, for all facilities at a given site
  - any wording or symbol used to indicate the state of irradiation, such as "beam ON", "beam OFF", "source exposed", and "source shielded" should be the same for all facilities of that type at a given site
  - where the colour of a light also serves as an indicator of the state of irradiation (such as green for "beam OFF" or "source shielded" and red for "beam ON" or "source exposed"), these colours should be the same for all facilities at a given site

The applicant may install additional indicators, such as source position, radio frequency (RF) ON, KV imaging ON, magnet ON, and so on, provided they do not jeopardize the effectiveness of the radiation warning system.

C.2.3 Pre-irradiation alarms

Submit a description of the audible pre-irradiation alarm. The purpose of the pre-irradiation alarm is to warn persons working in the exclusion area that irradiation will commence soon and that they must either exit that area or, if this is not possible, activate an emergency stop device to prevent irradiation. Consequently, the duration of the alarm must be sufficient for a person inside the area to activate an emergency stop device (section C.2.4). This alarm must sound before an irradiation is initiated, regardless of whether the exclusion area has been accessed since the previous irradiation.

An applicant must install a pre-irradiation alarm in every facility that is not used on persons and does not satisfy the exemption requirements of subsection 15(14) of the Class II regulations.

Applicants may propose other alarm systems if they can demonstrate that they provide an equivalent level of safety. Such proposals will be evaluated on a case-by-case basis.

C.2.4 Emergency stop buttons or devices

Submit a description of the design of all emergency stop buttons or equivalent devices. Every facility must be equipped with easily identifiable (coloured red, labelled, etc.) latching-type push buttons, or equivalent devices, that can be used in an emergency to immediately cause the Class II prescribed equipment to revert to a safe state.

These devices must be designed so that once activated, the prescribed equipment cannot be restarted from the control console without the emergency stop device first being reset from the location where it was activated.

For Class II prescribed equipment that does not satisfy the exemption described in section 15(14) of the Class II regulations, emergency stop devices must be located:

- at the control console
- on the inside of each entrance to the facility
- on both sides of the Class II prescribed equipment (except for brachytherapy remote afterloaders)
- for brachytherapy remote afterloaders, on the afterloader unit itself

The emergency stop devices must be located where they are unobstructed and easily accessible. With isocentric equipment, they must not be in the equipment's primary beam. For source-based equipment, moving towards the source of radiation should not be necessary in order to activate an emergency stop device.

Since all walls of a facility housing a robotic arm radiotherapy accelerator are considered primary shielding barriers, there must be one emergency stop device on each wall.

Depending upon the size and configuration of the facility, additional emergency stop devices may be required to ensure that they are readily accessible from all locations within the facility, including any enclosure located inside the facility such as an equipment room.

C.2.5 Radiation monitoring devices – General

All facilities containing Class II prescribed equipment that incorporate a sealed source, as well as all isotope production accelerators, must be equipped with a monitoring device independent of the prescribed equipment to warn facility staff of the presence of abnormally high radiation levels in the event the prescribed equipment does not return to its safe state when the facility door is opened.

Radiation monitoring devices must have a battery backup or be connected to the site emergency power supply to ensure that they continue to function in the event of a power failure.

Submit a description of the facility radiation monitoring devices, including the make, model and sensitivity of detector, and the backup power system.

A radiation monitor of this type is also recommended, but is not mandatory, for accelerator facilities.

C.2.5.1 Class II prescribed equipment incorporating sealed sources

Submit a description of the facility radiation monitoring devices. The radiation monitoring devices must:

- be capable of detecting when the source is not in the fully shielded position
- produce an audible alarm at the entrance to the room if the door is opened when the source is in an unshielded position
- operate independently from the Class II prescribed equipment
- be capable of continuously monitoring radiation dose rates
- have alarm thresholds appropriate to each area being monitored so they are not activated while the source is in the shielded position

Should the source not retract to its fully shielded position, the dose rate at the radiation monitoring device location would vary greatly depending on its location relative to the source, the orientation of the Class II prescribed equipment and the exact location where the source has jammed. Consequently, the radiation monitoring device must be sensitive enough to detect radiation levels as low as the normal ambient level with the source in its fully shielded position, while still remaining operational under the expected maximum exposure conditions. The alarm threshold should be adjusted to the lowest level that does not result in an alarm when the source is in the fully shielded position. Specify the monitoring thresholds proposed and justify their choice in terms of maintaining radiation doses ALARA.

C.2.5.2 Isotope production accelerators

Submit a description of the facility radiation monitoring devices.

The radiation monitoring devices must:

- be installed in the accelerator vault, the hot cells, the ventilation system and the isotope processing stations
- be capable of continuously monitoring radiation dose rates
- produce audible and visible alarms when detecting abnormally high radiation dose rates

- have alarm thresholds appropriate to each area being monitored so that they are not activated by dose rates expected under normal operating conditions
- in accelerators other than self-shielded accelerators, be interlocked with the access doors to prevent their opening if the radiation level inside the vault – or, if applicable, the hot cells – exceeds a pre-set value

Specify the thresholds proposed and justify the choice of these thresholds in terms of maintaining radiation doses ALARA.

C.2.6 Viewing system – Medical facilities

Submit a description of the proposed viewing system that would permit continuous observation of the treatment room.

A viewing system may consist of a closed-circuit television (CCTV) system or a shielded viewing window.

If a CCTV system is used, describe the actions to be taken should the system malfunction. If a shielded viewing window is used, include a radiation transmission calculation through the window as part of the dose rate and annual dose calculations.

C.2.7 Tools and equipment for stuck source emergencies

This applies to brachytherapy remote afterloaders and teletherapy machines.

Submit a list of the tools available in the facility to deal with emergencies such as stuck sources. The list may include T-bars, source handling tools, cutters and shielded containers.

In brachytherapy remote afterloader and teletherapy facilities, the tools required to deal with these situations must be available whenever the Class II prescribed equipment is used.

C.2.8 Radioisotope release monitoring and containment – Isotope production facilities

Submit a description of the system to monitor the containment and record releases of radioactive substances into the environment, and to warn the operator in the event of releases above normally expected levels.

The monitoring system should include radiation detectors installed in the exhaust ventilation systems from the hot cells, in the radioisotope processing stations and in the accelerator room.

The system should also incorporate an alarm that notifies the operator of abnormally high readings from these detectors, with adjustable alarm thresholds set to levels that are appropriate for each location.

If applicable, also submit a description of the systems to prevent or delay the release of gases from failed targets such as hold-up tanks or delay lines.

C.2.9 Ventilation airflow monitoring system – Isotope production facilities

Submit a description of the ventilation monitoring system.

A ventilation monitoring system must be installed in the hot cells, the radioisotope processing areas and the accelerator vaults.

The ventilation monitoring system should ensure that the required air flows and pressure differentials are maintained, and should warn workers in those areas and the operator if it fails.

C.2.10 Personnel contamination monitoring system – Isotope production facilities

Submit a description of the contamination monitoring system.

A personnel contamination monitoring system such as a hand and foot monitor unit should be installed:

- at each entrance to any area where isotopes are processed or handled
- at the common entrance to multiple connected laboratories and rooms, provided measures are in place to ensure that all normal access and egress is via this entrance

Specify the monitor sensitivity as per manufacturer specifications or include an analysis showing that its sensitivity is adequate for detecting contamination from the isotopes being handled based on the background radiation of the laboratory.

C.2.11 Pulsed dose rate brachytherapy afterloader remote alarm

If the pulsed dose rate brachytherapy afterloader control panel is not continuously monitored by staff during treatment, a remote alarm system must be installed to warn staff of any interruption of the treatment or unauthorized access to the treatment room.

Submit a description of the remote alarm system, including:

- a drawing illustrating the location of the control panel and nursing station relative to the brachytherapy treatment room
- the type and location of the remote audible alarm
- a flow chart or functional description of the remote audible alarm system
- confirmation that, once activated, it can only be reset from the treatment room

C.3 Other Requirements

The applicant must submit the information listed in the sections below when applying for a construction licence.

C.3.1 Public information program

Submit the plan for informing persons living in the vicinity of the facility of:

- the nature and characteristics of the facility
- the anticipated effects on the environment, and the health and safety of persons that may result from the facility’s operation

A public information program and disclosure protocol may be required for certain types of Class II nuclear facilities, such as pool-type irradiators and isotope production accelerators. See section D.1.1 and REGDOC-3.2.1 *Public Information and Disclosure* [9], for more information.

C.3.2 Preliminary decommissioning plan

Submit the facility preliminary decommissioning plan.

The plan should contain the following information:

- an overview of the buildings, structures, components, systems and equipment that will be affected by the decommissioning
- an outline of the main radiological and chemical hazards that may still exist at the end of operations
- the anticipated final end state of the facility such as installation and operation of new Class II prescribed equipment or release of the site for non-radiation-related uses
- an outline of how decommissioning will be done, who will do the work and how radioactive materials, nuclear substances and other hazardous substances will be identified, segregated and disposed of
- an estimate of the time and cost required to complete decommissioning following the end of facility operations

The applicant will have to apply for a facility decommissioning licence once the Class II prescribed equipment reaches the end of its operating life as set out in part G of this guide. A detailed final decommissioning plan will be required at that time.

However, early planning and provision for the decommissioning activities is essential. Consequently, applicants should submit a preliminary decommissioning plan when applying for a construction or operating licence. This plan should be reviewed at each licence renewal during the operating life of the facility.

