



Application Guide Certification of Radiation Devices or Class II Prescribed Equipment

RD/GD-254

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Certification of Radiation Devices or Class II Prescribed Equipment
RD/GD-254

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Document availability

This document is available in English and French on the CNSC website at nuclearsafety.gc.ca. A paper copy of the document in either official language can be ordered from:

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

Telephone: 613-995-5894 or 1-800-668-5284 (Canada only)
Facsimile: 613-995-5086
E-mail: info@cnsccsn.gc.ca

Preface

This application for certification guide is intended to help applicants to the Canadian Nuclear Safety Commission (CNSC) prepare and submit applications for certification of radiation devices and Class II prescribed equipment. It assists applicants and licensees in complying with the *Nuclear Safety and Control Act* (NSCA) and regulations and ensures that:

1. The radiation device or prescribed equipment is safe to use;
2. Adequate measures are in place to protect the environment, the health and safety of persons, and national security; and
3. The design meets Canada's international obligations.

Once a certificate has been issued for a radiation device or Class II prescribed equipment, it applies to a specific model design and to specific operating conditions only. Any future changes to the design or use may require a new certificate to be issued for the prescribed equipment or radiation device, as per instructions contained in this guide.

Nothing contained in this guide is to be construed as relieving any applicant or licensee from requirements associated with conventional codes and standards. It is the applicant or licensee's responsibility to identify and comply with all applicable regulations and licence conditions.

The application forms are available at nuclearsafety.gc.ca. CNSC staff can provide additional guidance upon request; contact CNSC at transport@cnsccsn.gc.ca.

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RD/GD-254 Certification of Radiation Devices or Class II Prescribed Equipment

1.0 Introduction

1.1 Purpose

This guide provides guidance for the completion and submission of the Application Form for Certification of Radiation Devices or Class II Prescribed Equipment, in accordance with the [Nuclear Safety and Control Act](#) (NSCA, the Act) and the regulations made under the NSCA.

1.2 Scope

This information is intended to help applicants to the Canadian Nuclear Safety Commission (CNSC) prepare and submit applications for the certification of radiation devices or Class II prescribed equipment. It provides a description of the type of information that should be included in an application for certification.

Once issued, the certificate applies to a specific model design and to specified operating conditions only. Any future changes to the design or use may require recertification of the prescribed equipment or radiation device.

1.3 Relevant Legislation

The provisions of the NSCA and the regulations made under the NSCA relevant to this guide are as follows:

1. [Nuclear Safety and Control Act](#), paragraphs 37(2)(a) and (b) and 44(1)(b) and (c);
2. [Class II Nuclear Facilities and Prescribed Equipment Regulations](#), Section 11;
3. [Nuclear Substances and Radiation Devices Regulations](#), Section 12;
4. [Radiation Protection Regulations](#), Section 20;
5. [Packaging and Transport of Nuclear Substances Regulations](#);
6. [General Nuclear Safety and Control Regulations](#), Section 15; and
7. [Canadian Nuclear Safety Commission Cost Recovery Fees Regulations](#);

Other legislation relevant to this guide is as follows:

1. Transport Canada's [Transportation of Dangerous Goods Regulations](#);
2. [Access to Information Act](#), sections 7, 8, 19 and 20;
3. [Privacy Act](#), Sections 18 to 24; and
4. [Regulations for the Safe Transport of Radioactive Material, 1996 Edition \(TS-R-1 ST-1, Revised\)](#) published by the International Atomic Energy Agency (IAEA).

2.0 Certification Process

2.1 General

Paragraph 21(1)(h) of the [NSCA](#) empowers CNSC to certify radiation devices and Class II prescribed equipment. The [Class II Nuclear Facilities and Prescribed Equipment Regulations](#) and the [Nuclear Substances and Radiation Devices Regulations](#) stipulate application requirements for the certification of radiation devices and Class II prescribed equipment.

This certification is not to be construed as a licence for use, servicing or installation. Most radiation devices, and equipment used in Class II nuclear facilities, must be certified by CNSC, before they can be licensed by CNSC for use in Canada.

