



Licence Application Guide **Radiotherapy**

RD/GD-120

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Licence Application Guide - Radiotherapy
RD/GD-120

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Ce document est également disponible en français sous le titre : *Guide de présentation d'une demande de permis : Radiothérapie.*

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: 613-992-2915
E-mail: info@cnsccsn.gc.ca

Preface

In accordance with the *Nuclear Safety and Control Act* (NSCA, the Act) and the regulations made under the NSCA, individuals wanting to construct, operate, or decommission those types of medical radiotherapy facilities that are classified as *Class II Nuclear Facilities* require a licence issued by the Canadian Nuclear Safety Commission (CNSC). The NSCA prohibits CNSC from issuing a licence unless CNSC considers 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 the Regulations.

This licence application guide provides information on the completion of the *Radiotherapy Application Form* including detailed instructions for completion. The application form is available at nuclearsafety.gc.ca.

CNSC staff can provide additional guidance upon request; contact CNSC at info@cnsccsn.gc.ca.

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RD/GD-120 Radiotherapy

1.0 Introduction

1.1 Purpose

This licence application guide provides guidance for the completion and submission of the Application Form for the construction, operation, or decommission of medical radiotherapy facilities classified as *Class II Facilities* in accordance with the *Nuclear Safety and Control Act* (NSCA, the Act) and the Regulations made under the NSCA.

1.2 Scope

All licence requirements are based on the *Nuclear Safety and Control Act* (NSCA) and its Regulations, which are administered by the Canadian Nuclear Safety Commission (CNSC). The NSCA empowers CNSC to issue licences to applicants who, in the opinion of CNSC, 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 information needed to make this determination.

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, 5 and 7 of the Class II Nuclear Facilities and Prescribed Equipment Regulations provide additional information which an application for a licence shall contain for the construction, operation, and decommission of Class II Nuclear Facilities.

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... (iii) control of occupational and public exposure to radiation”.*
6. Paragraph 3(1)(d) of the Nuclear Substances and Radiation Devices Regulations states that *“An application for a licence in respect of a nuclear substance or a radiation device, other than a licence to service a radiation device, shall contain...(d) the proposed location of the activity to be licensed, including a description of the site.”*
7. 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.”*

2.0 Process

2.1 General

The *Nuclear Safety and Control Act* (NSCA) prohibits CNSC from issuing a licence unless CNSC 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 the Regulations.

The application must show CNSC that an organization 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 complete this licence application when requesting a new licence or renewing an existing CNSC licence for radiotherapy.

Once completed and signed, the form and all supporting documentation must be submitted to CNSC.

2.3 Amending a licence

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

1. a description of the methods and procedures to be used
2. a statement identifying the changes to the information contained in the most recent licence application
3. a description of the effects of the requested changes, including effects on nuclear substances, land, areas, buildings, structures, components, equipment and systems

4. the proposed start date and expected completion date of any modifications described in the application

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

2.4 Renewing a licence

To request a licence renewal, the applicant must complete all relevant sections of the application form.

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

2.5 Revoking a licence

The applicant may request a revocation of an existing licence by sending an email to the CNSC indicating the nature of the request. The CNSC may contact the applicant if additional information is required to complete the request.

2.6 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](#)
 - To arrange payment by credit card, contact the CNSC Cost Recovery Group in Ottawa at: (613)995-5894 or Toll Free: 1-888-229-2672.

Provide two copies of the completed form, signed and dated, to CNSC 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 licensees 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.

A complete copy of the application should be kept by the applicant for their records. All information submitted is subject to the provisions of the [Access to Information Act](#) and the [Privacy Act](#).

3.0 Completion of Application Form

Applicants for licences should complete the *Radiotherapy Application Form*. This form can be found on the CNSC website: nuclearsafety.gc.ca.

For additional information please contact CNSC at:

- toll-free telephone number: 1-888-229-2672
- fax number: 613-995-5086
- email: info@cnsccsn.gc.ca

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

FOR ALL APPLICATIONS: Complete Sections A to E (inclusive) and complete and sign Section L.

Other sections of the application form are filled out depending on the type of request being made. For renewal of existing licences complete Section F and for all new licences complete the additional Sections specified below:

1. Construction – Sections G and H
2. Operating to Commission – Section I
3. Routine Operation (amendment) – Section J
 - the applicant must apply for and receive an amendment to an operating licence before routine operation of the facility can commence
4. Decommissioning – Section K

If the applicant is renewing or amending (e.g., from “Construction” to “Operating” status) a licence, the application may refer back to any information previously submitted which remains 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 the type of application. Any changes from the previous application should be clearly stated.

3.1 Section A – Applicant’s information

A1 Type of request

Indicate if this application is to obtain a:

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

Indicate the current licence number, if applicable.

When submitting an application for the renewal of a licence identify any changes in the information submitted in the previous application.

A2 Language of Licence

Choose the official language for the licence.

A3 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, and 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 CNSC within 15 days of any changes to this information.

Mailing Address - 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 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 CNSC within 15 days of any changes to this information.

A4 Policy on Public Access to Information

Indicate whether or not any part of this application is subject to a request for exemption from the CNSC policy on public access to the information encompassing the licence.

The CNSC policy is to make copies available, upon request, specific licensing and other documented information including the information provided in this application and supporting documentation unless the information is specifically exempted. A request for exemption should be made in writing to CNSC detailing the applicant's basis and reasons for such an exemption.

A5 Billing Contact Person

Provide the name of the person to be contacted regarding payment of fees for the licence. 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.

Financial Guarantees: Section 24 of the *Nuclear Safety and Control Act* allows the granting of a licence to be subject to financial guarantees. The purpose of this 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 C-206, "Financial Guarantees Guide for the Decommissioning of Licensed Activities".

3.2 Section B – Licenced Use Types, Activities and Locations

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

B1 Licenced Use types

Check only one use type. Each listed use type requires a separate licence with its own appropriate licence conditions. Also, CNSC requires that the applicant complete a separate application for a licence to construct, licence to operate (commissioning), licence to operate (routine), or licence to decommission for each facility (see section A1).

B2 Licenced Activities

Check as many activities as the applicant intends to conduct in association with the nuclear substances that are associated with or arise from the use type selected in B1.

The written application provides the basis on which a licence will be issued. Therefore, the applicant must clearly document all proposed licensed activities in this application and provide supporting documentation as required. If the applicant intends to transfer or export nuclear substances as part of the operation of their facility, the applicant must ensure that the information submitted under E11 and E12 includes appropriate procedures for packaging and shipping and for ensuring that personnel have the necessary Transportation of Dangerous Goods (TDG) training.

B3 Principal Location of Use and/or Storage

Provide the main address at which the radiotherapy facility is to be constructed, operated or decommissioned and for the applicant's use and/or storage of prescribed equipment or nuclear substances. The address must as a minimum consist of a room number, a street

name and number, city, province and postal code.

If the premises are rented or leased, provide a letter from the owner confirming that there are no objections to licensing this location for nuclear substances.

B4 Other Locations of Use and/or Storage

These are other rooms or buildings where the applicant may use or store prescribed equipment or sealed nuclear substances. For example, for High Dose Rate (HDR) brachytherapy remote afterloaders, the applicant may wish to temporarily store replacement sources in a location separate from the treatment bunker. For Low Dose Rate (LDR) brachytherapy units, the applicant may wish to have multiple treatment rooms for a single device. For each room, indicate clearly whether the room is intended for the operation of the prescribed equipment, the storage of the prescribed equipment or associated nuclear substances, or both.

