



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)

<input type="checkbox"/> New Certificate	<input type="checkbox"/> Changes to Certificate Information	<input type="checkbox"/> Renewal	<input type="checkbox"/> Revoke
Current Certificate Number, if applicable: _____			

#### A2 Language preference for the certificate (check as appropriate)

<input type="checkbox"/> English	<input type="checkbox"/> French	<input type="checkbox"/> Both
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#### A3 Radiation device or prescribed equipment category (check as appropriate)

<input type="checkbox"/> Radiation Device	<input type="checkbox"/> Class II Prescribed Equipment
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#### A4 Applicant's name

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#### 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: _____	Province/State: _____
City: _____	Postal/Zip code: _____ Telephone: _____

#### A7 Mailing address (if different from head office)

Street: _____	Province/State: _____
City: _____	Postal/Zip code: _____

**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)**

<p>Note that information provided may be made public.</p> <p>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.</p> <p><input type="checkbox"/> No      <input type="checkbox"/> Yes (Attach details of request for exemption)</p> <p>Exemption request appended as: _____</p> <p>_____</p>
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**PART B RADIATION DEVICE OR PRESCRIBED EQUIPMENT DESCRIPTION**

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**B1 Radiation device or prescribed equipment manufacturer and distributor**

<p><b>Manufacturer:</b></p> <p>Business Address: _____</p> <p>City: _____ Province/State: _____</p> <p>Postal/Zip code: _____ Country: _____</p> <p><b>Distributor:</b></p> <p>Business Address: _____</p> <p>City: _____ Province/State: _____</p> <p>Postal/Zip code: _____ Country: _____</p>
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**B2 Type of radiation device or prescribed equipment**

Radiation device (check as applicable)

<input type="checkbox"/> Attenuation correction device	<input type="checkbox"/> Exposure device – crawler	<input type="checkbox"/> Medical calibrator
<input type="checkbox"/> Beta backscatter gauge	<input type="checkbox"/> Exposure device – mobile	<input type="checkbox"/> Medical irradiator
<input type="checkbox"/> Bone mineral analyzer	<input type="checkbox"/> Exposure device – pneumatic	<input type="checkbox"/> Monitor
<input type="checkbox"/> Brachytherapy machine	<input type="checkbox"/> Fixed gauge	<input type="checkbox"/> Portable gauge
<input type="checkbox"/> Brachytherapy seed loader	<input type="checkbox"/> High dose rate afterloader	<input type="checkbox"/> Profile attenuation correction system
<input type="checkbox"/> Calibrator	<input type="checkbox"/> Intravascular brachytherapy	<input type="checkbox"/> Radioluminescent device
<input type="checkbox"/> Control unit – Exposure device crawler	<input type="checkbox"/> Ion chamber detector	<input type="checkbox"/> Smoke detector
<input type="checkbox"/> Core discharge monitor	<input type="checkbox"/> Irradiator	<input type="checkbox"/> Static detector
<input type="checkbox"/> Dewpointer	<input type="checkbox"/> Liquid scintillation counter	<input type="checkbox"/> Static eliminator
<input type="checkbox"/> Electron capture detector	<input type="checkbox"/> Logging	<input type="checkbox"/> Surge voltage protector
<input type="checkbox"/> Exposure device	<input type="checkbox"/> Low dose rate afterloader	<input type="checkbox"/> X-ray fluorescence analyzer
<input type="checkbox"/> Exposure device – cable	<input type="checkbox"/> Low energy imaging	<input type="checkbox"/> Other (specify)
	<input type="checkbox"/> Material analyzer	_____
		_____

Prescribed equipment (check as applicable)

<input type="checkbox"/> Calibrator Class II	<input type="checkbox"/> Linear accelerator	<input type="checkbox"/> Self-shielded accelerator
<input type="checkbox"/> Cyclotron	<input type="checkbox"/> Medical accelerator	<input type="checkbox"/> Teletherapy irradiator
<input type="checkbox"/> Geophysical logging accelerator	<input type="checkbox"/> Neutron generator	<input type="checkbox"/> Teletherapy machine
<input type="checkbox"/> Irradiator – Class II	<input type="checkbox"/> Radioisotope neutron source	<input type="checkbox"/> Other – Class II (specify)
	<input type="checkbox"/> Research accelerator	_____
		_____

**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:

\_\_\_\_\_

**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: \_\_\_\_\_

**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**

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**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**

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**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**

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**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

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### 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@cnscccsn.gc.ca