Part D: Commissioning Plan

This part describes the information an applicant must submit to obtain an operating licence for the purpose of commissioning. This includes a confirmation that:

- the facility has been constructed according to the specifications submitted with the construction licence application
- the safety systems have been installed at the locations specified in that application

Applicants must also provide a description of:

- the tests that will be performed to verify that the safety systems are operational
- the radiation survey that will be performed to verify the adequacy of the shielding

D.1 Facility Design Implementation – General

Submit the plan to confirm that the facility has been built according to its design specifications. This plan should include the following:

1. a stipulation that safety devices must be tested and verified prior to any other commissioning activity, and that records will be kept of all safety device testing performed during commissioning
2. a description of the tests to be performed to ensure that safety devices are functioning as intended; those tests must be performed on the following safety devices:
   a. the door interlock and last person out (LPO) time delay system
   b. all irradiation status indicators
   c. the pre-irradiation alarm, if applicable
   d. all emergency stop buttons and devices
   e. all radiation monitors and alarms
   f. the viewing system, if applicable
   g. any electrical or mechanical stops installed to limit beam orientation, if applicable
   h. the radiation warning system, including function of the audible alarm and battery backup, if applicable
   i. any other installed safety devices
3. the name and title of the person who will be responsible for planning and supervising the safety system tests, room survey, acceptance tests and commissioning tests – if it is not the facility radiation safety officer, describe the person's training and experience, and indicate their position and responsibilities in the facility's organization
4. emergency instructions to be followed to avoid injury and minimize radiation exposure to persons in the event of a malfunction of the Class II prescribed equipment or its related safety devices during commissioning
   a. for source-based radiotherapy applicants, these instructions should include provisions for dealing with a stuck source emergency
   b. the instructions must include the name of the persons who will be responsible for directing remedial actions
5. a description of the precautions taken to ensure occupational safety during the tests (e.g., electrical, fire, handling of hazardous materials)
6. confirmation that the density, composition and thickness of the shielding conform to the specifications described in the construction application and that all required safety systems have been installed in the locations specified in that application; this confirmation must be submitted by the applicant and include confirmation by both the applicant and the contractor after the construction is completed
7. performance of a radiation survey to verify the adequacy of the shielding; the plan for the survey should specify:
   a. the physical and administrative controls used to restrict access to the area during the survey
   b. where measurements will be taken, including all accessible areas adjacent to the facility where dose and dose rate were estimated
   c. the verification of dose and dose rate estimates in those areas
   d. the radiation detection instruments used for the survey, as well as their characteristics
   e. the conditions and operating parameters of the equipment during the survey
   f. whether photon or neutron radiation or both will be measured; a neutron survey must be performed for electron accelerators with a photon beam energy $\geq$ 10 MV or for low-energy accelerators in facilities whose maze has only one leg; neutron surveys are not mandatory, but are recommended for all other electron accelerators

g. for equipment with external radiation beams, radiation measurements beyond primary barriers will be performed with no other material in the beam path other than the barriers themselves
h. for equipment with external radiation beams, radiation measurements beyond secondary barriers will be performed with material in the beam path that is the same as or similar to that which will be irradiated under routine operation conditions, and at the same location

8. for source-based equipment, measurements to confirm the manufacturer's specified maximum equipment leakage dose rates with the source in the shielded (radiation off) position
9. an estimation of the proposed commissioning workload and, if applicable, a plan to address cases in which this workload may exceed the estimated routine operating workload that would be delivered over the same time period – if such a situation exists, include an explanation of what will be done to ensure that annual doses to persons in surrounding areas will not exceed the doses specified in section C.1.4

D.1.1 Medical and veterinary facilities

D.1.1.1 Accelerators

In addition to the requirements in section D.1, the commissioning plan should stipulate that the applicant will:

- take all dose measurements using the maximum dose rate at the isocentre, as well as maximum photon energy and field size
- take measurements of dose rates in the immediate vicinity of the gantry head due to activation, under conditions that represent an average treatment day
- verify the functionality of virtual beam stops for robotic arm radiotherapy facilities, if applicable

D.1.1.2 Brachytherapy afterloaders

In addition to the requirements in section D.1, the commissioning plan should stipulate that the applicant will take all dose measurements with no phantom and using the maximum source activity, with the sources in the most adverse orientation with respect to the barrier.

D.1.1.3 Source-based teletherapy facilities

In addition to the requirements in section D.1, the commissioning plan should stipulate that the applicant will:

- take all dose measurements using the maximum field or aperture size
- take dose measurements on teletherapy machine units with independently rotating heads using the minimum distance between the source and the primary barrier

D.1.2 Isotope production facilities

In addition to the requirements in section D.1, the commissioning plan should stipulate that the applicant will:

- confirm the stack height and dimensions
- confirm that all components of the release monitoring and containment systems are functional

- specify the target material irradiated during the radiation survey

For self-shielded cyclotrons, in addition to the requirements in section D.1, the commissioning plan should stipulate that the applicant will:

- perform dose rate measurements at the external surface of the cyclotron and at any potentially occupied area within the accelerator room
- confirm that the interlock or device designed to ensure closing of its shielding is operational
- confirm the shielding integrity

D.2 Facility Design Implementation – Isotope Processing Facilities

In addition to the requirements in section D.1, if radioisotope processing is encompassed by the licence, the plan should include:

- confirmation that the design of the laboratory conforms to the specifications described in the design assessment form for nuclear substance laboratories and nuclear medicine rooms
- a description of the tests to be performed on any interlock or other safety system associated with the hot cells or other processing equipment
- performance of air balancing measurements to confirm that the ventilation rates and pressure differentials are adequate
- a description of measurements to be taken to confirm the adequacy of the radiation shielding incorporated into the hot cells and along the transfer lines
- a plan to verify the extremity dose estimates submitted under section C.1.5.1, preferably through the use of extremity dosimetry on both hands of personnel during commissioning of the processing facilities

If it was not already submitted during the construction phase, applicants must submit a completed design assessment form for nuclear substance laboratories and nuclear medicine rooms, available in CNSC guidance document GD-52, *Design Guide for Nuclear Substance Laboratories and Nuclear Medicine Rooms* [1].

Part E: Management System and Radiation Protection Program

This section describes the information the applicant must submit regarding the following safety and control areas (SCAs):

- management system
- radiation protection
- human performance management
- waste management
- security
- packaging and transport
- fitness for service

More information about SCAs can be found on the CNSC's regulatory documents web page. The documents submitted to the CNSC, such as the policies and procedures required in the following sections, will form part of the licensing basis – that is, they will be referenced as part of the licence and their contents will be binding on the licensee. Licensees are required to notify the

CNSC whenever changes are made to these documents. Where possible, using position titles in policy/procedure documents instead of names may facilitate the management of your licence(s).

E.1 Management System

E.1.1 Public information program – Pool-type irradiators and isotope production accelerators

Submit a copy of the facility's public information program and disclosure protocol.

In addition to the public information required in section C.3.1, licence applicants for a pool-type irradiator or isotope production facility must maintain a public information program and disclosure protocol.

For more information about public information programs and disclosure protocols, please refer to REGDOC-3.2.1 *Public Information and Disclosure*.

E.1.2 Radiation safety officer job description

Every licensee who operates or services Class II prescribed equipment must have a radiation safety officer (RSO) certified by the CNSC. See regulatory document REGDOC-2.2.3 *Personnel Certification: Radiation Safety Officers* [10], for more information about the certification process. New applicants must certify an RSO within 60 days of receiving an operating or servicing licence. RSOs of licensees holding a CNSC construction licence are not required to be certified, as construction licences do not allow possession of nuclear substances or operation of Class II prescribed equipment.

Submit the RSO job description, which should include:

1. the required qualifications for the position
2. the authority to stop any activity related to the operation of a Class II nuclear facility or servicing of Class II prescribed equipment that might result in an unsafe situation or a non-compliance with the *Nuclear Safety and Control Act* (NSCA), the regulations or the licence
3. the responsibilities of the RSO, which may include:
   a. taking all reasonable precautions to protect the environment, and the health and safety of facility personnel and the public
   b. overseeing the implementation of the facility radiation protection program
   c. acting as the primary contact with the CNSC for licensing and compliance matters
   d. identifying radiation safety problems or concerns and implementing appropriate corrective actions
   e. ensuring compliance with CNSC regulatory requirements
   f. reporting regulatory non-compliances to the CNSC
   g. acting as the signing authority for CNSC licences
   h. developing procedures and policies related to radiation safety and training
   i. preparing the budget for radiation safety and related training
4. the time and the resources allocated to the RSO in order to carry out the duties of the position

The requirement for a certified RSO does not apply in respect of a Class II nuclear facility for which a person who has duties equivalent to those of an RSO is designated and who is certified under subsection 9(2) of the *Class I Nuclear Facilities Regulations*.

E.1.3 Organizational management

Submit a detailed description of the organizational management structure as it relates to radiation safety, including:

1. job titles of the persons responsible for:
   a. managing and operating the Class II prescribed equipment and handling the nuclear substances encompassed by the licence
   b. establishing and maintaining an adequate and effective quality assurance program
   c. developing and maintaining quality control procedures and tests to verify that the tests are effective, and are performed regularly and correctly
2. radiation safety related functions, responsibilities and authority of each position listed above
3. an organizational chart showing the lines of reporting and communication between all applicant representatives, including the RSO and senior management
4. management's accountability and responsibility for safety, for example:
   a. developing a learning-driven safety culture, including encouragement of a questioning attitude, promotion of a "no-blame" environment, and willingness to change
   b. promoting the value placed on safety culture, including balancing production pressure and safety, and encouraging staff to take responsibility for their own safety

E.1.4 Radiation safety committee

Submit the applicant's procedures and program currently in place to ensure the appropriate oversight and review of the effectiveness of the radiation safety program. Normally, oversight and overview of the radiation safety program are the responsibility of a radiation safety committee (RSC) or equivalent body. If applicable, submit the terms of reference or mandate of the RSC, or those of an equivalent body. Establishing the RSC is optional, but if there is none, the applicant should explain who has the level of authority and responsibility equivalent to that of an RSC.

Where applicable, the RSC (or equivalent) terms of reference should include:

1. the frequency of the meetings (should be at least once a year)
2. the job titles of the members of the RSC, and their roles
3. the name/job title of the person/body to whom the RSC reports, and how often
4. the roles of departments and services, and the operational activities overseen by the RSC
5. where applicable, the RSC's responsibilities with respect to:
   a. reviewing and approving a budget for radiation safety and related training
   b. reviewing and approving procedures and policies for radiation safety and training
   c. reviewing the effectiveness of the radiation safety program, including:
      i. outstanding items from the last management review meeting
      ii. results of internal and external audits
      iii. feedback from staff relating to program deficiencies
      iv. regulatory compliance
      v. outcomes of the corrective actions implemented or the recommendations for improvement

   d. reviewing all radiation safety related incidents
   e. acting in an advisory role to the RSO and management
6. the obligation to maintain records of the meetings
7. the number and job titles of the RSC members who must be in attendance in order for quorum to be met

E.1.5 Reporting requirements

Submit the policy and/or procedure describing how reportable occurrences are reported to the Commission within the required time period.

The policy should specify:

- the job title of the person responsible for filing the report
- the occurrences or events that must be reported to the CNSC in accordance with section 29(1) of the *General Nuclear Safety and Control Regulations* (GNSCR)
- the requirement for keeping a record of the report

The procedure should state that event reports must contain (in accordance with section 29(2) of the GNSCR) a description of:

- the event and its probable cause
- the date, time and location of the event
- the effects on the environment, the health and safety of persons and the maintenance of security that have resulted or may result from the event
- the effective dose and equivalent dose of radiation received by any person as a result of the event
- the actions taken or proposed with respect to the event

E.1.6 Quality assurance program

Submit the quality assurance (QA) program as it applies to radiation safety at the facility. Every applicant for a licence to construct, operate or decommission a Class II nuclear facility, or operate or service Class II prescribed equipment, must have a quality assurance program in place to ensure that the licensed activities are carried on in accordance with the NSCA, the regulations made pursuant to the NSCA, and the licence. The QA program should, at a minimum, address the following aspects of the licensed activities:

- conformance with the applicant's operating policies and procedures referenced in the licence
- the equipment, items and activities to which the program applies
- the periodic verification of the operation of safety systems and control mechanisms, including the procedures used to perform these verifications
- the provisions for reviewing and updating documentation, including manuals, policies and/or procedures because of equipment modifications or operating experience

Periodic evaluations of the radiation safety program by internal or external auditors should be conducted at least annually and their results reported to facility management.

