



# Licence Application Guide Class II Isotope Production Accelerators

RD/GD-289

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## **Licence Application Guide, Class II Isotope Production Accelerators**

RD/GD-289

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### **Document availability**

This document can be viewed on the Canadian Nuclear Safety Commission Web site at

[nuclearsafety.gc.ca](http://nuclearsafety.gc.ca)

To order a printed copy of the document in English or French, please contact:

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## Preface

In accordance with the *Nuclear Safety and Control Act* (NSCA) and regulations made under it, a person wanting to construct, operate or decommission an isotope production accelerator facility, defined as Class II Nuclear Facility, requires a licence issued by the Canadian Nuclear Safety Commission (the Commission).

The NSCA prohibits the Commission from issuing a licence unless the Commission believes that the applicant is qualified, has made adequate provision for the protection of the environment and the health and safety of persons, and otherwise meets the requirements of the provisions of the NSCA and regulations made under the Act.

This licence application guide provides detailed information on completing the Class II Isotope Production Accelerator Application Form. While the use of the application form is not a specific requirement for licencing, 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 at [nuclearsafety.gc.ca](http://nuclearsafety.gc.ca).

CNSC staff can provide additional guidance upon request; contact the CNSC at [info@cnsccsn.gc.ca](mailto:info@cnsccsn.gc.ca).



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## **RD/GD-289, Licence Application Guide**

### **Class II Isotope Production Accelerators**

## **1. Introduction**

### **1.1 Purpose**

This licence application guide provides direction for the submission of the information required for a licence to construct, operate, or decommission facilities comprising a particle accelerator dedicated to the production of isotopes and, where applicable, the associated processing facilities. Those facilities are defined as Class II Nuclear Facilities and hereafter will be referred to as isotope production accelerator facilities. This guide includes the requirements for the design and use of any associated radioisotope processing facility.

### **1.2 Scope**

All licence requirements are based on the NSCA and regulations made under the Act, which are administered by the Canadian Nuclear Safety Commission (the Commission). The NSCA empowers the Commission to issue licences to applicants who, in its opinion, are qualified and make adequate provisions for the protection of the environment and the security, health and safety of persons, and otherwise meet the requirements and other conditions of the NSCA.

Each application should demonstrate that the applicant is capable of, and committed to maintaining an effective radiation safety program. This guide will assist an applicant in providing the required information.

### **1.3 Relevant legislation**

Legislation relevant to this guide is as follows:

1. Subsection 24(4) of the NSCA states that “No licence may be issued, renewed, amended or replaced unless, in the opinion of the Commission, the applicant (a) is qualified to carry on the activity that the licence will authorize the licensee to carry on; and (b) will, in carrying on that activity, make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.”
2. Section 26 of the NSCA states that “Subject to the regulations, no person shall, except in accordance with a licence: (a) possess, transfer, import, export, use or abandon a nuclear substance, prescribed equipment or prescribed information; (b) mine, produce, refine, convert, enrich, process, reprocess, package, transport, manage, store or dispose of a nuclear substance; (c) produce or service prescribed equipment;...(e) prepare a site for, construct, operate, modify, decommission or abandon a nuclear facility...”
3. Section 3 of the *General Nuclear Safety and Control Regulations* provides a list of the general information which an application for a licence shall contain.
4. Sections 3, 4 and 5 of the *Class II Nuclear Facilities and Prescribed Equipment Regulations* provide additional information which an application for a licence to construct, to operate and to decommission a Class II Nuclear Facilities shall contain.
5. Subparagraph 4(a)(iii) of the *Radiation Protection Regulations* states that “Every licensee shall implement a radiation protection program and shall, as part of that program, (a) keep the amount of exposure to radon progeny and the effective dose and equivalent dose received by

and committed to persons as low as is reasonably achievable, social and economic factors being taken into account, through the implementation of (i) management control over work practices, (ii) personnel qualification and training (iii) control of occupational and public exposure to radiation (iv) planning for unusual situations”.

6. Section 21(1) of the *Packaging and Transport of Nuclear Substances Regulations* states that “No person, other than the consignor or the consignee of the package, shall open a package unless (a) measures are taken to prevent persons from receiving doses of radiation higher than the radiation dose limits prescribed by the Radiation Protection Regulations; and (b) the package is opened in the presence of an expert in radiation protection.”

## **2. Process**

### **2.1 General**

The NSCA prohibits the Commission from issuing a licence unless the Commission considers that the applicant is qualified, has made adequate provision for the protection of the environment and the security, health and safety of persons, and otherwise meets the requirements of the provisions of the NSCA and regulations made under the Act. The application must show the Commission that an applicant is capable and committed to maintaining an effective radiation safety program which is sufficient to support a licence.

### **2.2 Applying for a licence**

An applicant must provide the information outlined in this licence application guide when requesting or renewing a Commission licence for an isotope production accelerator facility.

### **2.3 Amending a licence**

To request a licence amendment, the applicant must submit a written request to the Commission containing the following information:

- a statement identifying the changes to the information contained in the most recent licence application
- a description of the effects of the requested changes, including effects on nuclear substances, land, areas, buildings, structures, components, equipment and systems
- the proposed start date and expected completion date of any modifications described in the application

If information previously submitted to the Commission as part of a licence application has not changed, the applicant can refer to the previous application rather than resubmitting the same information.

### **2.4 Renewing a licence**

To request a licence renewal, the applicant must provide the information required by all relevant sections of this guide. If information previously submitted to the Commission as part of a licence application has not changed, the applicant can refer to the previous application rather than resubmitting the same information.



## 2.5 Revoking a licence

The applicant may request a revocation of an existing licence by sending a request in writing (an email is acceptable) to the Commission. CNSC staff may contact the applicant if additional information is required.

## 2.6 Submitting an application

Before submitting an application to the Commission, ensure the following:

- the application is complete and has been signed by the appropriate authorities
- all supporting documents are attached, 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 two copies of the application—signed and dated—to the Commission at:

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

To submit the application electronically, the completed form and supporting documentation can be sent to the Commission email address found at the bottom of the application form.

The applicant should keep a completed copy of the application for their records. All information submitted is subject to the provisions of the *Access to Information Act* and the *Privacy Act*.

## 3. Completing an application

Applicants for licences must provide all required information to the Commission. The Class II Isotope Production Accelerator Application Form may be used by applicants to assist them in providing this information. The form can be found on the CNSC Web site: [nuclearsafety.gc.ca](http://nuclearsafety.gc.ca).

For additional information, please contact the CNSC:

- toll-free: 1-888-229-2672
- fax: 613-995-5086
- email: [info@cnsccsn.gc.ca](mailto:info@cnsccsn.gc.ca)

Ensure that information provided on the form and in the attached supporting documents is clear, precise, accurate and complete. Attachments should specify to which section of the application form they pertain. Provide the document titles, as well as any cross-references.

**For all applications:** Complete Sections A–E (inclusive) and Section L.

Depending on the type of request being made, additional information from other sections of this guide must be provided. For renewal of existing licences complete Section F, and for all new licences complete the additional sections specified below:

- construction – Sections G and H
- operation for the purpose of commissioning – Section I
- operation (amendment) – Section J
  - the applicant must receive an amendment to an operating licence before routine operation of the facility can commence
- decommissioning – Section K

If the applicant is renewing or amending a licence, (e.g., from “operation for the purpose of commissioning” to “operation” status) the application may refer to any information previously submitted that is unchanged (i.e., the applicant doesn’t have to resubmit the same information). References to previously submitted material should, at minimum, include the previous licence number, the date and type of document, and page number(s). Any change from the previous application should be clearly stated.

### **3.1 Section A – Applicant’s information**

#### **A.1 Type of request**

Indicate if the application pertains to a:

- construction licence
- operation to commission licence
- routine operation licence
- decommissioning licence

In addition, indicate whether the application is to:

- apply for a new licence
- renew an existing licence

Indicate the current licence number, if applicable.

#### **A.2 Language of licence**

Choose the official language for the licence.

#### **A.3 Applicant information**

In this section, provide the name of the corporation or sole proprietor who will be referred to as the “licensee” on the issued licence.

**Applicant** - Provide the name of the person or organization applying for the licence. Indicate the name as it appears on the proof of legal status documentation, such as the proof of incorporation or sole proprietorship.

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

**Head office address** - Provide the legal, physical address of the applicant’s head office, including the complete street name and number, rural route number if appropriate, city, province or territory, and postal code. A post office box address is not acceptable for a head office address.

Notify the Commission within 15 days of any changes to this information.

**Mailing address** - Provide the mailing address if different from the head office address, including the complete street name and number, rural route number if appropriate, city, province or territory, and postal code.

If no address is provided here, the licence issued in response to the application will be mailed to the head office address. A post office box is acceptable as a mailing address.

