Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire

REGULATORY GUIDE

Applying for a licence

- Diagnostic Nuclear Medecine

- Therapeutic Nuclear Medicine

- Human Research Studies

C-292

Issued for public consultation by the
Canadian Nuclear Safety Commission
April 2002

Canada

Document availability

This document can be viewed on the CNSC Internet site at www.nuclearsafety.gc.ca. To order a printed copy of the document in English or French, please contact:

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Regulatory Documents

The Canadian Nuclear Safety Commission (CNSC) operates within a legal framework that includes law and supporting regulatory documents. Law includes such legally enforceable instruments as acts, regulations, licences and orders. Regulatory documents such as policies, standards, guides, notices, procedures and information documents support and provide further information on these legally enforceable instruments. Together, law and regulatory documents form the framework for the regulatory activities of the CNSC.

The main classes of regulatory documents developed by the CNSC are:

Regulatory Policy: a document that describes the philosophy, principles and fundamental factors used by the CNSC in regulatory programs.

Regulatory Standard: a document that is suitable for use in compliance assessment and describes rules, characteristics or practices which the CNSC accepts as meeting the regulatory requirements.

Regulatory Guide: a document that provides guidance or describes characteristics or practices that the CNSC recommends for meeting regulatory requirements or improving administrative effectiveness.

Regulatory Notice: a document that provides case-specific guidance or information to alert licensees and others about significant health, safety or compliance issues that should be acted upon in a timely manner.

Regulatory Procedure: a document that describes work processes that the CNSC follows to administer the regulatory requirements for which it is responsible.

Document types such as regulatory policies, standards, guides, notices and procedures do not create legally enforceable requirements. They support regulatory requirements found in regulations, licences and other legally enforceable instruments. However, where appropriate, a regulatory document may be made into a legally enforceable requirement by incorporation in a CNSC regulation, a licence or other legally enforceable instrument made pursuant to the *Nuclear Safety and Control Act*.

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About this Document

This guide describes the information that is to be included in an application, under the *Nuclear Substances and Radiation Devices Regulations*, for a CNSC licence to conduct diagnostic nuclear medicine procedures, therapeutic nuclear medicine procedures, or human research studies. It contains information on regulatory framework, regulatory process and pertinent legislation, as well as a licence application form, and instructions on how to prepare and submit the licence application.

Comments

The CNSC invites interested persons to assist in the further development of this draft regulatory document by commenting in writing on the document's content and potential usefulness. Please respond by June 28, 2002. Direct your comments to the postal or e-mail address below, referencing file 1-8-8-292.

The CNSC will take the comments received on this draft into account when developing it further. These comments will be subject to the provisions of the federal *Access to Information Act*.

Document availability

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Contents

1 Purpose

This regulatory guide is intended to help applicants for Canadian Nuclear Safety Commission (CNSC) licences that authorize diagnostic nuclear medicine procedures, therapeutic nuclear medicine procedures, or human research studies, to prepare and submit licence applications that meet regulatory requirements.

2 Scope

This guide describes the information that is to be included in an application, under the *Nuclear Safety and Control Act* and its Regulations, for a CNSC licence to conduct diagnostic nuclear medicine procedures, therapeutic nuclear medicine procedures, or human research studies. It contains information on regulatory framework, regulatory process and pertinent legislation, as well as a licence application form, and instructions on how to prepare and submit the licence application.

3 Using this Guide

An application form, titled "Application Form for Nuclear Medicine and Human Research Studies", is attached as Appendix D of this guide. This form may be used, in conjunction with the necessary supporting documents, to apply to the CNSC for a licence to use nuclear substances and radiation devices for any of the following activities:

- to conduct diagnostic nuclear medicine procedures;
- to conduct therapeutic nuclear medicine procedures; or
- to conduct human research studies.

Section 5 of this guide provides step-by-step instructions on how to prepare an application for each of the above uses of nuclear substances and radiation devices, by filling out the pertinent sections of the application form, and adding any necessary supporting documents. The completed application form and its supporting documents, constitute a licence application under the *Nuclear Substances and Radiation Devices Regulations*.

To locate the sections of the guide that describe the respective application requirements for each of the above activities, consult the table of contents located at the front of this guide.

To help applicants prepare licence applications, this guide includes references to a number of publications that could prove helpful. The cited references include regulatory guides that have been published by the CNSC, as well as those published by the predecessor to the CNSC, the Atomic Energy Control Board (AECB). Copies of current CNSC guidance documents and the *NSC Act* are available on the CNSC website at www.nuclearsafety.gc.ca. However, the older AECB guides, both "R" and "INFO" series, are only published in paper form.

Licence applicants may order copies of AECB or CNSC publications through the CNSC website, or by calling the CNSC at (613) 995-5894 or, within Canada, 1-800-668-5284.

For assistance in completing a licence application, the applicant may contact the CNSC section that is responsible for licensing the use of nuclear substances and radiation devices by educational, medical, research and industrial organizations. The current CNSC contact numbers are:

telephone: 1-888-229-2672 (toll-free)
facsimile: (613) 995-5086

4 Background

4.1 Regulatory Framework

The CNSC is the federal agency that regulates the use of nuclear energy and materials to protect health, safety, security, and the environment, and to respect Canada's international commitments on the peaceful use of nuclear energy.

The CNSC operates under the *Nuclear Safety Control Act* (*NSC Act,* Act). The Act requires persons or organizations to be licensed by the CNSC in order to carry out the activities referred to in Section 26 of the Act, unless otherwise exempted. The associated regulations stipulate prerequisites for CNSC licensing and the obligations of licensees and workers.

4.2 Licensing Process

The *NSC Act* and regulations require all licence applicants to provide certain information, depending upon the specific circumstances, such as the type of facility, the licensing phase, or the activity, substance, or device to be licensed. Licence applications may incorporate (directly or by reference) new or previously submitted information, in accordance with legislated requirements and the best judgment of the applicant.

Upon receipt of a licence application that is complete, the CNSC reviews it to determine whether the applicant is qualified to carry on the proposed activity and has established adequate measures to protect 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. If satisfied, the CNSC may issue, renew, amend, or replace a licence that contains relevant conditions. This licence will incorporate the applicant's undertakings and contain other conditions that the CNSC considers necessary.

Accordingly, before a person may possess, use, store, transfer, import or export a nuclear substance or a radiation device, the person must obtain from the CNSC a licence to carry out the intended activity. To obtain the required licence, the applicant for the licence must submit the application required under the *Nuclear Substances and Radiation Devices Regulations.*

In response to licence applications made under the *Nuclear Substances and Radiation Devices Regulations,* the CNSC issues licences for a variety of common activities that involve the use of nuclear substances or radiation devices. These licences, based on the type of activity, are listed in the AECB *Cost Recovery Fees Regulations* 1996, and include licences to use nuclear substances and radiation devices in diagnostic nuclear medicine procedures, therapeutic nuclear medicine procedures, and human research studies, respectively.

4.3 Relevant Legislation

This subsection provides an overview of the legislation that is relevant to an application for a licence to use nuclear substances and radiation devices in diagnostic nuclear medicine procedures, therapeutic nuclear medicine procedures, or human research studies.

4.3.1 Nuclear Safety and Control Act

Section 26 of the *NSC Act* prohibits any person, except in accordance with a licence, from carrying on specified activities, including

- possessing, transferring, importing, exporting, using or abandoning a nuclear substance, prescribed equipment or prescribed information;
- packaging, transporting, managing, storing or disposing of a nuclear substance; and
- producing or servicing prescribed equipment.

The NSC Act states, in subsection 24 (4), that "no licence may be issued, renewed, amended or replaced unless, in the opinion of the Commission, the applicant

- is qualified to carry on the activity that the licence will authorize the licensee to carry on; and
- 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."

As set out by subsection 24(2) of the *Nuclear Safety and Control Act*, the CNSC may issue, renew, suspend in whole or in part, amend, revoke or replace a licence on receipt of an application

- in the prescribed form;
- containing the prescribed information and undertakings and accompanied by the prescribed documents; and
- accompanied by the prescribed fee.

4.3.2 General Nuclear Safety and Control Regulations

Subsection 3(1) of the *General Nuclear Safety and Control Regulations* specifies that applications for licences issued by the CNSC must contain information on the applicant, the activity to be licensed, the nuclear substance, facility and equipment to be encompassed by the licence, the waste that will be produced, the applicant's organizational management structure, any financial guarantee, and the proposed measures to ensure compliance with the *Radiation Protection Regulations* and the *Nuclear Security Regulations*.

In addition, under paragraph 3(1)(n) of *General Nuclear Safety and Control Regulations*, the Commission may request that a licence application contain any other

information that is necessary to enable the Commission to determine whether the applicant is qualified to carry on the activity to be licensed, and, will, in carrying out 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.

4.3.3 Nuclear Substances and Radiation Devices Regulations

The *Nuclear Substances and Radiation Devices Regulations* apply to all nuclear substances and sealed sources, and all radiation devices except Class II prescribed equipment. Under subsection 3(1) of these regulations, an application for a licence in respect of a nuclear substance or radiation device, other than a licence to service a radiation device, must contain, in addition to the information required under the *General Nuclear Safety and Control Regulations*,

- the methods, procedures and equipment that will be used to carry on the activity to be licensed; and
- the methods, procedures and equipment that will be used while carrying on the activity to be licensed, or during and following an accident, to
  - monitor the release of any radioactive nuclear substance from the site of the activity to be licensed,
  - detect the presence of and record the radiation dose rate and quantity in becquerels of radioactive nuclear substances at the site of the activity to be licensed,
  - limit the spread of radioactive contamination within and from the site of the activity to be licensed, and
  - decontaminate any person, site or equipment contaminated as a result of the activity to be licensed.