An application for certification needs to be submitted to CNSC, in order for a certificate to be issued. Upon receipt, CNSC reviews the submission to determine if:

- The radiation device or prescribed equipment is safe to use
- Adequate measures are in place to protect the environment, the health and safety and security of persons, and national security
- The design meets Canada's international obligations.

If satisfied that the design meets the above requirements, the CNSC, or a Designated Officer from the Directorate of Nuclear Substance Regulation (DNSR), may issue a certificate for the prescribed equipment or radiation device. The certificate will incorporate a description of the prescribed equipment or radiation device.

The required fee is applied as described in the [Canadian Nuclear Safety Commission Cost Recovery Fees Regulations](#).

2.2 Recertification

Certificates are issued for a limited duration, usually 15 years. This is to ensure that certified devices and equipment are still supported by the manufacturer and, if still in production, are manufactured to the same standards as were used at the time of the original certification. In the case where the radiation device or prescribed equipment is no longer supported by the manufacturer, a certificate may be issued, but the duration may be considerably shorter.

To obtain certification following the expiration of the radiation device or prescribed equipment, the applicant (typically the manufacturer, although another entity may also apply for certification) should submit a complete application. Where information has not changed from the original certification, a simple reference to the information originally submitted should clearly identify the specific document(s) involved.

If the certification request is being made by an organization other than the original manufacturer, justification must be provided on how the original standards and designs are being maintained.

2.3 Submission

Before submitting an application to CNSC, ensure the following:

- The application is complete and signed by the appropriate authorities
- All supporting documents are attached, clearly identified and cross-referenced
- The designated payment is enclosed, if subject to the [Canadian Nuclear Safety Commission Cost Recovery Fees Regulations](#).

Print a copy of the completed form, sign and date it, and mail to the CNSC's Directorate of Nuclear Substance Regulation at the address indicated below:

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

For applicants wanting to submit the application electronically, the completed form and supporting documentation can be submitted to the CNSC email address found at the bottom of the application form.

The applicant should keep a complete copy of the application for his records. All information submitted is subject to the provisions of the [Access to Information Act](#) and the [Privacy Act](#).

3.0 Completion of the Application Form

Applicants for certificates should complete the *Application Form for Certification of Radiation Devices or Class II Prescribed Equipment*. Additional information has been provided below to assist in completing the various parts of the application form.

For additional assistance in completing the application for certification of prescribed equipment, contact a Project Officer within the Class II Nuclear Facilities and Equipment Division.

For additional assistance in completing the application for certification of a radiation device, contact a Transportation Specialist in the Transport Licensing and Strategic Support Division.

The DNSR toll-free telephone number is 1-888-229-2672, and the fax number is 613-995-5086.

When preparing an application package, ensure that the information provided on the form and in the attached supporting documents is clear, precise, accurate, and complete. If attaching or appending supporting documentation, please specify to which section of the application form the information pertains. Provide the document titles, as well as any cross-references, which should be consistent with the numbered parts of the application.

3.1 Part A – Applicant’s information

The *Application Form for Certification of Radiation Devices or Class II Prescribed Equipment* must be completed by all applicants. The International System of Units (SI) should be used throughout the application.

A1 Type of request

Indicate if this application is for a new certificate; to update information regarding an existing certificate or renewal; to replace an expiring certificate; or to revoke a certificate. Indicate the current certificate number, if applicable.

Note: Requests for significant changes to existing certificates could result in new certificates being issued in addition to the existing ones, unless all existing units are being retrofitted.

A2 Language preference for the certificate

In the appropriate check box, indicate the preferred official Canadian language (or both) for correspondence from CNSC. A certificate issued in response to this application will be written in the official language(s) selected.

A3 Radiation device or prescribed equipment category

Identify to which category of equipment or devices the system under certification belongs. See the Glossary for definitions of terms and phrases used in conjunction with this application form.

A4 Applicant’s name

Print or type the name of the person or organization applying for the certificate. Indicate the name as it appears on the proof of legal documentation, such as the proof of incorporation, the partnership registration, or sole proprietorship.