Each listed location is subject to regulatory requirements until it has been decommissioned and the decommissioning report has been accepted by CNSC.

3.3 Section C – Nuclear Substances and Class II Prescribed Equipment

In this section, provide details about the nuclear substances and prescribed equipment that is to be licensed.

C1 Class II Prescribed Equipment

A. For medical accelerators:

Manufacturer - Enter the name of the manufacturer of the device.

Model name and number - Enter the model name and manufacturer number of the device.

CNSC certificate number - Enter the CNSC certificate number of the device, (available from manufacturer)

Serial Number - Enter the serial number of the device, if available.

Beam parameters - Enter the types of beam (e.g., electron, photon), the maximum output energies, and the maximum dose rate of the accelerator. For photons please specify BJR11 or BJR17 method of specifying beam energy.

B. For teletherapy machines and brachytherapy remote afterloaders:

Manufacturer - Enter the name of the manufacturer of the device.

Model name and number - Enter the model name and manufacturer number of the device.

CNSC certificate number - Enter the CNSC certificate number of the device, (available from manufacturer).

Serial Number - Enter the serial number of the device.

Nuclear Substance - Enter the name or symbol and mass number (e.g., Co-60) of the nuclear substances incorporated into the device.

Maximum quantity - For each radionuclide, enter the largest quantity contained in an individual source for which the device is approved.

Source Model Number - Enter the model of the sources incorporated into the device, if applicable.

Serial Number - Enter the serial numbers of the sources incorporated into the device, if available.

C2 Sealed Nuclear Substances which are NOT incorporated into Class II Prescribed Equipment

For sealed nuclear substances which are not incorporated in Class II prescribed equipment such as the replacement or spent sources which will be in the applicant's possession during source changes (e.g. for remote afterloader or cobalt teletherapy) or check sources for radiation detection instruments if they are not already covered by an existing CNSC licence at the facility, include:

Manufacturer - Enter the name of the manufacturer of the source.

Model number of source - Enter the manufacturer model number of the source.

Nuclear Substance - Enter the name or symbol and mass number (e.g., Co-60) of the nuclear substances that the applicant wishes to possess

Maximum quantity per source - Enter the largest quantity contained in an individual source, for **each** radioactive nuclide.

Serial Number - Enter the serial number of each source.

3.4 Section D – Radiation Safety Program

In this section, information is requested about various aspects of the applicant's radiation safety program. This includes the organization management structure and details about the workers who implement and supervise the program, and about the workers who use the nuclear substances and Class II prescribed equipment.

The radiation safety program components described in this guide do not prevent alternative proposals being made by the applicants to CNSC but any proposed radiation safety program should appropriately reflect the complexities and hazards of the activities described in a licensee's application. In addition, since the licensee is ultimately responsible for radiation safety related to all activities authorized by the licence, an effective radiation safety program must have the support, commitment and participation of management and staff.

D1 Radiation Safety Officer (RSO)

Provide the name of the Radiation Safety Officer (RSO), the CNSC certificate number of the RSO, and describe their qualifications, experience and duties.

Radiation Safety Officer is the title given to the person responsible for the management and control of the licensed activity and of the nuclear substances. The RSO is the person CNSC will contact about radiation safety and compliance matters. The RSO must be familiar with the radiotherapy facility operations described in this application and the use of nuclear substances in conjunction with the facility.

New RSO's for Class II radiotherapy facilities are subject to certification by the CNSC and must demonstrate adequate knowledge of radiotherapy physics,

radiation protection fundamentals, facility operations and the associated regulatory requirements. For more information regarding this certification process, please contact CNSC.

The radiation safety program includes provisions to designate an alternate RSO to cover periods during which the named RSO is absent from the facility. Should a situation arise in which it is known that the RSO will be absent for an extended period, the applicant must designate a new RSO for the duration of the absence and resubmit the information under D1 and D2

The applicant must notify CNSC, within 15 days, of a change in RSO or RSO position job description

D2 RSO Acknowledgement

Provide a copy of the RSO's signed consent.

Once an individual has been designated as the RSO by the applicant authority, the individual identified as RSO must sign a consent form, acknowledging his/her willingness to be designated as the applicant's RSO and accepting the responsibilities described in the job description submitted.

D3 Radiation Safety Officer – Job Description

Append or refer to the job description of the RSO. The job description should include the time and resources allotted to the RSO to carry out their duties. The applicant should authorize the RSO, in writing, to supervise and administer the radiation safety program. The RSO should be available to supervise the radiation safety program to make sure that the workers conduct the work to meet all regulatory requirements.

D4 Designated Supervising Physician (DSP)

No licensee may use Class II prescribed equipment on a person except as directed by a qualified medical practitioner, who is referred to in this guide as the Designated Supervising Physician (DSP). For radiotherapy applications, this role is typically fulfilled by the clinical head of the radiation oncology program.

Provide the name of the DSP and a copy of the document provided by the institutional medical regulatory body or a copy of institutional privileges authorizing the DSP to direct the use of nuclear substances and/or Class II prescribed equipment.

D5 DSP Acknowledgement

Provide a copy of the DSP's signed consent document.

Having signed the consent document, the person identified as the DSP acknowledges his or her willingness to be designated as the applicant's DSP and accepts the responsibilities of the position.

D6 Organizational Management Structure

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

- position and titles of the persons responsible for the management and control of nuclear substances / prescribed equipment during the activity to be licensed
- functions, responsibilities and authority of each position named above
- an organization chart that shows the lines of reporting, communications and responsibilities for radiation protection

D7 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. The primary role of the RSC is to advise RSOs and management on the quality and effectiveness of radiation safety policies and programs and the safety of employee work practices. Members of RSCs are usually selected or appointed because of their expertise or job-related interests in radiation safety.

D8 Radiation Detection Instruments

Append a list of all radiation detection instruments which are to be used in conjunction with the Class II prescribed equipment or nuclear substances, including their intended use. This list should include information on:

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

A calibrated radiation dose rate survey meter must be available at all times. In addition, the suitability of any survey meter should be verified prior to use. For example, many photon survey meters have been observed to respond inaccurately when subjected to the pulsed, high energy radiation fields produced by typical medical linear accelerators.

3.5 Section E – Radiation Safety Policies and Procedures

In this part of the application, provide the information supplied to workers regarding the applicant's radiation safety program.

All radiation safety programs should be documented and have detailed policies and procedures. Policies and procedures should be prepared under the supervision of the Radiation Safety Officer (RSO) and approved by senior management. It is recommended that policies and procedures be incorporated into an official radiation safety manual that is

readily available to all workers.

E1 ALARA (As Low As Reasonably Achievable)

Append or refer to the policy which 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’s guide, G-129 rev 1, *Keeping Radiation Exposures and Doses As Low As Reasonably Achievable (ALARA)* and section 4 of the *Radiation Protection Regulations*.

E2 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, they must investigate, take corrective action and notify CNSC within the time period specified in the licence.

Propose an action level as part of the licence application, *only* if an action level is to be part of the applicant’s overall radiation management program. The action levels will then be referred to in the licence. If action levels are not part of the radiation protection program, explain why they are not necessary.

In addition, the applicant must append or refer to the policies and procedures that will be used should an action level be reached.

E3 Worker Qualifications, Experience, Training and Authorization

Append or refer to the policy which specifies that only persons properly trained and informed of the hazards are authorized to handle nuclear substances or operate Class II prescribed equipment. Provide a description of the qualifications, training and experience required for workers. Include the required education and previous experience (e.g., type of degree, diploma, certification, or equivalent years of experience required) and an overview of the proposed in-house training program for each category of worker (e.g., therapists, physicists, service personnel, etc.).

