Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

CNSC Use Only

Application No.: _____

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

APPLICATION FORM FOR CERTIFICATION OF RADIATION DEVICES OR CLASS II PRESCRIBED EQUIPMENT

PART A APPLICANT'S INFORMATION

A1 Type of request (check as appropriate)

☐ New Certificate ☐ Changes to Certificate Information ☐ Renewal ☐ Revoke

Current Certificate Number, if applicable: _____

A2 Language preference for the certificate (check as appropriate)

☐ English ☐ French ☐ Both

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

☐ Radiation Device ☐ Class II Prescribed Equipment

A4 Applicant's name

_____

A5 Proof of legal status

Business Number: _____

Corporation Number: _____

Append proof of applicant's incorporation, registration or charter (specify the appendix name and number).

_____

For public institutions, specify the enabling legislation (act): _____

A6 Head office address

Street: _____ Province/State: _____

City: _____ Postal/Zip code: _____ Telephone: _____

A7 Mailing address (if different from head office)

Street: _____ Province/State: _____

City: _____ Postal/Zip code: _____

continued on next page

Canada

A8 Address of Canadian representative (for non-Canadian applicants only)

Legal Name: _____

Street: _____ Province: _____

City: _____ Postal code: _____

Telephone: _____

A9 Financial contact person (for applicants subject to cost recovery fees)

Name: _____ Fax: _____

Title: _____

Address (if different from head office): _____

Telephone: _____ Email: _____

A10 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 RADIATION DEVICE OR PRESCRIBED EQUIPMENT DESCRIPTION

B1 Radiation device or prescribed equipment manufacturer and distributor

Manufacturer:

Business Address: _____

City: _____ Province/State: _____

Postal/Zip code: _____ Country: _____

Distributor:

Business Address: _____

City: _____ Province/State: _____

Postal/Zip code: _____ Country: _____

B2 Type of radiation device or prescribed equipment

Radiation devices (check as applicable)

- [ ] Attenuation correction device
- [ ] Beta backscatter gauge
- [ ] Bone mineral analyzer
- [ ] Calibrator
- [ ] Control unit – Exposure device crawler
- [ ] Core discharge monitor
- [ ] Dewpointer
- [ ] Electron capture detector
- [ ] Exposure device
- [ ] Exposure device – cable
- [ ] Exposure device – crawler
- [ ] Exposure device – mobile
- [ ] Exposure device – pneumatic
- [ ] Fixed gauge
- [ ] Intravascular brachytherapy
- [ ] Ion chamber detector
- [ ] Irradiator
- [ ] Liquid scintillation counter
- [ ] Logging
- [ ] Low energy imaging
- [ ] Material analyzer
- [ ] Medical calibrator
- [ ] Medical irradiator
- [ ] Monitor
- [ ] Portable gauge
- [ ] Profile attenuation correction system
- [ ] Radioisotope neutron source
- [ ] Radioluminescent device
- [ ] Smoke detector
- [ ] Static detector
- [ ] Static eliminator
- [ ] Surge voltage protector
- [ ] X-ray fluorescence analyzer
- [ ] Other (specify)

Prescribed equipment (check as applicable)

- [ ] Brachytherapy machine
- [ ] Brachytherapy seed loader
- [ ] Calibrator Class II
- [ ] Cyclotron
- [ ] Geophysical logging accelerator
- [ ] High dose rate afterloader
- [ ] Irradiator – Class II
- [ ] Low dose rate afterloader
- [ ] Linear accelerator
- [ ] Medical accelerator
- [ ] Mobile accelerator
- [ ] Neutron generator
- [ ] Research accelerator
- [ ] Self-shielded accelerator
- [ ] Teletherapy irradiator
- [ ] Teletherapy machine
- [ ] Other – Class II (specify)

B3 Name and model number of radiation device or prescribed equipment

Identify the name and model number (designation) of the radiation device or prescribed equipment as it appears on the nameplate.

Appended as: _____

B4 Major associated components, options, accessories or configurations

Specify major components of the radiation device or prescribed equipment. List all accessories, options and configurations allowed by the design under certification.

Appended as: _____

B5 Purpose and intended use

Provide a detailed description of the intended purpose and use of the radiation device or prescribed equipment.

Appended as: _____

B6 Intended modes of use

Provide a description of the design-allowed intended modes of use of the radiation device or prescribed equipment. Indicate if the system is fixed or mobile.

Appended as: _____

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C1 Technical specifications of radiation device or prescribed equipment

Provide copies of the approved design specifications of the radiation device or prescribed equipment and major associated components and sub-systems.

Appended as: _____

C2 Technical drawings for radiation device or prescribed equipment

Provide copies of technical drawings for critical components and sub-systems of the radiation device or prescribed equipment. 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 of the radiation device or prescribed equipment. 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 Nuclear substances used and radiation source design

Provide the following:

- list of nuclear substances used in the radiation device or prescribed equipment
- physical and chemical form of nuclear substances
- description of the design details of the sealed source(s) used (if applicable)
- manufacturer name(s)
- model(s) and model number(s)
- copy of the certificate for Special Form if applicable
- source classification and technical and quality standards used

Append technical drawings, source performance certificates and material specifications for the source components.