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

A5 Proof of legal status

All first-time applicants must provide proof of their legal status, such as a proof of incorporation, registration, or charter, in a separate, appended document.

Proof of legal status (or written explanation) should also be provided when the applicant’s original organization name has changed.

In the space provided, indicate the title of the appended document.

A6 Head office address

Provide the legal, physical address of the applicant’s head office, including the complete street name and number, and rural route number if appropriate, city, province or territory, and postal code. Notify CNSC within 15 days of any changes to this information.

Note: A post office box address is not acceptable for a head office address.

A7 Mailing address (if different from above)

Provide the mailing address, if it is different than the head office address, including the complete street name and number, and rural route number if appropriate, city, province or territory, and postal code.

If no address is entered here, a certificate 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 CNSC within 15 days of any changes to this information.

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

Provide the address of the applicant's representative, if one is located in Canada.

Non-Canadian applicants: Certificates may be issued to a corporation or sole proprietorship located outside Canada. However, applicants should inform CNSC if they have a representative in Canada. Notify CNSC within 15 days of any changes to this information.

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

Complete this subsection only if you are subject to cost recovery fees for CNSC activities. Provide the name and title of a person in your organization who may be contacted concerning payment matters. Provide the telephone number, email address, fax number, and address of the financial office, if that address is different from that of the head office.

A10 Public access to information

Check the "No" box if information may be made public by CNSC.

Check the "Yes" box if requesting that the information provided not be disclosed publicly by CNSC.

Provide the details of the grounds for the request in a separate, appended, document. In the space provided, indicate the title of the appended document.

CNSC is a government institution subject to the [Access to Information Act](#). (ATIA). As such and pursuant to subsection 4(1) of the ATIA, every person who is a Canadian citizen or corporation present in Canada has a right to and shall, on request, be given access to any record under the control of a government institution. Exceptions to this right of access are found at sections 13 through 24 and 26 of the ATIA.

All documents submitted to the CNSC form part of the record and could therefore be disclosed subject to the exceptions mentioned above. Section 20 of the ATIA is an exception that deals with third party information.

It is the policy of the CNSC, wherever possible, to make information available to the public upon request without requiring a formal application under the ATIA.

3.2 Part B – Radiation Device or Prescribed Equipment Description

In this section, identify the name, model, design, intended use, nuclear substance(s), and labelling of the radiation device or prescribed equipment. This description will be used on the certificate.

B1 Radiation device or prescribed equipment manufacturer or distributor

Provide the name and address of the manufacturer and, if different from manufacturer, the distributor of the radiation device or prescribed equipment.

B2 Type of radiation device or prescribed equipment

Identify, as closely as possible, the type of system for which certification is being requested. Select one or more of the types listed. Note that this is not an exhaustive list; other equipment or device types may also be identified.

B3 Name and model number of radiation device or prescribed equipment

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

B4 Major associated components, options, accessories or configurations

- Provide the model number of the complete system and major components
- Indicate if the equipment has different model numbers or different names in other countries
- List all possible configurations (including all series) of the systems allowed by the design
- List all accessories that might be used in conjunction with this device (such as a source changer, beam collimators, targets or integrated imaging devices)
- List all accessories that might be used in conjunction with an exposure device.

B5 Purpose and intended use

Provide a detailed description of the intended purpose and use of the prescribed equipment or radiation device, consistent with the design specifications.

B6 Intended modes of use

Provide a detailed description of the intended modes of use of the system allowed by the design. Indicate if the system is mobile or fixed.

3.3 Part C – Radiation Device or Prescribed Equipment Design

C1 Technical specifications of radiation device or prescribed equipment

Provide copies of the approved design specifications for the radiation device or prescribed equipment, including major associated components and subsystems.

C2 Technical drawings for radiation device or prescribed equipment

Provide details on the design of the prescribed equipment or radiation device and its components in the form of engineering drawings (system assembly and component machining).

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.