4.3.4 Radiation Protection Regulations

The *General Nuclear Safety and Control Regulations*, which apply generally for the purposes of the *NSC Act*, require all applications for a licence to include the applicant's proposed measures to ensure compliance with the *Radiation Protection Regulations.* Accordingly, any application for a CNSC licence must include information that describes how the applicant, if licensed, will ensure compliance with the requirements of the *Radiation Protection Regulations*. The requirements of the *Radiation Protection Regulations* relate to a number of subjects, including the implementation of a radiation protection program, the ascertainment and recording of radiation doses, the use of action levels, the provision of information, the licensing and use of dosimetry services and the application of radiation dose limits. In particular:

- Section 2 of the *Radiation Protection Regulations* exempts certain persons from application of the regulations except for section 3 in respect of any dose of radiation received by or committed to a person. Accordingly, the dose limits prescribed by the *Radiation Protection Regulations* do not apply to persons

- undergoing medical examination, diagnosis or treatment under the direction of a medical practitioner who is qualified under applicable provincial legislation,
- acting as a care-giver, outside a medical facility and not as an occupation, to a person to whom a nuclear substance has been administered for therapeutic purposes, or
- volunteering to take part in a biomedical research study that is supervised by a medical practitioner who is qualified to provide such supervision under the applicable provincial legislation.

- Section 4 of the *Radiation Protection Regulations* requires licensees to implement a radiation protection program, and, as part of that program, to keep radiation exposures and doses as low as reasonably achievable, social and economic factors being taken into account, through the measures specified in paragraphs 4(a)(i) through 4(a)(iv). Subsection (b) of section 4 requires the licensee, as part of the same radiation protection program, to ascertain the quantity and concentration of any nuclear substance released as a result of the licensed activity, by direct measurement as a result of monitoring, or, under specified circumstances, by estimating them.
- Section 5 of the *Radiation Protection Regulations* requires licensees to ascertain and record the effective dose and equivalent dose received by and committed to each person who performs duties in connection with any licensed activity, or who is present where the activity is carried on. The section provides that ascertaining may be done by direct measurement as a result of monitoring, or, in specified situations, by estimation.
- Section 6 of the *Radiation Protection Regulations* provides that a licensee may, as part of a radiation protection program establish and use action levels - a specific dose of radiation or other parameter that, if reached, may indicate a loss of control of part of the licensee's radiation protection program and triggers a requirement for specific action to be taken.
- Section 7 of the *Radiation Protection Regulations* describes the licensee's obligations to inform each nuclear energy worker (NEW) of the specified information, including that the worker is a nuclear energy worker, of the risks of the radiation to which the worker may be exposed in the course of his or her work, of the applicable dose limits, and of the worker's radiation dose levels. In accordance with section 2 of the *NSC Act*, a nuclear energy worker is any person who is required, in the course of carrying out duties in connection with a nuclear substance or facility, to perform duties in such circumstances that there is a reasonable probability that the person may receive a dose of radiation greater than the prescribed limit for the general public.
- Section 8 of the *Radiation Protection Regulations* stipulates that every licensee must use a licensed dosimetry service to measure and monitor the radiation doses of nuclear energy workers who are likely to receive an effective dose greater than 5 mSv in a one-year dosimetry period.

- Sections 13 and 14 of the *Radiation Protection Regulations* prescribe effective and equivalent dose limits, respectively. There are separate dose limits for members of the public, and for NEWs.

4.3.5 Cost Recovery Fees Regulations

The CNSC charges fees for its regulatory activities, as set out in the *AECB Cost Recovery Fees Regulations, 1996.* Section 3 of the regulations specifies that the regulations do not apply to educational institutions, to not-for-profit health care institutions that receive funds from federal, provincial or municipal governments, nor to government departments as defined in Section 2 of the *Financial Administration Act.* Part II of the regulations specifies the cost recovery fees for all licence use types for those licensees subject to the fees.

4.3.6 Regulations on transport and packaging

The packaging and transportation of nuclear substances are subject to the *Packaging and Transport of Nuclear Substances Regulations* under the *NSC Act,* and the *Transportation of Dangerous Goods Regulations* administered by Transport Canada.

The *Packaging and Transport of Nuclear Substances Regulations* sets requirements for the packaging and transport of nuclear substances. The regulations apply in respect of the packaging of nuclear substances for transport by a consignor or by a carrier, and the receipt of the material by a consignee. They cover the design, production, use and maintenance of packaging and packages; the preparation, consignment, handling, loading, carriage and storage during transport of nuclear substances; and the receipt at final destination and the unloading of additional packages that contain a nuclear substance. The regulations also include other requirements related to recording, documenting, and reporting.

The *Transportation of Dangerous Goods Regulations* sets requirement for the handling, offering and transporting of dangerous goods, including nuclear substances. Some of the requirements relate to safety markers, placards, documentation, transport, training, and emergency response planning.

4.3.7 Legislation on accessing or protecting information

The right of the public to access information held by the CNSC is determined by applicable legislation, such as the *Access to Information Act*, the *Privacy Act*, and pertinent sections of the *General Nuclear Safety and Control Regulations.*

Subsection 2(1) of the *Access to Information Act* provides “a right of access to information in records under the control of a government institution in accordance with the principles that government information should be available to the public, that necessary exceptions to the right of access should be limited and specific and that decisions on the disclosure of government information should be reviewed independently of government.” Sections 13 to 24 of the *Access to Information Act* define some exemptions from the right of access to information.

Public access to information held by the CNSC is limited by sections 18 to 24 of the *Privacy Act,* which protect from public access certain personal information that is held in various government information banks. This protected information includes medical and radiation dose records.

Section 21 the *General Nuclear Safety and Control Regulations* defines "prescribed information" for the purpose of the NSC Act, and section 23 of the same regulations restricts the transfer or disclosure of such information to specific persons or circumstances. Prescribed information is defined to include information relating to the security arrangements of licensees, and the route or schedule for the transport of certain categories of nuclear substances.

5 Preparing an Application

This section describes how to prepare a licence application to obtain a licence for any of the following activities:

- to conduct diagnostic nuclear medicine procedures;
- to conduct therapeutic nuclear medicine procedures; or
- to conduct human research studies.

For the purposes of this guide, a licence application for a CNSC licence for any of the above activities consists of an application form that has been completed in accordance with the instructions in this guide and on the form, and includes any supporting documents that provide requested information.

5.1 The Application Form

Licence applicants can use the application form, attached as Appendix D of this guide, to apply for a CNSC licence to use nuclear substances and radiation devices for any of the three activities listed above, by filling out the designated sections for the licence required, in accordance with the instructions provided on the form and below. To provide the requested information, applicants will need to attach or enclose supporting documents. Identify these documents by entering a meaningful cross-reference on the application form.

Please note that applicants must complete a separate application form for each licence requested.

To satisfy regulatory requirements, and to aid regulatory review and processing, complete the relevant sections of the attached form, as follows:

- For a licence to conduct diagnostic nuclear medicine procedures, provide the information requested in sections A, B and C.
- For a licence to conduct therapeutic nuclear medicine procedures, provide the information requested in sections A, B, C and D.
- For a licence to conduct human research studies, provide the information requested in sections A, B, C and E.

When considering an application for a licence for any of the three uses of nuclear substances and radiation devices referred to above, the CNSC may, pursuant to paragraph 3(1)(n) of the *General Nuclear Safety and Control Regulations*, request any additional information that it considers necessary to enable it to determine whether the applicant is qualified to carry out the activity to be licensed, and will, in carrying out that activity, make adequate provision for the protection of the environment and the health and safety of persons.

5.2 Completing Section A of the Application Form: Applicant Information

Section A of the application form is to be completed by all licence applicants.

5.2.1 Subsection A1: Requested Language

Enter the official language(s) preferred in all correspondence with the CNSC. Any licence issued in response to the licence application will be in the official language(s) selected.

5.2.2 Subsection A2: Name of Applicant

Provide the name of the person or organization who is or will be the licensee. Name an individual as the applicant only if that person will be solely and completely responsible for the activity to be licensed.

5.2.3 Subsection A3: Proof of Legal Status

Provide proof of the legal status of the applicant, such as a proof of incorporation, partnership, registration, or charter.

5.2.4 Subsection A4: Public Access to 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 *Access to Information Act*.

However, the CNSC will, in accordance with applicable laws, consider any requests from licence applicants for the protection of information that they provide to the CNSC. Licence applicants who wish to request that information that they provide not be disclosed by the CNSC, can do so by checking the appropriate box on the application form. Such requests should be accompanied by a statement of the perceived legal grounds for the request.

5.2.5 Subsection A5: Canadian Head Office Address

Provide the complete address of the applicant's "head office" within Canada, including a complete street name and number, or a rural route number if appropriate, and the associated city, province and postal code.

A post office box address is not acceptable.

5.2.6 Subsection A6: Mailing Address

Provide the mailing address, where it is different than the Canadian Head Office Address. If an alternate address is not entered here, any CNSC licence that is issued in response to this application will be mailed to the Canadian Head Office Address provided above.

A post office box address is acceptable as a mailing address.

5.2.7 Subsection A7: Financial Contact Person

This section of the application form is to be completed by all licence applicants who are subject to cost-recovery fees for CNSC licensing activities.