Workers should be individually authorized for nuclear substance and Class II prescribed equipment work following successful completion of an appropriate training program. Retraining should be done following a significant change in procedures and periodic refresher training is also advisable.

The applicant should not assume that radiation safety training acquired from prior occupations or academic certification is adequate for their operations. Minimum training should provide site-specific and task-specific training for all workers. The applicant should tailor all training to the educational background and the practical needs of those attending. The applicant must maintain a record of worker training.

It is also recommended that basic radiation safety training be extended to auxiliary personnel (e.g., clerical, janitorial, maintenance, nursing and security staff).

E4 Nuclear Energy Workers (NEW) Designation

Append or refer to the policies and procedures used to designate Nuclear Energy Workers (NEW). The *Radiation Protection Regulations* require that NEWs be informed of their status, the risks associated with radiation to which the worker may be exposed, applicable effective dose limits, typical dose levels received and their obligations. 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.

The procedures must clearly state which positions/categories of staff members are to be declared as NEWs, who is responsible for ensuring they are notified, the method of notification and who is responsible for retaining the list of NEWs.

E5 Personal Dose Monitoring

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

E6 Rooms – Posting

Append or refer to the policy for posting of rooms where nuclear substances and prescribed equipment are stored or used.

A durable and legible radiation warning sign must be posted at the boundary of, and at every point of access to, an area, room or enclosure where there is a quantity of nuclear substance greater than 100 times its exemption quantity, or where there is a reasonable probability that a person will be exposed to a radiation dose rate greater than 25 $\mu\text{Sv/h}$. The name or job title and telephone number of a person who can be contacted 24 hours a day in case of an emergency must be posted at the entrance of each facility.

E7 Decommissioning Procedures

Provide the policies and procedures for decommissioning of a Class II radiotherapy facility. Licensees must obtain a Class II decommissioning licence prior to decommissioning medical linear accelerator or cobalt teletherapy facilities (see section K).

For brachytherapy remote afterloaders, a separate decommissioning licence is not required. However, before the applicant can release a room listed in subsection B3 for non-radioactive use, the applicant must:

- Remove all nuclear substances, and dispose of them appropriately (see E11).
- Conduct a radiation survey to confirm there is no residual contamination. During the survey, the applicant should also ensure that the radiation dose rates produced within the room by the operation of any adjacent facilities are acceptable for the new occupancy of the room.
- Remove or deface all radiation warning signs and labels.

- Submit a summary report to CNSC and have the room deleted from the licence or the licence revoked.

E8 Access Control and Security

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

Access to nuclear substances and prescribed equipment 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, such as replacement sources for HDR brachytherapy units, 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 radiotherapy equipment outside of normal treatment hours.

E9 Inventory Control and Records

The applicant must maintain an inventory of nuclear substances. The applicant controls the purchase and transfer of nuclear substances and they must know what is in storage, in use or awaiting disposal. Append or refer to policies and procedures for inventory control.

Purchase records must be maintained and available for inspection. Transfers from other licensees should be included in the purchase records in order to have a record of what the applicant has acquired. These records must include:

- name, quantity and form of the nuclear substance
- the date received
- name, address and licence number of the supplier
- 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
- make, model and serial number of the radiation device, if applicable

E10 Receipt of Packages

Append or refer to the procedure for receiving shipments of nuclear substances.

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. Outside normal working hours, packages should be placed where they will be secure and separate from workers until they can be properly examined. Workers who receive packages should be suitably trained and authorized.

E11 Disposal of Nuclear Substances

Radioactive waste must be handled and disposed of in such a way that no risk is imposed on the public or environment. Append or refer to the policies and procedures for disposing of nuclear substances.

For disposal, nuclear substances may be returned to the supplier, transferred to AECL or another organization authorized to handle radioactive waste, or held for decay. The applicant can only transfer nuclear substances to a recipient who holds a valid licence. When transferring a sealed source, the applicant must give the recipient the most recent leak test result.

Disposal records must indicate:

- name, quantity and form of the nuclear substance
- the date of transfer or disposal
- the disposal method
 - name, address and licence number for returns to supplier
 - name, address and licence number for transfers to an organization having a Waste Nuclear Substance Licence
- the serial number of each sealed source.

E12 Source Changes for Radioactive Source Teletherapy and Brachytherapy Remote Afterloaders

Append or refer to the policies indicating who may perform source changes, and procedures to ensure radiation safety during source change operations.

Source changes for Class II prescribed equipment may only be performed by persons authorized to do so under the terms and conditions of a Class II Prescribed Equipment Servicing Licence. Information regarding how to apply for a licence for servicing of Class II equipment is available in RD/GD-207 – *Licence Application Guide – Servicing Class II Prescribed Equipment*.

E13 Maintenance and Use of Meters

Append policies and procedures for the maintenance and use of portable photon radiation dose rate survey and neutron meters.

For the purpose of measuring a dose rate, there is a prohibition for use of any radiation survey meter that has not been calibrated within the preceding 12 months. Provide information about the methods, procedures and equipment that will be used to calibrate the meters.

If a commercial calibration service is used, please provide the name and contact information of the company performing the calibration.

Before each use, the user must verify that the survey meter is properly functioning by performing:

- battery check
- high voltage check (if applicable)
- source/response check

- calibration date check

3.6 Section F – Information for Licence Renewals

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

F1 Radiation Dose Summary

Append a report summarizing the annual radiation dosimetry results for all monitored workers over the last year. 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
- > 0.2 but ≤ 0.5 mSv
- > 0.5 but ≤ 1.0 mSv
- > 1.0 but ≤ 5.0 mSv
- > 5.0 but ≤ 20.0 mSv
- > 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*.

F2 Sealed Sources Acquired

Append a list of all of the sealed sources acquired within the past year, pursuant to the licence the applicant is renewing, with corresponding serial numbers/lot numbers and activities.

F3 Sealed Sources Disposed or Transferred

Append a list of all of the sealed sources disposed of or transferred within the past year, pursuant to the licence the applicant is renewing, with corresponding serial numbers/lot numbers and activities. For each sealed source, indicate whether it was:

- returned to the supplier
- sent to Atomic Energy of Canada Limited or other organization authorized to possess and store radioactive waste
- otherwise disposed (e.g., by transfer to another licenced facility, disposal as normal waste after decay, etc.)

Transfers to another licensee must include the licensee's name, address and licence number.

F4 Incidents

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

F5 Occupancy Review

Append an update on the information required in G3 of this guide, regarding the purpose and occupancy of the areas surrounding the Class II nuclear facility. Highlight any changes from the original facility design.

F6 Class II Prescribed Equipment Operating Workload

For Accelerators and teletherapy:

Append the current total annual primary beam workload in centiGray (cGy) delivered at isocentre (please specify the source axis distance (SAD)). For accelerators, if the total number of monitor units (MU) delivered differs significantly from the dose delivered at isocentre (e.g., due to frequent use of Intensity Modulated Radiation Therapy (IMRT), wedges, or compensators), also specify the total annual number of MU delivered.

State the maximum annual workload allowed for in the facility design. If the design workload is not available (e.g., for radioactive source teletherapy facilities originally licenced prior to 2000), show the historical trend of the total workload for the past 5 years.

For HDR, PDR, and LDR:

Append the current total annual workload for the brachytherapy remote afterloader. Refer to G4 b) for a description of suitable reporting formats for workload of brachytherapy remote afterloaders.

State the maximum annual workload allowed for in the facility design. If the design workload is not available, show the historical trend of the total workload for the past 5 years.