Where applicable, include schematic diagrams of radiation safety-related control systems and descriptions of their operation (such as doors and other radiation-enabling machine interlocks, source exposure and beam activation control circuits).

Provide a copy of the overall assembly drawing, and indicate the position of any radioactive source or accelerator beam target in respect to the radiation shielding incorporated into the device.

All drawings should be legible and clearly marked with the release dates, scale, drawing numbers, and an associated parts list or bills of materials. The quantity and type(s) of radiation source(s), and the name and model number of the prescribed equipment or radiation device must be indicated on the general assembly drawing. A unique number is assigned to each drawing.

Any future changes to the design with respect to structure, mechanism or source type (occurring during the certification assessment or after the certificate has been issued) is forwarded, with proper documentation and supporting drawings, to the CSNC for reassessment before the changes are implemented.

Note: After the certificate has been issued, any significant changes to the prescribed equipment or radiation device that may affect the radiation safety of the system may need to be reassessed and a new certificate may be required. Notify CNSC immediately about any planned design changes.

C3 Technical and safety standards used

List major technical and safety standards used to design the radiation device or prescribed equipment, if applicable. Some of these organizations include:

- Canadian Standards Association (CSA)
- Underwriters Laboratories (UL)
- Technischer Überwachungs-Verein (TUV, Technical Monitoring Association)
- International Electrotechnical Commission (IEC)
- International Organization for Standardization (ISO)

- American National Standards Institute (ANSI).

Explain how these standards were applied to the design and how compliance to their requirements was verified. If applicable, provide design validation including verification protocols and reports. Attach any relevant test and analysis results.

C4 Design validation and risk assessment records

Provide copies of the technical validation records, including test reports. Include records of the failure effect mode analyses, device hazard and risk assessment files.

C5 Nuclear substances used and radiation source design

Specify all nuclear substances incorporated into the prescribed equipment or radiation device, using the radionuclide name and mass number, as applicable.

Provide technical details of the design of radiation sources to be used in the prescribed equipment or radiation device.

The following information is submitted for each radioactive source used in the device:

- Nuclear substance and quantity
- Physical and chemical form
- Name of nuclear source manufacturer
- Model number of the source
- A current copy of the certificate for Special Form, if applicable
- Detailed drawings of the source capsule and source assembly, if applicable
- Source classification (based on, for example, standards of ANSI, ISO or similar institution).

Note: All activities should be expressed in Becquerel units (e.g., Bq, GBq or TBq).

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, in the following form:

- Model number(s) of the source holder(s) and source assembly(ies), if applicable
- Complete set of engineering drawings of the source holder and shielding, with the list of materials. These drawings should give sufficient detail to show the construction, dimensions and materials used to enable the reviewer to understand how the various parts of the design are assembled (e.g. welds, bolts, screws, glue, etc.) and to understand the operation of any moving parts
- Drawings of details of the source mounting and retention within the device, with specific overall weight and dimensions of the device
- Details of safety features such as the shutter mechanism, source lock mechanism, collimator, radiation warning lights, and safety interlocks

- Details on the prescribed equipment or radiation device classification, including results of the tests conducted
- Results of reliability tests of the shutter mechanism
- Details of any other test results pertaining to radiation safety that have been performed
- Source securing method for transport (the means of positive fastening to prevent movement from the shielded position), if applicable.

C7 Radiation shielding

Provide a description of the radiation shielding used in the prescribed equipment or radiation device, and specify material(s) used for shielding.

If the shielding includes depleted uranium, provide the weight of this material.

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) to be used and model number(s) for identification. Enclose applicable technical drawings and part numbers.

C9 Activated components (for Class II prescribed equipment only)

For particle accelerators:

- List all major activation products that may result from the equipment operations
- List radioisotope names, half-lives, and maximum initial quantities in terms of radioactivity or emitted radiation
- Specify the radiation dose rate at 30 cm from the activated components at a given time following the activation (state the conditions of irradiation).