E.1.7 Control of records

Submit the policy and procedure governing the retention of records. The policy should specify:

1. the applicant's commitment to maintain records as required by applicable regulations
2. the job title of the person responsible for maintaining the records
3. the record retention period specified in the regulations or, if not specified, one year after the expiration of the licence
4. the obligation to notify the Commission at least 90 days prior to the date of disposal of records
5. the obligation to have records available for inspection
6. the record storage requirements, including the media, that is, electronic vs. paper
7. the record review requirements, including:
   a. identification of the records subject to periodic review
   b. frequency of the review
   c. the job title of the person responsible for reviewing and maintaining the records
8. the provisions for ensuring regulatory compliance of record control, including the reporting of inaccuracies and deficiencies in records to the Commission within 21 days of becoming aware of the inaccuracy or deficiency
9. prevention of the unauthorized disposal of records referred to in the NSCA, the regulations or the licence unless they are no longer required to be kept

The procedure should identify the records to be kept, such as:

1. personnel records, including:
   a. the names of the persons operating or servicing the Class II prescribed equipment or handling nuclear substances
   b. the names and job categories of nuclear energy workers
   c. the training received by each person working with or servicing the Class II prescribed equipment or handling nuclear substances, including the date and subject of training
2. operating and performance records, including:
   a. Class II prescribed equipment workload
   b. any other record required by operational and servicing procedures
3. facility and Class II prescribed equipment records, including:
   a. the results of radiation surveys required by the regulations or the licence
   b. the inspections, verifications and tests of the Class II prescribed equipment
   c. the transfer of Class II prescribed equipment, including the date of transfer, the licence number of the organization to which the equipment was transferred, and the model and serial number of the equipment
   d. the facility plans and drawings, and design specifications
   e. the facility commissioning test procedures and test results
   f. if applicable, the quality assurance program for the design and testing of experimental targets
   g. the list of laboratories, rooms and other locations designated for the use or storage of nuclear substances
   h. the facility decommissioning reports
   i. the modifications, repairs, maintenance and return to operation of the Class II prescribed equipment and facility equipment, including the records from third-party service providers, where applicable
4. nuclear substance records, including:
   a. the acquisition, disposal or transfer of nuclear substances and transport documents

   b. the inventory of sealed and unsealed sources
   c. the physical and radiological characteristics of waste and activated components to be stored or disposed of, and the methods used for their storage or disposal
5. radiation protection records, including:
   a. the inventory and calibration of radiation detection instruments
   b. if applicable, the contamination monitoring results
   c. if applicable, the leak test monitoring results
   d. the dosimetry results
   e. records of internal investigations and action level exceedances
   f. if applicable, the internal bioassay results
6. for licensees conducting third-party servicing operations:
   a. the name and address of the client for whom the servicing was performed
   b. the licence number of the client for whom the servicing was performed
   c. the brand name, model number and serial number of the Class II prescribed equipment being serviced
   d. a summary of the work and the date on which the servicing was performed
7. the records of emergencies and other incidents involving the Class II prescribed equipment or nuclear substances
8. incident/event reports
9. any other record specified by the NSCA, the regulations or the licence

The CNSC may require additional records as specified in the licence conditions.

E.2 Radiation Protection

The applicant must describe their radiation safety program. This program should be documented and have detailed policies and procedures that are prepared under the supervision of the RSO and approved by the RSC or senior management. These policies and procedures should be readily available to all workers.

The radiation safety program components described in this guide do not prevent applicants from proposing alternatives, but any proposed radiation safety program should reflect the complexity and hazards of the activities to be authorized by the licence.

E.2.1 Policy for keeping doses as low as reasonably achievable (ALARA)

Submit the policy that demonstrates the applicants' commitment to keeping occupational and public doses as low as reasonably achievable, and social and economic factors taken into consideration.

The policy should promote:

1. management control over work practices and, specifically:
   a. delegating the responsibilities for radiation safety to qualified individuals only
   b. providing adequate financial and human resources
   c. ensuring the development and maintenance of radiation safety policies and procedures in accordance with industry best practices
   d. comparing the applicant's radiation protection policies and procedures with industry best practices, adopting improvements where appropriate
   e. providing for periodic internal reviews, such as self-audits, to verify workers' adherence to the licensee's radiation protection procedures

   f. having senior management review the radiation safety program and follow up to ensure the implementation of any corrective actions, as required
2. personnel qualification and training:
   a. providing adequate training to new staff
   b. on an ongoing basis, verifying that existing staff maintain their competence and providing training as required to address perceived gaps in staff knowledge (see section E.3.2 for details of the expected training content)
3. control over occupational and public exposure to radiation by monitoring radiation doses, investigating unusual doses and setting performance indicators; indicators may include:
   a. personal dose trends
   b. number of non-personal badge exposures
   c. number of instances where action levels were exceeded
   d. number of reported incidents
   e. when possible, benchmarking of exposure doses against those of similar facilities
4. developing and maintaining emergency procedures for dealing with radiological incidents related to the licensed activities

For more information on the expectations of the ALARA policy, applicants should consult section 4 of the *Radiation Protection Regulations* and CNSC regulatory guide G-129, rev. 1*Keeping Radiation Exposures and Doses "As Low as Reasonably Achievable (ALARA)*" [2].

E.2.2 Designation of nuclear energy workers

Submit the policy and the procedure to designate positions as nuclear energy workers (NEWs). If there is a reasonable probability that a worker's effective dose may exceed the dose limit of 1 mSv/year for the public, the applicant must designate that position as a NEW and inform the worker of this designation.

The *Radiation Protection Regulations* require that NEWs be informed of their status, the risks associated with the radiation levels to which they may be exposed, the applicable effective dose limits, their radiation dose levels and their obligations.

The policy should specify:

- the categories of workers who will be designated as NEWs
- the rationale for that designation
- the job title of the person responsible for designating positions as NEWs and for notifying workers occupying these positions of their status as NEWs
- the job title of the person responsible for keeping a record of the workers being informed of their status as NEWs and of the signed acknowledgement that those workers have received the required information

The procedure should describe:

1. the personal information required of each person who occupies a position that has been designated as a NEW, including the worker exposure history
2. the notification to be given in writing to workers, including:
   a. their designation of their position as a NEW
   b. the risks associated with their radiation exposure
   c. their regulatory dose limits

   d. their obligations
   e. the rights and obligations of a pregnant NEW
3. the requirement to obtain written acknowledgement from each NEW that they have received this information
4. the requirement to maintain a record of the written notifications to the workers and of their acknowledgement of having received these notifications
5. any accommodation required for pregnant NEWs

If the applicant elects not to designate positions as NEWs, this decision should be justified. In such a case, the applicant is nevertheless obliged to train their workers and to monitor the doses to those workers.

E.2.3 Personal dose monitoring – General

Submit the policy and procedure for personal dose monitoring that demonstrate that adequate provisions are in place for monitoring workers' occupational doses.

The policy should specify:

1. the applicant's commitment to monitor occupational doses to staff
2. the provisions for keeping records of personal doses
3. the categories of workers who will be required to wear a dosimeter
4. the obligation of workers to wear the dosimeter when on duty
5. the provisions for monitoring doses to visitors to the facility, if applicable
6. the job title of the person responsible for distributing and collecting the dosimeters
7. the job title of the person responsible for notifying workers of their doses
8. the dosimeter exchange periods
9. the CNSC licensed dosimetry service used, if applicable

The procedure should describe:

1. the type of dosimeters normally used, such as extremity or whole-body dosimeters
2. the types of other personal dosimeters available
3. the instructions to workers on the proper handling, wearing and storing of the dosimeters
4. the provisions for replacing lost or damaged personal dosimeters
5. the provisions for notifying the RSO of non-personal exposure of a dosimeter
6. the requirement to wear extremity dosimeters when handling nuclear substances or activated components, or servicing the equipment
7. the methods for actively notifying workers of their doses

If monitoring doses to staff without using personal dosimeters, provide justification for using other monitoring methods and clearly demonstrate the adequacy of those methods for determining doses. Such methods are subject to CNSC approval.

For further guidance, the applicant should refer to regulatory guide G-91, *Ascertaining and Recording Radiation Doses to Individuals* [3].

E.2.3.1 Personal dose monitoring – Electronic personal dosimeters

Applicants for the following licensed activities must have a policy on the use of electronic personal dosimeters (EPDs) by the workers:

- operation an isotope production facility
- operation an industrial or research accelerator
- operation a mobile or a portable accelerator

Applicants other than those listed here may also wish to use EPDs for certain circumstances; if EPDs are to be used, then the applicant must have a policy for their use.

Submit the policy and procedure requiring the use of EPDs with direct reading display.

The policy should specify:

- if, where and when an EPD should be used
- that an EPD must not be used unless it has been calibrated within the last 12 months
- the daily or per-job dose limits to workers
- the workers' obligation to:
  - wear the EPDs when on duty
  - verify the functioning of the EPD's visual display and audible alarm
  - verify that it has been calibrated within the last 12 months

The procedures should describe:

- where EPDs are kept
- the instructions to workers on the use of those dosimeters
- the pre-set alarm level
- actions to be taken if the alarm sounds

E.2.4 Action levels

Submit the policy on action levels and the procedure describing the actions to be taken when an action level has been exceeded.

Action levels are intended to alert management to a potential loss of control of a part of the radiation protection program before regulatory limits are reached and should be set at values close to the workers' expected occupational doses. For this reason, it may be appropriate to define different dose action levels for different groups of workers.

The policy should specify:

- the proposed action levels for different groups of workers and for:
  - quarterly and/or annual whole-body exposure
  - extremity exposures
  - pregnancy exposures
- the proposed action level related to environmental releases or radioactive contamination
- the job title of the person responsible for establishing the cause for reaching an action level, and for identifying and implementing the appropriate corrective actions

The procedure should identify:

- the timelines for implementing corrective actions when an action level has been exceeded
- the feedback to be given to a worker who has exceeded an action level
- the job title of the person responsible for notifying the CNSC within the time specified in the licence

If action levels are not part of the applicant's radiation safety program, the applicant should demonstrate that measures are in place to ensure an equivalent level of safety.

Exceeding an action level does not imply a regulatory non-compliance. However, failure to report when an action level has been exceeded is a violation of the *Radiation Protection Regulations*.