Applicants who are exempt from cost recovery fees under Section 3 of the *AECB Cost Recovery Fees Regulations 1996*, or applicants who are applying for a licence on behalf of a person or organization exempt from licensing fees under the regulations, do not complete this section. Educational institutions; not-for-profit health-care institutions that receive funds from federal, provincial, or municipal governments; and government departments that are listed in Schedules I and II of the *Financial Administration Act* are exempt from paying licensing fees under the *AECB Cost-Recovery Fees Regulations* of 1996.

Licence applicants who are not exempt and must pay a cost-recovery fee for CNSC licensing should identify a person in their organization who may be contacted concerning payment matters.

When completing this section, provide the address of the financial office, if that address is different than the head office address in A5 of the application form.

5.2.8 Subsection A8: Applicant Authority

If applying for a licence as a representative of someone else, complete and sign subsection A8 of the application form, "Applicant Authority":

- to confirm that the representative has the authority to sign the licence application and to designate persons in accordance with the Regulations;
- to designate the Radiation Safety Officer (RSO) as the person who has authority to act for the licensee in dealings with the Commissions, and in functions related to the management and control of the licensed activity and the nuclear substances; and
- to certify that all statements and representations made in the application and on supplementary pages are true and correct to the best of the representative's knowledge and are binding on the applicant.

5.3 Completing Section B of the Application Form: Purpose of the Licence

Section B identifies and describes the activity that is to be licensed. Accordingly, Section B of the application form is to be completed by all licence applicants.

5.3.1 Subsection B1: Description of Proposed Activity

Provide a brief description of the activity that is to be licensed (e.g., diagnostic nuclear medicine procedures), and the magnitude and scope of the proposed activities using nuclear substances or radiation devices.

5.3.2 Subsection B2: Locations

Provide the addresses of any locations where the activity to be licensed will be conducted. Provide a complete street name and number, the name of the city or town, the province and the postal code. Include any other available identifiers relating to the physical location or building, such as "Medical Arts Building" or "Research Wing".

If the proposed locations are rented or leased, provide written confirmation that the lease or rental agreement contains no restrictions or prohibitions against conducting the activities proposed for licensing at those premises.

5.3.3 Subsection B3: Unsealed Sources

Estimate, to the degree practical, the types and quantities of unsealed sources that will be needed for the activity to be licensed. To determine whether a licence is required for the proposed possession and use of a specific nuclear substance, in the form of an unsealed source, consult the applicable regulations, including section 5, "General Exempted Activities", of the *Nuclear Substances and Radiation Devices Regulations.*

For each radionuclide, include the following information:

- its name or symbol and its mass number: e.g., Technetium-99m or Tc-99m, I-131, Tl-201;
- the maximum quantity, in Becquerels, that the applicant expects to possess, under the terms of the licence, at any one time - i.e., all quantities in use, held for decay, in storage, or present in waste, in all locations covered by the licence; and
- a credible estimate, in Becquerels, of the total quantity to be purchased or acquired during a typical one-year period.

5.3.4 Subsection B4: Sealed Sources

Using the space provided, or an attachment, provide the requested information on the characteristics and quantities of the sealed sources that the applicant proposes to use during the activities to be licensed. To determine whether a licence is required for the proposed possession and use of a specific nuclear substance, in the form of a sealed source, consult the applicable regulations, including section 5, "General Exempted Activities", of the *Nuclear Substances and Radiation Devices Regulations.*

Where practical, identify each sealed source to be acquired for use in the activity to be licensed by providing the name, symbol and mass number of the associated radionuclide (e.g., Cobalt-57 or Co-57).

For the purposes of this subsection, the term "maximum quantity contained in any single source" means, for a given radionuclide, the maximum quantity of that radionuclide in any of the sources that the applicant proposes to acquire. For example, if a licensee acquires several sealed sources containing Co-57 that range from 10 MBq to 100 MBq, the "maximum quantity (of Co-57) contained in a single source" is "100 MBq".

5.3.5 Subsection B5: Radiation Devices

Provide a list of all radiation devices to be used in the activity to be licensed. To determine whether a licence is required for the proposed possession and use of a radiation device, consult the applicable regulations, including section 5, "General Exempted Activities", of the *Nuclear Substances and Radiation Devices Regulations.*

For each radiation device to be used, provide the following information:

- the type, model and manufacturer of the radiation device;
- the name or symbol, and the mass number of each radionuclide contained in the device (e.g., Cobalt-60 or Co-60); and
- the quantity, in Becquerels, of each radionuclide in the device.

Under section 11 of the *Nuclear Substances and Radiation Devices Regulations*, no person shall use a radiation device unless it is a certified model, or unless it is used in accordance with a licence that authorizes its use for development purposes. Further, no person shall transfer a radiation device for use in Canada unless it is certified model.

Accordingly, before applying for a CNSC licence to use a radiation device, contact the CNSC, where necessary, to verify that the model of each radiation device to be licensed is certified by the CNSC, and eligible for licensing for use. If the device has not been certified, a prospective applicant may wish to contact the manufacturer of the device to find out whether the manufacturer intends to apply to the CNSC to have the device certified.

5.4 Completing Section C of the Application Form: Radiation Protection Program

Section C of the application form is to be completed by all licence applicants. The information provided by the licence applicant for the purpose of this section will constitute the applicant's proposed radiation protection program, for implementation during the activity to be licensed. Accordingly, the applicant's proposed radiation protection program should address the corresponding requirements for implementation under section 4 of the *Radiation Protection Regulations*.

Section 4 of the Radiation Protection Regulations states, in part:

"Every licensee shall implement a radiation protection program and shall, as part of that program,

- keep the amount of exposure to radon progeny and the effective dose and equivalent dose received by and committed to persons as low as reasonably achievable, social and economic factors being taken into account, through the implementation of
  - management control over work practices,
  - personnel qualification and training,
  - control of occupational and public exposure to radiation, and
  - planning for unusual situations."

When designing a radiation protection program for the proposed activities, the applicant should ensure that the program includes provisions to keep post-licensing radiation doses "ALARA", in order to meet the implementation requirement of the regulations.

If the applicant's proposed radiation protection program is accepted by the CNSC for licensing purposes, key elements may be incorporated, by licence condition, into the licence subsequently issued to the applicant.

For additional information on designing a radiation protection program, or on keeping doses "ALARA" as part of a radiation protection program, consult Regulatory Guide G-121, *Radiation Safety in Educational, Medical and Research Institutions*; and CNSC Regulatory Guide G-129, *Guidelines on How to Meet the Requirements to Keep All Exposures As Low As Reasonably Achievable*.

For information on developing and using action levels as part of a radiation protection program, consult Regulatory Guide G-228, *Developing and Using Action Levels*.

For information on measuring, estimating and recording radiation doses, applicants may consult Draft Regulatory Guide C-091/Rev.1, *Ascertaining and Recording Radiation Doses to Individuals*.

5.4.1 Subsection C1: Management Structure

Provide detailed information on the management and organization structure that relates to radiation safety matters, including:

- the names and position titles of the persons that are to be responsible for the management and control of nuclear substances or radiation devices during the conduct of the activity to be licensed;
- the proposed functions, responsibilities and authority of each of the persons named above; and
- a copy of the proposed organization chart that shows the lines of communication and responsibilities for radiation safety matters.

5.4.2 Subsection C2: Radiation Safety Committee

Provide a copy of the proposed terms of reference or mandate for any proposed Radiation Safety Committee, or any equivalent "Health and Safety Subcommittee(s)" that are to be formed as part of the applicant's radiation protection program.

Licensees may form a Radiation Safety Committee (RSC) to advise on, monitor, or evaluate the radiation protection program. The primary role of an RSC should be to advise Radiation Safety Officers (RSOs) and management on the quality and effectiveness of radiation protection policies and procedures, 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.

Applicants may consult CNSC Regulatory Guide G-121, *Radiation Safety in Educational, Medical and Research Institutions* for additional information on the roles of RSOs and RSCs.

5.4.3 Subsection C3: Radiation Safety Officer

Provide the name, position title, and the indicated contact information for the person who is to be the applicant's Radiation Safety Officer (RSO). Append a description of the proposed RSO's qualifications, experience and job responsibilities that relate to radiation safety. Have the proposed RSO sign in the indicated space to confirm acceptance of the applicant's description of the RSO's potential duties.

A Radiation Safety Officer (RSO) is typically the person who is responsible for managing a licensee's radiation protection program to control radiation doses and exposures. Accordingly, the licence applicant's proposed RSO must have qualifications that are acceptable to the CNSC. This requires that the proposed RSO be knowledgeable regarding the conduct and radiation implications of the activities to be licensed, the qualifications of the persons who are to use nuclear substances and radiation devices in the proposed activities, and the proposed locations of use of the nuclear substances and radiation devices.

If a licence applicant intends to use nuclear substances or radiation devices at more than one location, the applicant may need to provide for the management and control of radiation safety at all locations, by the assignment of a commensurate number of additional persons (e.g., "assistant" or "site" RSOs) to assure radiation safety, under the direction of the RSO. These persons should be able to provide initial assistance to meet radiation safety needs and initial responses to emergencies.

If the applicant is licensed for the proposed use of nuclear substances or radiation devices, the CNSC will address its post-licensing correspondence to the applicant's designated RSO.

For additional information on the typical functions of an RSO, refer to CNSC Regulatory Guide G-121, *Radiation Safety in Educational, Medical and Research Institutions.*

5.4.4 Subsection C4: Medical Practitioner

Under section 16 of the *Nuclear Substances and Radiation Devices Regulations* "no licensee shall use a radioactive nuclear substance or a radiation device on a person except as directed by a medical practitioner who is qualified to give such direction under the applicable provincial legislation."