C10 Radiation leakages

Provide values of the expected radiation dose rates around the equipment in all modes of operation. Include the measurements and calculation methods used to establish the dose rates. The distances for radiation field measurements should correspond to the values required by technical standards used to specify the survey conditions. Otherwise, use the external surface of the shield, 30 cm and 1 m from the surface as reference distances.

- Provide a description of the radiation profile measurements. Include details such as the environmental conditions, distances from the source, shutter positions, and exact locations of the radiation detector
- State the make and model of the radiation survey meter(s), the date(s) of measurements, and the calibration date(s)
- State the maximum dose rate that the prescribed equipment or radiation device can deliver, the operating conditions that can produce this dose rate, and the areas where this dose rate may exist
- Where applicable, indicate the following:

- a) Neutron leakage measurement results
- b) Photon leakage measurement results
- c) The neutron content in the photon beam
- d) Limits to the radiation beam orientation
- e) Locations of activated components and radiation dose rates at 30 cm from those components
- f) Type(s) of beam producible and their maximum energy

Radiation profiles must be submitted for each type of source (nuclear substance) to be used in the prescribed equipment or radiation device. If the radiation profile may be affected by variation in the design (various series), a radiation profile should be provided for each of the design variations.

Note: If the device incorporates a shutter, measurements must be submitted with the shutter in both the open and the closed position.

C11 Radiation output (for Class II prescribed equipment only)

As applicable, specify beam particle types, energy and intensity of radiation to be expected at a reference point in each mode of operation consistent with the design and intended use (append a list of specifications, if necessary). Specify the intensity and energy of the neutrons generated in the primary beam.

Specify the intensity of the radiation emitted by the prescribed equipment or radiation device inside the useful radiation field in the point and conditions of reference.

C12 Physical size

Provide the overall dimensions and weight of the prescribed equipment or radiation device.

C13 Labelling, safety marks and instructions

Refer to the [*Radiation Protection Regulations*](#), section 20, for detailed requirements on the marking and labelling of nuclear devices, and provide a description of the labelling of the prescribed equipment or radiation device by including the following information:

- A sample, photograph or a detailed drawing of a durable radiation warning label and source identification labels, or safety marks used on the equipment
- Depiction of how the equipment nameplate will be affixed to the equipment or device
- Specifications of where the labels and safety marks will appear on the prescribed equipment or radiation device
- Safety instructions and warnings for users and service personnel.

Provide photographs of the radiation device or prescribed equipment from at least two camera angles. Include a reference object in the photographs, so that the relative size is evident.

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

For radiation devices and prescribed equipment with external safety devices, describe the available connections, such as:

- Door interlocks
- Last person out buttons
- Emergency stop devices (buttons, pull cords, etc.)
- Radiation state indicators
 - g) radiation on, off, ready
 - h) beam on, off, ready, etc.
- Any other connections that may be in place.

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.

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

If the applicant has used a simulation program based on the Monte Carlo code (i.e., MCNP 5, MCNPX, GEANT, TART, FLUKA, etc.) for the assessment of doses (leakage, activation components, etc.), radiation profiles, radiation output, neutron source term, gamma source term etc., the applicant should provide:

- A brief description of the simulation (geometry, materials, source definition, tallies, doses, graphics)
- Input and output files
- Shielding techniques employed (importance, weight windows)
- Mesh Tally graphics (pdf, psc, jpg, etc.)
- Information concerning other related MCNP program used (e.g., ALICE-91), with respective information (as above).

3.4 Part D – Transport, Storage, Use and Operation of the Radiation Device or Prescribed Equipment

Provide the radiation safety instructions pertinent to the use, operation and storage of the prescribed equipment or radiation device.

Radiation safety instructions are contained in the operating manual that is to be provided to the end-user. Include copies of the operating manual and radiation safety instructions.

D1 Radiation safety instructions for use, operation and storage

Provide any limitations on the use of the system, such as operating temperature range, vibration levels, pressure, and recommended environmental conditions.

Provide the procedure for source replacement provided to the end-user, indicate if this can only be done by the manufacturer, or indicate if it is not applicable for this device or equipment.

Proposed radiation safety instructions should appropriately reflect the complexities, conditions and hazards involved in using the radiation device.