E.2.5 Radiation detection instruments

Submit the policy and procedure governing the use and calibration of gamma survey meters, neutron survey meters and EPDs.

The policy should specify:

1. which instrument should be used, and where and when it should be used
2. the job title of the person responsible for:
   a. ensuring the instruments have been calibrated in the last 12 months
   b. removing from service those instruments whose calibration certificate has expired
   c. ensuring that all calibration certificates are kept on file and available for inspection
   d. training users to operate instruments
3. the workers' obligation to verify prior to using the instrument that:
   a. it has been calibrated within the last 12 months
   b. it is functioning properly

The procedures should include:

- the description of locations where those instruments are kept
- the instructions to workers on the use of those instruments
- if applicable, the name and contact information of the calibration services used

See the CNSC web page titled Regulatory Expectations for Calibration of Survey Meters for information regarding suitability of survey meters by application and information on survey meter calibration.

E.2.6 Radioactive contamination control

Submit the policy and the procedures for monitoring the workplace for evidence of radioactive contamination.

Monitoring for radioactive contamination can be done by indirect or direct methods. The indirect method involves collecting wipe samples from workplace surfaces and measuring the removable contamination with liquid scintillation counters. The direct method involves using portable instruments in areas with low background radiation to measure removable and fixed contamination. If the measurement shows that contamination exceeds the limits described below, the licensee must take appropriate corrective action. See the CNSC web page Radioisotope Safety

– Monitoring for Radioactive Contamination for more information on contamination monitoring procedures.

The policy should specify:

1. the job title of the person responsible for carrying out the monitoring
2. the instruments available for monitoring contamination
3. the frequency of contamination monitoring (which should be commensurate with the isotope being handled), for example:
   a. weekly
   b. after each production run
   c. after spills or incidents
   d. before the equipment is released for non-radioactive use
   e. before and after decommissioning
4. the corrective actions to be taken if contamination limits are exceeded
5. the job title of the person responsible for maintaining contamination monitoring records

The procedures should include:

- a description of the types of contamination that would dictate the use of either the indirect or the direct method
- evidence that the instrument to be used can detect contamination at the limits identified in the section below
- a description of the algorithm used to convert measurement results – for example, in counts per unit time – to equivalent levels of surface contamination in Bq/cm^2
- a description of the precautions to be taken when using the indirect or the direct method, including personal protective equipment
- a drawing of the physical layout of the rooms where contamination monitoring may be required

The amount of removable contamination permitted in an area is regulated through a licence condition in the facility operating licence.

For Class A, Class B and Class C nuclear substances, which are typically long-lived alpha emitters, long-lived beta or gamma emitters, and short-lived beta or gamma emitters, respectively, removable contamination must not exceed the following limits when averaged over a surface area of not more than 100 cm^2:

- in controlled areas:
  - 3 Bq/cm^2 of Class A radionuclides
  - 30 Bq/cm^2 of Class B radionuclides
  - 300 Bq/cm^2 of Class C radionuclides
- in public areas and for decommissioning:
  - 0.3Bq/cm^2 of Class A radionuclides
  - 3 Bq/cm^2 of Class B radionuclides
  - 30 Bq/cm^2 of Class C radionuclides

A list of Class A, B and C nuclear substances is available on the CNSC website. The applicant may request approval for other contamination limits if it can demonstrate that the resulting maximum effective dose to any individual is less than 10 µSv/year.

E.2.7 Rooms – Posting

Submit the policy requiring the posting of rooms where Class II prescribed equipment and nuclear substances are stored or used.

The policy should require:

1. posting a durable and legible radiation warning sign with the words "RAYONNEMENT – DANGER – RADIATION" and the universal radiation warning symbol defined in Schedule 3 of the *Radiation Protection Regulations* at the boundary of, and at every point of access to an area, room or enclosure where there is more than 100 times the exemption quantity of a nuclear substance, or where there is a reasonable probability that a person will be exposed to a radiation dose rate greater than 25 µSv/h
2. posting at each entrance of a Class II facility a durable, legible sign indicating the job title and telephone number of a person who can be contacted 24 hours a day in case of an emergency in accordance with section 11 of the Class II regulations
3. posting a copy of the licence, or a notice of licence in a conspicuous place at the site of the licensed activity, in accordance with subsection 14 (1) of the *General Nuclear Safety and Control Regulations*
4. removal of radiation warning signage when no nuclear substances or Class II prescribed equipment is present

E.2.7.1 Rooms – Posting of facilities processing or handling unsealed sources

Submit the policy to ensure that required safety posters are displayed in areas where unsealed nuclear substances will be handled. See GD-52, *Design Guide for Nuclear Substance Laboratories and Nuclear Medicine Rooms* [1], for more information regarding room classification.

Applicants may download poster templates for the following laboratories from the CNSC's web page, Licensing: Nuclear substances and radiation devices:

- Basic Level – Use of Unsealed Nuclear Substances
- Intermediate Level – Use of Unsealed Nuclear Substances
- High Level – Use of Unsealed Nuclear Substances
- Containment Level – Use of Unsealed Nuclear Substances

E.2.8 Sealed source changes

Source changes for Class II prescribed equipment may only be performed by persons authorized to do so under the terms and conditions of a Class II prescribed equipment servicing licence.

Submit the policy and the procedure to ensure radiation safety when radiation sources are changed.

The applicant should demonstrate how sources used in Class II prescribed equipment are received, changed, stored and disposed of in a manner that provides for the security of the sources, and the safety of the workers and the public.

The policy should specify the following (items marked with an asterisk (*) are not required for third-party servicing organizations):

1. that only workers trained on the requirements of the *Packaging and Transport of Nuclear Substances Regulations, 2015* may handle the sources
2. * the job title(s) of the person(s) who should be notified of the arrival of the source
3. * the job title(s) of the person(s) responsible for inspecting the source container upon its arrival
4. the job title(s) of the person(s) who will perform the source change, if source changes are being performed by the applicant's workers
5. * the requirement for listing the source in the source inventory
6. * the process for returning the spent source
7. for IAEA Category I and II sources, the requirement to notify the CNSC of receipt of the source
8. that security provisions during source changes are described in the facility security plan or transport security plan (see section E.5.1.1)

The procedure should describe:

1. the inspection required to detect signs of tampering or damage on the shipping package
2. the tools that will be required during the source change
3. the responsibilities of the supplier representative, or of a person trained and qualified by the supplier, for:
   a. removing the spent source and installing the new source
   b. packing the spent source in the appropriate shipping container
   c. completing the paperwork for shipping the source container to the supplier
   d. taking measurements of radiation dose rates to verify that the dose rate with the source in its shielded position at 1 m does not exceed the manufacturer's specifications
   e. ensuring, in the presence of the owner of the prescribed equipment and prior to departure from the site, that safety systems continue to function as expected before releasing prescribed equipment for use after servicing
4. if applicable, the protocol for taking measurements of radiation dose rates at all accessible locations adjacent to the room housing the equipment, with the source exposed

If the applicant's workers will not be performing source changes, provide the CNSC with the name and CNSC licence number of the organization that will perform source changes for the applicant.

E.2.9 Sealed source handling

Submit the policies for receiving, storing and transferring sealed sources.

The policy for receiving sealed sources should specify that:

- only authorized workers with training in the transportation of dangerous goods may handle packages containing sealed sources
- packages received during normal working hours should be moved without undue delay to a designated nuclear substance storage location
- packages that appear to be damaged or leaking should not be handled by receiving personnel, and the RSO should be contacted immediately
- outside normal working hours, packages should be stored in a designated, secure location

The policy for storing sealed sources should specify that sources must be stored in:

- the room specified in the CNSC licence that complies with the requirements of the *Nuclear Security Regulations* and is accessible to authorized facility staff only
- the appropriately shielded container or enclosure

The policy for transferring sealed sources should specify that:

- sources can only be transferred to another CNSC licensee authorized to possess this nuclear substance
- any workers handling the package must have training in the transportation of dangerous goods

See the CNSC web page titled Guidelines for Handling Packages Containing Nuclear Substances for additional information for handling packages containing nuclear substances.

E.2.10 Post-treatment patient survey – Brachytherapy remote afterloader

Submit the policy and the procedure ensuring that patients are free of nuclear substances following treatment.

The policy should include:

- the obligation to survey every patient following a treatment with a brachytherapy remote afterloader to ensure there is no residual activity within the patient
- the job title of the person responsible for surveying the patient and recording the result

The procedure should include:

- the type and model of the surveying instrument
- instructions for recording the results of post-treatment patient surveys

E.2.11 Post-implant accounting of sources

Submit the procedure used to account for manual brachytherapy sources following permanent implants and, for temporary implants, for the recovery of the sources following the treatment.

The procedure should describe the method used for:

- verifying that the number of sources implanted and spare sources remaining after the implant correspond to the pre-implant source inventory
- recovering all sources used in temporary implants
- verifying, via radiation survey, that all non-implanted sources are collected, thus ensuring that they will not leave the procedure room
- maintaining records

E.2.12 Instructions to patients following an implant

Submit the instruction sheet given to patients implanted with permanent manual brachytherapy sources and to their families. The instructions should cover:

- how to respond when a source is expelled from the body (referred to as a "passed source")
- how to reduce radiation exposures to others, including caregivers
- how to respond to radiation alarms at airports and border crossings
- the limitation or prohibition of cremation as specified in provincial regulations
- the job title of the person to contact if patients or their families have questions

E.2.13 Control of patient treatment rooms

Submit the policy regarding the room where patients undergoing manual brachytherapy treatments are hospitalized.

The policy should ensure that:

- the room is equipped with a private washroom
- access to the room is restricted
- radiation warning signs and the name of an emergency contact person are posted
- the radiation dose rate in occupied areas adjacent to the room does not exceed 2.5μSv/h
- the room will not be released for cleaning or reoccupation until a survey of the room shows that no nuclear substance is present

E.2.14 Fire response

Submit the plan to familiarize the responding fire department with facility operation and its potential hazards.

The plan should include details of the training given to fire department staff and the familiarization tours made with them to ensure they are prepared to deal with fire scenarios at the facility.

E.3 Human Performance Management

E.3.1 Qualifications and duties of workers

Submit the policy on the qualifications and duties of workers.

The policy should specify:

- the qualification requirements for each job category in terms of education, training and experience
- the proposed responsibilities and duties of workers in each job category

Submit a list of all job categories of workers who will be operating or servicing the prescribed equipment or handling the nuclear substances encompassed by the licence.

The applicant must demonstrate that their workers have the appropriate qualifications and are formally authorized to operate or service the Class II prescribed equipment and to handle nuclear substances.

E.3.2 Training program

Submit a description of the proposed training program for workers.