F7 Radiation Survey

Append the results of the most recent radiation survey. This survey should be made under 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 surrounding areas listed in F5.

3.7 Section G – Facility Planning and Design Parameters

G1 Site Control

Provide evidence that the applicant listed in A3 is the owner of the proposed construction site or that the applicant has the authority from the owner of the site to construct the facility.

Describe any limitation that the presence of the facility may impose on future changes to the surrounding areas. Describe how the applicant will exercise the control required by these limitations.

Describe the program the applicant will have 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 Class II nuclear facility.

G2 Nuclear Facility Plans and Drawings

Provide to scale plans and elevation drawings containing sufficient information to enable CNSC staff to evaluate the proposed facility. Once the construction licence is issued it will require that the construction be done in accordance with the statements and representations made in the application. 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, etc.)
- the location of the facility with respect to nearby occupied or potentially occupied areas
- a room number, name or description for each of the areas adjacent to the facility, which can be used to reference the written descriptions of their purpose and occupancy required in section G3
- the layout of the Class II prescribed equipment and its related equipment within the boundary of the facility
- where applicable, the direction of the primary beam, or, in the case of an isocentric unit, the plane of beam rotation and any limits to beam orientation. The isocentre should be clearly marked on the drawings
- the location, type, and thickness of shielding materials used on all sides of the Class II prescribed equipment, including the floor and the ceiling. Where applicable, this should include drawings illustrating the type, thickness and configuration of shielding materials incorporated in the door
- the location and dimensions of access ways, exits, service ducts and other penetrations and voids in the shielding.

G3 Descriptions, Occupancy and Classification of Adjacent Areas

Describe the purpose (e.g., office space, corridors, control areas, other treatment bunkers, etc.) of all areas adjacent to the treatment room, including areas above and below. Based on the planned use of each area, classify each as a:

- non-controlled area

- controlled area
- exclusion area.

In a Non-controlled area there are no access restrictions. In a Controlled area access is restricted to appropriately trained and authorized personnel. In an Exclusion area no one can gain access when the Class II prescribed equipment is in operation.

List the occupancy factor (T) for each area (i.e., the fraction of the normal operating day for the facility during which a person might reasonably be expected to occupy a given area).

G4 Class II Prescribed Equipment Design Workload

For Accelerators and Teletherapy:

Estimate the maximum anticipated annual primary beam workload, in cGy delivered at isocentre (please specify the Source Axis Distance (SAD)), based upon the anticipated use of the machine for each type of operation.

Sample table for workload estimation:

Type of Usage	Annual Dose Delivered at Isocentre (in cGy) in Each Mode			
	Low Energy Photons	High Energy Photons	Electrons	
Treatment*: Conventional - IMRT - TBI				
Dosimetry				
Maintenance				
Research				
TOTALS				

* For accelerators, if the total number of monitor units (MU) to be delivered is expected to differ significantly (e.g., by 50% or more) from the dose delivered to the patient (e.g., due to use of Intensity Modulated Radiation Therapy (IMRT), compensators or extended SSDs for total body irradiation (TBI)); also provide an estimate of the total annual number of monitor units (MU) to be delivered. Define or describe any factors or assumptions used in this estimation.

For HDR, PDR and LDR:

For brachytherapy remote afterloaders, the workload must be expressed in a manner which facilitates estimation of maximum dose rates and annual doses to surrounding areas. Acceptable methods of specifying brachytherapy workloads include:

- the product of the source activity and the exposure duration summed over all exposures during the year (e.g., in GBq minutes)

- the total annual exposure or dose which would have been delivered in air at one meter from the unshielded source (i.e., the product of the source activity, the exposure duration and the specific gamma ray constant)
- any other equivalent measure.

Estimate the maximum anticipated annual workload based upon the projected treatment, QA and research protocols and the maximum number of those procedures which are expected to be performed in a year. Outline the method of estimation and the assumptions used (e.g., average source activity during use, treatment types, average exposure times for each type of treatment, etc.).

G5 Dose Rates and Annual Dose Calculations for Adjacent Areas

For Accelerators and Teletherapy:

Append detailed calculations of the maximum dose rates and annual doses expected in each of the surrounding areas listed in G3. Describe the method of calculation. Any assumptions and the value of each parameter used in the calculations must be stated. These should include factors such as:

- maximum photon dose rate at isocentre
- maximum photon energy produced by the Class II prescribed equipment
- annual workload (W)
- beam orientation/use factor (U)
- occupancy factor (T, Note: Occupancy factors less than one sixteenth (1/16) require an explanation of why they are justified)
- source axis distance (SAD)
- distance from radiation source to the point of interest
- beam on photon and neutron head leakage specifications
- maximum field size at isocentre
- scatter angle
- type and thickness of materials used in barriers
- shielding properties/transmission factors of barriers.

The calculations should also consider:

- the contributions from primary, leakage and scattered radiation
- the contribution from both photons and neutrons, including neutron capture gamma rays
- increases in the doses outside secondary barriers due to use of IMRT.

An example of a typical calculation table is given in Appendix A.

For HDR, PDR and LDR:

Append detailed calculations of the maximum dose rates and annual doses expected in each of the surrounding areas which are listed under G3. Describe the method of calculation. Any assumptions and the value of each parameter used in the calculations must be stated. These should include factors such as:

- maximum photon dose rate at one meter from the unshielded sources

- annual workload (W)
- occupancy factor (T, Note: Occupancy factors less than one sixteenth (1/16) require an explanation of why they are justified)
- distance from radiation source to the point of interest
- type and thickness of materials used in barriers
- shielding properties/transmission factors of barriers.

The calculations should consider the contributions from both primary and scattered radiation.

G6 Other Design Considerations

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

Include: flow rate, location of intakes and discharge points, and indicate whether the air will be recirculated or once through. 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) produced by the accelerator must be evaluated and used to justify the adequacy of the ventilation system.

3.8 Section H – Safety System Requirements

In this section, the applicant must describe the safety systems to be installed at the facility. The listed safety systems are either explicitly required in the *Class II Nuclear Facilities and Prescribed Equipment Regulations* or the *Radiation Protection Regulations*; or are “industry standard” requirements which are implicitly expected to be part of any Class II nuclear facility. Any substitute system should be justified by demonstrating that it provides an equivalent level of safety.

The applicant must provide 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 Class II prescribed equipment.

H1 Door or Entrance Interlocks

For Accelerators, Teletherapy, HDR and PDR:

In facilities which have a shielded door* as part of the room shielding, there must be an interlock which shuts off the beam or retracts the source if the door is opened during operation. This interlock must be such that a person leaving the room must first press a push button inside the room and then, within a specified time delay, close the door in order to enable the transition of the equipment to the ready state condition. If the door is reopened, the irradiation or ready state condition must be terminated until the sequence is repeated. Furthermore the safety interlock must be FAIL-SAFE (i.e. designed such that any defect or component failure in the interlock system prevents operation of the prescribed Class II equipment).

*(For facilities with doors, if there is a lock on the door it must be designed such that it is not possible to lock someone inside the room.)

A “doorless” treatment room, or one which has an unshielded door intended only for security or cosmetic purposes, must retain the same functionality (i.e., a timed last person out reset circuit is still required). However, in this case, the interlock switch at the door may be replaced with:

- active infrared sensors located at the inner entrance and the outer entrance of the maze
- motion detectors located within the maze
- any other equivalent system (subject to CNSC approval).

For LDR:

The treatment room door must have an interlock which retracts the sources if the door is opened during operation.