D2 Instructions for packaging and transport

Append or enclose policies and procedures for the packaging and transport of the prescribed equipment or radiation device. This information is not required for prescribed equipment that does not incorporate radioactive material.

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.

The procedures will depend on the type of packaging used and the transport activities undertaken. The most common package configurations are:

- The radioactive source is removed from the prescribed equipment or radiation device for shipment, in a separate package
- The prescribed equipment or radiation device, including the source, is inserted into a separate package
- The prescribed equipment or radiation device, including the source, is shipped without any additional protection.

For any of the above configurations, the details described under “Required Documentation” (as found below, in section D7) will apply. Details on package classification and qualification are found in the [Packaging and Transport of Nuclear Substances Regulations](#).

D3 Package type and classification

All claims must be supported with appropriate documentation as explained below.

- Package classification includes:
 - a) Excepted packages (instrument or article, limited quantity of material, articles manufactured from natural uranium or depleted uranium or natural thorium)
 - b) Type A packages
 - c) Type B packages
- If a claim is made that the radioactive source is a Special Form, a copy of the certificate for Special Form must be submitted. This certificate is normally

issued by a Competent Authority in the country of origin of the sealed source design.

For a radiation device to be classified as an instrument or article, the source and its shielding must be part of the device and enclosed by the body of the device. Source holders alone are not instruments.

D4 Package details

The following information must be submitted to permit assessment of the proposed package:

- Details of the technical specifications of the package design, including specifications of the package materials, design and construction. Specify if additional packaging is required for the device to meet the package classification
- Information that demonstrates that the Type A package meets the requirements for a Type A package (as specified in the [Packaging and Transport of Nuclear Substances Regulations](#)) if applicable. This information includes details on the test results demonstrating the package can withstand normal conditions of transport
- A description of the quality assurance program applied in the design, manufacture, testing, documentation, use, maintenance, and inspection of the package
- Details of the means to provide fastening and sealing of the shutter(s) or sources(s), prior to transportation. This information is not required if the source is shipped separate from the device package
- Details of any additional markings that will be affixed to the package.

If the package used for the transport of the prescribed equipment or radiation device has been certified as a Type B package by CNSC, only the reference to the CNSC certificate number is required.

A separate application must be submitted to CNSC for the certification of a package, or for the endorsement of a foreign certification as a Type B package. When a package has been certified as a Type B package, the user must register its use separately. A device used as a Type B package must be certified by CNSC both as a device and as a Type B package.

The user may only transport the package after receiving confirmation of the registration for transport of the package.

D5 Transport accidents

For devices being transported frequently (i.e., portable devices), submit the emergency procedures to be followed in case of a transportation accident involving the prescribed equipment or radiation device.

D6 Emergency procedures

Append or enclose policies and procedures for dealing with accidents in which the prescribed equipment or radiation device may be involved. Provide a copy of the instructions that are supplied to the end-user. Procedures should include actions to:

- Limit the spread of contamination
- Reduce the radiation fields
- Detect and estimate the quantity of nuclear substances released
- Decontaminate the affected site, equipment, workers, and other persons
- Monitor radiation releases from the site
- Maintain lists of the emergency spill equipment and emergency personnel contacts.

D7 Required documentation

The following must be submitted with the application:

- Instructions for packing, unpacking and transporting the package. These should include a copy of the packaging instructions to be supplied to the end-user for the return of the prescribed equipment or radiation device, and a copy of the preparation for shipping instructions supplied to the end-user. These instructions should include all actions required to properly prepare the radioactive material for transport, including items such as properly closing or locking shutters, or additional packaging, as applicable
- A copy of maintenance procedures for the package, if the package is to be re-used.

For particle accelerators: An application for certification of Class II prescribed equipment consisting of a particle accelerator does not require the equipment package information, unless the accelerator, as shipped, incorporates radioactive material.

If the radiation device is to be shipped, and requires additional packaging, indicate what type of packaging will be used.

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) in the prescribed equipment or radiation device. Provide a copy of the instructions that are provided to the end-user.