The applicant must demonstrate that all workers understand the hazards associated with the licensed activities and that they will take all reasonable precautions to ensure their own safety, the safety of other persons at the site of the licensed activity, the protection of the environment, the protection of the public, and the maintenance of the security of nuclear facilities and of nuclear substances. The training should be commensurate with the role of the worker.

The authorization of workers should be contingent on the successful completion of initial and ongoing refresher training. Operating staff must receive radiation safety training as well as training on the operating procedures specific to each type of Class II prescribed equipment or to the nuclear substance(s). Any significant change to operating procedures should require retraining in the use of the changed procedures.

The training program should include the following six elements:

Training requirements

For each job title or category (e.g., service technician, physicist, ancillary staff), provide a summary of the training topics that must be completed for that position. Examples include:

- application of the ALARA principle
- transportation of dangerous goods
- proper handling of unsealed sources
- security awareness
- servicing hazards

Responsibilities

Provide the job title of the persons responsible for:

- preparing, verifying and maintaining the content of the program
- approving the content of the program
- delivering training and verifying comprehension

Training delivery methods

Training delivery may consist of:

- formal classroom training
- supervised hands-on training
- Web-based training
- self-study
- job shadowing

Training may be delivered by the applicant or a third party such as an equipment vendor.

Verifying comprehension

Once the training has been completed, a qualified person should verify comprehension and formally sign off on it. Verification methods may consist of:

- written or online tests
- demonstration of competency
- quizzes
- oral assessment

Refresher training frequency

Refresher training should be provided at regular intervals or:

- when a gap in knowledge is identified
- following a significant change in technology
- following a change in operating or servicing procedures
- when workers are assigned to roles different from their normal ones
- when a worker returns from an extended absence from the position

Hands-on emergency exercises should be practised at least annually. For source-based radiotherapy, simulated stuck-source emergencies must be performed at least annually.

Training records

The following records must be maintained for each worker:

- date and subject of the training
- evidence of training completion (e.g., sign-in sheet)
- verification of comprehension

Additional guidance for developing a training program can be found in REGDOC-2.2.2 *Personnel Training* [11].

E.3.2.1 Operational procedure content

Submit a list of the safety-related topics to be included in the operational procedure training.

Safety-related topics may include:

- daily verification of safety system operational capability
- security of Class II prescribed equipment, including access control
- response to equipment malfunction, including location and use of emergency stops and other safety equipment
- interlock bypass procedures

E.3.2.2 Radiation safety training content

Submit an overview of the radiation safety training content.

Applicants should not assume that the radiation safety training that workers have obtained elsewhere is adequate for their operations. Applicants should provide all new employees with site- and task-specific radiation safety training. This training should be tailored to the educational background and practical needs of those attending. Auxiliary personnel who may work in the vicinity of prescribed equipment or nuclear substances, such as clerical, janitorial, maintenance and security staff, should also be instructed in basic concepts of radiation safety.

E.3.2.3 Transportation of dangerous goods training content

Submit an overview of the transportation of dangerous goods (TDG) training and the list of the categories of workers to be trained.

Staff involved in packaging, shipping or receiving nuclear substances must be trained in the relevant requirements of Transport Canada's *Transportation of Dangerous Goods Regulations* and must possess a valid TDG certificate for Class 7 dangerous goods.

E.3.2.4 Servicing of Class II prescribed equipment

Provide a list of all job categories for workers who will be performing servicing activities encompassed by the licence (junior/senior technicians, trainees, etc.). Include a brief description of the proposed roles, responsibilities and duties for each category, as well as the qualifications and experience required for personnel to carry them out.

The method of training (manufacturer courses, job shadowing, etc.) should also be described, as well as the criteria for advancement and methods of verifying knowledge.

E.4 Waste Management

E.4.1 Radioactive waste

Submit a list of any radioactive waste or activated components to be handled, transferred or disposed of as a result of the licensed activities, including the following:

- nuclear substances:
  - isotope name and atomic weight
  - approximate activity (in Bq)
  - physical or chemical form
- activated materials:
  - description of activated material (accelerator target, shielding, etc.)
  - weight and/or volume or other measure of quantity (such as number of targets) of the waste
  - physical or chemical form

Submit the procedures for handling, transferring and disposing of radioactive waste. The following disposal methods may be authorized:

- storing for radioactive decay
- returning to the supplier
- transferring to a facility possessing an appropriate CNSC licence
- any other waste disposal method proposed must be justified

See the CNSC web page titled Conditional clearance levels for the disposal, recycling and reuse of activated medical accelerator components for more information.

E.4.2 Other hazardous waste

Submit a list of non-radioactive hazardous substances related to or resulting from the operation of Class II prescribed equipment. For each substance include:

- the name of the substance
- the quantity
- the physical or chemical form
- the nature of the hazard associated with the substance
- the method of disposal

E.5 Security

E.5.1 Access control and physical security

Submit the policy for restricting access to nuclear substances and Class II prescribed equipment outside normal working hours to authorized workers only. The policy should specify:

- the requirement to store all nuclear substances and Class II prescribed equipment containing nuclear substances in locked areas, rooms or enclosures when not in use or when not under the direct supervision of authorized staff
- the measures in place to prevent unauthorized access to those rooms, areas or enclosures
- the measures to control access to radioactive material and sources destined for disposal
- the job titles of the persons who may have unrestricted access outside working hours to rooms containing nuclear substances or Class II prescribed equipment

E.5.1.1 Access control and security – High- and medium-risk sources

For medium- and high-risk sealed sources (IAEA Categories I-III), the applicant must have technical security measures in place to prevent unauthorized access to these sources and protect against their illegal removal or sabotage. Applicants must describe these measures in a site security plan.

In the site security plan, applicants must detail the planned technical security measures, including a description of the intrusion detection system and of the physical barriers in place.

Details of the technical security measures are considered prescribed information and may only be transmitted by secure means such as mail or courier. Electronic submission of this information to the CNSC is not currently supported.

Unlike sealed sources dealt with in the Sealed Source Tracking System (SSTS), whose activity is the individual source activity, the activity of Category I to III sources is determined by their aggregate activity.

- the measures in place to prevent unauthorized access to those rooms, areas or enclosures
- the measures to control access to radioactive material and sources destined for disposal

- the job titles of the persons who may have unrestricted access outside working hours to rooms containing nuclear substances or Class II prescribed equipment

The security program for these sources should include provisions for detecting, delaying and responding to security threats. The following items must be addressed in the site security plan:

- maintenance and testing of the intrusion detection systems
- access control
- response protocol
- security awareness training
- personal trustworthiness and reliability verification
- if applicable, transport security

The site security plan should be submitted at the same time as the application, but may be sent separately. In the application, confirm that the security program for medium- and high-risk sealed sources has been submitted securely to the CNSC. Provide details of the carrier used to submit the document, as well as the tracking number provided by the carrier. If no tracking number was issued, provide the date on which the document was sent to the CNSC.

REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources and Category I, II, and III Nuclear Material* [4], contains information on the categorization of sources and their activity, design of the site security plan, and guidance for secure transmission.

E.5.1.2 Personal reliability and trustworthiness: Servicing

REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources and Category I, II, and III Nuclear Material* [4], requires licence applicants to verify the trustworthiness and reliability of all persons who may have access to medium- and high-risk sealed sources (IAEA Categories I-III) or to prescribed/sensitive information, including servicing companies and/or contractors who require access without escort. The trustworthiness and reliability verification must be updated on a regular basis – at a minimum, every five years.

Submit the policy that states that all staff who will have unsupervised access to medium- and high-risk sealed sources or to prescribed information will undergo personal trustworthiness and reliability checks at least every five years.

E.5.2 Inventory control

Submit the policy and the procedure for inventory control. The applicant must maintain a current inventory of sealed sources or other nuclear substances in their possession, including activated components. The purpose of the inventory is to alert the applicant to any missing, stolen or unaccounted-for source or nuclear substance. The policy should specify:

- the requirement to keep a current inventory of sealed sources and other nuclear substances in the applicant’s possession
- the job title of the person responsible for keeping the inventory up to date
- the requirement to have the inventory available for inspection
- the requirement to periodically verify the validity of the inventory by visual confirmation

The procedure should prescribe that the following information be captured in the inventory records:

- the name, quantity and form of the nuclear substance in the source, and its location (room number)
- the serial number of the source
- if applicable, the source country of origin
- the date the source was received
- the name, address and licence number of the supplier
- the job title of the person responsible for the secure storage, inventory verification and safe use of each source

E.6 Packaging and Transport of Nuclear Substances

Submit the policy and procedures for the packaging and transport of nuclear substances.

Packaging and transport of nuclear substances must comply with the relevant requirements of Transport Canada's *Transportation of Dangerous Goods Regulations* and the *Packaging and Transport of Nuclear Substances Regulations, 2015*.

The policy should specify:

1. the obligation to comply with the applicable requirements of Transport Canada and the CNSC regulations listed above
2. the job title of the person responsible for ensuring compliance with those requirements and regulations
3. that only persons with a valid TDG certificate are authorized to receive, ship or handle packages containing nuclear substances

The procedure should describe:

1. the safety instructions to be followed for the handling of packages containing nuclear substances
2. the requirement to:
   a. inspect packages for damage or leakage
   b. measure dose rates at the package surface and at one metre from the unopened package
   c. verify that packages are below contamination limits
   d. store the package in a secure area upon its arrival or when it is awaiting shipment
   e. verify that the shipping documents correspond to the contents of the package
3. if applicable, the requirement to complete the "Shipper's Declaration for Dangerous Goods" form required for air transport
4. the job title of the person responsible for maintaining shipping document records

E.7 Fitness for Service

Submit the policy to ensure that Class II prescribed equipment, components and systems are functioning as expected.

Failure of any Class II prescribed equipment or component of the prescribed equipment should result in its being removed from service until it has been repaired and shown to be functioning once again as expected.

The policy should apply to equipment, components or systems that:

1. have undergone extensive servicing
2. were involved in accidents or operated under conditions more severe than their design operating conditions
3. require periodic monitoring or calibration
4. are part of a safety system including, if applicable:
   a. the last person out (LPO) activation switch
   b. the door interlock
   c. any other switch, sensor or additional door interlock, which will be incorporated into the entrance interlock and LPO circuit
   d. any irradiation state indicator
   e. any pre-irradiation alarm
   f. any emergency stop devices
   g. the viewing system
   h. any interlock that has been bypassed
   i. any radiation monitoring system
5. are part of a radioisotope release monitoring and containment system
6. are part of a ventilation monitoring system
7. are part of a personnel contamination monitoring system
8. are part of a pulse dose rate brachytherapy remote afterloader alarm system
9. are sealed sources and nuclear substances used for shielding
10. must be removed from service following a failure to operate as intended

E.7.1 Post-servicing verification

Submit the procedure to be followed to ensure that the Class II prescribed equipment is safe for use after servicing.