H2 Warning Lights

All facilities must have, at each entrance to the treatment room, a warning display indicating the status of the machine. This warning display must flash or illuminate when the accelerator beam is on or the teletherapy or brachytherapy sources are unshielded.

Append a detailed description of the warning display and indicate their locations on the plans of the treatment room submitted in G2.

H3 Radiation Warning System

If applicable, append a detailed description of the radiation warning system and its function. Indicate its location on the plans of the treatment room submitted in G2.

For Teletherapy, HDR, PDR and LDR:

In each treatment room, the applicant must have an area radiation warning system that is independent of the therapy device. This radiation warning system must be capable of detecting when the source is not in the shielded (radiation off) position. For LDR, it must be capable of detecting any single source when not in the shielded position. The warning system must have a battery back-up or equivalent power supply to ensure that it continues to function in the event of a power failure.

For rooms with doors, the radiation warning system must produce an audible alarm which sounds at the entrance to the therapy room if the door is open when the sources are in the unshielded position.

For doorless facilities, the system must produce an audible alarm which sounds at the entrance to the therapy room if any of the entrance sensor interlocks are tripped while the sources are in the unshielded position.

Additional requirement for LDR:

If the treatment room door is not in the direct view of the nursing station, there should be an audible alarm which can be readily heard at the nursing station to indicate when the treatment has been interrupted.

H4 Emergency Off Buttons

Every facility must be equipped with easily identifiable push buttons, or equivalent devices, which can be used to immediately shut off the beam or retract the sources in an emergency.

Append a description of the design and function of the emergency stop buttons both inside and outside the treatment room. Indicate their locations on the plans of the treatment room submitted in G2.

All emergency stops must be located such that they are not in the direct beam. They should require manual resetting so that the Class II prescribed equipment cannot be restarted from the control console without first resetting the interlock safety circuit from inside the treatment room.

For Accelerators and Teletherapy:

As a minimum, emergency stops must be located:

- at the control console outside the treatment room
- inside the treatment room entrance (for rooms with a maze, the emergency stop should be located near the inner maze entrance)
- on each side of the Class II prescribed equipment main frame, 30 centimeters outside the direct beam.

Depending upon the size and configuration of the treatment room, additional emergency stops may be required to ensure that they are readily accessible from all locations within the facility, including inside the enclosed equipment areas which are often built inside the treatment room behind an accelerator.

For HDR and PDR:

As a minimum, emergency stops must be located:

- at the control console outside the treatment room
- inside the treatment room entrance (for rooms with a maze, the emergency stop should be located near the inner maze entrance)
- either on the Class II prescribed equipment or at least two walls of the treatment room

Manual resetting of the emergency stop button is preferable. An interlock system which does not require manual resetting of the emergency stop button, but which requires the operator to reenter the treatment room to reset the last person out circuit after and an emergency stop has been pressed, is an acceptable alternative.

For LDR:

As a minimum, emergency stops shall be located at the control console outside the treatment room.

H5 Beam Stops

For Accelerators and teletherapy:

If some sections of the treatment room walls, ceiling or floor are not designed to adequately shield adjacent areas from the direct beam, it will be necessary to physically restrict use of primary beam in these directions. Describe the electrical, mechanical or other physical means to be used to prevent the primary beam from impinging upon these barriers.

For HDR, PDR and LDR:

If portable shielding is to be used to reduce the dose rates to surrounding areas, provide details of the shield design (i.e., size, thickness, composition) and append the policies and procedures which ensure the portable shield is used and placed correctly before each treatment.

H6 Viewing System

Append a description of the viewing system used to monitor the interior of the room during treatment.

For Accelerators, teletherapy, HDR and PDR:

Each facility must be equipped with a viewing system that permits continuous observation inside the treatment room. If a closed circuit television system is used, describe the actions to be taken in case of malfunction of the system. If a shielded viewing window is used, include a radiation transmission calculation through the window as part of the dose rate and annual dose calculations in section G.

For LDR, this part is not applicable.

H7 Warning Signs

For all facilities, CNSC Regulations require that any area in which a person could be exposed to a dose rate exceeding 25 $\mu\text{Sv/hr}$ be clearly marked with a radiation warning sign. The applicant should indicate the size and location of any radiation warning signs which are to be placed in or around the proposed facility.

H8 Tools and Equipment for Stuck Source Emergencies

For Teletherapy, HDR, PDR and LDR:

These facilities must have the equipment necessary to deal with an emergency such as a stuck source. Provide a list the tools (T-bars, source handling tools, source

storage containers, etc.) which will be kept available in the facility to deal with these types of emergencies whenever the Class II prescribed equipment is used.

For accelerators, this part is not applicable.

3.9 Section I – Class II Prescribed Equipment, Operating Licence to Commission

The initial operating licence restricts the applicant to performing only acceptance testing and commissioning on the Class II prescribed equipment. Patient treatment is expressly forbidden at this stage. Before beginning tests involving the production of radiation, the applicant must first ensure that all safety systems are functioning properly. The next step is a thorough radiation survey to evaluate the room shielding, using worst case operating parameters. During this survey, the applicant must restrict access to the areas surrounding the facility until the applicant has verified the adequacy of the shielding. The applicant may only continue with the operational acceptance and commissioning tests on Class II prescribed equipment after the applicant has ensured the safety of persons working in the vicinity of the facility. Once the applicant has received a commissioning licence, the applicant should request revocation of their construction licence (provided there are no other facilities still under construction on the same licence).

In this section, the applicant is first asked to confirm that the facility has been constructed according to the specifications submitted in section G. The applicant then provides details of the proposed safety system tests and room survey protocol, including a description of all safety precautions to be taken during these tests.

I1 Confirmation of Facility Design

After the completion of the construction submit a statement, signed by both the contractor and the signing authority of the applicant which clearly states that the shielding was built according to the density, composition and thickness specifications submitted by applicant in section G.

I2 Supervision, Planning and Safety Precautions for Commissioning

Submit the following information:

- The name and title of the person who will be responsible for planning and supervising the safety system tests, the room survey, the acceptance tests and the commissioning tests. If it is not the RSO named in D1, describe the person's training and experience and include his/her position and responsibilities in the facility's organization.
- A description of the testing program to ensure that all personnel participating in safety device tests, the room survey, the acceptance tests and the commissioning tests have received proper instruction prior to the tests.
- Emergency instructions to be followed to avoid injury and minimize radiation exposure to persons in the event of a malfunction of the Class II prescribed equipment or its related safety devices during commissioning. For teletherapy, HDR, PDR and LDR, these instructions should include provisions for dealing with a stuck source emergency. The instructions

must include the name of the persons that will be responsible for directing remedial actions.

- A description of the precautions taken to ensure basic safety during the tests (e.g., electrical, fire, handling of hazardous materials).
- The proposed workload (see section G4) to be delivered during commissioning. For accelerators, also provide a breakdown of the distribution of the workload between the modes (photon and/or electron) and energies to be tested.
- If the proposed commissioning workload exceeds the estimated routine operating workload which would be delivered over the same time period, provide an explanation of what will be done to ensure that annual doses to persons in surrounding areas will not exceed the design doses specified in G5.
- A list of acceptance and commissioning tests that the applicant intends to perform on the Class II prescribed equipment to verify its performance.

I3 Safety Device Tests

Describe the tests the applicant will perform on the safety devices to ensure that they will operate as intended. Tests must be performed on the following safety devices:

- the door or entrance interlocks
- the last person out time delay interlock
- the radiation on/off indicator lights
- all emergency off push buttons
- the viewing system
- if applicable, any electrical or mechanical stops installed to limit beam orientation
- if applicable, the radiation warning system, including function of the audible alarm and battery back up.