Accordingly, this subsection of the application form requests that the licence applicant designate by name a medical practitioner for the above purpose during the activity to be licensed, and that the medical practitioner confirm acceptance of the designation. Accordingly, enter the name of the designated medical practitioner, and have the practitioner confirm acceptance by signing and dating the declaration statement.

The primary role of the medical practitioner relates to patient safety - which is outside the mandate of the CNSC. However, where the delivery of patient care and the activity to be licensed could impact on each other, they should be coordinated, as warranted to assure radiation safety.

5.4.5 Subsection C5: Classifying Workers and Monitoring Doses

For licensing purposes, a worker is a person who performs work referred to in a licence. Workers must follow the procedures to keep radiation doses as low as reasonably achievable while performing work with, or in proximity to, nuclear substances or radiation devices. The licensee must ascertain the radiation doses that will be received by these workers by direct measurement as a result of monitoring, or if the costs of measurement outweigh the benefits, by estimating the doses.

Further, if it is determined that there is a reasonable probability that a worker's effective dose may exceed 1 mSv in a one-year dosimetry period, the worker must be classed as a Nuclear Energy Worker (NEW).

If a NEW has a reasonable probability of exceeding an effective dose of 5 mSv in a one-year dosimetry period, the licensee must use a licensed dosimetry service to monitor the dose received by and committed to the NEW.

Accordingly, to complete this subsection of the form:

- State whether there are to be any NEWs in the operation to be licensed. Provide a description of the proposed policy and procedures to classify workers as NEWs.
- List the anticipated job categories of workers, and the anticipated number of NEWs and workers in each category. Describe the proposed roles, responsibilities, duties, qualifications and experience of these workers. Include both temporary and contract workers.
- Provide the name of any licensed dosimetry service that is to be used to monitor worker's doses during the proposed activities, such as where the licence applicant expects that the activities to be licensed will involve NEWs who will need to have their doses monitored by a licensed dosimetry service, or NEWs who will require radioiodine thyroid screening, because of their probable doses.

Refer to 5.4.7, below, for further guidance on submitting information on the monitoring of radiation doses.

The CNSC encourages licensees to use a licensed dosimetry service to measure the radiation doses to NEWs when the effective dose could reach 2 mSv per year.

The CNSC typically requires, as a condition of the applicable licence, that workers who manipulate more than 5 MBq of volatile Iodine-131 or Iodine-125 must undergo thyroid screening within seven days.

5.4.6 Subsection C6: Worker Training

Provide a detailed description of a proposed worker radiation safety training program for the activity to be licensed. Describe how the program will incorporate the principles of the "systematic approach to training" (SAT) in a manner appropriate to the activities to be licensed.

Before working independently with nuclear substances, workers must successfully complete appropriate radiation safety training. Accordingly, the licence applicant should not assume that any radiation safety certification, experience or training that has been previously obtained by a potential worker in the applicant's proposed activities will likewise be adequate for the applicant's proposed activities. Accordingly, the applicant should provide for post-licensing training that is site-specific, task-specific and tailored to the education and experience of the trainees. Provision should be made for worker retraining prior to assuming any significant change in tasks, and for periodic refresher training at appropriate intervals; typically, every two years.

The applicant should also provide for the instruction of auxiliary personnel, such as clerical, janitorial, maintenance, nursing and security staff, in radiation safety basics.

When designing a proposed radiation safety training program, the applicant should ensure that the relevant requirements of Transport Canada's *Transportation of Dangerous Goods Regulations* are taken into account. These regulations require workers who handle or open packages, or who offer for transport or transport nuclear substances, to be trained, and to be issued a Certificate of Training, before they perform such duties.

5.4.7 Subsection C7: Ascertaining and Recording Doses to Workers

Provide a description of the procedures proposed to ascertain and record the radiation doses to each person who will perform duties in connection with the activity to be licensed, or who will be present where the proposed activity is carried on.

Under the *Radiation Protection Regulations*, the doses received by workers during licensed activities must be ascertained by direct measurement as a result of monitoring, or when the costs and resources of such monitoring outweigh the usefulness of the results, by estimating them.

Some methods of direct measurement as a result of monitoring include:

- the use of whole-body dosimeters;
- the use of finger-ring dosimeters (e.g., to address the handling of high-energy beta-emitting nuclear substances); and
- the use of radiobioassay procedures (e.g., to screen or monitor workers for the intake of volatile radionuclides such as I-125, I-131 and H-3).

Methods to estimate doses include dose calculations, using area, job or historical monitoring data.

For further information on ascertaining and recording radiation doses to individuals, consult the *Radiation Protection Regulations*, Draft Regulatory Guide C-091/Rev.1, *Ascertaining and Recording Radiation Doses to Individuals*, or the Atomic Energy Control Board safety poster, INFO-0688, *Proper Use and Care of Personal Dosimeters*.

For information on radiobioassay screening procedures, consult Atomic Energy Control Board Regulatory Guide R-58, *Bioassay Requirements for I-125 and I-131 in Medical, Teaching and Research Institutions.*

5.4.8 Subsection C8: Action Levels

Describe any proposed action level for the activity to be licensed, and the actions to be taken if the action level is reached.

Section 6 of the *Radiation Protection Regulations,* defines an action level as "a specific dose of radiation or other parameter that, if reached, may indicate a loss of control of part of a licensee's radiation protection program and triggers a requirement for specific action to be taken." Under paragraph 3(1)(f) of the *General Nuclear Safety and Control Regulations*, it is up to licensees to choose whether or not to propose and use action levels as part of an overall management program. This discretion reflects the fact that the use of action levels may not be warranted for all situations (e.g., such as for those where radiation exposures are unlikely to exceed trivial levels.)

However, if the applicant does not propose to use action levels in the activity to be licensed, the applicant should describe how the effectiveness of the radiation protection program will be evaluated.

For more information on action levels, consult CNSC Regulatory Guide G-228, *Developing and Using Action Levels*.

5.4.9 Subsection C9: Control of Radioactive Contamination

Submit the proposed procedures and methods to be used to detect, monitor and control radioactive contamination. Describe the radiation detection instruments that will be used, and the actions that will be taken when any contamination limits in a CNSC licence are exceeded.

If the proposed activities will use nuclear substances in the form of unsealed sources provide for the monitoring, by direct or indirect methods, of radioactive contamination.

A direct method of contamination monitoring involves using a portable radiation contamination meter in areas with low background radiation, to measure the emissions from any contamination present on a surface. An indirect method of contamination monitoring, called a “wipe test”, involves taking a wipe sample from a surface, and testing the resulting wipe sample for the presence of any nuclear substances transferred from the swiped surface.

The table that is attached as Appendix B of this guide provides the limits of removable surface contamination, for commonly used radionuclides, that are typically incorporated into CNSC licences to use nuclear substances or radiation devices. When the measured contamination levels exceed any relevant limit in a licence, corrective action must be taken. In the case of contamination by a mixture of radionuclides, the determination of whether the measured levels meet the licence limits should be based on the license limit and the measured level for the most restrictive nuclide present in the mixture.

For additional information, applicants may consult Atomic Energy Control Board document INFO-0545, *Radioisotope Safety: Monitoring for Radioactive Contamination*.

5.4.10 Subsection C10: Radiation Detection Instruments

Describe the number, types and models of radiation detection instruments that are to be used to meet regulatory requirements during the activities to be licensed. For each instrument, provide the name of the manufacturer of the instrument, as well as information on its energy response, type of detector and intended use. Provide the proposed procedures for maintaining and using portable radiation detection meters. If a survey meter is to be used to assess compliance with regulatory requirements, provide a description of the methods, procedures and equipment to be used to calibrate the meter, or the name of the service provider who will perform such calibrations.

Not all radiation detection instruments are suitable for, or sensitive enough to detect, all types of radiation. Radiation detection instruments may consist of contamination monitors or survey meters. Contamination monitors, which include contamination meters and well-counters, are specifically designed to measure contamination. Survey meters are designed to measure radiation dose rates. Licensees who conduct nuclear medicine activities require the use of contamination meters, and may also require the use of survey meters. These survey meters must be calibrated by a person or company that is licensed by the CNSC for that purpose.

For more information on the use or maintenance of radiation monitoring instruments, consult Annex II and III of the Atomic Energy Control Board publication, INFO-0545, *Radioisotope Safety: Monitoring for Radioactive Contamination.* Additional information on the calibration of survey meters can be found in the Atomic Energy Control Board guide, Regulatory Document R-117, *Requirements for Gamma Radiation Survey Meter Calibration*.

5.4.11 Subsection C11: Leak Testing of Sealed Sources

Provide a copy of the proposed procedures to be followed for leak testing, or provide the name of a CNSC- licensed service provider who will perform leak testing during the activities to be licensed. Include the proposed instructions for the proposed leak test sampling and leak test analysis (measurement), as well as facsimiles of the records to be kept of leak-testing activities.

A leak test consists of taking a wipe sample of the exterior of a sealed source or radiation device, and analyzing the sample to determine if there is any leakage of the contained nuclear substance. The CNSC typically requires, by licence condition, a leak test of all sealed sources that contain more than 50 MBq of a nuclear substance.

For additional information on leak testing consult Regulatory Document *R-116, Leak Testing of Sealed Sources*.

5.4.12 Subsection C12: Room Classifications

Provide a plan or drawing for every room and adjoining area where the proposed activities are to be conducted. Using the table below, assign a classification to each of the rooms that reflects the relative risk associated with the work to be performed in the room.