The procedure should describe:

- the tests, measurements, verifications and analyses required to confirm that the equipment is safe for use
- the obligation to have a documented, independent review and sign-off to attest that the equipment was correctly repaired before being released for use after servicing
- the job title(s) of the person(s) qualified to approve the return of the equipment to normal use following various types of servicing (e.g., interlock clearing, dosimetric, safety systems)
- the job title(s) of the person(s) responsible for maintaining records of the servicing and approvals

E.7.2 Verification following accident

Submit the procedure to return to service equipment that was involved in an accident or operated under conditions more severe than its design operating conditions.

The procedure should describe:

- the accidents or abnormal conditions that would require discontinuing the use of the equipment
- the tests and inspections required to verify that the equipment is operational
- the job title(s) of the person(s) qualified to approve the return of the equipment to normal use

- the job title(s) of the person(s) responsible for maintaining records of the verifications and approvals

E.7.3 Stack monitor calibration

Submit the procedure for calibrating stack monitors and for correlating count rates to equivalent activities in Bq.

The procedure should:

1. describe the required maintenance and mechanical checks of the exhaust system
2. describe the requirements to:
   a. calibrate annually the stack monitor system and the detectors
   b. test annually the algorithm correlating stack detector count rate to actual count rate
3. describe the calibration of the air flow monitoring system
4. describe the verification that the stack detectors have been calibrated in the last 12 months
5. include the verification of the alarm set points for air flow rates
6. describe the verification of the dose alarm threshold related to the radioactive releases
7. describe the type and amount of radioactive material that is released during the calibration
8. include the job title of the person responsible for maintaining records of the results of the annual stack monitor calibration

E.7.4 Leak testing

Submit the procedure for leak testing of sealed sources and of nuclear substances used as shielding.

The Class II regulations require licensees who possess or use sealed sources containing 50 MBq or more of a nuclear substance or use nuclear substances as shielding to conduct leak tests at prescribed frequencies. The leak testing procedure should:

1. describe any nuclear substances used as shielding, and their location
2. describe the method used to determine if the shielding components are safe and fit for continued operation
3. include the frequency of leak tests
4. describe the circumstances that would require a leak test
5. describe the sampling technique, including:
   a. the tools used
   b. the locations where swipes will be taken
   c. the safety precautions to keep radiation exposure to staff ALARA during sampling
6. describe the detection instruments, including:
   a. manufacturer, model, radiation types detected and useable energy range
   b. tests or calculations that demonstrate that the instrument can detect 200 Bq or less of the isotopes of interest
   c. the algorithm or correction factor used to convert swipe measurement results to activity in Bq
7. describe the actions to be taken if the nuclear substance is found to be leaking
8. include the job title of the person responsible for maintaining records of leak test results

If a commercial leak testing service is used, provide the name and contact information of the organization performing the tests.

E.7.5 Servicing of safety systems

Typically, operating Class II prescribed equipment without one or more of the safety systems that were approved during licensing of the facility requires previous approval from the CNSC.

Submit the procedure to return Class II prescribed equipment to routine operation following the failure of one or more of the equipment's safety systems.

The procedure should:

1. describe the safety systems whose failure to operate would require discontinuing the use of the equipment
2. describe the methods in place to alert staff of any intended bypass, or of a malfunction of a safety system
3. include the job title(s) of the person(s) qualified to authorize a bypass
4. describe the tests and inspections required to verify that the safety systems are operational
5. describe the methods to notify staff that malfunctions have been repaired or that bypasses have been removed
6. include the job title(s) of the person(s) qualified to approve the return of the equipment to normal use
7. include the job title(s) of the person(s) responsible for maintaining records of the verifications and approvals

Part F: Routine Operation and Confirmation of Facility Design

F.1 Routine Operation

Information requested in this section is required prior to issuance of a routine operation licence. Applicants must demonstrate that the radiation protection program is sound and, for Class II prescribed equipment being operated in a facility, that the facility design previously submitted to the CNSC has been confirmed in a demonstrable manner, such as a radiation survey.

If not already submitted, provide the information listed in the following sections when requesting a routine operation amendment of an existing operation to commission licence.

F.1.1 General operating procedures

Submit the facility operating procedures.

These procedures should:

- include the job title(s) of the person(s) who may operate or service the prescribed equipment (only qualified and authorized personnel should operate or have access to the Class II prescribed equipment and radiation areas)
- describe the methods, equipment and instructions for performing radiation surveys, including:
  - the frequency of the surveys
  - the location where surveys should be performed
- include instructions provided to workers for ensuring that no one is in the room when radiation is being produced (for medical facilities, this means persons other than the patient being treated)

F.1.1.1 Isotope production facility – Operating procedures

In addition to the applicable requirements in section F.1.1, submit the procedures to be followed in the event of a failure of the ventilation system and for the periodic review of stack release monitor data.

F.1.2 Isotope production facility – Processing procedures

In addition to the applicable requirements in section F.1.1, submit the procedures for processing isotopes, including:

- the list of the radioisotopes processed
- the description of:
  - the provisions to prevent spills and mitigate their effects
  - the methods and equipment used for contamination control
  - the methods and instruments for performing contamination surveys, including the frequency of surveys
  - the means of transferring finished product out of containment
  - the means used to remove radioactive or other hazardous waste from containment
  - the provisions for container labelling

F.1.3 Geophysical logging accelerator – Operating instructions

Submit the instructions to workers for the safe operation of the accelerator.

These instructions should include a description of:

- the specific tools that may be used, for example, remote handling tools
- the inspection and verification program for the equipment encompassed by the licence
- the field operations, including instructions for preparing the site (erecting barriers/signage if necessary, etc.)
- the safety instructions given to workers

F.1.4 Emergency procedures

Submit the procedures used in the event of a radiological emergency that may result in radiation exposures to staff or the public, contamination with nuclear substances, or both.

Prompt and proper action is a prime factor in limiting the damage that may result from a radiological accident.

The emergency procedures should:

1. include the job title(s) of the persons responsible for identifying and directing remedial actions
2. describe the location of emergency equipment and the instructions for their use
3. if applicable, describe the provisions for:
   a. evacuating the immediate area of the incident and controlling entry to the site
   b. limiting radiation doses to facility staff
   c. dealing with a fire
   d. limiting the spread of contamination

e. monitoring any potential release from the site
f. identifying, isolating and treating workers or other persons who may be contaminated or may have received high radiation doses
g. detecting or estimating the quantity of nuclear substances involved
h. decontaminating the site and equipment, as well as the workers and other persons
i. recording the details of the emergency and notifying the Commission pursuant to regulatory requirements

F.1.4.1 Emergency procedures for a source-based facility

In addition to the applicable procedures listed in section F.1.4, for all Class II prescribed equipment that incorporates a moveable sealed source, submit the procedure for dealing with a stuck source.

F.1.4.2 Emergency procedures for an isotope production facility

In addition to the applicable procedures listed in section F.1.4, submit the procedures addressing the following situations:

1. a malfunction of the accelerator
2. the loss of containment of isotopes for any reason, including:
   a. during production or processing
   b. following a target failure
   c. rupture of transfer lines
   d. laboratory spills
3. spills of toxic chemicals
4. loss or theft of nuclear substances
5. accidental radiation exposures to facility staff or the public

F.1.4.3 Emergency procedures for a geophysical logging accelerator

In addition to the applicable procedures listed in section F.1.4, submit the procedures to be used in unusual circumstances, including:

- recovering lost geophysical logging accelerators from a borehole, that is, “fishing”
- abandoning geophysical logging accelerators when they cannot be recovered
- maintaining a list of the available emergency equipment and a list of emergency contacts

F.1.5 Safety system verification

Submit the procedure that addresses the verification of safety system and control mechanisms.

The procedure should:

- describe the steps required for performing the tests
- include the frequency of tests (test frequencies should meet or exceed industry standards)
- include the job title(s) of the persons responsible for performing the tests
- include the checklist or other recording formats used for recording test results
- describe the course of action to be taken when a malfunction is detected
- describe the procedure for verifying that this equipment is operational following a bypass of any safety system

F.1.5.1 Safety system verification for robotic arm radiotherapy

In addition to the applicable procedures specified in F.1.5, submit:

- the procedure for verifying that this equipment is operational following a bypass release
- if applicable, the procedure for verifying the integrity of the virtual beam stops

F.1.6 Special instructions for nursing staff for a pulsed dose rate brachytherapy facility

Submit the special instructions for nursing staff at pulsed dose rate (PDR) brachytherapy facilities, including:

- the general safety instructions and precautions to be followed to ensure that exposure of nursing staff to radiation is kept ALARA
- the instructions to be followed in the event of a fault or an interruption in treatment
- the radiation safety instructions for responding to medical emergencies of PDR patients, such as cardiac or respiratory arrests

F.1.7 Servicing procedures

Submit the servicing procedures for each make and model of Class II prescribed equipment encompassed by the servicing/consolidated licence. The servicing procedures should include:

- a description of the procedures and equipment used for ensuring the safety of servicing personnel
- information on the system/process that will be used to inform Class II prescribed equipment users of its operational status
- the information to be contained within records of servicing (e.g., description of the problem, description of the resolution, date of the servicing activity, identifier of the person(s) performing the servicing); for more information regarding records to be maintained, see section F.1.7

Procedures should be commensurate with the level of servicing chosen for the Class II prescribed equipment in section B.3.

F.1.8 Requirements for licensees who do not have a Class II prescribed equipment servicing licence

Extensive servicing of Class II prescribed equipment can only be performed under a CNSC Class II prescribed equipment servicing licence or a consolidated licence, which lists the manufacturer and model of the equipment being serviced.

Applicants planning to operate Class II prescribed equipment but who do not currently hold a servicing licence and are not planning to apply for one, must inform the CNSC as to how the equipment will be serviced in the event of failure or planned maintenance of the equipment. Options include a service contract or “on-demand” servicing with a third party licensed to service Class II equipment. Other possibilities may be proposed by the applicant, with supporting information.

Even if the applicant does not intend to obtain a licence to service, some types of routine maintenance are still permitted, subject to CNSC approval. In this case, a description of:

1. the routine maintenance activities that the applicant intends to perform on Class II prescribed equipment
2. the conditions under which this maintenance may be performed, including who is authorized to perform it
3. any operation that may require bypassing or overriding any internal or external safety interlock, including software interlocks; for any proposed maintenance procedure that requires intentional bypass of an interlock, submit the proposed policy for bypassing the interlock, specifying:
   a. the job title(s) of the person(s) responsible for authorizing the bypass
   b. the requirement to keep a record of the bypass
   c. the requirement to post a warning sign at the control console if bypassing any safety system listed in section C.2
   d. the requirement to remove the bypass and test the operation of the interlock prior to returning the equipment to normal use

F.1.9 Perimeter access control for temporary work sites – Mobile or portable accelerators

Submit the procedure to restrict access to any controlled area in which the dose rate could exceed 0.1 mSv/hr during operation of the mobile or portable accelerator.