I4 Radiation Survey Procedure

Provide the following:

- A description of the physical and administrative controls used to restrict access to the surrounding areas during the survey
- A description of the radiation detection instruments that the applicant will use for the survey, if the instruments are different than those previously described in Subsection D9. For accelerators, include a description of the instruments to be used for measuring neutron dose rates
- The plan that will be followed for performing the radiation survey. This plan should include:
 - A description of the conditions and operating parameters to be applied during the survey;

For accelerators and teletherapy: all measurements should be made using the maximum dose rate at isocentre, photon energy (accelerators) and field size. Measurements outside primary

barriers should be made with the beam in the most adverse orientation with respect to the barrier; with no phantom in the beam. Measurements of radiation levels in areas not in the line with the direct beam should be made during irradiation of a tissue equivalent phantom at the normal treatment distance.

For brachytherapy remote afterloader, all measurements should be made using the maximum source activity, with the sources in the most adverse orientation with respect to the barrier and no phantom.

- A measurement of the dose rate at all accessible points where calculations were made in subsection G5. For accelerators, both photon and neutron fields should be measured.
- A thorough survey of dose rates at all accessible locations outside the facility to ensure the calculations were made at the points where the thinnest shielding and the highest radiation dose rates are encountered.
- For radioactive source teletherapy and brachytherapy remote afterloader machines, measurements to confirm the manufacturer's specified maximum equipment leakage dose rates with the source in the shielded (radiation off) position.
- For accelerators, a survey of the dose rates produced in the immediate vicinity of the gantry head due to activation, under conditions which represent an average treatment day.

3.10 Section J – Licence for Routine Operation

For an application for a licence for routine operation, the applicant is required to submit plans for testing of the safety systems and for performing a thorough radiation survey of the facility. In this section, the applicant is asked to provide the results of those tests and to outline any corrective action taken in the event that a malfunction or unacceptable dose rate was detected.

Also, for an application for a licence to construct, the applicant is required to submit copies of the key radiation safety policies governing the operation of the Class II nuclear facility. Such policies may be very broad in scope, and their implementation as part of the daily operation of the facility is typically accomplished by means of operating procedures detailing exactly how the equipment is to be used. In this section, the applicant is asked to provide the routine operating procedures for the facility. These procedures should be directed to specific groups of facility staff and must be designed to ensure safety of the facility and compliance with the *Class II Nuclear Facilities and Prescribed Equipment Regulations*.

J1 Results of Safety System Tests

Report the results of the tests performed on the safety systems as per I3 of the application for an operating licence for commissioning. Indicate any change made to the test protocol which the applicant had submitted. Include the time delay setting on the person out interlock. If a malfunction was detected in any system, outline the actions taken to correct the problem and the current status of that safety system.

J2 Results of Radiation Survey

Report the results of the radiation survey. Indicate any change made to the survey procedures which the applicant submitted in I4 of the application for an operating licence for commissioning. If any of the measured dose rates were found to exceed the design dose rates calculated in G5 describe the remedial actions (e.g., adding shielding, access controls) implemented to ensure that annual radiation doses to persons occupying adjacent areas will not exceed the ALARA target doses used for designing the facility. If these remedial actions include adding more shielding to any barrier, indicate the location, thickness and composition of the added shielding and the dose rates measured following its addition.

J3 Overview of Facility Operation

Submit evidence of device model certification in the form of a photograph or suitable alternative with the request for amendment. Evidence will be deemed acceptable if it includes clear indication of the device model name and number.

Submit procedures governing operation of the facility in relation to the following topics:

- the intended uses and corresponding operating modes of the equipment (e.g., use of “clinical”, “physics” and “service” modes of accelerators for clinical treatment, dosimetry or QA testing, service and maintenance, research, etc.)
- who (i.e., what categories of employee) may operate the Class II prescribed equipment in each mode and for each purpose, the process by which they obtain authorization to use the equipment, and the persons who can provide this authorization
- how deviations from normal operating procedures are authorized.

J4 Basic Operating Instructions for Class II Prescribed Equipment

Submit basic operating instructions for equipment including:

- daily start-up, warm-up, radiation on/off and shut down procedures
- operator instructions to ensure no one (other than the patient being treated) is in the room when the radiation is on
- emergency instructions to be followed to avoid injury and minimize radiation exposure to persons in the event of a malfunction of the Class II prescribed equipment or its related safety devices during routine operation. If they are identical to those previously submitted for commissioning in I2,

simply reference the previous submission. For teletherapy, HDR, PDR and LDR, these instructions should include provisions for dealing with a stuck source emergency. The instructions must include the name of the persons that will be responsible for directing remedial actions

- the procedure for limiting access to the control keys or passcodes required to operate the equipment for radioactive source teletherapy and brachytherapy remote afterloader, append the applicant's procedures for leak testing of sealed sources. All sealed sources greater than 50 MBq must be leak tested in accordance with Regulatory Document R-116, *Requirements for Leak Testing Selected Sealed Radiation Sources*; using instruments and procedures that would detect an activity of 200 Bq or less. Appropriate corrective actions must be taken if the measured leakage exceeds this limit. If using a commercial leak testing service, please provide the name and contact information of the company performing the tests. Otherwise provide:
 - Sampling Technique
 1. the materials used for sampling
 2. the locations where swipes will be taken
 3. the safety precautions used to keep exposures ALARA during sampling
 - Detection Instruments
 1. manufacturer, model, radiation types detected, useable energy range
 2. tests or calculations which demonstrate that the instrument can detect 200 Bq or less of the isotopes of interest
 3. details of any calculations or correction factors required to convert measurement results into total swipe activity in Bq
 - Frequency
 1. leak testing must be performed at least:
 - a. every 6 months for sealed sources which are in use
 - b. every 12 months for sealed sources in a radiation device or Class II prescribed equipment
 - c. every 24 months for sealed sources in storage
 - d. before using a sealed source removed from 12 months or more of storage
 - e. after an event which may have damaged the source

J5 Quality Assurance Program

Provide the following information regarding the quality assurance program for the Class II nuclear facility:

- the program for ensuring that all of the safety devices previously described in section H are tested regularly to ensure proper operation. The information should include:
 - the procedures for performing these tests;
 - the frequency of testing (test frequencies must meet or exceed those recommended in AAPM report no. 46, “Comprehensive QA for Radiation Oncology”, and the Canadian Association of Provincial Cancer Agencies (CAPCA) “Standards for Quality Control at Canadian Radiation Treatment Centres”);
 - the name of the persons responsible for performing the tests;
 - a copy of the log or other recording format to be used for recording test results; and
 - the procedures to be followed in the event that a malfunction is detected.

- a brief overview of the remainder of the equipment QA program, including any requirement for periodic equipment performance checks
- an overview of the QA system used to periodically examine and evaluate the performance of the radiation safety program at the facility
- The policies for reviewing and updating manuals and procedures in accordance with operating experience and modifications of the equipment. Clearly state who will be responsible for these updates.