ROOM CLASSIFICATION	DESCRIPTION
Storage Room	A room where sealed or unsealed nuclear substances are kept without being handled. Examples include storage of waste and/or decaying nuclear substances and supplies of nuclear substances held for future use
Patient Room	A room where patients reside during treatments with unsealed sources
Nuclear Medicine Room	A room used for the preparation or administration of radio-pharmaceuticals to humans, such as hot labs, injection rooms and scanning rooms.

For information on the designs of rooms that are likely to be acceptable to the CNSC for the proposed activities, consult the Atomic Energy Control Board guide, R-52, Rev. 1, *Design Guide for Basic and Intermediate Level Radioisotope Laboratories*. This guide describes some standards for intermediate level laboratories, such as those for nuclear medicine facilities that are acceptable to the CNSC. Although R-52, Rev. 1, includes guidance on the construction or renovation of laboratories where unsealed sources are to be used, licence applicants may also propose, for CNSC consideration, alternative designs for rooms where unsealed sources are to be used during the activities to be licensed.

5.4.13 Subsection C13: Access Control and Security

Provide a description of the proposed procedures to restrict access to nuclear substances to authorized workers.

Access to a nuclear substance or radiation device is to be controlled from the time of acquisition until disposal. When not in use, or not under the direct supervision and control of an authorized worker, nuclear substances and radiation devices should be secured in a locked area, room, enclosure or vehicle, and the appropriate warning signs posted.

5.4.14 Subsection C14: Receipt of Packages

Provide a description of the proposed procedures, during conduct of the activity to be licensed, for receiving and opening shipments that contain nuclear substances or radiation devices. Address how packages, upon receipt, are to be inspected for evidence of damage, tampering, leaking or contamination.

For guidance on developing such procedures, consult the Atomic Energy Control Board poster, INFO-0426*, Radioisotope Safety: Identifying and Opening Radioactive Packages*.

5.4.15 Subsection C15: Packaging and Transport of Nuclear Substances

Provide a description of the procedures that are to be followed during the activity to be licensed; on packaging and transporting nuclear substances and radiation devices

When developing the required procedures, consult the *Packaging and Transport of Nuclear Substances Regulations* under the *NSC Act* and Transport Canada's *Transportation of Dangerous Goods Regulations* to determine the related requirements that apply to the activity to be licensed.

5.4.16 Subsection C16: Inventory Control of Nuclear Substances

Provide a description of the proposed procedures to ensure that the inventory of nuclear substances and radiation devices does not exceed any applicable limit in any CNSC license issued for the proposed activity. Address the tracking and control of nuclear substances and radiation devices from the time they are acquired to the time they are transferred or disposed of.

5.4.17 Subsection C17: Management of Radioactive Wastes

Provide a description of the proposed procedures for handling, transferring and disposing of wastes that contain nuclear substances. Consider waste volume reduction methods, such as segregating radioactive waste on the basis of its half-life and levels of contamination. Ensure that the proposed methods of waste disposal or release meet applicable laws and ordinances.

Some of the options for disposing of waste that contains nuclear substances are as follows:

- Release through the municipal garbage system may be appropriate for solid waste that contains nuclear substances of solid or insoluble form that are uniformly distributed within the waste, and has a concentration of nuclear substance by weight that is less than any applicable limit in a relevant CNSC licence. This method is commonly authorized by the CNSC where the total amount of waste that contains radioactive material is less than three tonnes per year for each address where a proposed activity is to be conducted.
- Release through the municipal sewage system may be appropriate for waste nuclear substances that are in water-soluble liquid form, where the total annual quantity of the waste substances is less than the prescribed limit in the licence for each building where the activity to be licensed is to be conducted.
- Release into the atmosphere may be acceptable for wastes containing nuclear substances where the wastes are in gaseous form, and in quantities that are incidental to the gaseous wastes from non-nuclear activities and less in quantity than three million cubic metres per year. This option is not typically permitted under a CNSC licence as a routine means of disposal, and, accordingly, disposal by this option requires the prior approval in writing from the CNSC.
- Transfer to a CNSC licensee that is authorized to accept wastes containing nuclear substances, or the transfer or return to a supplier of a nuclear substance or radiation device, are other disposal options.

Applicants may request approval for other methods of waste disposal that comply with regulatory requirements.

Appendix B of this guide provides the radionuclide discharge limits that are typically incorporated in CNSC licences to use nuclear substances and radiation devices.

5.4.18 Subsection C18: Emergency Procedures

Provide a description of the procedures for dealing with accidents, including fires and spills, in which nuclear substances may be involved. These procedures should include, for the activity to be licensed, provisions to:

- limit the spread of contamination;
- limit the exposure of persons to radiation;
- detect and estimate the quantity of nuclear substances present;

- decontaminate the affected site, equipment, workers and other persons;
- monitor and detect releases from the site; and
- maintain a list of the emergency spill equipment and emergency contacts.

For example, in all licensed rooms or locations, basic cleaning and decontamination supplies should be available at all times for the purpose of dealing with radioactive spills. At locations where larger volumes of liquid nuclear substances are handled, adequate quantities of absorbent materials should be provided, as a contingency measure to cope with spills. For large scale operations, specialized or sophisticated preventive or contingency measures may be needed.

For more information on contingency planning, refer to the CNSC poster, INFO-0534, *Nuclear Substance Safety: Spill Procedures.*

5.5 Section D of the Application Form: Therapeutic Nuclear Medicine

Section D of the licence application form is to be completed by all applicants for a licence to conduct therapeutic nuclear medicine. Other applicants do not complete Section D.

Since the doses of radiation administered to patients by qualified physicians are not subject to regulatory dose limits, the CNSC's regulatory interest in such situations involves limiting any radiation exposure to persons other than the patient. To address this interest, section D requests certain information on the proposed management of patients treated with nuclear substances for therapeutic purposes.

Patients who undergo therapeutic nuclear medicine are often administered large quantities of nuclear substances. For several days after the administration of nuclear substances, patients become a potential source of radiation exposure for those with whom they come in contact. Accordingly, applicants for a CNSC licence to conduct therapeutic nuclear medicine procedures should make provisions for carrying out the activities to be licensed, in a way that minimizes the radiation exposures of:

- workers in a hospital or clinic;
- workers engaged in home-care activities;
- the members of a patient's family; and
- the members of the public, in accordance with regulatory requirements.

5.5.1 Subsection D1: Administration of Nuclear Medicine Therapy Doses

Provide a description of the proposed policy and procedures for delivering radiation doses to patients for therapeutic reasons during the activities to be licensed, including:

- the preparations to be undertaken prior to administering nuclear substances;
- the proposed manner of administering nuclear substances;
- the precautions to be followed after administering the nuclear substance; and
- how radiation exposures to persons other than the patient will be controlled.

The CNSC publishes INFO-0442, *Guidelines on the Management of Patients Treated with Iodine-131*. If adhered to, with appropriate adjustments to meet case-specific needs and circumstances, these guidelines are designed to adequately protect workers, families and the public, and to assure compliance with the regulatory dose limits for persons other than patients. Proposed deviations from the guidelines should be justified by dose calculations or other evidence that demonstrates that the effective dose limits set out in the *Radiation Protection Regulations* will be met during the proposed activity.

For patients treated with nuclear substances other than I-131, the associated safety requirements will depend upon the characteristics (e.g., type of emissions, biological half-life) of the nuclear substances used, and other factors such as the routes of excretion.

5.5.2 Subsection D2: Instructions to Care-givers

Provide a copy of the precautionary instructions that are to be given to persons who will care for a patient who has undergone nuclear medicine therapy. Provide instructions for all potential care-givers such as medical professionals, hospital workers and persons who may provide extended-care and home-care services.

Good hygiene practices, infection control measures and "universal" precautions are typically sufficient to address most hazards associated with caring for a person who has undergone nuclear medicine therapy. However, special precautions are usually necessary to control the spread of radioactive contamination due to the excretions of nuclear medicine patients.

5.5.3 Subsection D3: Instructions to Patients of Nuclear Medicine Therapy and Their Families

Provide a copy of the precautionary instructions that are to be given to patients who have recently received nuclear therapy, in order to control radioactive contamination effects and radiation doses to individuals. The proposed precautionary measures should take into account the radiation exposure limit that, typically, is set as a condition for the patient's release from the hospital or treatment facility.

5.5.4 Subsection D4: Release of Patients

Provide a copy of the proposed policy and procedures for determining when patients that have received nuclear therapy must be isolated, and when they may be released from isolation. Propose the criterion, in terms of the patient's radiation activity level, that is to be used to determine when the patient must be isolated from other patients, as well as the limit below which no further precautions for radiation protection purposes will be required.

The CNSC publishes INFO-0442, *Guidelines on the Management of Patients Treated with Iodine-131*. The associated recommendations concerning isolation or release of patients treated with Iodine-131 are:

- If the activity remaining in the patient after treatment is less than 300 MBq and the approximate radiation dose rate at 2 m is less than 4 μSv/h, no hospitalization and only minimal precautions are required.
- If the activity remaining in the patient after treatment is less than 1100 MBq and the approximate radiation dose rate at 2 m is less than 16 μSv/h, precautions should be taken, whether the patient is hospitalized or released.
- If the activity remaining in the patient after treatment is greater than 1100 MBq and the approximate radiation dose rate at 2 m exceeds 16 μSv/h, the patient should be isolated in the hospital, and strict precautions implemented to limit the exposure of other persons.

Licence applicants may submit, for CNSC consideration, proposed protocols that differ from the INFO-0442 guidelines for Iodine-131. Applicants should substantiate their proposed protocols by dose calculations or estimates that demonstrate that the protocols, if implemented, will assure that members of the public will not receive doses in excess of the limits stipulated for the public in the *Radiation Protection Regulations*.