The procedure should include:

- the requirement to install a barrier and to post a sufficient number of durable and legible signs along the barrier that bear the radiation warning symbol set out in Schedule 3 to the *Radiation Protection Regulations* and the words “RAYONNEMENT — DANGER — RADIATION”
- the description of the steps taken to minimize radiation exposure to persons if their movement cannot be controlled by the barrier

F.1.10 Portable shielding

Submit the policy that ensures that the portable shield is used and placed correctly when its use is required.

The policy should specify that a survey must be performed to identify the position of the portable shield that results in dose rates in unrestricted areas not greater than those for members of the general public.

If portable shielding is used, specify the size, thickness and composition of the shielding.

F.2 Confirmation of Facility Design Implementation

F.2.1 Confirmation of safety system functionality

Submit a report showing the results of the commissioning tests performed to verify that all safety systems are operational. If any safety device was found non-operational, the report must include a

description of the remedial actions taken and the subsequent tests performed to confirm that the malfunction has been corrected. The report should include the results of the tests performed on:

1. if applicable, the door interlock and LPO time delay circuit
2. the irradiation status indicators
3. if applicable, the pre-irradiation alarm
4. the emergency stop devices
5. if applicable, the area monitors and alarms
6. if applicable, all components of the radioactive release monitoring and containment systems
7. for robotic arm medical accelerators, the door interlock following bypass release
8. for self-shielded cyclotrons, any interlock or device designed to verify proper closure of the cyclotron shielding or to monitor its integrity
9. any other safety interlock incorporated into the facility

F.2.2 Radiation survey

Submit the results of the radiation survey, including:

1. the Class II prescribed equipment operating conditions
2. the make, model, serial numbers and calibration date for each radiation survey instrument used
3. the background radiation dose
4. the measurements of photon and, if required, neutron radiation
5. the locations on the facility plans and drawings where measurements were taken
6. a re-evaluation of the projected annual doses to staff and the general public given in section C.1.5 based on the measured dose rates; if the dose rates in any area exceed those estimated in the original shielding design, describe the remedial actions taken to reduce the doses that could potentially be incurred by persons occupying the area (those actions may include adding shielding, having access restrictions or controls, reducing the proposed workload or demonstrating that the resulting doses are still ALARA and that no remedial action is required)
7. for isotope production and research accelerators, the target material irradiated during the survey

F.2.3 Commissioning results – Isotope processing facilities

Submit a report containing:

1. the confirmation that the processing facilities have been built according to the specifications listed in the CNSC's design assessment form for nuclear substance laboratories and nuclear medicine rooms; proposed design changes to correct flaws discovered during the commissioning phase must be submitted to CNSC staff for evaluation and approval
2. the results of the tests performed on any interlock or other safety system associated with the hot cells or other processing equipment
3. the results of the stack monitor calibration
4. the confirmation that the ventilation system is operational
5. the results of the radiation survey to verify the adequacy of the shielding incorporated into the hot cells and along the transfer lines
6. an evaluation of anticipated extremity doses

Part G: Decommissioning Plan

The application for a licence to decommission a facility must demonstrate that there is a clearly defined and appropriate plan of action for decommissioning both the Class II prescribed equipment and the associated facilities (such as isotope processing facilities). The plan should include the measures taken to ensure that staff participating in the decommissioning work will have the supervision, training and equipment needed to perform their duties in a safe manner.

G.1 Overview of Decommissioning Plan

Submit an overview of the decommissioning work, including:

- a list setting out the land, buildings, structures, components, systems, equipment, nuclear and hazardous substances that will be affected by the decommissioning
- a decommissioning schedule
- a description of the effects, if any, on the environment and the health and safety of persons that may result from the decommissioning, and the measures that will be taken to prevent or mitigate those effects
- a description of the planned state of the site upon completion of the decommissioning – specify whether any radioactive material, contamination or hazardous substance will remain onsite after the decommissioning

G.2 Personnel Qualifications and Training

Provide the job title of the person responsible for planning and supervising the decommissioning activities; if this person is not the RSO named in this application, describe the person's training, experience, position and responsibilities in the facility's organization.

Provide the proposed responsibilities, qualifications and training requirements for workers participating in decommissioning activities. If the applicant is contracting out any part of the decommissioning work, provide the name and contact information of the contracting firm and specify how the applicant will ensure that contract personnel have received radiation safety training that is commensurate with the work they will be performing.

G.3 Estimate of Types, Activities and Radiation Doses from Nuclear Substances

Submit a description of the nature, type and activity of any nuclear substance or contamination at the facility. Submit a list of open and sealed sources, and of activated or contaminated items or components present at the time of decommissioning.

Based on that information, submit an estimate of the anticipated maximum dose rates persons may be exposed to, and of the maximum dose of radiation that may be received by any person as a result of decommissioning.

G.4 Disposal of Class II Prescribed Equipment, Nuclear Substances and Hazardous Materials

Describe the method of disposal for all major components of the Class II prescribed equipment. If the applicant intends to transfer all of the equipment or any of its major components to another institution where the equipment or its components could be reused, provide the name and contact information of the recipient.

Specify the method of disposal for all nuclear substances and activated components. See the CNSC web page Conditional clearance levels for the disposal, recycling and reuse of activated medical accelerator components for more information. Specify the disposal method for potentially hazardous material such as SF6. If these substances will be released into the environment, specify the maximum quantities and concentrations that may be released. Confirm that all releases of nuclear substances will be in compliance with the limits specified in the *Nuclear Substances and Radiation Devices Regulations*. If the applicant intends to transfer nuclear substances or activated components to another licensee, provide the licensee's name, address and licence number.

G.5 Disposal of Class II Prescribed Equipment, Nuclear Substances and Hazardous Materials – Isotope Production Facilities

Describe the proposed methods of disposal of all major components of the processing facilities, including the hot cells. Specify the proposed measures to control releases of nuclear substances and hazardous substances into the environment.

Appendix A: Cross-Reference Listing of Licence Application Information Requirements and Relevant Legislation

Legend:

GNSCR: *General Nuclear Safety and Control Regulations*
CNSCCRFR: *Canadian Nuclear Safety Commission Cost Recovery Fees Regulations*
CII: *Class II Nuclear Facilities and Prescribed Equipment Regulations*
NSRDR: *Nuclear Substances and Radiation Devices Regulations*
RPR: *Radiation Protection Regulations*
PTNSR: *Packaging and Transport of Nuclear Substances Regulations, 2015*

Section	Title	Relevant legislation
Part A: General Information		
A.1	Application Type	GNSCR, paragraph 3(1)(m)
A.2	Language of Licence	*Official Languages Act*, section 26
A.4	Number of Bunkers or Rooms	GNSCR, paragraph 3(1)(d)
A.5	Name of Applicant's Authorized Representative	GNSCR, section 15
A.6	Applicant's Name and Business Address	GNSCR, paragraph 3(1)(a)
A.7	Financial Contact Person	CNSCCRFR, Part 2, Part 3, Part 5
A.8	Radiation Safety Officer	CII, section 15.01
A.9	Alternate Radiation Safety Officer	CII, subsection 15(1)
A.10	Signing Authority	GNSCR, paragraph 15(b)
A.11	Applicant Authority	GNSCR, paragraph 15(b)
A.12	Proof of Legal Status	GNSCR, paragraph 3(1)(a)
A.13	Financial Guarantees	GNSCR, paragraph 3(1)(l)
A.14	Public Access to Information	*Access to Information Act*, section 20
Part B: Activities and Facilities To Be Licensed		
Licence Type and Phase		
B.1	Licence Type and Phase	GNSCR, paragraph 3(1)(b)
B.1.1	Construction	GNSCR, paragraph 3(1)(b)
B.1.2	Commissioning (with option to service)	GNSCR, paragraph 3(1)(b)
B.1.3	Operation (with option to service)	GNSCR, paragraph 3(1)(b)
B.1.4	Decommissioning	GNSCR, paragraph 3(1)(b)
B.1.5	Licensed activities for sealed nuclear substances	GNSCR, paragraph 3(1)(b)
Licensed Locations		
B.2.1	Fixed facilities: Principal location of use or storage or both	GNSCR, paragraph 3(1)(d); CII, paragraphs 3(a), 3(e), 4(a), 5(a)

Section	Title	Relevant legislation
B.2.2	Prescribed equipment not in a fixed facility: Principal location of use or storage or both	GNSCR, paragraph 3(1)(d); CII, paragraph 4(a)
B.2.3	Sealed sources or activated components - Principal location of use or storage or both	NSRDR, paragraph 3(1)(d)
B.2.4	Unsealed nuclear substances - Principal location of processing, use or storage	NSRDR, paragraph 3(1)(d)
B.2.5	Servicing	GNSCR, paragraph 3(1)(a)
B.2.6	Additional locations	GNSCR, paragraph 3(1)(a)
Class II Prescribed Equipment and Nuclear Substances		
B.3.1	Class II prescribed equipment	CII, paragraphs 3(c), 3(k), 4(e), 4(i), 7(a); GNSCR, paragraph 3(1)(d); CII, section 10
B.3.2	Nuclear substances – Sealed sources and activated components	GNSCR, paragraph 3(1)(c)
B.3.3	Accelerator targets – Isotope production	GNSCR, paragraph 3(1)(c); CII, paragraphs 3(c), 3(k)
Part C : Facility Construction		
Facility Design		
C.1.1	Facility plans and drawings	GNSCR, paragraph 3(1)(d); CII, paragraphs 3(e), 3(h)
C.1.2	Classification of adjacent areas	GNSCR, paragraph 3(1)(d); CII, paragraph 3(f)
C.1.3	Workload	CII, paragraphs 3(n), 3(o), 4(p), 4(q);
C.1.4	Instantaneous dose rates and annual dose calculations	CII, paragraph 3(l), 3(p); GNSCR, paragraph 3(1)(i); RPR, paragraph 4(a)
C.1.5.1	Instantaneous dose rates and annual dose calculations – Accelerator	CII, paragraph 3(l), 3(p); GNSCR, paragraph 3(1)(i); RPR, paragraph 4(a)
C.1.5.2	Description of the isotope production targets	GNSCR, paragraph 3(1)(c); CII, paragraph 3(c); 3(k)
C.1.5.3	Description of the isotope processing facilities	NSRDR, paragraph 3(1)(l)
C.1.5.4	Description of radiochemical hot cells and processing stations	NSRDR, paragraphs 3(1)(a), 3(1)(l)
C.1.5.5	Transfer and processing of isotopes	NSRDR, paragraphs 3(1)(a), 3(1)(l)
C.1.5.6	Other design considerations – Isotope production facilities	CII, paragraph 3(i)
C.1.6	Beam limiting	CII, paragraph 3(m), 4(j)
C.1.7	Evaluation of air activation and ozone production - industrial electron beam accelerators and pool-type irradiators	GNSCR, paragraph 3(1)(i)
C.1.9	Technical security measures – Construction	GNSCR, paragraph 3(1)(g); GNSCR, paragraph 3(1)(h)

Section	Title	Relevant legislation
Safety Systems – Nuclear Facilities		
C.2.1	Entrance interlocks	CII, subsection 15(2); CII, subsection 15(3)
C.2.2	Irradiation state indicators	CII, subsection 15(5)
C.2.3	Pre-irradiation alarms	CII, paragraph 4(n); CII, subsection 15(6)
C.2.4	Emergency stop buttons or devices	CII, subsections 15(8), 15(9)
C.2.5	Radiation monitoring devices – General	CII, subsection 15(6)
C.2.6	Viewing system – Medical facilities	CII, subsection 15(4)
C.2.7	Tools and equipment for stuck source emergencies – Brachytherapy remote afterloaders and teletherapy machines	CII, paragraphs 16(2)(b), 16(2)(c)
C.2.8	Radioisotope release monitoring and containment – Isotope production facilities	GNSCR, paragraph 12(1)(f); NSRDR, subparagraph 3(1)(b)(i)
C.2.9	Ventilation airflow monitoring system – Isotope production facilities	GNSCR, paragraph 12(1)(c); CII, paragraph 3(i)
C.2.10	Personnel contamination monitoring system – Isotope production facilities	GNSCR, paragraph 12(1)(f); NSRDR, subparagraph 3(1)(b)(iii)
C.2.11	Pulsed dose rate brachytherapy afterloader remote alarm	CII, paragraph 16.1(2)(a)
Other Requirements		
C.3.1	Public information program	CII, paragraph 3(r)
C.3.2	Preliminary decommissioning plan	CII, paragraph 3(s); GNSCR, paragraph 3(1)(j)
Part D: Commissioning Plan		
D.1	Facility Design Implementation – General	CII, paragraphs 3(g), 3(j), 4(b), 4(k)
D.1.1	Medical and veterinary facilities	CII, paragraphs 4(b), 4(k)
D.1.2	Isotope production facilities	CII, paragraphs 4(b), 4(k)
D.2	Isotope Processing Facilities	CII, paragraph 4(b)
Part E: Management System and Radiation Protection Program		
Management system		
E.1.2	Radiation safety officer job description	GNSCR, paragraphs 3(1)(k), 3(1)(l)
E.1.3	Organizational management	GNSCR, paragraph 3(1)(k)
E.1.4	Radiation safety committee	GNSCR, paragraph 3(1)(k)
E.1.5	Reporting requirements	GNSCR, section 29
E.1.6	Quality assurance program	CII, paragraphs 4(h), 3(j)
E.1.7	Control of records	CII, section 21; RPR, section 24; GNSCR, sections 27, 28

Section	Title	Relevant legislation
Radiation protection		
E.2.1	Policy for keeping doses as low as reasonably achievable (ALARA)	RPR, paragraph 4(a)
E.2.2	Designation of nuclear energy workers	RPR, sections 7, 9, 10, 11
E.2.3	Personal dose monitoring – General	RPR, section 5
E.2.4	Action levels	RPR, section 6; GNSCR, paragraph 3(1)(f)
E.2.5	Radiation detection instruments	CII, section 18; NSRDR section 20
E.2.6	Radioactive contamination control	GNSCR, paragraph 12(1)(f); NSRDR, subparagraph 3(1)(b)(iii)
E.2.7	Rooms – Posting	RPR, sections 21, 22; NSRDR, paragraph 23(a); CII, subsection 15(11)
E.2.8	Sealed source changes	CII, paragraph 7(c); section 17
E.2.9	Sealed source handling	PTNSR, sections 15, 12; GNSCR, paragraph 12(1)(c)
E.2.10	Post-treatment patient survey – Brachytherapy remote afterloader	CII, paragraph 16.1(1)
E.2.11	Post-implant accounting of sources	GNSCR, paragraph 3(1)(h)
E.2.12	Instructions to patients following an implant	RPR, section 3
E.2.13	Control of patient treatment rooms	GNSCR, paragraph 12(1)(c)
E.2.14	Fire response	GNSCR, paragraph 12(1)(c)
Human performance management		
E.3.1	Qualifications and duties of workers	CII, paragraphs 4(s), 7(d)
E.3.2	Training program	CII, paragraph 4(s), 7(d), 21(2)(b); RPR, subparagraph 4(a)(ii); GNSCR, paragraph 12(1)(j)
Waste management		
E.4	Waste Management	GNSCR, paragraph 3(1)(j)
Security		
E.5.1	Access control and physical security	GNSCR, paragraphs 3(1)(g), 12(1)(g), 12(1)(h), 12(1)(j); CII, subsection 15(12)
E.5.2	Inventory control	GNSCR, paragraphs 3(1)(g), 12(1)(g), 12(1)(h), 12(1)(j); CII, paragraph 21(5); NSRDR, subsection 36(1)
Packaging and transport		
E.6	Packaging and Transport of Nuclear Substances	PTNSR, sections 13, 15

Section	Title	Relevant legislation
Fitness for service		
E.7	Fitness for Service	CII, section 18; CII, subsection 16(2); NSRDR, paragraph 3(1)(i);
E.7.1	Post-servicing verification	CII, paragraphs 7(c), 21(2)(c); CII, section 17; GNSCR, paragraph 3(1)(1)
E.7.2	Verification following accident	GNSCR, paragraph 3(1)(1)
E.7.3	Stack monitor calibration	GNSCR, paragraph 3(1)(1); RPR, paragraph 4(a); CII, subsection 15(6)
E.7.4	Leak testing	CII, section 19
E.7.5	Servicing of safety systems	CII, paragraph 7(c), subsection 15(13) GNSCR, paragraphs 3(1)(1), 12(1)(d)
Part F: Routine Operation and Confirmation of Facility Design		
Routine Operation		
F.1	Routine Operation	CII, paragraph 4(f)
F.1.2	Isotope production facility – Processing procedures	NSRDR, paragraph 3(1)(a)
F.1.3	Geophysical logging accelerator – Operating instructions	CII, paragraph 4(f); GNSCR, paragraph 12(1)(e)
F.1.4	Emergency procedures	RPR, subparagraph 4(a)(iv)
F.1.5	Safety system verification	GNSCR, paragraph 12(1)(d)
F.1.6	Special instructions for nursing staff for a pulsed dose rate brachytherapy facility	GNSCR, paragraph 12(1)(b)
F.1.7	Servicing procedures	CII, paragraph 7(c)
F.1.8	Requirements for licensees who do not have a prescribed equipment servicing licence	CII, paragraph 11(1)(p)
F.1.9	Perimeter access control for temporary work sites – Mobile or portable accelerators	GNSCR, paragraph 3(1)(g)
F.1.10	Portable shielding	GNSCR, paragraph 12(1)(c)
Confirmation of Facility Design Implementation		
F.2.1	Confirmation of safety system functionality	CII, paragraph 4(c)
F.2.2	Radiation survey	GNSCR, paragraph 3(1)(i); CII, paragraph 4(c)
F.2.3	Commissioning results – Isotope processing facilities	GNSCR, paragraph 3(1)(i); CII, paragraph 4(c)
Part G: Decommissioning Plan		
G.1	Overview of decommissioning plan	CII, section 5
G.2	Personnel qualifications and training	CII, paragraph 5(j)
G.3	Estimate of types, activities and radiation doses from nuclear substances	CII, paragraph 5(g)

Section	Title	Relevant legislation
G.4	Disposal of Class II prescribed equipment, nuclear substances and hazardous materials	CII, paragraphs 5(f), 5(h), subsection 21(4); GNSCR, paragraph 3(1)(j), section 13; NSRDR, subsection 5(1)(1), subsection 19(2)
G.5	Disposal of Class II prescribed equipment, nuclear substances and hazardous materials –Isotope production facilities	CII, paragraphs 5(f), 5(h), subsection 21(4); GNSCR, paragraph 3(1)(j), section 13; NSRDR, subsection 5(1)(1), subsection 19(2)

Glossary

For definitions of terms used in this document, see REGDOC-3.6, *Glossary of CNSC Terminology*, which includes terms and definitions used in the *Nuclear Safety and Control Act* and the regulations made under it, and in CNSC regulatory documents and other publications. REGDOC-3.6 is provided for reference and information.

References

1. Canadian Nuclear Safety Commission, (CNSC), GD-52, *Design Guide for Nuclear Substance Laboratories and Nuclear Medicine Rooms*, Ottawa, 2010.

2. CNSC, G-129, rev. 1*Keeping Radiation Exposures and Doses "As Low As Reasonably Achievable (ALARA)"*, Ottawa, 2004.

3. CNSC, G-91, *Ascertaining and Recording Radiation Doses to Individuals*, Ottawa, 2003.

4. CNSC, REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources and Category I, II, and III Nuclear Material*, Ottawa.

5. International Atomic Energy Agency, *Code of Conduct on the Safety and Security of Radioactive Sources*, Vienna, 2004.

6. CNSC, REGDOC-1.5.1, *Application Guide: Certification of Radiation Devices or Class II Prescribed Equipment*, Ottawa.

7. National Council on Radiation Protection and Measurements, NCRP Report No.151, *Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities*, Bethseda, 2005.

8. American National Standards Institute / Health Physics Society, ANSI/HPS N43.10-2019, *Safe Design and Use of Panoramic, Wet Source Storage Gamma Irradiators (Category IV) and Dry Source Storage Gamma Irradiators (Category II)*, New York, 2001.

9. CNSC, REGDOC-3.2.1, *Public Information and Disclosure*, Ottawa.

10. CNSC, REGDOC-2.2.3, *Personnel Certification: Radiation Safety Officers*, Ottawa.

11. CNSC, REGDOC-2.2.2, *Personnel Training*, Ottawa.

CNSC Regulatory Document Series

Facilities and activities within the nuclear sector in Canada are regulated by the Canadian Nuclear Safety Commission (CNSC). In addition to the *Nuclear Safety and Control Act* and associated regulations, these facilities and activities may also be required to comply with other regulatory instruments such as regulatory documents or standards.

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- 2.1 Management system
- 2.2 Human performance management
- 2.3 Operating performance
- 2.4 Safety analysis
- 2.5 Physical design
- 2.6 Fitness for service
- 2.7 Radiation protection
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- 2.9 Environmental protection
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