Canada's Nuclear Regulator
L'organisme de réglementation nucléaire du Canada

CNSC Use Only

Application No.: _____

Date Received: _____ / _____ / _____ (YYYY / MM / DD)

Certification of Radiation Devices or Class II Prescribed Equipment Application Form

PART A - APPLICANT'S INFORMATION

A1 Type of request (check as appropriate)

☐ New certificate ☐ Amendments to certificate information ☐ Renewal

Current certificate number, if applicable:

A2 Language preference for the certificate (check as appropriate)

☐ English ☐ French ☐ Both

A3 Radiation device or Class II prescribed equipment category (check as appropriate)

☐ Radiation Device ☐ Class II prescribed equipment

A4 Applicant's organization name

A5 Proof of legal status

Append proof of applicant's incorporation, partnership, registration or charter.

Proof of legal status appended as:

A6 Head office address

Street: City:

Province/State: Country (if other than Canada):

Postal/Zip code: Telephone:

A7 Mailing address (if different from head office)

Street: City:

Province/State: Country (if other than Canada):

Postal/Zip code: Telephone:

A8 Manufacturer and distributor

Manufacturer:

Name:

Street: City:

Province/State: Country (if other than Canada):

Postal/Zip code: Telephone:

Distributor:

Name:

Street: City:

Province/State: Country (if other than Canada):

Postal/Zip code: Telephone:

A9 Canadian representative (for non-Canadian applicants only)

Name:

Street: City:

Province/State: Country (if other than Canada):

Postal/Zip code: Telephone:

A10 Financial contact person (for applicants subject to cost recovery fees)

Name:

Title:

Address (if different from head office):

Telephone: Fax:

Email:

A11 Technical contact person

Name:

Title:

Address (if different from head office):

Telephone: Fax:

Email:

A12 Public access to information (check as appropriate)

Note that information provided may be made public.

Is any part of this application subject to a request for exemption from the CNSC policy on public access to certification information?

Check the "Yes" box if an exemption is requested.

☐ No ☐ Yes (Attach details of request for exemption)

Exemption request appended as:

PART B - DESCRIPTION

B1 Name and model number

Identify the name and model number (designation) as it appears on the nameplate, purchase order, contract agreement or any other legal document:

B2 Type

Select one or more of the types listed in appendix A of the application guide, or other, if required.

B3 Purpose and intended use

Provide a detailed description of the intended purpose and use, consistent with the design specifications.

Appended as:

B4 Intended modes of use

☐ Fixed ☐ Mobile ☐ Both

B5 General description

Provide a brief general description including the major components, design features, materials and functional operation.

Include a basic drawing or photograph with the major components labelled.

Appended as:

B6 Associated equipment, accessories, options and different configurations

List all possible options and configurations allowed by the design and, if applicable, associated software.

List all associated equipment or accessories that might be used in conjunction with the prescribed equipment.

Appended as:

B7 Nuclear substances

Provide the following:

- List of nuclear substances incorporated, using the radionuclide name and mass number
- Quantity and activity (list the maximum, where the maximum is the nominal plus manufacturing tolerances)
- Physical and chemical form
- Manufacturer name(s)
- Model number of the source and the source holder, if applicable
- Copy of the certificate for special form if applicable
- Source classification and technical and standards used

Appended as:

B8 Accelerator radiation output *(for Class II prescribed equipment only)*

Specify:

- Beam particle types and the maximum energy for all modes of operation (i.e. IMRT, FFF)
- Intensity of radiation to be expected at a reference point for each energy and mode of operation

If applicable, specify the intensity and energy of the neutron source term.

Appended as:

PART C - DESIGN

C1 Technical specifications

Provide copies of the approved design specifications, including major associated components and sub-systems.
The supplied specifications should address the following:

- If applicable, details on how the nuclear substance is incorporated into the equipment
- For particle accelerators, details on the radiation beam target
- The overall dimensions and weight of the equipment and main components
- Description of the shielding, including the weight of any depleted uranium used,
- Any limitations on the use of the system, such as operating temperature range, vibration levels, pressure and recommended environmental conditions,
- The expected lifetime of use

Appended as:

C2 Technical drawings

Provide copies of technical drawings for critical components and sub-systems.
The supplied drawings should address the following:

- General assembly of the device
- Location(s) of the source(s) of radiation and location of the shielding
- Source holder, radiation source and beam target design
- Safety features such as shutters, collimators, warning lights and interlock circuits
- Associated accessories to be used with the device

The information listed in section 11 of the *Class II Nuclear Facilities and Prescribed Equipment Regulations* or section 12 of the *Nuclear Substances and Radiation Devices Regulations* must be provided.

Appended as:

C3 Technical and safety standards used

List major technical and safety standards used to design the radiation device or prescribed equipment, if applicable.

Appended as:

C4 Design validation and risk assessment records

Provide records of the technical validation, possible failure modes analyses and hazard and risk assessment related to the design, modes of use and intended applications.

Address the safety of the public, operator, service personnel and the environment. Include results of all reliability, durability and design integrity tests.

Appended as:

C5 Activated components *(for Class II prescribed equipment only)*

For particle accelerators, list all major activation products, their half-lives and maximum quantities. Specify the radiation dose rate at 30 cm from the activated components at a given time following the activation (state the conditions of irradiation).

Appended as:

C6 Radiation dose rates

Provide the following;

- The maximum expected radiation such as photon (Bremsstrahlung, gamma ray, etc), electron and neutron dose rates that would result from leakage and scatter in all modes of operation (as applicable)
- A description of the measurement or calculation method, conditions and instruments used
- The technical standards used
- Measurements at 0 cm, 30 cm and 100 cm from the surface or use applicable industry standards.
- For Class II equipment, a description of any simulation (such as Monte Carlo, etc.) used in the assessment of dose profiles, radiation profiles, radiation output, source term (gamma, photon, neutron), etc.

Appended as:

C7 Labelling, safety marks and instructions

Provide technical drawings, photographs or samples of the safety labelling (refer to section 20 of *Radiation Protection Regulations* for required marking).

Appended as:

C8 Safety features

Provide details of safety features such as the shutter mechanism, source lock mechanism, collimator, radiation warning lights and safety interlocks.

Describe the connections available for external safety devices. Describe how these devices are connected in order to prevent, stop, or indicate the production of radiation. Include schematics and, if necessary, software flow diagrams.

Appended as:

PART D – USE, STORAGE AND TRANSPORT

D1 Instructions for use and storage

Provide the instructions for use and storage, including copies of the operating manual and radiation safety instructions provided to the end-user.

Appended as:

D2 Emergency procedures

Enclose copies of policies and procedures for dealing with radiological emergencies.

If applicable, include emergency procedures to be followed in case of a transportation accident.

Appended as:

D3 Leak testing of sealed sources and shielding material

Enclose copies of procedures for conducting leak tests of the sealed sources and shielding used (for depleted uranium only). Provide a copy of the instructions that are to be supplied to the end-user of the radiation device or prescribed equipment.

Refer to Section 19 of the *Class II Nuclear Facilities and Prescribed Equipment Regulations* or section 18 of the *Nuclear Substances and Radiation Devices Regulations* for leak testing requirements.

Appended as:

D4 Inspection, servicing, maintenance and disposal

Provide details of the recommended inspections, servicing and maintenance programs, and disposal instructions that are made available to the end-user.

Describe the method and tools required to replace radioactive sources, if applicable.

Also provide information as required by paragraph 3(1)(o) of the *Nuclear Substances and Radiation Devices Regulations*.

Appended as:

D5 Instructions for packaging and transport

If applicable, append or enclose policies or procedures used for packaging and transport.

The applicant is required to demonstrate compliance with the CNSC's *Packaging and Transport of Nuclear Substances Regulations, 2015* and Transport Canada's *Transportation of Dangerous Goods Regulations* by implementing and maintaining approved procedures.

Appended as:

D6 Package classification and details

Provide information related to the classification of the package used for transport.

If the nuclear substance is special form radioactive material, a copy of the certificate must be provided.

Provide technical details demonstrating that the package used meets the requirements specified in the *Packaging and Transport of Nuclear Substances Regulations, 2015*.

If the package used has been certified as a Type B package by the CNSC, only reference the CNSC certificate number.

Appended as:

PART E – QUALITY ASSURANCE PROGRAM AND DESIGN CONTROL

E1 Quality assurance

Append a copy of a quality assurance program (manual) that is to be followed during design and during the production and supplier's maintenance program (if applicable).

Appended as:

E2 Design control

Append a copy of a design control manual, and associated policies and procedures, to be followed during design, and production and service.

Appended as:

PART F – APPROVALS AND REGISTRATIONS

F1 Health Canada medical device licence

Include a copy of the Health Canada medical device licence, if applicable.

Appended as:

F2 Medical device approvals and registrations

Include a copy of the following documents, if applicable:

- U.S. FDA medical device registration
- EU Council medical device directive registration
- CSA approval

Appended as:

F3 Other applicable jurisdiction approvals and registrations

Include a copy (copies) of the following documents, if applicable:

- ISO series (and related standards) registration
- U.S. NRC registration
- Approvals and registrations of pertinent provincial or state authorities
- Certificate(s) of compliance with applicable technical safety standards not covered above (list or append copies)

Appended as:

PART G – LEGAL SIGNING AUTHORITY

G1 Applicant authority

I certify that all information submitted is true and correct to the best of my knowledge.

Name:

Title:

Address (if different from head office):

Telephone: Fax:

Email:

Signature: Date:

The completed application form, together with all relevant documentation, can be sent by mail, fax or e-mail, to:

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

Fax: 613-995-5086 **Email:** CNSC.forms-formulaires.ccsn@canada.ca