5.5.5 Subsection D5: Assignment of Nuclear Medicine Therapy Rooms

Provide a copy of the proposed procedures to assure that patients undergoing nuclear therapy with Iodine-131 will be assigned to a specifically designated private room with a private washroom. Typically, access to such rooms should be restricted, the flooring should be sealed against contamination and easy to decontaminate, and radiation warning signs and the name of an emergency contact person should be clearly posted.

The CNSC recommends that the radiation dose rate in an occupied area adjacent to a room occupied by a patient who is undergoing, or who has undergone, radiation therapy should not exceed 2.5 μSv/h, and that a patient who has not received nuclear therapy should not receive a radiation dose in excess of 500 μSv during a hospital stay. Licence applicants may propose deviations from these guidelines, but should justify the proposed deviations and obtain CNSC approval of their proposals before implementing the proposals as part of the activity to be conducted.

5.5.6 Subsection D6: Decontamination and Reuse of Treatment Rooms

Provide a copy of the proposed procedures for returning rooms that have been used for nuclear medicine therapy to a condition where they can be safely cleaned and reused (i.e., “released”) for other purposes.

Any licence issued by the CNSC in response to an application for a licence to conduct nuclear medicine therapy will include decontamination limits that must be met before nuclear medicine therapy treatment rooms can be released for reuse. Accordingly, the applicant’s proposed procedures and criteria for decontaminating rooms used for

nuclear medicine therapy should assure compliance with the anticipated licence limits. For Class A, B and C radionuclides, as defined in Appendix C of this guide, the relevant surface contamination limits, expressed in terms of removable surface contamination averaged over an area not exceeding 100 cm^2, are as follow:

- 0.3 Bq/cm^2 for all Class A radionuclides, which are typically relatively long-lived, and emit alpha radiation;
- 3 Bq/cm^2 for all Class B radionuclides, which are typically relatively long-lived and emit beta or gamma radiation; and
- 30 Bq/cm^2 for all Class C radionuclides, which are typically short-lived and emit beta or gamma radiation.

The CNSC Poster, *Radioisotope Safety: Monitoring for Radioactive Contamination* INFO-0545 provides guidance on monitoring for radioactive contamination.

5.5.7 Subsection D7: Medical Emergencies

Provide a copy of the proposed policy and procedures for dealing with medical emergencies that involve patients treated with nuclear substances during the activities to be licensed. Include basic procedures that address requirements for emergency surgery, the death of a therapy patient, the availability of emergency supplies, and the role of the RSO or the RSO's delegate.

The CNSC recommends that the above procedures include a "first response" provision, to make emergency care workers aware of the nature of the emergency and the associated radiation hazards, without restricting them from performing their health care duties. Applicants should provide for the availability during the activities to be licensed of basic cleaning and decontamination supplies to handle radioactive spills, including body fluids, and for the availability of radiation safety experts to provide advice during the emergency.

For additional information on procedures to address radioactive spills, consult the CNSC poster, INFO-0534*, Nuclear Substance Safety: Spill Procedures*.

5.6 Completing Section E of the Application Form: Human Research Studies

Section E of the licence application form is to be completed by all applicants for a licence to conduct human research studies. Other applicants do not complete Section E.

A CNSC licence to conduct human research studies is required for all situations where a nuclear substance is to be used on or in a human volunteer for a purpose that is not related to assessing, assuring or improving the volunteer's personal medical health.

Pursuant to paragraph 2(2)(c) of the *Radiation Protection Regulations*, only section 3 of the *Radiation Protection Regulations* applies to a licensee in respect of a dose of radiation received by or committed to a person as a result of the person's voluntary participation in a biomedical research study supervised by a medical practitioner who is qualified to provide such supervision under the applicable provincial legislation. Section 3 of the *Radiation Protection Regulations* requires that, when a nuclear substance is administered to a person

for therapeutic purposes, the licensee shall, before the person leaves the place where the substance is administered, inform the person of methods for reducing the exposure of others to radiation from that person. Pursuant to the applicable provincial legislation under which the physician is licensed, these studies must be supervised by a medical practitioner who is qualified to work with nuclear substances and radiation devices.

Since the dose limits in the *Radiation Protection Regulations* do not apply to the biomedical research situation described above, the CNSC typically incorporates in the licences that it issues for conducting human research studies, dose constraints that are intended to adequately protect volunteers, workers and the public during the licensed activities. These constraints are established on the basis of the CNSC publication, INFO-0491, *Guidelines for Research on Human Subjects Using Radionuclides.*

The CNSC holds licensees who engage in human research studies responsible for reviewing and monitoring individual research proposals, and for obtaining the informed consent of the participants. The CNSC requires, as a condition of licensing, that the licensee fulfill this responsibility through the establishment and activities of a review committee that is commonly designated the "Human Research Review Committee (HRRC)", or the "Scientific and Ethical Review Committee (SERC)".

5.6.1 Subsection E1: Human Research Review Committee

Provide, for the activities to be licensed, a description of the authority, composition and duties of a proposed Human Research Review Committee (HRRC).

To meet their specific institutional needs and circumstances, licence applicants may propose for CNSC consideration, appropriate deviations from INFO-0491, *Guidelines for Research on Human Subjects Using Radionuclides.* However, the applicant should provide for the formation of a HRRC, or equivalent body that has the authority and resources to ensure adequate provision of radiological protection to participants in research studies involving nuclear substances in, or on, human volunteers.

5.6.2 Subsection E2: Authorization of Research Studies

Provide, for the activities to be licensed, a description of the proposed process and criteria by which the HRRC or its equivalent will assess and authorize human research studies.

The feasibility, applicability and scientific merits of each planned research study should be reviewed by the HRRC before the study proceeds, and only studies that meet the committee's criteria and approval should be allowed to proceed. Each proposed human research study should receive an independent scientific review in advance of implementation of the study. In addition, before nuclear substances are used in a human research study, the study should be subjected to a credible ethical review to assure that the study and proposed use of nuclear substances respect current moral and ethical standards.

5.6.3 Subsection E3: Classification of Research Studies

Provide a statement of the proposed categories of the research studies, and the proposed radiation dose constraints for each category.

For radiation protection purposes, the proposed research studies should receive a depth of scrutiny that is proportional to their potential radiological consequences, as reflected in the probable annual effective radiation doses to the volunteer participants in the study.

For example, Table 1 of INFO-0491 suggests, for the Class, Class II and Class III radionuclides listed in Appendix C of this guide, the following responses:

RADIONUCLIDE	DOSE	RESPONSE
Class I	< 0.1 mSv	no radiological protection review
Class II	< 1 mSv	minimal radiological protection review
Class III	< 20 mSv	full radiological protection review

Where the anticipated effective dose from a proposed research study exceeds the Class III limit recommended in INFO-0491, a CNSC licence for the study will not be granted without adequate justification by the applicant.

5.6.4 Subsection E4: Selection of Volunteer Participants

Provide a description of the proposed policy and criteria for selecting or excluding human volunteers from participation in human research studies.

5.6.5 Subsection E5: Consent Form

Provide a description of the proposed policy and procedures for obtaining and assuring the informed consent of volunteers. Include a copy of a blank consent form.

Typically, a comprehensive consent form may state:

- the aims of the study to be engaged in;
- the procedures that the subject will undergo;
- the risks inherent in these procedures;
- areas of uncertainty in the research study, including explicit declarations that acknowledge any experimental procedures and that the participant may not benefit from the research;
- that a participant can decline to participate in or withdraw from the study at anytime, without prejudice;

- the duration of the study;
- the name of the institution conducting the study and its letterhead;
- the name and telephone number of the contact person for the study; and
- the procedures that will be implemented to preserve the confidentiality of the participant's identity.

5.6.6 Subsection E6: Records of Studies

Specify where the records of all studies using nuclear substances in or on human volunteers are to be maintained and made available for the Commission's inspection.

Typically, the records of a study should include:

- the composition, including names, of the HRRC that reviewed the study;
- the nature of the study;
- the number of similar studies conducted by the licensee;
- the number of participating volunteers; and
- the total quantity of nuclear substance administered to each study participant.

6 Licensing Fees

Educational institutions; not-for-profit health-care institutions that receive funds from federal, provincial, or municipal governments; and government departments that are listed in Schedules I and II of the *Financial Administration Act* are exempt from paying licensing fees under the *AECB Cost-Recovery Fees Regulations* of 1996.

Other applicants for CNSC licenses must pay licensing fees that are assessed according to the type of facility or activity to be licensed. The respective fees for licences to conduct diagnostic nuclear medicine procedures, therapeutic nuclear medicine procedures or human research studies are listed in Part II of the *AECB Cost-Recovery Fees Regulations 1996*.

Applicants who are subject to cost-recovery fees must include payment of the fees with their licence applications. Payment may be made by a cheque or money order, made payable to the Receiver General for Canada, or by a credit card. To arrange payment by credit card, applicants should contact the cost-recovery unit within the CNSC Finance division in Ottawa at:

telephone	(613) 996-2843 or 1-888-229-2672 (toll-free)
facsimile	(613) 995-5086
e-mail	finance@cnsc-ccsn.gc.ca

7 Submitting an Application

When submitting a licence application, the applicant should:

- ensure that the application is complete and signed by the appropriate authorities;
- ensure that the documents and information that supports the application form are attached to, or enclosed with the form, and that they are clearly and properly identified, and cross-referenced by title and number to the relevant sections of the application form;
- enclose the designated payment, if the applicant is subject to cost-recovery fees; and
- retain an accurate copy of the application, including the form and all supporting documents.