Notify the Commission within 15 days of any changes to this information.

#### **A.4 Proof of legal status**

First time applicants must provide proof of legal status by appending proof of incorporation or sole proprietorship.

#### **A.5 Policy on public access to information**

Indicate whether any part of this application is subject to a request for exemption from the Commission policy on public access to the information.

As a government agency, the Commission is subject to the *Access to Information Act* (ATIA) and the *Privacy Act*. Pursuant to subsection 4(1) of the ATIA, 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 section 20 of the ATIA—is made available to the public, on request. Requests for exemption must be made in writing to the Commission, detailing the applicant's basis and reasons for such an exemption.

- If information may be made public, the applicant must check the “No” box
- If requesting that the information submitted not be disclosed, the applicant should check the “Yes” box and reference the exception that justifies the request.

#### **A.6 Billing contact person**

Provide the name of the contact person 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.7 Financial guarantees**

Section 24 of the NSCA allows the granting of a licence to be subject to financial guarantees. The purpose of that section is to ensure that licensees have detailed plans for decommissioning including how the associated costs will be funded. The attachment of financial guarantees to a licence will be determined upon assessment of each application. For more information about financial guarantees and licensing, consult G-206, *Financial Guarantees Guide for the Decommissioning of Licensed Activities*.

### **3.2 Section B – Licensed activities and locations**

In this section, the applicant must identify the activities associated with its operations as they relate to the *Canadian Nuclear Safety Commission Cost Recovery Fees Regulations*.

#### **B.1 Licensed activities**

Check as many activities as the applicant intends to conduct with the accelerator and the nuclear substances encompassed by the licence.

**B.2 Principal location of use or storage or both**

Provide the main address at which the isotope production accelerator facility is to be constructed, operated or decommissioned and for the use or storage or both of the accelerator or nuclear substances. The address must—at minimum—consist of a room number, a street name and number, city, province and postal code.

For construction licence applications, either provide evidence that the applicant is the owner of the site or that it has the authority from the owner to construct and operate a nuclear facility at this site.

**B.3 Other locations**

If the nuclear substances encompassed by the licence are to be used or stored at locations other than those shown in section B.2, identify the additional locations in the space provided.

For each location, indicate whether nuclear substances will be used (including processing), or stored at that location. Additional locations may be appended on a separate sheet if required.

**3.3 Section C – Nuclear substances and Class II prescribed equipment****C.1 Class II prescribed equipment****A. Isotope production accelerators**

Before licensing isotope production accelerators, which are defined as Class II prescribed equipment, their design must be certified by the Commission unless they are used in accordance with a licence that authorizes their use for development purposes or scientific research. For more information about the certification of isotope production accelerators, please refer to the CNSC Regulatory Guide RD/GD-254, *Certification of Radiation Devices or Class II Prescribed Equipment*.

No person is permitted to use Class II prescribed equipment not certified by the Commission unless exempt as per the *Class II Nuclear Facilities and Prescribed Equipment Regulations*.

For each isotope production accelerator the applicant will be using, provide the CNSC certificate number and the following information:

- the name of the device's manufacturer
- the device's model name and manufacturer number
- the types of beam and the accelerator's maximum energy and current

**B. Accelerator targets**

Specify the targets to be used for isotope production. At a minimum, this should include the manufacturer's part or model number (if known), the nuclear reaction used to produce the desired isotope with that target, the material the target is made from, the accelerator beam characteristics to be used in conjunction with each target, and the typical end of beam (EOB) yields.

The following table, based on a typical positron emitting tomography (PET) isotope production cyclotron, provides a typical format for this information.

Target chamber				Maximum beam current ( $\mu\text{A}$ )	Bombardment time (min)	Maximum EOB Activity (GBq)
Part No.	Nuclear reaction	Product	Material			
ABC123	$^{18}\text{O}(\text{p},\text{n})^{18}\text{F}$	$^{18}\text{F}^-$	Niobium	45	120	40
DEF456	$^{16}\text{O}(\text{p},\alpha)^{13}\text{N}$	$^{13}\text{N}$ $\text{NH}_3$	Aluminium	20	10	30
DEF456	$^{14}\text{N}(\text{p},\alpha)^{11}\text{C}$	$^{11}\text{C}$ $\text{CO}$ , $\text{CO}_2$	Aluminium	40	40	50
HIJ789	$^{14}\text{N}(\text{d},\text{n})^{15}\text{O}$	$^{15}\text{O}$ gas	Aluminium	50	30	10

Additional information regarding the targets, including technical drawings and specifications, will be required under section G.3 as part of the application for a licence to construct. If the applicant intends to design and test new targets, a detailed description of the corresponding quality assurance program for the targets' design and testing and the safety procedures to conduct those tests is also required in section G.3.

## C.2 Nuclear substances

The isotopes produced using an accelerator are typically in liquid or gaseous form and are considered open sources. 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 activity** for each isotope produced in one calendar year. Note that a Class I licence and environmental assessment will be required if the total activity for all isotopes processed exceeds  $10^{15}$  Bq in one calendar year.

When determining the **maximum quantity** that may be present on site, considerations should include the maximum 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 which will be kept on hand locally for quality control purposes or as waste; and the isotope's half-life.

If sealed sources such as check sources are also to be included under the licence, list the isotope, manufacturer, model number, and **maximum individual source activity for each source**.

## 3.4 Section D – Radiation safety program

In this section, describe the applicant's radiation safety program. The description must include the organization management structure, the title and position in the organization of persons supervising and implementing the program and of those using the accelerator and the nuclear substances.

The radiation safety program components described in this guide do not prevent applicants from proposing alternatives, but any proposed radiation safety program should appropriately reflect the complexities and hazards of the activities described in the application. In addition, since the licensee is ultimately responsible for radiation safety related to the activities authorized by the

licence, an effective radiation safety program must have the support, commitment and participation of management and staff.

#### **D.1 Radiation Safety Officer**

The Radiation Safety Officer (RSO) is the person responsible for the management and control of the licensed activities and is the person CNSC staff will contact about radiation safety and compliance matters. The RSO must be familiar with the accelerator facility operations described in this application and the use of nuclear substances encompassed by the licence.

On the application form, provide the name of the person to be designated as RSO. New RSOs for all Class II facilities are subject to certification by the Commission.

- If the designated RSO has already been certified by the Commission, provide the certificate number
- If this person has not been certified as the RSO for this facility, please contact CNSC staff for more information regarding the certification process

The regulations include provisions for designating an alternate RSO for periods when the named RSO is absent from the facility. If the RSO will be absent for an extended period, the applicant must designate a new RSO for the duration of the absence and apply for certification of the new RSO. For more information consult section 15.1 of the *Class II Nuclear Facility and Prescribe Equipment Regulations*.

The applicant must notify the Commission within 15 days of a change in RSO or the RSO's job description.

#### **D.2 Radiation Safety Officer job description**

Append the job description of the RSO, which should include the time and resources allotted for the RSO to carry out the duties of the position. The applicant should authorize the RSO, in writing, to supervise and administer the radiation safety program to ensure that work is conducted in accordance with all regulatory requirements.

#### **D.3 Radiation Safety Officer acknowledgement**

Once the applicant authority has designated an RSO, the RSO must acknowledge their willingness to be the RSO and to accept the responsibilities outlined in the job description.

Have the RSO sign Box D.3 of the application form to acknowledge their willingness to be so designated.

#### **D.4 Organizational management structure**

Provide a detailed description of the management and organization structure relating to radiation safety, including:

- positions and titles of the persons responsible for the management and control of the accelerator operation and the nuclear substances under the licence
- functions, responsibilities and authority of each position named above
- an organization chart that shows the lines of reporting, communications and responsibility for radiation protection

### **D.5 Radiation Safety Committee terms of reference**

If applicable, append a copy of the Radiation Safety Committee's (RSC) or Health and Safety Subcommittee's terms of reference or mandate, for radiation safety. RSCs are formed to monitor, advise on, or oversee radiation safety matters, and their primary role is to advise RSOs and management on the quality and effectiveness of radiation safety policies and programs, and the safety of work practices. Members of RSCs are usually selected or appointed because of their expertise or job-related interests in radiation safety.

## **3.5 Section E – Radiation safety policies and procedures**

In this section provide the information given to workers regarding the applicant's radiation safety program.

A radiation safety program should be documented and have detailed policies and procedures that are prepared under the supervision of the RSO and approved by senior management. It is recommended that these policies and procedures be incorporated into a radiation safety manual that is readily available to all workers.

### **E.1 ALARA (as low as reasonably achievable)**

Append the policy that ensures that radiation exposure is as low as reasonably achievable (ALARA).

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

### **E.2 Qualifications and duties of workers**

Provide a list of all anticipated job categories of workers who will be working with the accelerator or nuclear substances encompassed by the licence. Include a brief description of the proposed roles, responsibilities and duties for each category, as well as the qualifications and experience workers must have to perform these duties. Submit an overview of any proposed additional in-house training program for each category of worker.

Workers should be individually authorized to work with nuclear substance and isotope production accelerators following successful completion of an appropriate training program. Any significant change to procedures should require re-training in the use of these procedures. Periodic refresher training is also advisable.

### **E.3 Worker radiation safety training**

Describe in detail the proposed radiation safety training program. The applicant should not assume that radiation safety training obtained elsewhere is adequate for its operations. Applicants should provide site- and task-specific radiation safety training for all new workers, and training should be tailored to the educational background and practical needs of those attending. Records of worker training must be maintained.

Workers should be retrained before being asked to perform tasks that have been significantly changed. In addition, periodic refresher training should be given to all workers at appropriate intervals (the Commission recommends every two years). Auxiliary personnel, such as clerical, janitorial, maintenance and security staff should also be instructed in the basic concepts of radiation safety.

Staff who will be involved in packaging, sending or receiving shipments of nuclear substances must be trained in the relevant requirements of Transport Canada's *Transportation of Dangerous Goods (TDG) Regulations*, and must possess a valid TDG certificate.

#### **E.4 Designation of nuclear energy workers (NEWs)**

If there is a reasonable probability that a worker's effective dose may exceed the general public dose limit of 1 mSv per year, the worker must be designated as a nuclear energy worker (NEW).

Append the policies and procedures to designate NEWs. The *Radiation Protection Regulations* require that NEWs be informed of their status, the risks associated with radiation to which they may be exposed, the applicable effective dose limits, the worker's radiation dose levels and their obligations. The procedures must clearly state which positions or categories of staff must be designated as NEWs; who is responsible for ensuring they are notified of this designation; the method of notification; and who is responsible for retaining the list of NEWs. Include the information provided to each female NEW regarding her rights and obligations if pregnant. Licensees must obtain written acknowledgement from each worker that this information has been received.

#### **E.5 Personal dose monitoring**

Append the procedure for monitoring radiation exposure in accordance with the *Radiation Protection Regulations* and Regulatory Guide G-91, *Ascertaining and Recording Radiation Doses to Individuals*.

#### **E.6 Action levels**

Action levels are designed to alert licensees before regulatory limits are reached. When a licensee becomes aware that an action level has been reached, it must investigate, take corrective action and notify the Commission within the time period specified in the licence.

Propose an action level as part of the licence application only if that action level is to be part of the overall management of the radiation safety program. The action level will then be referred to in the licence and the applicant must append the policies and procedures to follow when an action level is reached.

If action levels are not part of the radiation safety program, explain why they are not necessary.

#### **E.7 Radiation detection instruments**

Append a list of all gamma radiation survey meters, neutron survey meters and contamination monitors which are to be used in conjunction with the accelerator and nuclear substances. This list should include the following information:

- manufacturer
- model
- serial number
- type of detector
- energy range
- sensitivity of each instrument

Calibrated radiation survey meters must be available at all times. The suitability of any survey meter should be verified prior to use, as some photon survey meters respond



inaccurately to the pulsed, high energy radiation fields produced by typical electron linear accelerators. Instruments with analog displays (e.g., magnetic deflection meters) are not suitable for use in the strong magnetic fields in the immediate vicinity of cyclotrons.

Submit the policies or procedures for the use and calibration of these instruments. If a commercial calibration service is used, please provide the name and contact information of the company performing the calibration.

Before using any portable survey meter, the user should confirm that it has been calibrated within the last 12 months and verify that the instrument is functioning properly by performing:

- battery check
- high voltage check (if applicable)
- source/response check
- any other pre-operation test specified in the instrument's operating manual

## **E.8 Radioactive contamination control**

Append the policies and the procedures for monitoring the workplace for evidence of radioactive contamination. The procedures must include the following elements.

### **Monitoring procedure**

Monitoring for radioactive contamination can be done by indirect or direct methods. The indirect method of contamination monitoring involves systematically collecting and counting wipe samples from workplace surfaces and measuring removable contamination, while 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, corrective actions must be taken.

### **Sampling locations**

Provide a map illustrating the physical layout of all rooms in which radioisotopes are to be processed or handled, and where contamination monitoring may be required.

### **Detection instruments**

For each contamination monitor identified in section E.7 provide:

- evidence that the instrument can detect isotopes being produced at the corresponding contamination limits identified in the contamination limits section below
- calculations to convert measurement results (e.g., in counts per unit time) to equivalent levels of surface contamination in Bq/cm<sup>2</sup>

### **Frequency**

Specify when contamination must be monitored. For example:

- at least weekly
- after each production run
- after spills or incidents
- before equipment is released for non-radioactive use
- before decommissioning

### **Records**

Indicate how contamination monitoring results will be recorded and who will be responsible for ensuring these records are maintained.

**Contamination limits**

The amount of removable contamination permitted in an area is regulated through a licence condition incorporated into the facility operating licence. Typically, a licence will require that removable contamination not exceed the following limits when averaged over a surface area of not more than 100 cm<sup>2</sup>.

For controlled areas:

- 3 Bq/cm<sup>2</sup> of Class A radionuclides, which are long-lived and emit alpha radiation
- 30 Bq/cm<sup>2</sup> of Class B radionuclides, which are long-lived and emit beta or gamma radiation
- 300 Bq/cm<sup>2</sup> of Class C radionuclides, which are short-lived and emit beta or gamma radiation

For supervised public areas and for decommissioning:

- 0.3 Bq/cm<sup>2</sup> of Class A radionuclides
- 3 Bq/cm<sup>2</sup> of Class B radionuclides
- 30 Bq/cm<sup>2</sup> of Class C radionuclides

A list of Class A, B and C radionuclides is provided in Appendix A. The applicant may request approval for other contamination limits if they can demonstrate that the resulting maximum effective dose to any individual is less than 10 µSv per year.

**E.9 Rooms – posting**

The *Radiation Protection Regulations* require posting a durable and legible radiation warning sign 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. In addition the *Class II Nuclear Facility and Prescribed Equipment Regulations* require posting at the entrance of a Class II facility a durable, legible sign indicating the name or job title and telephone number of a person who can be contacted 24 hours a day in case of an emergency.

In addition, based on the risk level of the laboratory, the licence may require posting of the following information:

- basic-level – *Basic Level – Use of Unsealed Nuclear Substances* (INFO-0728-1)
- intermediate-level – *Intermediate Level – Use of Unsealed Nuclear Substances* (INFO-0728-2)
- high-level – *High Level – Use of Unsealed Nuclear Substances* (INFO-0728-3)

Append the policy for posting of rooms where accelerators and nuclear substances are stored or used.

**E.10 Access control and security**

Access to nuclear substances and accelerators must be controlled wherever they are used or stored. In addition, access to radioactive shipments and to sources destined for disposal must also be controlled. Nuclear substances must be stored in a locked area, room or enclosure when not in use or when not under the direct supervision of an authorized worker. Security measures should address prevention of unauthorized access to, or operation of, equipment outside of normal working hours.

Append the policy for restricting access to nuclear substances and Class II prescribed equipment to authorized workers only.

**E.11 Inventory control and records**

The applicant must maintain an inventory of nuclear substances, and because they control the purchase and transfer of nuclear substances, they must know what is in storage, in use or awaiting disposal.

Append policies and procedures for inventory control.

Purchase records must be maintained and available for inspection. Transfers from other licensees should be included in purchase records in order to keep track of the applicant's acquisitions. These records must include:

- name, quantity and form of the nuclear substance
- the date received
- name, address and licence number of the supplier
- the country of origin
- the serial number of each sealed source

Inventory records must show the total quantity of nuclear substances in storage, in use or awaiting disposal. These records must include:

- name, quantity, form and location (room number) of the nuclear substance
- the name of the person responsible for secure storage and safe use at that location
- the serial number of each sealed source

**E.12 Receipt of packages**

Packages should be promptly moved from the receiving area to a secure storage room where the package may be examined for damage and, if necessary, checked for contamination. During off-duty hours, deliveries should be stored in a specified location which will provide security and prevent unnecessary exposure.

Append the procedure for receiving shipments of nuclear substances.

**E.13 Packaging and transporting nuclear substances**

The radiation safety training program shall include the relevant requirements of Transport Canada's *Transportation of Dangerous Goods Regulations* and the CNSC *Packaging and Transport of Nuclear Substances Regulations*.

Append the procedures to be followed for packaging and transporting nuclear substances.

**E.14 Leak-testing of sealed sources (if applicable)**

The *Class II Nuclear Facilities and Prescribed Equipment Regulations* require that leak tests be conducted by licensees who possess or use sealed source containing 50 MBq or more of a nuclear substance.

Append the procedures for leak-testing of sealed radioactive sources. Include the proposed instructions for the leak-test sampling and analysis (measurement), as well as copies of the forms for recording leak-testing activities. Additionally, include the proposed actions to be taken if a sealed source is found to be leaking. If a commercial leak testing service is used, provide the name and contact information of the company performing the testing.

**E.15 Management of radioactive and other hazardous wastes****Radioactive waste**

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

- isotope name of the nuclear substance(s)
- activity (in Becquerels)
- description of activated component
- weight or volume of the material or both
- physical or chemical form of the nuclear substance

Append the procedures for handling, transferring and disposing of radioactive waste. Any or all of the following methods for the disposal of radioactive waste may potentially be authorized:

- storing for radioactive decay
- returning to the supplier
- sending to a facility possessing an appropriate Commission licence

Should the applicant propose waste disposal methods other than those listed above, it must provide a detailed explanation and justification. For each unsealed and sealed nuclear substance, append a summary of the annual quantity of radioactive waste transferred, disposed of, released or abandoned for the previous licensing period.

The applicant may select the year-end date.

For each substance, report the quantities and the method of release, such as to municipal garbage systems, municipal sewers, the atmosphere and other destinations.

**Other hazardous waste**

Append a list of any other, non-radioactive hazardous material which is to be handled, including the following:

- name of the substance
- quantity
- physical or chemical form
- country of origin
- nature of the hazard presented by the material

**E.16 Emergency procedures**

Prompt and proper action is a prime consideration in limiting the damage which may result from an accident. A radiological emergency may involve exposure to radiation, contamination with nuclear substances, or both. Procedures must include plans for dealing with possible incidents and accidents.

Append or refer to the methods, procedures and equipment that will be used during and following an accident resulting from operation of the isotope production accelerator or associated processing activities. Some examples of emergencies for which procedures should be developed include:

- malfunction of the accelerator
- loss of containment of isotopes during production or processing, including target failure, rupture of transfer lines, lab spills and environmental release
- fires
- spills of toxic chemicals

- lost or stolen nuclear substances
- radiation exposures

Emergency procedures should address each of the following as required:

- evacuating the immediate area of the incident and controlling entry to the site
- location and use of emergency equipment
- limiting the radiation dose to involved personnel
- limiting the spread of contamination
- monitoring any potential release from the site
- identifying, isolating and treating workers or other persons who may be contaminated or may have received high radiation exposures
- detecting and estimating the quantity of nuclear substances involved
- decontaminating the site, equipment, workers and other persons
- recording the details of the emergency and notifying the Commission pursuant to regulatory requirements

#### **E.17 Reporting requirements**

Append the policies and procedures for ensuring reportable occurrences are reported to the Commission within the required time period. The policies and procedures include a list of events that would prompt such a report to the Commission and the information required in the report in accordance with section 29 of the *General Nuclear Safety and Control Regulations*.

#### **E.18 Record keeping requirements**

Append the policies and procedures that ensure all required records are kept and available for inspection. Records must be retained for the time period specified in the regulations or, if no period is specified in the regulations, for one year after the expiry of the licence and cannot be disposed of without first notifying the Commission.

A record control procedure must include provisions for:

- ensuring that records are stored in a defined location and are easily retrievable
- defining how each record will be stored (i.e., electronically vs. on paper)
- ensuring that records are legible and readily identifiable
- identifying the records that must be periodically reviewed to ensure completeness, consistency and accuracy; the focus being on records that are filled regularly or by different staff or both
- specifying the frequency of the review
- identifying title of the person responsible for reviewing the records
- keeping a record of the reviews
- reporting inaccuracies and deficiencies in records to the Commission within 21 days of becoming aware of the inaccuracy or deficiency

The record control procedure must apply to the following records:

- the names of persons who work with the accelerator or handle nuclear substances
- the names and job categories of nuclear energy workers
- the training received by each worker who works with the accelerator or handles nuclear substances, including the date and subject of training
- dosimetry results
- internal bioassay results, if applicable

- surveys of radiation dose rates required by the licence
- accelerator workload
- inspections, verifications, servicing and tests of the accelerator and of facility equipment. Records of servicing and tests must include a description of the work done, its results as well as the date on which it was performed
- modifications, repairs, maintenance and return to operation of the accelerator and of facility equipment
- transfer of an accelerator, including the date of transfer, the licence number of the organization to whom the equipment was transferred, and the model and serial number of the equipment
- any record required by operational procedures
- facility design plans and construction specifications
- commissioning test procedures and test results
- quality assurance program for the design and testing of experimental targets
- facility decommissioning reports
- a list of laboratories, rooms and other locations designated for the use or storage of nuclear substances
- records of acquisitions, disposals, transfers of nuclear substances
- the inventory of both sealed and unsealed sources
- the inventory and calibration records of radiation detection equipment
- contamination monitoring results
- records of methods and characteristics of radioactive waste disposal
- nuclear substance transfer and transport documents
- leak test monitoring results
- details of emergencies and other incidents involving the accelerator or nuclear substances
- any other record specified under the NSCA, its Regulations or the licence

#### **E.19 Quality assurance (QA)**

Every licensee who constructs, operates, services or decommissions a Class II nuclear facility must have a quality assurance program in place to ensure that the licensed activities are conducted in accordance with the *Nuclear Safety and Control Act*, the regulations made pursuant to the Act and licence conditions. The required QA program must—at minimum—address the following aspects of how the licensed activities are conducted:

- conformance with the licensees' operating policies and procedures as referenced in the licence
- periodic verification of the functioning of key safety systems and control mechanisms

The licensee must identify the safety related aspects of the operation that will require QA.

The following set of program elements is suggested as the basis for developing the required QA program:

- definition
- policy
- organization and responsibilities
- personnel capability
- use of experience
- work planning and control

- work process control
- verification
- non-conformance
- corrective action
- change control
- document and record control
- audits

Append the QA program as it applies to radiation safety at the facility.

## **E.20 Decommissioning**

The licensee will be required to apply for a decommissioning licence for the facility once the accelerator reaches the end of its operating lifespan (see section K of this guide). A detailed final decommissioning plan will be required at that time.

However, early planning and provisions for decommissioning are essential. Consequently, a preliminary decommissioning plan is required in conjunction with the construction and operating licence applications, and must be reviewed at each licence renewal during the operating life of the facility.

The preliminary decommissioning plan should contain the following elements:

- a brief overview of the principal radiological, chemical and physical conditions and potential hazards predicted to exist at the end of operations
- a statement of the predicted final end state objectives for the facility (e.g., reuse for a new accelerator, release for other non-radiation related uses)
- a brief overview of how decommissioning will be conducted, with emphasis on who will conduct the work and how radioactive materials and other hazardous substances will be identified, segregated and disposed of
- a reasonable estimate of the time and cost required to complete decommissioning following the end of operations

Note that section 24 of the NSCA allows a licence to be granted, subject to financial guarantees. The attachment of financial guarantees for decommissioning to a licence is determined on a case-by-case basis during the assessment of each application. For more information about financial guarantees and licensing, consult the CNSC guidance document G-206, *Financial Guarantees Guide for the Decommissioning of Licensed Activities*.

## **3.6 Section F – Renewals**

This section outlines the information the applicant must submit to renew an existing Class II nuclear facility licence. Most of the information required essentially updates key elements of the information submitted in a previous licence application or an annual compliance report (ACR).

### **F.1 Radiation dose summary**

Append a report summarizing the most recent annual radiation dosimetry results for all monitored workers. Where groups of monitored workers have significantly different exposures, the summaries should group similar job types, types of exposure, nuclear substances handled, or work location. Provide the name of the dosimetry service used.

For the summary, report the number of persons who receive an annual dose in each of the following ranges:

- < 0.2 mSv
- $\geq 0.2$  but < 0.5 mSv
- $\geq 0.5$  but < 1.0 mSv
- $\geq 1.0$  but < 5.0 mSv
- $\geq 5.0$  but < 20.0 mSv
- $\geq 20.0$  mSv

Separately, list the names of any monitored workers whose recorded doses exceeded any limit specified in section 13 of the *Radiation Protection Regulations*.

## **F.2 Sealed sources acquired, transferred, or disposed of**

Provide a list of any sealed sources that were acquired, purchased, transferred or disposed of during the previous licensing period.

Acquisitions include gifts, loans or transfers from other licensees. The regulations require that acquisition, release and transfer records include the following:

- name, quantity and form of the sealed sources acquired, purchased, transferred, or disposed of
- date of receipt, transfer or disposal
- supplier or recipient's name, address and licence number
- sealed source model and serial number

## **F.3 Nuclear substance inventory**

Provide an inventory of nuclear substances in the applicant's possession. Include material in stock or storage, material in use, and material waiting for disposal. Inventory records must include the following:

- name, quantity, form and location
- source model and serial number
- what it is used for
- who will use or handle the nuclear substance

## **F.4 Incidents**

Append a brief description of any occurrence or incident during the previous licensing period that required investigation and, if needed, of any remedial action taken to prevent their recurrence. If the applicant has previously reported an incident to the Commission, reference the report.

## **F.5 Occupancy review**

Append an update on the information required in G.6 of this guide regarding the purpose and occupancy of areas adjacent to the Class II nuclear facility. Highlight any change from the original facility design.

## **F.6 Accelerator operating workload**

Provide a summary of the accelerator annual workload (including each of the parameters given in the summary table included with the application form) or their equivalent. For each reaction and end product listed, also provide the maximum annual workload allowed for in the facility design.



**F.7 Radiation survey**

Append the results of the most recent photon and neutron radiation surveys. This survey should be made while considering the worst case conditions, as outlined in section I. The results must include drawings of the facility clearly showing the measurements points. Measurements should be made in each of the adjacent areas listed in F.5.

**3.7 Section G – Facility design**

Submit detailed plans and drawings illustrating the shielding design of the facility and the purpose and occupancy of adjacent areas. Estimate the radiation dose rates that will be present in adjacent areas as a result of the operation of the proposed facility, and the resulting annual radiation doses which will be incurred by workers and others occupying these areas. Once the licence to construct is issued, the facility must be constructed in accordance with the plans submitted.

**G.1 Information program**

Describe the program that will be in place to inform persons living in the vicinity of the site of the general nature and characteristics of the anticipated effects on the environment and the health and safety of persons that may result from the operation of the facility.

For more information about public information programs, please refer to the CNSC Guide GD-217, *Licensee Public Information Programs* or its successor documents.

**G.2 Accelerator facility plans and drawings**

Provide plans to scale and elevation drawings containing sufficient information to allow CNSC staff to evaluate the proposed facility. On these plans and drawings, the applicant must show:

- the direction of north
- the scale of the drawings (e.g., 50:1, ¼ inch per foot)
- the location of the facility with respect to nearby occupied or potentially occupied areas
- the location and purpose of the adjacent areas, such as public areas, offices, laboratories, change rooms, washrooms and storerooms; include the areas above and below the facility. For each area, provide the room number, name or its description: they will be used to reference their purpose and occupancy as required in section G6
- the layout of the accelerator and its related equipment within the boundary of the facility
- the location, type and thickness of shielding materials used on all sides of the facility including the floor and ceiling. Where applicable, include drawings illustrating the type, thickness and configuration of shielding materials incorporated in the facility's entrance door
- the location and dimensions of access ways, exits, service ducts and other penetrations and voids in the shielding
- the location and dimensions of the ventilation system and characteristics of the filtration system
- if applicable, the location of any holding tank or other containment system used to trap isotopes in the event of an accidental release (e.g., due to a ruptured target window or inadvertent release inside a hot cell)

- if applicable, the location, dimensions and shielding thicknesses for any radioactive waste storage pit that is an integral part of the facility

### G.3 Description of the targets

Append the drawings and technical specifications for the targets to be used, and provide information demonstrating that the targets will not fail in a way that would result in the release of radioactivity.

If the licensee wishes to develop experimental targets, include the technical specifications for the proposed targets. In addition, the applicant must provide a detailed description of quality assurance program for the design and testing of the targets which will ensure that targets are engineered in a manner which is fully compatible with the intended irradiation conditions. Additional safety procedures may also be required to accommodate all anticipated experimental configurations.

### G.4 Description of the processing facilities

**Important:** The sections of this guide pertaining to processing of isotopes are only intended for use in situations where the isotope production accelerator and the associated processing facilities are integrated into a single radiopharmaceutical production site, and the total quantity of radioactive material to be processed is less than  $10^{15}$  Bq/year. If the radioisotopes produced by the accelerator are to be shipped to and processed at a site independent from the accelerator, then processing should be licensed separately as per the *Nuclear Substances and Radiation Devices Regulations*. If the facility is expected to process more than  $10^{15}$  Bq of radioisotopes per year, it qualifies as a Class IB nuclear facility under the NSCA and will be subject to the *Class I Nuclear Facility Regulations*.

In either of these cases, please contact the CNSC to obtain further information regarding licensing of processing operations.

For integrated production and processing facilities handling less than  $10^{15}$  Bq/year, applicants must submit:

- drawings to scale illustrating the layout of processing facilities; these drawings must clearly show:
  - the location of all key components of the processing system, including hot cells
  - the location of the processing facilities with respect to the accelerator and other nearby occupied or potentially occupied areas
  - if applicable, the location of any transfer line used for delivering isotopes from the accelerator to the processing facilities, including details of any shielding, radiation warning indicators and signs to be incorporated along the length of the transfer lines
  - 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 radiation doses expected, and the pressures to be used. Include the specifications for gas regulators and other critical components of the transfer system
  - a description of the chemical processes to be 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 materials handled

- the ventilation system for the radiochemical fume hoods and hot cells, including details of filter media to be used
- a completed Design Assessment Form for Nuclear Substance Laboratories and Nuclear Medicine Rooms from the CNSC guidance document GD-52, *Design Guide for Nuclear Substance Laboratories and Nuclear Medicine Rooms*

### **G.5 Description of radiochemical hot cells/processing stations**

Provide a description of the hot cell or other shielded containment used for hot chemistry. It should include calculations or measurements to demonstrate that the shielding incorporated in the hot cells is adequate to ensure that doses to staff and the public will be ALARA. Include a description of any remote handling tool or shielded container used to further reduce doses.

### **G.6 Classification of adjacent areas**

Describe the purpose (e.g., office space, corridors, control areas) of all areas adjacent to the facility, including areas above and below. Based on the planned use of each area and an evaluation of the shielding (see section G.9), classify each area as:

**Non-controlled:** In a non-controlled area, access is not restricted to any person

**Controlled:** In a controlled area, access is restricted to appropriately trained and authorized personnel. For each controlled area, identify the proposed access control measures, which should be commensurate with the radiation doses that may be incurred in that area.

**Exclusion:** An exclusion area must have access controls interlocked to the accelerator so that no one can gain access to the area when the accelerator is in operation. The interlock systems required are described in section H.

List the occupancy factor (T) for each area (i.e., the fraction of the facility's normal operating day during which a person might reasonably be expected to occupy a given area).

### **G.7 Accelerator workload**

Provide the anticipated maximum annual workload for the accelerator facility. List each isotope to be produced, the nuclear reactions to be employed for production (beam type/target material combination), the total hours of beam used per year for the production of each isotope, and the total quantity of each isotope produced. A typical workload table is provided in the application form.

### **G.8 Isotope pathway**

Provide a detailed description of the isotope product pathway in the facility. In the description, include:

- the number of production runs per day anticipated for each target and isotope produced
- the duration of each production run
- the method used to transfer the target to the processing facilities (if applicable)
- the duration of the transfer process
- a description of the processing procedures, (if applicable), including the sequence of steps, the locations where the each isotope will be handled, the chemical agents and the equipment used and the estimated duration for each step

- a description of the product quality control activities, including the amount of product used (Bq), the method used to verify its activity, the sequence of steps, the locations where each isotope will be handled and the estimated duration for each step of the quality control activities
- a description of the packaging process prior to transport

### **G.9 Dose rates and annual dose calculations for adjacent areas**

Append detailed calculations of the maximum dose rates and annual doses expected in each of the adjacent areas listed in subsection G6. Any assumption made and the value of each parameter used in the calculations must be clearly stated and referenced.

Estimated doses meeting the recommendations in the CNSC guide G-129 rev. 1, *Keeping Radiation Exposures and Doses “As Low As Reasonably Achievable (ALARA)”* will normally be accepted as being ALARA without further justification. Cost-benefit analysis must be provided to justify any annual dose in excess of that recommended in G-129. Under no circumstance may the projected dose to persons exceed the annual limits prescribed in the *Radiation Protection Regulations*.

The calculated dose rate and dose estimates for the facility should explicitly include assessment of:

#### **Whole body (effective) annual doses in mSv/year from:**

- operation of the accelerator, including commissioning
- rebuilding of accelerator targets or maintenance of activated components
- transfer of product from the accelerator to the processing facilities
- any processing activity conducted under the licence
- packaging of isotopes for shipment
- routine and potential accidental environmental releases (e.g., stack releases)

#### **Annual extremity (equivalent) doses in mSv/year from:**

- rebuilding or replacing accelerator targets or maintenance of activated components (e.g., dees, stripping foils)
- processing, quality control, packaging and contamination cleaning activities

The calculations should explicitly include consideration of factors such as:

#### **For the accelerator:**

- the source term – a calculation or other estimation of the prompt gamma and neutron radiation produced during bombardment for each beam/target/reaction combination. Note that for self-shielded accelerators, such as some models of PET cyclotrons, the manufacturer’s specifications for the radiation leakage dose rates outside the accelerator shielding under typical operating conditions may be used provided that these specifications reasonably correspond with the proposed operating conditions for the accelerator.
- the annual workload in terms of the anticipated number of hours of operation for each beam/target/reaction/beam current combination
- type and thickness of materials used in shielding barrier
- shielding properties or transmission factors of barriers for the types and energies of radiation produced
- occupancy and utilization of adjacent areas
- distance from the radiation source to the point of interest
- neutron and photon scatter down entrance mazes, ducts and other penetrations of the shielding

**For the transfer of product from the accelerator to the processing facilities, processing activities and packaging of isotopes for shipment.**

- type and activity of the isotopes
- proximity to source
- shielding in hot cells, lead glass shields and storage or packaging containers
- duration of each procedure
- number of procedures per year

**For doses due to routine and potential accidental environmental releases:**

- maximum activity potentially released
- proximity of stack to potentially occupied areas
- stack height above building
- height of building
- stack exit velocity
- stack inner diameter
- stack exhaust temperature
- assumptions of atmospheric condition and wind speed and direction used in the calculation

If Monte-Carlo simulations or other commercial shielding calculation software are used, the applicant must identify the code or software package and any key input parameters used in the calculations.

In the case of open beam systems, such as electron linacs, where significant air activation may occur within the accelerator vault, submit an evaluation of the concentrations of toxic gases (e.g., ozone) produced by the accelerator and the anticipated radiation doses to staff from radioactive gases (nitrogen 13 and oxygen 15). This evaluation must demonstrate the adequacy of the proposed ventilation system.

For accelerators that use beam stops, such as Faraday cups, submit an evaluation of the adequacy of the beam stop and the radiation dose rates produced with the beam stop inserted.

**G.10 Other design considerations**

Describe the proposed means of verifying the shielding density and composition.

Also describe air pressures and flows in the processing area, the hot cells and the accelerator vault and the means of achieving the air balance required to ensure proper containment of the radioisotopes produced and the instrumentation to be used for monitoring and recording these pressures.

**3.8 Section H – Safety system requirements**

In this section, describe the safety systems to be installed at the facility. The safety systems listed here are either explicitly required by the *Class II Nuclear Facilities and Prescribed Equipment Regulations* or are industry standard requirements that are implicitly expected to be part of any isotope production accelerator facility. Any substitute system should 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 provide:

- a diagram illustrating the location of each safety system with respect to the physical layout of the accelerator and processing laboratories
- wiring schematics for the safety interlocks (i.e., the last person out circuit, door or entrance interlocks and emergency stops) that are external to the accelerator

### **Safety system exemptions**

Subsection 15(14) of the *Class II Nuclear Facilities and Prescribed Equipment Regulations* exempt a facility from the requirement for an entrance interlock (Section H.1), a start-up alarm (Section H.3) and emergency stop buttons at locations other than the console (Section H.4, items b and c) if the accelerator meets at least one of the following criteria:

- its radiation dose rate at 30 cm is not greater than 200  $\mu\text{Sv}$  per hour when operating in the manner that produces the maximum dose rate as limited either by its characteristics or interlocks, and it is in a room 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  $\mu\text{Sv}$  per hour when operating in the manner that produces the maximum dose rate as limited either by its characteristics or interlocks

### **H.1 Door interlocks**

The exemptions above notwithstanding, append a description of the door interlock system.

There must be an interlock for every entrance to an exclusion area that terminates irradiation if the door is opened while the accelerator is in operation. This interlock must require the person leaving the room to activate the circuit via a switch (commonly referred to as a “last person out” or LPO) inside the room and then, within a specified time, close the door to transition to the ready-state condition.

The LPO switch should be in a location that allows operators to verify that no one else remains inside the room prior to starting the irradiation. If the door is reopened, the irradiation state condition must be terminated until the sequence described above is repeated. Furthermore, the safety interlock should be designed such that any defect or component failure in the interlock system will prevent operation of the accelerator.

Doorless entrances must retain the same functionality (i.e., a timed LPO reset circuit is required). However, in such cases, the interlock switch at the door may be replaced with alternate devices, such as electric eyes, active infrared sensors or motion detectors located at the entrance and or within the entrance maze. Such systems will be evaluated on a case-by-case basis, and the applicant must demonstrate that they provide equivalent functionality and level of safety.

### **H.2 Warning lights**

Provide a description of the warning light system, which must indicate the status of the accelerator at each entrance to the accelerator vault. This warning display must—at minimum—illuminate when the accelerator beam is on. Additional indications (e.g., Radio Frequency (RF) on, magnet on, interlocks clear) may be added at the discretion of the applicant. Installation of warning lights inside the accelerator room itself is

recommended for self-shielded accelerators. Describe all warning lights included in the facility design and clearly mark their location on one of the facility plans submitted in G.2.

### **H.3 Pre-irradiation alarms**

Every isotope production accelerator facility not satisfying the exemption requirements described in Section 15(14) of the *Class II Nuclear Facilities and Prescribed Equipment Regulations* must be equipped with a device that provides a continuous audible signal within the vault for a period of time before irradiation begins. Its purpose is to warn persons working in the accelerator vault that the radiation beam will commence soon and they must either exit that area or, if this is not possible, activate an emergency stop device to prevent beam on. Consequently, the duration of the alarm must be sufficient for a person inside the vault to activate an emergency stop device (see H.4). Ideally, this alarm will sound prior to initiating an irradiation, regardless of whether the accelerator vault has been accessed since the previous irradiation.

Applicants may propose an alternate configuration for the alarm if they can demonstrate that it will provide an equivalent level of safety. Alternate proposals will be evaluated on a case-by-case basis.

### **H.4 Emergency off buttons**

Every facility must be equipped with easily identifiable push buttons (or equivalent devices) that can be used in an emergency to immediately shut off the beam and cause the accelerator to automatically revert to a safe state. Emergency stops must be designed so that once activated, the accelerator cannot be restarted from the control console without first resetting the interlock safety circuit from the location where the emergency stop device was activated.

Every isotope production accelerator must have an emergency stop on the accelerator control console.

For accelerators that do not satisfy the exemption requirements described in the introduction to Section H, emergency stops must also be located:

- on the inside of each entrance to the vault
- on both sides of the accelerator, either on the walls or on the accelerator itself

Additional emergency stops may be required depending on the nature and layout of the proposed facility.

Append a description of the design of all emergency stop devices and clearly mark their locations on the facility design plans submitted in G.2.

### **H.5 Radioisotope release monitoring and containment**

Exhaust ventilation from hot cells, the radioisotope processing laboratory and the accelerator room should be equipped with devices which monitor and record releases of radioactive substances to the environment. For accelerators used for the production of isotopes in gaseous form, the hot cell ventilation system must include a system to automatically detect and contain any accidental release of radioactive material.

Append a description of the proposed devices to monitor and contain releases of radioactive material into the ventilation system.

**H.6 Radiation monitors**

The hot cells, ventilation system, isotope processing station and the accelerator room should be equipped with radiation detectors that continuously monitor radiation dose rates. The detectors should trigger audible and visible alarms when they detect abnormally high radiation dose rates. Alarm thresholds should be suitable for each area being monitored, so that they are not activated by dose rates expected under normal operating conditions and procedures for each area.

Radiation area monitors inside non-self-shielded accelerator vaults and hot cells should be interlocked to the access doors, preventing them from opening if the radiation level inside the vault or the hot cell exceeds a preset value. In such cases, the applicant must indicate the thresholds proposed and justify their choice in terms of maintaining radiation doses ALARA.

**H.7 Ventilation monitoring**

The ventilation system of the hot cells, radioisotope processing area and accelerator vault should be equipped with a monitoring system to ensure that the required air flows and pressure differentials are maintained. The monitoring system must provide a warning to workers in those areas if ventilation fails.

**H.8 Personnel contamination monitoring system**

There must be a dedicated system for personnel contamination monitoring (hand and foot) at each entrance to an area where isotopes are processed or handled. If multiple connected laboratories and rooms share a common main entrance, a single system at the main entrance is acceptable, provided that measures are in place to ensure that all normal access and egress by staff is via this entrance.

Provide a description of the contamination monitoring system including its sensitivity as per manufacturer specifications or an analysis showing that its sensitivity is adequate for the isotopes being handled.

**3.9 Section I – Class II Nuclear Facility Operating Licence for the purpose of Commissioning**

The initial operating licence, hereafter referred to as a commissioning licence, will restrict the applicant's operations to those required for verifying the functionality of safety systems, confirming the adequacy of the radiation shielding incorporated into the facility, and performing commissioning tests of the accelerator and of the isotope processing facilities. Note that only sufficient quantities of radioisotope required for commissioning activities should be produced. Full-scale production is not permitted under a commissioning licence.

The applicant must provide the following information:

**I.1 Accelerator commissioning plan**

The commissioning plan for an isotope production accelerator facility must include the following elements:

- a confirmation that the facility has been constructed according to the specifications submitted by the applicant for the shielding density, composition and thickness, stack height and dimensions, and that all required safety systems have been installed. This confirmation must be signed by both the applicant's signing authority and the contractor after the construction is completed



- the program that ensures that all personnel participating in commissioning tests have received proper instruction prior to commencing with commissioning tests
- the name and title of the person responsible for planning and supervising the tests the applicant intends to perform. If this person differs from the RSO named under section D.1, describe this person's training and experience, and include the person's position and responsibilities in the facility's organization
- a detailed description of the tests that will be conducted to ensure safety devices are functioning properly. Safety systems must be tested and verified to be functioning properly prior to commissioning activities involving irradiation of a target and production of isotopes. Tests must be performed on the following safety devices:
  - the door interlock and LPO time delay system (if applicable - see H.1)
  - all irradiation status warning displays (see H.2)
  - the pre-irradiation alarm (if applicable - see H.3)
  - all emergency stop devices (see H.4)
  - all components of the release monitoring and containment systems (see H.5)
  - all area monitors and alarms (see H.6)
  - any other safety interlocks incorporated into the facility. For self-shielded cyclotrons, this must include any interlock or device designed to verify proper closure of its shielding or to monitor the integrity of the shielding
- a description of the radiation survey that will be performed to verify the adequacy of the radiation shielding. The description must include:
  - the accelerator operating conditions and target material to be irradiated during the radiation survey
  - the physical and administrative controls used to restrict access to the area during the survey
  - identification of the locations at which measurements are to be made, including all accessible areas immediately adjacent to accelerator vault for which dose and dose rate estimates were provided in section G.9
  - a thorough scan of all accessible areas to verify that the dose and dose rate estimates in section G.9 were made for the locations in which the highest radiation dose rates exist
  - for self-shielded cyclotrons, the radiation survey must also include measurements of the dose rates at the external surface of the cyclotron and at any potentially occupied locations within the accelerator room
  - measurements of both photon and neutron radiation
  - a list and description of the radiation detection instruments that will be used for the survey, if the instruments are different from those previously listed under section E.7

## **I.2 Commissioning of the radiochemical processing facilities**

If radioisotope processing is to be included under the licence, the commissioning licence application must include the following information:

- a plan for reviewing and confirming that the design of the laboratory adheres to specifications in the Design Assessment Form for Nuclear Substance Laboratories and Nuclear Medicine Rooms previously submitted under section G.4
- the tests to be performed on any interlock or other safety system associated with the hot cells or other processing related equipment

- the procedure for calibrating stack monitors to correlate count rates to equivalent activities in Bq
- confirmation of ventilation rates and pressure differentials (air balance report)
- measurements to verify the adequacy of radiation shielding incorporated into the hot cells and along the transfer lines
- a plan to verify the extremity dose estimates submitted under section G.9, preferably by use of extremity dosimetry on both hands of personnel during commissioning of the processing facilities

### **3.10 Section J – Class II Nuclear Facility Operating Licence**

The information required in an application for a licence permitting the routine operation of a radioisotope production accelerator facility includes two main components: the results of the commissioning tests and the operating procedures that are relevant to the safe operation of the facility.

#### **J.1 Accelerator safety system test results**

Append a report or summary detailing the results of the commissioning tests conducted to ensure that all safety systems are functioning properly. If any safety device was found not to be functioning properly, the report must include a description of the remedial actions taken and the subsequent tests conducted to confirm that the malfunction has been corrected. The report must include the results of the tests performed on:

- the door interlock and LPO time delay system (if applicable - see H.1)
- all irradiation status warning displays (see H.2)
- the pre-irradiation alarm (if applicable - see H.3)
- all emergency stop devices (see H.4)
- all components of the release monitoring and containment systems (see H.5)
- all area monitors and alarms (see H.6)
- any other safety interlock incorporated into the facility. For self-shielded cyclotrons, the report must include any interlock or device designed to verify proper closure of the cyclotron shielding or to monitor its integrity

#### **J.2 Accelerator radiation survey**

Append a copy of the results of the radiation survey indicating:

- the accelerator operating conditions and target material irradiated during the radiation survey
- the make, model, serial numbers and calibration date for each radiation survey instrument used
- the measurements of both photon and neutron radiation
- a clear reference to the previously submitted facility plans and drawings for each location where measurements were made
- a re-evaluation of the projected annual doses to staff and the general public (see section G.9) based on the measured dose rates. If the dose rate in any area exceeds that predicted in the original shielding design estimates, the applicant must either describe the remedial actions taken to reduce the doses that could potentially be incurred by persons occupying the area (e.g., additional shielding, access restrictions/controls, limitations/reductions in the proposed accelerator workload) or demonstrate that the resulting doses are ALARA and no remedial action is required

**J.3 Processing facilities commissioning results**

Append a report containing:

- the confirmation that the processing facilities have been built in accordance to specifications submitted in the Design Assessment Form for Nuclear Substance Laboratories and Nuclear Medicine Rooms under section G.4. Proposed design changes required to respond to flaws discovered during the commissioning phase shall be submitted to CNSC staff for assessment and approval.
- the result of the tests performed on any interlock or other safety system associated with the hot cells or other processing related equipment
- the results of the stack monitor calibration
- the confirmation that the ventilation system is functioning as designed
- the results of the radiation survey to verify the adequacy of the radiation shielding incorporated into the hot cells and along the transfer lines
- the results of the extremity dose evaluation

**J.4 Accelerator operating procedures**

Append the facility operating procedures that describe:

- the titles of the persons who may operate or may perform maintenance on the accelerator. Note that only authorized and trained personnel should operate or have access to the accelerator controls and radiation areas
- the program for ensuring that all safety devices specified in section H are tested regularly to ensure they continue to function properly. The program must include:
  - a detailed description of the procedure for testing each device
  - the frequency of the tests
  - who is responsible for performing the tests
  - the method of recording the tests
  - the actions to be taken in the event that a safety device malfunctions
- the procedures to be followed in the event of a failure of the ventilation system
- the proposed methods, procedures and equipment for conducting radiation surveys, including the frequency of the surveys and the location of radiation survey points
- procedures for periodically reviewing stack release monitor data
- the policies for reviewing and updating manuals and procedures in accordance with operating experience and modifications of the equipment. The policies must clearly state who will be responsible for these updates

**J.5 Processing procedures**

Append the procedures for the processing of isotopes. These procedures must describe:

- the provisions to prevent or mitigate spills within the hot cell or other containment devices
- the means of transferring finished product (unit doses or other) out of containment
- the procedures, methods and equipment used for contamination control
- the proposed methods, procedures and instruments for conducting contamination surveys, including the frequency of surveys
- the policy for container labelling
- the means used to remove radioactive or other hazardous waste from the containment

### **3.11 Section K - Decommissioning**

The application for a licence to decommission a radioisotope production accelerator facility must demonstrate that there is a clearly defined and appropriate plan of action for decommissioning both the accelerator and any associated isotope processing facilities. The plan should include measures to ensure that any staff participating in the decommissioning will have the supervision, training and equipment necessary to perform their duties in a safe manner. The plan should consider:

- removal and disposal of the accelerator and all of its components, including activated concrete and rebar, activated steel from the accelerator, activated foils and target bodies
- removal and disposal of processing equipment such as hot cells
- identification and disposal of any radioactive material used in conjunction with the facility or produced a result of its operation
- disposal of waste generated during decommissioning, such as protective clothing, tools, filters, brushes, gloves, rags and related equipment used during dismantling and decontamination of the facility
- handling and disposal of any other hazardous material, including excess chemicals associated with the facility
- final contamination monitoring of the entire site, including both the accelerator vault and all processing facilities and laboratories, upon completion of decommissioning activities
- submission of a final decommissioning report to the CNSC

The facility will not be released from regulatory control and the applicant will be responsible for safety at that location until the decommissioning is properly completed and the licence has been revoked.

#### **K.1 Overview of decommissioning plan**

Submit a brief overview of the decommissioning work, including:

- a summary of the land, buildings, structures, components, systems, equipment, nuclear substances and hazardous materials 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. State whether any radioactive material, contamination or other hazardous substance will remain on-site after the decommissioning

#### **K.2 Personnel qualifications and training**

Provide the following information:

- the name and title of the person responsible for planning and supervising decommissioning activities. If this person is not the RSO named in D.1, describe the person's training, experience, position and responsibilities in the facility's organization
- the proposed responsibilities, qualifications and training requirements for workers participating in decommissioning activities. If the applicant is contracting out any aspect of the decommissioning work, provide the name and contact information of

- the contracting firm and indicate how the applicant will ensure contract personnel have received radiation safety training for the work they will be performing
- a Class II Prescribed Equipment Servicing Licence is required to dismantle the accelerator. Include the licence number under which this work is being performed and the names of the persons supervising this aspect of the decommissioning (if different from above)

### **K.3 Estimation of types, activities and radiation doses from nuclear substances**

Describe the nature, type and activity of any radioactive nuclear substance or contamination at the facility, including activated components of the accelerator. Provide a list of open and sealed radioactive sources, and of any activated item and component that the applicant anticipates will be present at the time of decommissioning. For activated components, include an estimate of the isotopes and activities of each item or component, and provide a brief rationale for the estimates.

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

### **K.4 Disposal of Class II prescribed equipment, nuclear substances and hazardous materials**

Indicate the proposed disposition of all major components of the accelerator. If the applicant intends to transfer the entire accelerator or any of its major radiation generating components to another institution where this equipment could potentially be reused, provide the name and contact information of the recipient.

Indicate the proposed means of disposal for all major components of the processing facilities, including all hot cells, and identify the proposed measures to control releases of radioactive nuclear substances and hazardous substances into the environment.

Specify the proposed disposal method for all nuclear substances and potentially hazardous materials, and indicate whether any of this material will be released into the environment. If so, specify the maximum quantities and concentrations that may be released and demonstrate that all releases will be in compliance with the limits specified in the *Nuclear Substances and Radiation Devices Regulations*.

## **3.12 Section L – Legal signing authority**

Section 15 of the *General Nuclear Safety and Control Regulations* requires that the CNSC be notified of any persons who have authority to act for the applicant or licensee.

### **L.1 Signing authority**

The application must be signed by an authorized representative of the applicant. The Signing Authority is the person who has prepared the application and 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. The Signing Authority will receive all correspondence from the CNSC and will be the CNSC contact for all matters associated with the licence.

Since the Signing Authority is the only person who can request changes to a licence, it is recommended that the Radiation Safety Officer (D.2 of the licence application) be designated as the Signing Authority.

**L.2 Applicant authority**

One of the applicant's executive officers signs to certify the designation of the person identified as the Signing Authority and to acknowledge that the designated person's signature binds the applicant. Provide the name, title, address, email address and telephone number of the individual who signed the application as the Applicant Authority.

The Applicant Authority understands that all statements and representations made in its application and on supplementary pages are binding on the applicant.

## Appendix A: Classes of Nuclear Substances

The following table organizes a number of common nuclear substances, including those for which surface contamination and waste disposal limits are typically incorporated into CNSC licences, into three classes—Class A, Class B, or Class C—on the basis of common radiological characteristics.

To find out the classification, for regulatory purposes, of any nuclear substance that is not listed below, contact a CNSC Licensing Specialist at 1-888-229-2672.

CLASS	RADIONUCLIDE				
CLASS A	All alpha emitters and their daughter isotopes			Ag-110m	Ar-41
	C-11	Co-56	Co-60	F-18	Ga-68
	Ga-72	I-124	La-140	Mn-56	N-13
	Na-22	Na-24	Nb-98	O-15	Sb-124
	Ta-182	V-48	Y-86	Zn-65	
CLASS B	As-74	Au-198	Ba-133	Br-82	Co-58
	Cu-64	Fe-59	Ga-67	Gd-153	Hg-194
	Hg-203	I-131	In-111	In-113m	In-114m
	Ir-192	K-42	Kr-79	Kr-81m	Nb-95
	Pa-233	Rb-84	Rb-86	Ru-103	Sc-46
	Se-75	Sm-153	Sn-123	Sr-85	Sr-90
	Xe-127				
CLASS C	Au-195m	C-14	Ca-45	Cd-109	Ce-141
	Ce-144	Cl-36	Co-57	Cr-51	Fe-55
	Ge-68	H-3	I-123	I-125	In-114
	Kr-85	Lu-177	Ni-63	P-32	P-33
	Re-186	Re-188	S-35	Sn-113	Sr-89
	Tc-99	Tc-99m	Tl-201	V-49	W-188
	Xe-133	Y-86	Y-90	Yb-169	





## Glossary

**action level**

A specific dose of radiation or other parameter that if reached, may indicate a loss of control of part of a licensee's radiation protection program and triggers a requirement for specific action to be taken

**activity**

The number of nuclear transformations occurring per unit of time, as measured in becquerels (Bq).

**As Low As Reasonably Achievable (ALARA) - social and economic factors taken into account**

A fundamental principle of radiation protection whereby the protective measures implemented to minimize radiation exposure are optimized with respect to the level of risk reduction and the cost of implementation.

**Class II nuclear facility**

A facility that includes Class II prescribed equipment.

**Class II prescribed equipment**

- an irradiator that uses more than  $10^{15}$  Bq of a nuclear substance;
- an irradiator that requires shielding which is not part of the irradiator and that is designed to deliver a dose of radiation at a rate exceeding 1 cGy/min at a distance of 1 m;
- a radioactive source teletherapy machine;
- a particle accelerator that is capable of producing nuclear energy and has a beam energy of less than 50 MeV for beams of particles with a mass equal to or less than 4 atomic mass units;
- a particle accelerator that is capable of producing nuclear energy and has a beam energy of no more than 15 MeV per atomic mass unit for beams of particles with a mass greater than 4 atomic mass units; or
- a brachytherapy remote afterloader.

**dosimetry service**

A prescribed facility for the measurement and monitoring of doses of radiation

**dosimeter**

A device for measuring a dose of radiation that is worn or carried by an individual

**effective dose**

A measure of radiation as defined in the Radiation Protection Regulations.

**fail-safe**

An electronic circuit which is designed such that the failure of any component will result in the circuit reverting to a "safe" state.

**general public**

Any person who is not designated as a nuclear energy worker (NEW). The prescribed Effective Dose limit for the general public is 1 mSv per calendar year.

**isotope production accelerator**

A particle accelerator defined as a Class II prescribed equipment in the *Class II Nuclear Facilities and Prescribed Equipment Regulations* and which is designed and used for the purpose of producing nuclear substances by irradiating a target material.

**leak test**

A method of verifying the integrity of the encapsulation of a sealed source that involves swiping the source encapsulation and measuring the nuclear substances collected on the wipe sample.

**licensed activity**

Any activity prescribed under section 26 of the Nuclear Safety and Control Act.

**Nuclear Energy Worker (NEW)**

A person who is required, in the course of the person's business or occupation in connection with a nuclear substance or nuclear facility, to perform duties in such circumstances that there is a reasonable probability that the person may receive a dose of radiation that is greater than the prescribed limit for the general public.

**nuclear substance**

- deuterium, thorium, uranium or an element with an atomic number greater than 92;
- a derivative or compound of deuterium, thorium, uranium or of an element with an atomic number greater than 92;
- a radioactive nuclide;
- a substance that is prescribed as being capable of releasing nuclear energy or as being required for the production or use of nuclear energy;
- a radioactive by-product of the development, production or use of nuclear energy; and
- a radioactive substance or radioactive thing that was used for the development or production, or in connection with the use, of nuclear energy.

**occupancy factor (T)**

The factor, between 0 and 1, by which the workload should be multiplied to correct for the degree of occupancy of the area in question while the source of radiation is 'ON'.

**possess**

To have the care and control of a nuclear substance or prescribed equipment.

**prescribed equipment**

See Class II prescribed equipment.

**radiation survey meter**

An instrument that is capable of measuring radiation dose rates.

**sealed source**

A radioactive nuclear substance in a capsule that is sealed or in a cover to which the substance is bonded, where the capsule or cover is strong enough to prevent contact with or the dispersion of the substance under the conditions for which the capsule or cover is designed.

**servicing**

In respect of Class II prescribed equipment, means any maintenance of the equipment, including installation, repair or dismantling, other than any installation, repair or dismantling that constitutes routine operating procedures

- as indicated in the manufacturer's operating manual for the equipment; or
- as authorized in the licence issued in respect of the possession or use of the equipment.

**store**

To lay away for future purposes.

**transfer**

To change the possession of a nuclear substance or prescribed equipment from one person to another.

**unsealed source**

A radioactive source other than a sealed source.

**worker**

A person who performs work that is referred to in a licence.

**workload**

A parameter which characterizes the amount of use of Class II Prescribed Equipment over defined period, and which is related directly to the resulting radiation doses in to persons occupying adjacent areas over that period.