J6 Special Requirements for Facilities which do NOT have a Class II Prescribed Equipment Servicing Licence

Major servicing of Class II prescribed equipment can only be performed under a CNSC Class II Prescribed Equipment Servicing licence, which specifically lists the manufacturer and model of equipment being serviced. However, some types of routine maintenance are permissible subject to CNSC approval and only under restricted conditions. If the applicant does not intend to obtain a Class II Prescribed Equipment Servicing licence for a new facility, please provide the following:

- a description of the types of routine maintenance, if any, which the applicant intends to perform on Class II Prescribed Equipment. Identify any operation which may require bypassing or overriding any internal or external safety interlock, including software interlocks
- a description of the conditions under which this maintenance may be performed, including who is authorized to perform it
- if any proposed maintenance procedure requires the intentional bypassing of an interlock (see item a) above), submit the proposed policy and procedure for bypassing the interlock. The policy and procedure must include:

- the names of the persons responsible for authorizing the bypass;
- a requirement that the bypass is recorded in a permanent log;
- a requirement that a warning be posted at the control console if bypassing any safety system listed in section H; and
- a requirement to remove the bypass and test the interlock prior to putting the facility back into normal use.

J7 Special Instructions for Nursing Staff at LDR Brachytherapy Facilities

Append or refer to the following:

- the general safety instructions and precautions which are to be taken by nursing staff to ensure their exposure to radiation is kept ALARA when caring for LDR brachytherapy patients
- the procedure nursing staff follow in the event of a fault or an interruption in the treatment
- the radiation safety procedures to be followed when responding to medical emergencies of LDR patients (e.g. cardiac or respiratory arrests).

J8 Records and Reporting System

Append or refer to the policies and procedures that ensure that all required records are kept and will be available for inspection. Records must be retained for the time periods specified in the Regulations and cannot be disposed of without first notifying CNSC.

The Regulations require that the following records be maintained:

- names of persons involved, in the use and handling of nuclear substances
- names and job category of persons designated as nuclear energy workers (NEWs)
- training for workers who handle nuclear substances or operate Class II prescribed equipment
- the daily workload (see G4) resulting from the operation of the equipment
- storage locations of nuclear substances or Class II prescribed equipment
- personnel dosimetry results
- inventory of sealed sources and Class II prescribed equipment
- details of incidents involving nuclear substances or Class II prescribed equipment
- purchases and transfers of nuclear substances or Class II prescribed equipment
- leak test results
- decommissioning results
- radiation detection equipment inventory and calibration tests

- radioactive waste disposal
- dates of source changes
- transport documents.

Additional records may be required by CNSC as specified in licence conditions.

3.11 Section K – Licence for Decommissioning (Accelerators Only)

The application for a licence to decommission an accelerator facility must demonstrate that there is a clearly defined and appropriate plan of action for decommissioning. 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
- identification and disposal of any radioactive material which have been produced as a result of the operation of the facility
- handling and disposal of any other hazardous material associated with the facility
- final monitoring of the site upon completion of decommissioning activities
- preparation and submission of a final decommissioning report to 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 either the room has been deleted from the operating licence or the entire licence has been revoked.

K1 Overview of Decommissioning Plan

Submit a brief overview of the decommissioning work. In the overview, include:

- 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 substances will remain on-site after the decommissioning.

K2 Personnel Qualifications and Training

Provide with the application the following information:

- the name and title of the person who will be responsible for planning and supervising decommissioning. If it is not the RSO named in D1, 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. If the applicant is contracting out any aspect of the decommissioning work to an external agency, provide the name and contact information of that agency, and indicate how the applicant will ensure contract personnel have received radiation safety training commensurate with the work they will be performing
- a Class II Prescribed Equipment Servicing licence is required to dismantle the accelerator. Provide the CNSC 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).

K3 Estimation of Types, Activities and Radiation Doses from Nuclear Substances

Describe the nature, type and activity of any radioactive nuclear substances or contamination at the nuclear facility. It is expected that nuclear substances will generally be restricted to activated components along the beam line or, in some cases, activated building materials. Provide a list of items/components which the applicant anticipates will be active at the time of decommissioning include an estimate of the isotopes and activities of each item/component. Provide a brief rationale in support of 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.

K4 Disposal of Class II Prescribed Equipment, Nuclear Substances and Hazardous Materials

Indicate the proposed final disposition of the major components of the accelerator (e.g., sold or discarded as scrap, returned to the manufacturer, transferred to another facility for potential reuse, or kept by the licensee for future reuse). 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 for the recipient.

Outline the proposed measures to control releases of radioactive nuclear substances and hazardous substances into the environment. Specify the proposed disposal method for activated components and potentially hazardous materials (e.g., SF₆). Indicate whether any of this material will be released into the environment. If so, specify the maximum quantities and concentrations of nuclear substances and hazardous substances that may be released.

3.12 Section L – Legal Signing Authority

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

L1 Signing Authority

The application must be signed by an authorized representative of the applicant. By the title of “Signing Authority,” CNSC refers to the person who has prepared the application and who has 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 his or her knowledge. The Signing Authority will receive all correspondence from CNSC and will be CNSC’s 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 (D2 of the licence application) be designated as the Signing Authority.

L2 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 this application and on supplementary pages are binding on the applicant.

Appendix A

Examples of Typical Shielding Calculation Formulas and Tables

NOTE: This appendix is provided for illustrative purposes only, as an example of some of the types of calculations expected as part of an application for a licence to construct a Class II nuclear facility. It does not restrict the applicant from using other approaches to shielding calculations. In addition, if the applicant wishes to use the methods outlined here, it is strongly recommended that they consult the references at the end of this appendix.

- 1) Formulas for determining required photon transmission factors (B_{\max}) and thicknesses of barriers needed to achieve desired target doses (H), for accelerators and radioactive source teletherapy.

When designing an accelerator or cobalt teletherapy facility, the following equations (ref. NCRP 49, NCRP 51, ANSI N43.3) may be helpful in determining the thickness of shielding required.

<p>Primary</p> $B_{\max} = \frac{(H)(d^2)}{(SAD)^2(W)(U)(T)}$
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<p>Secondary: Head Leakage</p> $B_{\max} = \frac{1000(H)(d^2)}{(SAD)^2(W)(T)}$

<p>Secondary: Scatter</p> $B_{\max} = \frac{(H)(d_{\text{sec}}^2)(d_{\text{sca}}^2)(400)}{(SAD)^2(W)(T)(a)(F)}$
--

Where:

B_{\max}	= Maximum allowable transmission factor for the barrier
H	= Design dose limit [Sv/y] (see ref. G129)
W	= Workload referenced at the SAD [Gy/y]
SAD	= Source axis distance [m]
d	= Distance from the radiation source to the location of interest [m]
d_{sca}	= Distance from source to scattering medium [m]
d_{sec}	= Distance from scattering medium to the location of interest [m]
U	= Use factor
T	= Occupancy factor
F	= Field area at the scattering surface [cm ²]
a	= Ratio of scattered to incident exposure (referenced to 1 meter, for a 400 cm ² scattering area)

B_{\max} can then be converted to an equivalent thickness of shielding material using the barrier transmission graphs in NCRP 49, NCRP 51 or ANSI N43.3; or by using the following equation:

Shielding Thickness Required

$$L = \text{TVL}_{m,E} (-\log B_{\max})$$

Where:

L = Equivalent thickness of shielding material [m]
 $\text{TVL}_{m,E}$ = Broad beam dose equivalent tenth value layer for the type of shielding material m and photon energy E of interest.

Note that the TVL will not necessarily be the same for primary, leakage and scattered radiation because of energy considerations.

- 2) Formulas for determining required photon transmission factors (B_{\max}) and thicknesses of barriers to achieve desired target doses (H), for brachytherapy remote afterloader.

The formulas used for accelerators and radioactive source teletherapy can readily be adapted for use in designing brachytherapy remote afterloader facilities. All barriers are primary (since the radiation is uncollimated). The basic equation for primary barrier calculations is still applicable, provided that the workload is defined as the annual dose delivered in air at a distance SAD from the unshielded sources. Assuming this reference distance (SAD) is 1 meter, and noting that U will be 1 for all barriers, this can be reduced to:

Primary

$$B_{\max} = \frac{(H)(d^2)}{(W)(T)}$$

With all other terms as defined previously. The thickness of shielding required can then be derived from B_{\max} in the exact same manner as for accelerators and teletherapy.

- 3) Formulas for deriving photon dose rates and annual photon doses outside of barriers

Once the applicant has completed designing the facility, the applicant must report to CNSC the dose rates and annual doses that the applicant anticipates will be produced in all areas adjacent to the facility. This is essentially the reverse of the design process. For primary barriers, the dose rate (R) and annual dose (H) outside each barrier can be derived using:

<p>Primary, Annual Dose</p> $H = \frac{(10^{-L/TVL})(SAD)^2(W)(U)(T)}{(d^2)}$
--

<p>Primary, Dose Rate</p> $R = \frac{(10^{-L/TVL})(SAD)^2(R_{iso})}{(d^2)}$
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Where:

R = the photon dose rate at the point of interest [Sv/h]

R_{iso} = the maximum photon treatment dose rate at isocentre [Gy/h]

For secondary barriers, the doses rates (R) and annual doses (H) are given by the sum of the contribution from head leakage and scatter at each point. These contributions may be derived using:

<p>Secondary: Head Leakage Annual Dose</p> $H = \frac{(10^{-L/TVL})(SAD)^2(W)(T)}{1000 (d^2)}$
<p>Secondary: Head Leakage, Dose Rate</p> $R = \frac{(10^{-L/TVL})(SAD)^2(R_{iso})}{1000 (d^2)}$

<p>Secondary: Scatter, Annual Dose</p> $H = \frac{(10^{-L/TVL})(SAD)^2(W)(T)(a)(F)}{(d_{sec}^2)(d_{sca}^2)(400)}$
<p>Secondary: Scatter, Dose Rate</p> $R = \frac{(10^{-L/TVL})(SAD)^2(R_{iso})(a)(F)}{(d_{sec}^2)(d_{sca}^2)(400)}$

4) Neutron calculations for accelerators

When designing an accelerator facility, the dose rate and annual dose contributions from neutrons must also be considered. Evaluation of neutron leakage can be complex, especially when examining neutron streaming down mazes, access ways and ducts. NRC 38, NCRP 51 and NCRP 79 are useful references for performing neutron calculations.

5) Sample calculation table for reporting projected dose rates and annual doses

Location	Primary or Secondary	Occupancy Type (NEW or public)	Distance d (m)	U	T	Shielding Thickness (cm)	# of TVL	B _{max}	Dose Rate (μSv/hr)	Annual Dose (mSv/yr)

Occupancy Type: GP = General Public (50 μSv/a)
 NEW = Nuclear Energy Worker (1.0 mSv/a)

References:

- ANSI N43.3** *ANSI Standard N43.3 – 1993, “Installations Using Non-Medical X-Ray and Sealed Gamma-Ray Sources, Energies Up To 10 MeV”*
- G-121** *CNSC Guide G121, “Radiation Safety in Educational, Medical and Research Institutions”*
- G-129** *CNSC Guide G129 rev 1, “Keeping Radiation Exposures and Doses As Low As Reasonably Achievable (ALARA)”*
- NCRP 38** *NCRP Report No.38 “Protection Against Neutron Radiation”*
- NCRP 49** *NCRP Report No.49 “Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma-Rays of Energies Up to 10 MeV”*
- NCRP 51** *NCRP Report No.51, “Radiation Protection Design Guidelines for 0.1-100 Mev Particle Accelerator Facilities”*
- NCRP 79** *NCRP Report No.79 “Neutron Contamination from Medical Electron Accelerators”*
- NCRP 144** *NCRP Report No.144 “Radiation Protection for Particle Accelerator Facilities”*

Abbreviations

ACR	Annual Compliance Report
AECL	Atomic Energy Canada Limited
CNSC	Canadian Nuclear Safety Commission
DSP	Designated Supervising Physician
HDR	High Dose Rate
IMRT	Intensity Modulated Radiation Therapy
LDR	Low Dose Rate
LPO	Last Person Out
MU	Monitor Unit
NEW	Nuclear Energy Worker
PDR	Pulsed Dose Rate
RSO	Radiation Safety Officer
SAD	Source Axis Distance
SSD	Source Skin Distance
TBI	Total Body Irradiation
TDG	Transportation of Dangerous Goods

Glossary

ALARA

Principle of radiation protection that exposures to radiation are kept As Low As Reasonably Achievable, with social and economic factors taken into account.

Brachytherapy machine

A device that is designed to place, by remote control, a sealed source inside or in contact with a person for therapeutic purposes and to remove the source once a preset dose has been reached or preset time has elapsed.

Class II nuclear facility

A facility consisting of Class II Prescribed Equipment, which includes the land, structures, buildings, shielding and safety systems associated with the operation of that equipment.

Class II Prescribed Equipment

A particle accelerator with a beam energy of less than 50 MeV that is capable of producing nuclear energy, an irradiator that uses more than 10^{15} Bq of a nuclear substance, an irradiator that requires shielding which is not a part of the irradiator and that can deliver a dose rate of radiation at a rate exceeding 1 centigray per minute at 1 m, a radioactive source teletherapy machine, or a brachytherapy remote afterloader.

Fail-safe

An electronic circuit having the property that any failure causes a sequence of actions which always results in a safe situation.

General public

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

High dose rate (HDR) brachytherapy machine

A brachytherapy machine, other than an IVB machine, which uses a total activity of the sealed nuclear substance which, if exposed, will produce a dose rate in air of 10 mGy/h or greater at a distance of 1 meter from the source(s).

Head leakage

All radiation coming from within the teletherapy source housing or accelerator target housing other than the primary beam.

Inner maze entrance

The point at which the entrance maze merges with the treatment room containing the Class II prescribed equipment.

IVB machine

IntraVascular Brachytherapy machine. A brachytherapy machine which utilizes only pure β^- emitting nuclear substances.

Isocenter

For teletherapy equipment, the intersection between the central axis of the primary beam and the axis of gantry rotation.

Low dose rate (LDR) brachytherapy machine

A brachytherapy machine, other than an IVB machine, which uses a total activity of the sealed nuclear substance which, if exposed, will produce a dose rate in air of less than 10 mGy/h at a distance of 1 meter from the source(s).

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.

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'.

Primary barrier

Any barrier which is designed to attenuate the primary beam.

Primary beam

The collimated beam of radiation produced by teletherapy equipment for treatment purposes.

Scatter radiation

Radiation that, during passage through matter, has been deviated in direction. It may also have been modified by a decrease in energy.

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.

Secondary radiation

The sum of the scattered radiation and leakage radiation.

Secondary barrier

Any barrier which is designed to attenuate secondary radiation but not the primary beam.

Servicing

Any maintenance of the Class II prescribed equipment including repair, installation or dismantling, other than that which is prescribed by the manufacturer as being part of the routine operating procedures, or which is otherwise authorized in an operating license.

Teletherapy machine

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

Unsealed source

A radioactive source other than a sealed source.

Use factor (U)

The fraction of the total workload during which the radiation under consideration is directed at a particular barrier.

Worker

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

Workload

For teletherapy machines, the total annual radiation dose delivered at isocentre. For brachytherapy machines, the total annual exposure or dose which would have been delivered in air at one meter from the unshielded source (i.e., the product of the source activity, the exposure duration and the specific gamma ray constant).