Mail the completed application package to:

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

Glossary

Action Level
A specific dose of radiation or other parameter that, if reached, may indicate a loss of control on the part of the licensee's radiation protection program, and triggers a requirement for a specific action to be taken.

ALARA
As Low As Reasonably Achievable, economic and social factors being taken into account. A concept in which optimized protective measures result in doses that are considered to be as low as reasonably achievable. Licensee requirements with respect to ALARA are in Section 4 of the *Radiation Protection Regulations.*

Contamination meter
A radiation detection instrument designed to measure surface contamination.

Diagnostic nuclear medicine
Administration of unsealed nuclear substances to humans for diagnostic purposes related to their health care; processing of radio pharmaceuticals and laboratory studies which are part of the diagnostic studies are included.

Dosimetry period - One-year
As defined in section 1 of the *Radiation Protection Regulations*, the period of one calendar year beginning on January 1 of the year following the year in which these Regulations come into force, and every period of one calendar year thereafter**.**

Dosimetry period - Five-year
As defined in the *Radiation Protection Regulations*, the period of five calendar years beginning on January 1 of the year following the year in which the CNSC Regulations come into force, and every period of five calendar years thereafter.

Exemption Quantity
A quantity of a radioactive nuclear substance as defined in the *Nuclear Substances and Radiation Devices Regulations*.

Export
To send a nuclear substance or prescribed equipment out of Canada

Human Research Study
Administration of unsealed nuclear substances to, or external irradiation of, humans for purposes not related to their personal health care; includes processing of radio pharmaceuticals and laboratory studies which are part of the human research study.

Import
To bring a nuclear substance or prescribed equipment into Canada

Licensed Activity
For the purpose of this regulatory guide, an activity, in relation to a nuclear substance or a radiation device described below, that a licence authorizes the licensee to carry on, such as:

- possess, transfer, import, export, use or abandon a nuclear substance, prescribed equipment or prescribed information;
- mine, produce, refine, convert, enrich, process, reprocess, package, transport, manage, store or dispose of a nuclear substance; or
- produce or service prescribed equipment.

Location
Any land, base(s) of operations, or premises the licensee occupies, where the licensee uses or stores nuclear substances for more than 90 consecutive days.

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.

Possess
To have the care and control of a nuclear substance or prescribed equipment

Radiation device
- 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; and
- a device that contains a radium luminous compound.

Radiation survey meter
An instrument that is capable of measuring radiation dose rates (mrem/h or mSv/h).

Radiobioassay
Measurement of the amount or concentration of radioactive nuclear substances in the body or in biological material excreted or removed from the body and analyzed for purposes of estimating the quantity of radioactive nuclear substance in the body.

Systematic Approach to Training (SAT)
A phased approach to training consisting of:

- an analysis phase, which is the identification of the competencies in terms of knowledge and skills required by the person

- a design phase, which is the conversion of competency requirements into training objectives and the production of a training plan
- a development phase, which is the preparation of the training material to meet the training objectives
- an implementation phase, which is conducting the training using the material developed
- an evaluation phase, which is the collection and collation of data obtained during each of the phases of the systematic approach to training, to be followed by appropriate actions to improve training effectiveness.

Screening - Thyroid
The practice of estimating the activity of radioiodines deposited in the thyroid.

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

Store
To lay away for future purposes

Therapeutic Nuclear Medicine
Administration of unsealed nuclear substances to humans for therapeutic purposes related to their health care; processing of radio pharmaceuticals and laboratory studies which are part of the therapy are included.

Transfer
To change the possession of a nuclear substance or prescribed equipment from one person to another

Unsealed source
A source other than a sealed source. Also called “open source”; usually in liquid form, but may be in solid, gel, bead powder or gaseous forms.

Wipe test
An indirect form of contamination monitoring that involves swiping a suspect surface and measuring the nuclear substances collected on the wipe sample.

Worker
A person who performs an activity that is referred to in the licence

Appendix A
Measurement Units Conversion Table

1 Converting to Système Internationale (SI) Units

1.1 converting from rad to grays (Gy)

conversion ratio: 100 rad (rad) = 1 Gray (Gy)
example: 1 rad (rad) = 10 milligrays (mGy)

1.2 converting from rem to sievert (Sv)

conversion ratio: 100 rem (rem) = 1 Sievert (Sv)
example: 1 rem (rem) = 10 millisieverts (mSv)

1.3 converting from curies to becquerels*

*1 Bq = 1 disintegration per second

conversion ratio:1 curie (Ci) = 3.7×10^{10} becquerels (Bq)
example:1 millicurie (mCi) = 37 megabecquerels (MBq)

2 Converting from SI Units

2.1 converting from grays to rad

conversion ratio: 1 gray (Gy) = 100 rad (rad)
example:1 milligray(mGy) = 100 millirad (mrad)

2.2 converting from sievert to rem

conversion ratio:1 sievert (Sv) = 100 rem (rem)
example:1 millisievert (mSv) = 100 millirem (mrem)

2.3 converting from becquerels to curies

conversion ratio:1 becquerel (Bq) = 2.7×10^{-11} curies or 27 picocuries (pCi)
example: 1 megabecquerel (MBq) = 27 microcuries (FCi)

Appendix B
Exemption Quantities*, Surface Contamination Limits, and Waste Disposal Limits for Nuclear Substances

		Surface Contamination Limits		Waste Disposal Limits		
Nuclear Substance	Exemption Quantity	For Controlled Areas	For Publically Accessible Areas	Releases to Garbage (solids)	Releases to Sewer (liquids, water soluble)	Releases to Atmosphere (gaseous)
Br-82	0.1 MBq	30 Bq/cm^2	3 Bq/cm2			
C-14	100 MBq	300 Bq/cm^2	30 Bq/cm^2	3.7 MBq/kg	10000 MBq/yr	
Co-57	0.1 MBq	300 Bq/cm^2	30 Bq/cm^2	0.37 MBq/kg	1000 MBq/yr	
Co-58	0.1 MBq	30 Bq/cm^2	3 Bq/cm^2	0.37 MBq/kg	100 MBq/yr	
Co-60	0.1 MBq	3 Bq/cm^2	0.3 Bq/cm^2	0.01 MBq/kg	0.1 MBq/yr	
Cr-51	1 MBq	300 Bq/cm^2	30 Bq/cm^2	3.7 MBq/kg	100 MBq/yr	
F-18	0.01 MBq	30 Bq/cm^2	3 Bq/cm^2	0.01 MBq/kg		
Fe-59	0.1 MBq	30 Bq/cm^2	3 Bq/cm^2	0.01 MBq/kg	1 MBq/yr	
Ga-67	1 MBq	30 Bq/cm^2	3 Bq/cm^2	0.037 MBq/kg	100 MBq/yr	
H-3	1000 MBq	300 Bq/cm^2	30 Bq/cm^2	37 MBq/kg	1000000 MBq/yr	37 kBq/m^3
I-123	10 MBq	300 Bq/cm^2	30 Bq/cm^2	37 MBq/kg	1000 MBq/yr	3 kBq/m^3
I-125	1 MBq	300 Bq/cm^2	30 Bq/cm^2	0.037 MBq/kg	100 MBq/yr	0.03 kBq/m^3
I-131	0.01 MBq	30 Bq/cm^2	3 Bq/cm^2	0.037 MBq/kg	10 MBq/yr	0.175 kBq/m^3
In-111	0.1 MBq	30 Bq/cm^2	3 Bq/cm^2	0.037 MBq/kg	100 MBq/yr	
Na-22	0.01 MBq	3 Bq/cm^2	0.3 Bq/cm^2	0.01 MBq/kg	0.1 MBq/yr	
P-32	0.01 MBq	300 Bq/cm^2	30 Bq/cm^2	0.37 MBq/kg	1 MBq/yr	
P-33	1 MBq	300 Bq/cm^2	30 Bq/cm^2	1 MBq/kg	10 MBq/yr	
Ra-226	0.01 MBq	3 Bq/cm^2	0.3 Bq/cm^2	0.01 MBq/kg	1 MBq/yr	
S-35	100 MBq	300 Bq/cm^2	30 Bq/cm^2	0.37 MBq/kg	1000 MBq/yr	
Sb-124	0.01 MBq	3 Bq/cm^2	0.3 Bq/cm^2	0.37 MBq/kg		
Sr-85	0.1 MBq	30 Bq/cm^2	3 Bq/cm^2	0.37 MBq/kg	10 MBq/yr	0.175 kBq/m^3
Tc-99m	10 MBq	300 Bq/cm^2	30 Bq/cm^2	3.7 MBq/kg	1000 MBq/yr	
T1-201	1 MBq	300 Bq/cm^2	30 Bq/cm^2	0.037 MBq/kg	100 MBq/yr	
Xe-133	100 GBq	300 Bq/cm^2	30 Bq/cm^2	1 MBq/kg		3.7 kBq/m^3

* The Exemption Quantity is a regulatory quantity set out in the *Nuclear Substances and Radiation Devices Regulations*. The other limits listed are only requirements when specified as such in a licence.

Appendix C
Classes of Nuclear Substances

The following table organizes a number of common nuclear substances, including those for which surface contamination and waste disposal limits are typically incorporated into CNSC licences, into three classes – "Class A," "Class B," or "Class C" – on the basis of common radiological characteristics.

To find out the classification, for regulatory purposes, of any nuclear substance that is not listed below, contact a CNSC licensing officer at 1-888-229-2672.