All sealed sources greater than 50 MBq must be leak tested, using instruments and procedures that enable the detection of a leak of 200 Bq or less of the nuclear substance.

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.

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

Provide details of the recommended inspection, servicing program, and describe the conditions of retiring the prescribed equipment or radiation device from operation and disposal of the radiation source(s) or activated components supplied to the end-user. Also provide information as required by paragraph 3(1)(o) of the [Nuclear Substances and Radiation Devices Regulations](#).

Provide a list of the parts that are serviceable:

- By the end-user
- By an authorized service provider
- Not permitted.

Specify the expected lifetime of use of the prescribed equipment or radiation device allowed by the design.

3.5 Part E – Design Control and Quality Assurance Program**E1 Quality assurance manual**

A quality assurance (QA) program is required for the design and manufacture of prescribed equipment and radiation devices. List documents used in the QA program. A copy of the QA manual is provided to CNSC for review. In addition, if the applicant is ISO 9000 registered or certified, provide a copy of the registration or certification obtained and the approval date.

Append or enclose the policy regarding the QA program that was followed during the design of the prescribed equipment or radiation devices and that will be followed during its production and service.

E2 Design control system

Provide copies of the design control manual and associated policies to be followed during the design of the prescribed equipment or radiation device, as well as during production.

3.6 Part F – Approvals and Registrations for the Radiation Device or Prescribed Equipment**F1 Health Canada medical device licence**

If this prescribed equipment or radiation device is a medical device for which a licence has been issued by Health Canada, include a copy of that licence.

F2 Medical device approvals

Include a copy of the following documents, if applicable:

- United States Food and Drug Administration (USFDA) Medical Device registration

- European Union (EU) Council Medical Device Directive registration
- Canadian Standards Association (CSA) approval.

F3 Other applicable jurisdiction approvals

Include a copy of the following documents, if applicable:

- International Organization for Standardization (ISO) 9000 Series (and related standards) registration
- Certificate(s) of compliance with applicable technical standards
- United States Nuclear Regulatory Commission (USNRC) registration
- Approvals of pertinent national, provincial or state authorities.

3.7 Part G – Legal Signing Authority

To comply with Section 15 of the [*General Nuclear Safety and Control Regulations*](#), every applicant must provide information to CNSC about its legal representatives.

G1 Applicant authority

This person has the authority to apply on behalf of the applicant, and by doing so, certifies that the information submitted is true and correct to the best of his or her knowledge.

This person acts for the applicant in dealings with CNSC. Provide the name of the person, telephone number, fax number and email address.

4.0 Cost Recovery Fee Regulations

As set out in the [*Canadian Nuclear Safety Commission Cost Recovery Fees Regulations*](#), CNSC charges fees for its regulatory activities. Cost recovery fees and exemptions are listed in these Regulations.

Some licensees are exempt from paying fees, including the following:

- Educational institutions
- Not-for-profit health care institutions that receive funds from federal, provincial, or municipal governments
- Government departments listed in Schedules I and II of the [*Financial Administration Act*](#)
- Provincial and local governments.

For details on exemptions, refer to the [Canadian Nuclear Safety Commission Cost Recovery Fees Regulations](#).

Applicants who are subject to cost recovery fees must pay the fees that are assessed according to the extent of the certification activity. The fee schedule is posted on the CNSC Web site at nuclearsafety.gc.ca. For assistance in determining the fees particular to a specific prescribed equipment or radiation device, applicants should contact the CNSC cost recovery unit listed below.

Payment of cost recovery fees must accompany the certification application. Payment may be made by cheque or money order made payable to the Receiver General for Canada, or by credit card. To arrange payment by credit card, applicants should contact the Cost Recovery Officer in the CNSC Accounting, Systems and Controls Division in Ottawa at

Telephone: 613-991-9791 or 1-888-229-2672
Fax: 613-995-5086
Email: finance@cnsccsn.gc.ca

Glossary

Brachytherapy machine

A device designed to place, by remote control, a sealed source inside or in contact with a person, for therapeutic purposes.

Class II prescribed equipment certificate

A document issued by the Commission or by a designated officer authorized under paragraph 37(2)(a) of the [NSCA](#), indicating that a model of Class II prescribed equipment is certified for use.

Class II prescribed equipment

Means:

- (1) An irradiator that uses more than 10^{15} Bq of a nuclear substance;
- (2) 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 centigray per minute at a distance of 1 m;
- (3) A radioactive source teletherapy machine;
- (4) A particle accelerator that is capable of producing nuclear energy and has a beam energy of less than 50 MeV (mega electron volts) for beams of particles with a mass equal to or less than 4 atomic mass units;
- (5) 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
- (6) A brachytherapy remote afterloader.

Excepted package

A package that meets the requirements of paragraph 515 of the *IAEA Regulations*.

Exposure device

A radiation device that is designed for carrying out gamma radiography, and includes any accessory to the device such as a sealed source assembly, a drive mechanism, a sealed source assembly guide tube and an exposure head.

IAEA Regulations

The [Regulations for the Safe Transport of Radioactive Material, 1996 Edition \(TS-R-1 ST-1, Revised\)](#) published by the International Atomic Energy Agency.

Irradiator

A device that is designed to contain a nuclear substance and to deliver controlled doses of radiation from that substance to any target, except persons.

Nuclear substance

A nuclear substance includes the following:

- (1) Deuterium, thorium, uranium or an element with an atomic number greater than 92;

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

Operate

For an exposure device, operate includes coupling the drive mechanism to the exposure device, uncoupling the drive mechanism from the exposure device, locking or unlocking the exposure device, and all activities involving the device that take place while the sealed source assembly is not locked inside the device in the fully shielded position.

For other devices, equipment or facilities, operate means turning on and using the device, equipment or facility for its intended purpose and in accordance with the manufacturer's instructions. Operate includes minor upkeep as per the operating manual.

Possess

To have the care and control of a nuclear substance or radiation device.

Radioactive source teletherapy machine (see also teletherapy machine)

A teletherapy machine designed to deliver controlled doses of radiation produced by a nuclear substance, for therapeutic purposes.

Radiation device

Either of the following:

- (1) A device that contains more than the exemption quantity of a nuclear substance and that enables the nuclear substance to be used for its radiation properties;
- (2) A device that contains a radium luminous compound.

Radiation device certificate

A document issued by the Commission or by a designated officer, authorized under paragraph 37(2)(a) or (b) of the [NSCA](#), indicating that prescribed equipment or a person is certified.

Sealed source

A radioactive nuclear substance in a sealed capsule 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.

Sealed source assembly

A sealed source designed to be used in an exposure device, which includes the components that are permanently attached to the sealed source.

Special form radioactive material

An indispersible solid radioactive material or a sealed capsule containing radioactive material and which has demonstrated that it met the requirements for special form radioactive material, as specified in IAEA Regulations, and for which a certificate of approval from a competent authority has been issued.

Service

The action to perform preventive or corrective maintenance on a radiation device or prescribed equipment, which may include:

- (1) Installation;
- (2) Relocation or dismantling of equipment;
- (3) Source installation or replacement;
- (4) Maintenance or repair (including any adjustment) involving any mechanism on the device, control consol, or interlocks that could expose the source, reduce the shielding around the source, or affect the source drive control for radiotherapy.

Store

To lay away between uses, or for future purposes.

Teletherapy machine

A device designed to deliver controlled doses of radiation, in a collimated beam, for therapeutic purposes.

Type A package

A package that is designed to meet the requirements of paragraphs 413, 414 and 633 of the *IAEA Regulations*.

Type B package

A package that is designed to meet the requirements of paragraph 415 or 416 and paragraph 650 or 665 of the *IAEA Regulations*.

Transfer

To change the possession of a nuclear substance or radiation device from one person to another.

Transport

To handle, carry, store in transit and receive goods at the final destination. Transport includes normal and accident conditions encountered in carriage and in storage during transit.

Unsealed source

A source other than a sealed source.