Appended as: _____

C6 Incorporating the nuclear substance into the radiation device or prescribed equipment

Provide details on incorporating the nuclear substance into the radiation device or prescribed equipment. Include information such as:

- complete set of engineering drawings of the source holder
- drawings and details of the source mounting and retention within the device
- details of safety features
- industry classification of the prescribed equipment or radiation device
- results of reliability tests of the shutter mechanism
- details for positive fastening of shutters or sources to prevent movement from the shielded position, if the equipment is shipped with sources in place

Appended as: _____

C7 Radiation shielding

Describe the radiation shielding used in the radiation device or prescribed equipment.

Specify quantities for depleted uranium.

Appended as: _____

C8 Accelerator beam target *(for Class II prescribed equipment only)*

For particle accelerators, provide design specifications for the radiation beam target. Specify the material(s) and model number(s) to be used. Enclose applicable technical drawings, material specifications and part numbers.

Appended as: _____

C9 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: _____

C10 Radiation leakages

- Provide the maximum expected photon and neutron radiation dose rates around the radiation device or prescribed equipment that would result from leakage and scatter in all modes of operation (as applicable)
- Describe the measurement or calculation method, conditions and instruments used
- Quote the technical standards used

Conduct the measurements at the covers and at 1 m from the source or use applicable industry standards.

Appended as: _____

C11 Radiation output *(for Class II prescribed equipment only)*

As applicable, specify the following:

- Beam particle type
- Maximum energy
- Intensity of radiation to be expected at a reference point that the radiation device or prescribed equipment can deliver in each mode of operation
- Intensity and energy of the contaminating neutrons generated in the primary beam where applicable
- Indicate any limitations to the beam orientation if applicable

Appended as: _____

C12 Physical size

Specify the weight and external dimensions of the entire system or all its components separately.

Appended as: _____

C13 Labelling, safety marks and instructions

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

Appended as: _____

C14 External safety devices *(for Class II prescribed equipment only)*

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: _____

C15 Monte Carlo simulation *(for Class II prescribed equipment only)*

Describe any simulation used in the assessment of dose profiles, radiation profiles, radiation output, neutron source term, gamma source term, etc.

Appended as: _____

PART D TRANSPORT, STORAGE, USE AND OPERATION OF THE RADIATION DEVICE OR PRESCRIBED EQUIPMENT

D1 Radiation safety instructions for use, operation and storage

Provide radiation safety instructions for the operation and storage of the radiation device or prescribed equipment, including environmental requirements and instructions for the source replenishment, if applicable.

Appended as: _____

D2 Instructions for packaging and transport

If applicable, append or enclose policies, procedures, drawings and technical specifications for the packaging and transport of the radiation device or prescribed equipment.

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

Appended as: _____

D3 Package type and classification

Provide information related to the type of package used to transport the radiation device or prescribed equipment.

If the the nuclear substance is in special form, a copy of the certificate for Special Form must be provided.

Appended as: _____

D4 Package details

Provide technical details demonstrating that the package used meets the requirements specified in the *Packaging and Transport of Nuclear Substances Regulations.* If the package used has been certified as a Type B package by the CNSC, only reference the CNSC certificate number.

Appended as: _____

D5 Transport accidents

For portable devices, provide the emergency procedures to be followed in case of a transportation accident involving the radiation device or prescribed equipment.

Appended as: _____

D6 Emergency procedures

Enclose copies of radiation safety manuals, policies and procedures for dealing with radiological emergencies, in which the radiation device or prescribed equipment may be involved.

Appended as: _____

D7 Required documentation

Provide the instructions for packing, unpacking and transporting the package given to the end-user. Provide a copy of the maintenance procedure to be followed if a package is to be re-used.

Appended as: _____

D8 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: _____

D9 Inspection, servicing and disposal of the radiation device or prescribed equipment

Specify the expected lifetime of use of the radiation device or prescribed equipment allowed by the design, and provide details of the recommended inspections, servicing program and disposal instructions for the radiation device or prescribed equipment that are made available to the end-user. Describe the method and tools required to replace radioactive sources, if applicable.
Specify the recommended lifetime of the system.
Also provide information as required by paragraph 3(1)(o) of the *Nuclear Substances and Radiation Devices Regulations*.

Appended as: _____

PART E DESIGN CONTROL AND QUALITY ASSURANCE PROGRAM

E1 Quality assurance manual

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

Appended as: _____

E2 Design control system

Append a copy of a design control manual, and associated policies and procedures, to be followed during the design of the radiation device or prescribed equipment and that will be followed during its production.

Appended as: _____

PART F APPROVALS AND REGISTRATIONS FOR RADIATION DEVICE OR PRESCRIBED EQUIPMENT

F1 Health Canada medical device licence

Include a copy of the Health Canada Medical Device licence, if applicable.

Appended as: _____

F2 Medical device approvals

Include a copy of the following documents, if applicable:

- USFDA Medical Device registration
- EU Council Medical Device Directive registration
- CSA approval

Appended as: _____

F3 Other applicable jurisdiction approvals

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

- ISO 9000 Series (and related standards) registration
- USNRC 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: _____

Telephone: _____ Fax: _____

Address: _____ Email: _____

Signature: _____ Date: _____

Mail the completed application form, together with all relevant documentation to:

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

Fax: 613-995-5086 **Email:** forms-formulaires@cnsc-ccsn.gc.ca