CLASS	**RADIONUCLIDE**				
CLASS A	all alpha emitters and their daughter isotopes			Na-22	Na-24
	Co-60	Ir-192	Sb-124	Ta-182	Zn-65
CLASS B	As-74	Au-198	Br-82	Co-58	F-18
	Fe-59	Ga-67	Gd-153	Hg-203	I-131
	In-111	In-114m	Nb-95	Rb-84	Rb-86
	Sc-46	Se-75	Sm-153	Sn-113	Sn-123
	Sr-85	Sr-90			
CLASS C	Au-195m	C-14	Ca-45	Cd-109	Ce-144
	Cl-36	Co-57	Cr-51	H-3	I-123
	I-125	Ni-63	P-32	P-33	Re-186
	Re-188	Ru-103	S-35	Sr-89	Tc-99
	Tc-99m	Tl-201	Y-90	Yb-169	

Appendix D
Application Form for Nuclear Medicine and Human Research Studies

Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

Form C292 - 2002
Application Form for Licences for Nuclear Medicine and Human Research Studies

A

SECTION A APPLICANT INFORMATION

A1 Requested Language

☐ English ☐ French ☐ Both

A2 Name of Applicant

_____

A3 Proof of Legal Status

Append proof of incorporation, partnership, registration or charter etc.

A4 Public Access to Information

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

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

A5 Canadian Head Office Address

Street: _____ Province: _____
City: _____ Postal Code: _____

A6 Mailing Address (if different from above)

Street: _____ Province: _____
City: _____ Postal Code: _____

A7 Financial Contact Person

Name: _____ Title: _____
Telephone: _____ Facsimile: _____
E-Mail: _____

continued on next page

Canada

A

SECTION A APPLICANT INFORMATION

A8 Applicant Authority

The representative for the applicant signs the application

I, _____ (Name of Applicant Authority), have the authority to sign the application and to designate persons for the purpose of section 15 of the *General Nuclear Safety and Control Regulations,* and,

designate the person named in C3 of this application (Radiation Safety Officer) as the person who has the authority to act in dealings with the Commission and responsible for the management and control of the licensed activity and nuclear substances, and

certify that all statements and representations made in the application and on supplementary pages are true and correct to the best of my knowledge and are binding to the applicant.

Title: _____

Signature: _____ Date: _____

B

SECTION B - PURPOSE OF THE LICENCE

B1 Description of Proposed Activity

Indicate only one purpose. (A separate application is needed for each)

☐ diagnostic nuclear medicine

☐ therapeutic nuclear medicine

☐ human research studies

Provide a brief description of the activity that is to be licensed and the magnitude and scope of the proposed activities using nuclear substances or radiation devices.

Append if necessary.

B2 Locations

Building: _____ Room #: _____

Street: _____ City: _____

Province: _____ Postal Code: _____

☐ used at ☐ stored at ☐ both **Other locations appended as:** _____

Is the location to be rented or leased?

☐ Yes ☐ No

If yes, provide written confirmation that the lease or rental agreement contains no restrictions or prohibitions against conducting the proposed activiities at the rented or leased premises.

Requested information appended as:

Continued on next page

B

SECTION B - PURPOSE OF THE LICENCE

B3 Unsealed Sources

(Please select one only.)

☐ Diagnostic Nuclear Medicine ☐ Therapeutic Nuclear Medicine ☐ Human Research Studies

Radionuclide	Maximum quantity to be in possession	Total quantity to be acquired per year (estimate)

B4 Sealed Sources (Diagnostic Nuclear Medicine Only)

Radionuclide	Maximum quantity to be contained in any single source	Number of sealed sources greater than 50 MBq to be acquired (estimate)

B5 Radiation Devices (Diagnostic Nuclear Medicine Only)

Radionuclide	Quantity in Bq	Manufacturer of device	Name, model of device

C

SECTION C - RADIATION PROTECTION PROGRAM

C1 Management Structure

Append a description of the management and organizational structures that relate to radiation safety. Include the name, position title, function, responsibilities and authority of each person, and a copy of the organization chart.

Description appended as: _____

C2 Radiation Safety Committee

Append a copy of the terms of reference of the Radiation Safety Committee, or its equivalent.

Copy appended as: _____

C3 Radiation Safety Officer (RSO)

Name: _____ Title: _____
Telephone: _____ Facsimile: _____
E-Mail: _____

RSO's acknowledgement:
I accept the applicant's RSO job description, as appended.

Date: _____ Signature: _____

Description of the RSO's qualifications, experience and job responsibilities appended as:

_____

C4 Medical Practitioner

Name: _____ Title: _____
Telephone: _____ Facsimile: _____
E-Mail: _____

Acknowledgement of practitioner:
I accept the designation of medical practitioner for the activities to be licensed.

Date: _____ Signature: _____

Continued on next page

C

SECTION C - RADIATION PROTECTION PROGRAM

C5 Classifying Workers and Monitoring Doses

List all job categories for workers. Note the number of workers and NEWs in each job category. Append a description of roles, responsibilities, duties, qualifications and experience of workers. Include temporary and contract workers.

Append a copy of the policy and procedures for classifying workers and NEWs. Provide the name of the licensed dosimetry service that will be used to monitor workers' doses.

Requested information appended as:

C6 Worker Training

Append a detailed description of the proposed radiation safety training program for workers.

Description appended as:

C7 Ascertaining and Recording Doses to Workers

Append a copy of the procedures for ascertaining and recording the radiation dose to each person who will perform duties in connection with the activity to be licensed, or to those who will be present when the activity is carried on.

Copy appended as:

C8 Action Levels

Append a description of any proposed action levels and the actions to be taken if they are reached; or a description of the proposed measures to evaluate the effectiveness of the radiation protection program.

Description appended as:

C9 Control of Radioactive Contamination

Append a copy of the procedures for monitoring contamination. Describe the radiation detection instruments that will be used, and the actions to be taken if contamination limits are exceeded.

Requested information appended as:

C10 Radiation Detection Instruments

Append a list of all radiation detection instruments to be used. For each instrument, provide name of manufacturer, energy response, detector-type, and maintenance procedure.

Requested information appended as:

C11 Leak Testing of Sealed Sources

Append a copy of the procedures to be followed for leak testing, or the name of the licensed service provider who will perform any of the leak testing.

Copy or name appended as:

C

SECTION C - RADIATION PROTECTION PROGRAM

C12 Room Classifications

Append a plan for every nuclear medicine room or department, and adjacent areas. Include a list of the rooms, and their classifications, where the activities to be licensed are to be conducted.

Requested information appended as:

C13 Access Control and Security

Append a copy of the procedures for restricting access to nuclear substances to authorized workers.

Copy appended as:

C14 Receipt of Packages

Append a copy of procedures for receiving and opening shipments containing nuclear substances.

Copy appended as:

C15 Packaging and Transport of Nuclear Substances

Append a copy of the procedures for packaging and transporting nuclear substances and radiation devices.

Copy appended as:

C16 Inventory Control of Nuclear Substances

Append a copy of the procedures to ensure that the inventory of nuclear substances does not exceed the licence limit for each substance. Include sample inventory forms and the procedures for tracking nuclear substances and radiation devices.

Requested information appended as:

C17 Management of Radioactive Wastes

Append a copy of the procedures for handling, transferring and disposing of waste containing nuclear substances.

Copy appended as:

C18 Emergency Procedures

Append a copy of the procedures that will be used during an emergency involving a nuclear substance or radiation device.

Copy appended as:

D

SECTION D - THERAPEUTIC NUCLEAR MEDICINE

To be completed and submitted only by applicants for licences for therapeutic nuclear medicine

D1 Administration of Nuclear Medicine Therapy Doses

Append copies of the policy, procedures, and precautions for preparing, administering and controlling therapy doses.

Copies appended as:

D2 Instructions to Caregivers

Append a copy of the instructions to be given to caregivers for nuclear medicine therapy patients.

Copy appended as:

D3 Instructions to Patients of Nuclear Medicine Therapy and Their Families

Append a copy of the instructions to be given to patients of nuclear medicine therapy, to reduce radiation exposure to others.

Copy appended as:

D4 Release of Patients

Append copies of the policy and procedures for determining when a patient's radiation levels require that the patient be isolated.

Copies appended as:

D5 Assignment of Nuclear Medicine Therapy Rooms

Append a copy of the procedures for assigning rooms to hospitalized patients.

Copy appended as:

D6 Decontamination and Reuse of Treatment Rooms

Append a copy of the procedures for decontaminating and reusing therapy treatment rooms.

Copy appended as:

D7 Medical Emergencies

Append copies of the policy and procedures for responding to medical emergencies involving nuclear medicine patients.

Copies appended as:

E

SECTION E - HUMAN RESEARCH STUDIES

To be completed and submitted by applicants of licences for human research studies only.

E1 Human Research Review Committee

Append a description of the authority, composition, and duties of the proposed Human Research Review Committee, or its equivalent.

Description appended as:

E2 Authorization of Research Studies

Append a description of the proposed process and criteria whereby the Human Research Review Committee or its equivalent will authorize human research studies.

Description appended as:

E3 Classification of Research Studies

Append a statement of the proposed categories of research studies, and the proposed radiation dose constraints for each category.

Statement appended as:

E4 Selection of Volunteer Participants

Append a description of the policy and criteria for including or excluding human volunteers for research studies.

Description appended as:

E5 Consent Form

Append copies of the policy and procedures for obtaining the informed consent of study volunteers. Provide a copy of a blank consent form.

Copies appended as:

E6 Records of Studies

Specify where the records of all studies using nuclear substances on human volunteers are to be maintained and made available for CNSC inspection.

Description of location appended as: