



Class IB Facilities Licence Application Guide: Class IB Processing Facilities

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Preface

This regulatory document is part of the CNSC's Class IB Facilities series of regulatory documents. The full list of regulatory document series is included at the end of this document and can also be found on the [CNSC's website](#).

Regulatory document REGDOC-1.2.2, *Licence Application Guide: Class IB Processing Facilities*, sets out requirements and guidance on submitting a formal application to the CNSC to obtain a licence to prepare a site for, construct, operate and/or decommission a Class IB processing facility in Canada, and identifies the information that should be included in the application.

This document will be used to assess licence applications for proposed new processing facilities and for licence renewals for existing processing facilities. Once the Commission has granted a licence, the safety and control measures described in the licence application and the documents needed to support the application will form part of the licensing basis.

This document is the first version.

For information on the implementation of regulatory documents and on the graded approach, see REGDOC-3.5.3, *Regulatory Fundamentals*.

The words “shall” and “must” are used to express requirements to be satisfied by the licensee or licence applicant. “Should” is used to express guidance or that which is advised. “May” is used to express an option or that which is advised or permissible within the limits of this regulatory document. “Can” is used to express possibility or capability.

Nothing contained in this document is to be construed as relieving any licensee from any other pertinent requirements. It is the licensee's responsibility to identify and comply with all applicable regulations and licence conditions.

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Licence Application Guide: Class IB Processing Facilities

1. Introduction

1.1 Purpose

This licence application guide identifies the information to be provided in support of an application for a licence to prepare a site for, construct, operate or decommission a Class IB nuclear facility for:

- processing, reprocessing or separation of an isotope of uranium, thorium or plutonium;
- the manufacturing of a product from uranium, thorium or plutonium; or
- processing or use, in a quantity greater than 10^{15} Bq per calendar year, of nuclear substances other than uranium, thorium or plutonium

This guide sets out requirements and guidance on submitting a formal application to the Canadian Nuclear Safety Commission (CNSC) to obtain a licence.

Following the information in this regulatory document will prepare applicants to submit the appropriate information to demonstrate that they are qualified and will make adequate provisions for the protection of the environment and the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.

1.2 Scope

This document is a guide in the preparation of a licence application for a licence to prepare a site for, construct, operate and/or decommission a proposed new Class IB processing facility or for the renewal of a licence for an existing facility.

1.3 Relevant legislation

The following provisions of the [Nuclear Safety and Control Act](#) (NSCA, the Act) and the regulations made under it are relevant to this document:

- NSCA, subsection 24(4) and paragraphs 26(a) and (e)
- *General Nuclear Safety and Control Regulations* (GNSCR), subsection 3(1.1)

Other relevant sections of the regulations made under the NSCA are included in the content of this document. Appendix A maps a list of relevant clauses from the NSCA and the regulations made under the NSCA to the related sections of this licence application guide.

The applicant must also comply with all applicable laws and regulations at all jurisdictional levels.

Note: This regulatory document includes select requirements that are based on the NSCA and the regulations made under the NSCA. While each section of the regulatory document addresses select requirements related to the safety and control area (SCA) or other topics of regulatory interest, applicants are responsible for ensuring that all requirements under the NSCA and regulations, for the proposed activities, are addressed in an application.

1.4 National and international standards

Key principles and elements used in developing this document are consistent with national and international standards. Furthermore, this regulatory document is compatible with the safety objectives and principles in IAEA SSR-4, *Safety of Nuclear Fuel Cycle Facilities* [1].

1.5 CNSC contact information

A single point of contact from the CNSC is assigned to work with every licensee or applicant. This point of contact can provide the licensee or applicant with additional information or explanation of the information contained within this document.

To contact the CNSC, refer to the [CNSC's website](#).

Note: An applicant who intends to possess Category I and/or Category II nuclear material should consult with CNSC staff to identify additional relevant requirements for the site prior to submitting an application.

2. Licensing Basis, Process and Submission

This section provides information on the licensing basis, licensing process, and on completing and submitting the licence application.

2.1 Licensing basis

The licensing basis sets the boundary conditions for a regulated activity and establishes the basis for the CNSC's compliance program for that regulated activity. The concept of the licensing basis is explained in REGDOC-3.5.3, *Regulatory Fundamentals* [2].

CNSC staff review both the application and the supporting documentation, and assess whether the information is sufficient and acceptable. If the Commission grants a licence, the information submitted by the applicant will form part of the licensing basis.

2.2 Licensing process

REGDOC-3.5.1, *Licensing Process for Class I Nuclear Facilities and Uranium Mines and Mills* [3], clarifies the licensing process in the context of the NSCA.

In addition to the information provided in this licence application guide (REGDOC-1.2.2), the CNSC may request additional information as necessary to evaluate the application.

The licensing process is initiated when the applicant submits a licence application. Applicants should ensure they include sufficiently detailed information to allow the licensing process to proceed efficiently. Early engagement with CNSC staff is encouraged.

Protecting the environment is part of the CNSC's mandate. The CNSC requires the environmental effects of all licensed activities to be assessed and considered when licensing decisions are made. Environmental reviews are based on the scale and complexity of the environmental risk associated with a nuclear facility or activity.

For more information on the CNSC's environmental review and licensing processes, see:

- REGDOC-2.9.1, Environmental Protection: Environmental Principles, Assessments and Protection Measures [4]
- REGDOC-3.5.1, Licensing Process for Class I Nuclear Facilities and Uranium Mines and Mills, [3]

Note: The information provided in this document does not prevent applicants from proposing alternatives. However, any proposed alternative should appropriately reflect the complexities and hazards of the proposed activities and should be supported by suitable information.

2.3 Structuring the licence application

The application may be completed in either of Canada's official languages (English or French). This licence application guide describes the expected safety and control measures, organized by the CNSC's safety and control area (SCA) framework. The CNSC uses SCAs as the technical topics to assess, review, verify and report on regulatory requirements and performance across all regulated facilities and activities, as follows (see appendix B):

- management system
- human performance management
- operating performance
- safety analysis
- physical design
- fitness for service
- radiation protection
- conventional health and safety
- environmental protection
- emergency management and fire protection
- waste management
- security
- safeguards and non-proliferation
- packaging and transport

Each of the 14 SCAs is further divided into specific areas that cover topics addressed in a complete assessment and review.

The applicant may choose to organize the information in any structure. However, the applicant is encouraged to organize the licence application according to the SCA framework to facilitate CNSC staff review.

2.4 Completing the licence application

The applicant is responsible for ensuring that the licence application contains sufficient information to meet regulatory requirements. The applicant should provide cross-references to detailed information in other sections as appropriate.

Early in the licensing process, the CNSC may provide guidance to the applicant identifying the appropriate version (publication date and revision number) of each document to be cited or addressed in the application. This supplemental guidance may also indicate documents other than those listed in appendix C that the applicant should consider and address in the application. The

application should cite the regulatory documents, codes and standards that were used to demonstrate the applicant's ability to meet the regulatory requirements set under the NSCA.

The applicant may provide references to any documents included in a previous licence application.

The application should indicate the relevant sections of each supporting document.

New licence applications

For new licence applications, the applicant should consult with CNSC staff to confirm which editions of the codes and standards applicable to the facility are acceptable. This should be done prior to developing proposed safety policies, programs, processes, procedures and other safety and control measures.

Licence renewals

For the renewal of an existing licence, the applicant shall indicate if any information was submitted with previous licence applications. Subsequent applications shall provide a list of the supporting documents and clearly identify which information was previously submitted.

Note: If the document version in the supporting information has changed, the applicant shall provide the CNSC with the new version number and a revised copy of the document.

2.5 Submitting the licence application

The applicant should ensure that the application is complete, dated and signed by the appropriate authority, and that all supporting documents are clearly identified and cross-referenced. All information submitted is subject to the *Access to Information Act* and the *Privacy Act*. It is the responsibility of the applicant to identify, with justification, any material that is not suitable for public disclosure. All submitted information may be presented to the Commission to support the licensing decision. Any such information is also made available to the public upon request, subject to confidentiality requirements.

If the licence application is subject to the *Canadian Nuclear Safety Commission Cost Recovery Fees Regulations*, the applicant should ensure that payment is enclosed. For further details, contact the [CNSC Cost Recovery Advisory Group](#) at 613-995-5894 or toll-free at 1-888-229-2672.

Applicants are strongly encouraged to submit the documents in electronic format. Secure devices may be used. Applicants who choose to submit a licence via email must submit the application to the [CNSC Secretariat](#).

If the applicant chooses to submit the licence application in printed (hard copy) format, the applicant should provide two printed copies of the application (signed and dated) to the Commission at:

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

The applicant shall keep a record of licence information, as required by section 27 of the *General Nuclear Safety and Control Regulations*.

Note that it is prohibited to submit prescribed information via unencrypted email. Prescribed information, such as details of the security program, shall be submitted in accordance with sections 21 and 23 of the *General Nuclear Safety and Control Regulations*. Guidance for the protection and transmission of prescribed information can be found in REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material* [5].

3. General Application Requirements

This section addresses the requirements of the following regulations under the NSCA:

- *General Nuclear Safety and Control Regulations*, paragraphs 3(1)(a), (b), (c), (d) and (k), and section 15
- *Class I Nuclear Facilities Regulations*, paragraphs 3(a), (b), (c) and (i)
- *Nuclear Security Regulations*, section 41

The licence application shall include the following general information to satisfy the regulations and should also include additional general information where appropriate, as listed below. The applicant shall identify the appropriate information and documents that are subject to confidentiality requirements.

3.1 Identification and contact information

3.1.1 Current licence number

If the licence application is for the renewal of an existing licence, the applicant shall provide the current licence number.

3.1.2 Applicant's name and business address

The applicant shall provide the applicant's name and business address.

The name shall be that of the persons or organization applying for the licence, as it appears on the proof of legal status documentation (such as the proof of incorporation or sole proprietorship). The applicant should name an individual, only if that person is a sole proprietor or will be solely responsible for the licence.

The business address shall be the legal, physical address of the applicant's head office, including the complete street name and number, city, province or territory, and postal code. A post office box number is not acceptable.

The applicant shall notify the Commission within 15 days of any changes to this information.

3.1.3 Mailing address

If the mailing address is different from the head office address, the applicant should provide the mailing address, including the complete street name and number, rural route number if appropriate, city, province or territory, and postal code.

If no address is provided, any licence issued in response to the application will be mailed to the head office address. A post office box number is acceptable as a mailing address.

The applicant should notify the Commission within 15 days of any changes to this information.

3.1.4 All persons who have authority to interact for the applicant with the CNSC

The applicant shall notify the Commission of the persons who have authority to act for them in their dealings with the Commission.

The applicant shall notify the Commission within 15 days of any changes to this information.

The applicant should provide a list of names, positions and contact information of all persons who are authorized by the applicant to interact with the CNSC. **Note:** The applicant may request, for security reasons, this information be subject to confidentiality requirements.

3.1.5 Proof of legal status

Applicants shall provide proof of legal status by appending proof of incorporation, corporation number or charter. When submitting an application to renew a licence, proof of legal status need only be provided if the applicant's original organization name has changed.

If the applicant is a corporation, the application should include the following information:

- corporation's legal name
- corporation number
- date of incorporation
- registered office address (if different from the head office address)

3.1.6 Evidence that the applicant is the owner of the site or has authority from the owner of the site to carry on the activity to be licensed

The applicant shall provide evidence that the applicant is the owner of the site or has authority from the owner of the site to carry on the activity to be licensed.

3.1.7 Identification of persons responsible for management and control of the licensed activity

The application shall contain the applicant's organizational management structure insofar as it may bear on the applicant's compliance with the NSCA and the regulations made under it, including the internal allocation of functions, responsibilities and authority.

The applicant shall notify the Commission of the names and position titles of the persons who are responsible for the management and control of the licensed activity and the nuclear substance, nuclear facility, prescribed equipment or prescribed information encompassed by the licence. The applicant shall notify the Commission within 15 days of any changes to this information.

To satisfy these requirements, the applicant should provide a summary list of all persons responsible for management and control of the licensed activity, including:

- names
- positions (job titles)
- contact information (email, telephone, facsimile)
- mailing addresses (if different from the business mailing address)

3.1.8 Billing contact person

The applicant shall provide the following information for the person responsible for the licence fee payments:

- name
- position
- contact information (email, telephone, facsimile)
- mailing addresses (if different from the business mailing address)

3.1.9 Legal signing authority

The applicant shall provide the name, title and contact information (address, email address and telephone number) of the individual who is signing the application, as the applicant authority.

The signature of the applicant authority indicates that all statements and representations made in the application and on supplementary pages are binding on the applicant.

3.2 Facility and activities to be licenced

3.2.1 Licence period

The applicant should state the requested licence period (years or months).

The licensee may request a specific licence period to match planned activities or anticipated change in status.

3.2.2 Statement of the main purpose

The applicant shall provide:

- information about all activities to be licensed and their purpose
- a description of any nuclear facility, prescribed equipment or prescribed information to be encompassed by the licence

This information may be provided in summary format; for example, by listing facilities, equipment or information.

3.2.3 Description of site

The application shall contain:

- a description of the site of the activity to be licensed, including the location of any exclusion zone and any structures within that zone
- plans showing the location, perimeter, areas, structures and systems of the nuclear facility

If the licence processes or stores Category III nuclear material, an application for a licence in respect to a nuclear facility shall contain a description of the physical protection measures to be taken to ensure compliance with sections 42 to 48 of the [Nuclear Security Regulations](#) in addition to the information required by sections 3 to 8 of the *Class I Nuclear Facilities Regulations*.

3.2.4 Description of the facility's existing licensing status, if any

If an activity on the site is currently licensed by the CNSC, or a previous licence application is pending, the applicant shall provide a description of the licensing status.

3.2.5 Nuclear and hazardous substances

The applicant shall provide:

- the name, maximum quantity and form of any nuclear substance to be encompassed by the licence
- the name, form, characteristics and quantity of any hazardous substances that may be on the site while the activity to be licensed is carried on

The applicant should provide the scientific name of each nuclear and hazardous substance.

This information may be provided in summary format; for example, by providing a table of the nuclear and hazardous substances and the information required for each substance.

3.3 Other relevant information

3.3.1 Permits, certificates and other licences

The applicant should describe the relationship of this application to any previous licences (for example, siting, construction or operation) issued by the CNSC for activities at this facility, including any changes to the licensing basis that were included in previous licences.

The applicant should reference any other CNSC licences that apply to the use of other nuclear substances and authorized activities conducted at the facility; for example, licences for nuclear substances and radiation devices, dosimetry service, and import/export of nuclear substances.

3.3.2 Similar facilities (for a licence application for a new facility)

If this licence application is for a new facility, the applicant should provide a list of any similar facilities owned or operated by the applicant that have been assessed and licensed by either the CNSC or any foreign regulatory body. The list should include the following information:

- facility name
- location
- date when the most recent licence was granted
- description of the facility

3.3.3 Supporting information

Where applicable, supporting information includes:

- the results of experimental programs, tests or analyses (for example, results of manufacturers' material tests and qualification data)
- those that have been submitted to, received from, or published by a foreign national regulatory body
- information published by a national agency or an international nuclear agency such as the International Atomic Energy Agency (IAEA) or the International Commission on Radiological Protection (ICRP)

4. Safety Policies, Programs, Processes, Procedures and Other Safety and Control Measures

The applicant shall ensure to include in the application sufficiently detailed information about the safety policies, programs, procedures and other documents that describe safety and control measures. All policies and programs should allow for continuous development, on an on-going basis for all lifecycle stages of the facility.

Note: Appendix A shows all relevant clauses in regulations for a licence to prepare a site, construct, operate, or decommission a Class IB processing facility. It is up to the applicant to ensure sufficient details are provided for each activity.

4.1 Management system

The management system SCA establishes the framework for the processes and programs required to ensure an organization achieves its safety objectives, continuously monitors its performance against these objectives, and fosters a healthy safety culture.

This section addresses the requirements of the following regulations made under the NSCA:

- *General Nuclear Safety and Control Regulations*, paragraphs 3(1)(k), 12(1)(a), and 17(c) and (e), and sections 15, 27 and 28
- *Class I Nuclear Facilities Regulations*, paragraphs 3(d), (d.1) and (f), 4(d), 5(c), (g), (i) and (l), 6(d), (e), (g), (h), (k), (l), (m) and (n) and 7(c), (f), (i) and (j) and subsections 14(1), (2), (4) and (5)
- *Nuclear Security Regulations*, subsections 37(1), (2) and (3), and section 38
- *Nuclear Substances and Radiation Devices Regulations*, subsection 36(1)

4.1.1 General considerations

The application shall describe the management system programs, processes and procedures that have been or will be put in place to protect health, safety and the environment, as well as a description of the organizational management structure.

The application shall also describe the safety policies, the roles of external safety assessment organizations and the advisory committees that will advise the management of the organization that will carry out licensed activities.

The application should refer to CSA N286-12, *Management system requirements for nuclear facilities* [6] to meet the requirements for the management system SCA. If an application does not use CSA N286-12, it should provide the alternate standard used with justification.

4.1.2 Management system

The application shall describe how the applicant's management system is compliant with relevant requirements and how the management system will be implemented.

4.1.3 Organization

The application shall describe the organizational structure.

4.1.4 Performance assessment, improvement and management review

The applicant shall describe the programs covering performance assessment, improvement and management review.

The application shall describe the adequate provisions made for an objective internal self-evaluation program supported by periodic external reviews and taking into account national and international experience and feedback from the nuclear industry.

The application should describe how organizational effectiveness and safety performance are measured, including the use of performance indicators to detect any shortcomings and deteriorations in safety.

The application should describe how organizational changes are managed to prevent degradation of safety performance.

The applicant should demonstrate that the analysis of the causes of significant events will consider technical, organizational and human factors aspects, and that the necessary arrangements have been made to report and analyze near-miss events.

The application should clearly state how the applicant intends to present, promote and assess the key characteristics of good safety performance by all workers, at the facility, including contractors and subcontractors. The application should provide a proposed timeline and milestones for completion of specific detailed safety performance documentation that will be developed later.

4.1.5 Operating experience

The application should describe how the program for feedback of operating experience has been implemented during site evaluation and design activities, and how it will continue during the construction, commissioning and operating phases of the processing facility's lifecycle.

4.1.6 Change management

The application should describe change management within the processing facility.

4.1.7 Safety culture

The application shall demonstrate that the applicant's approach to foster a healthy safety culture is in accordance with REGDOC-2.1.2, *Safety Culture* [7].

4.1.8 Configuration management

The application should describe the provisions to establish and maintain configuration from concept until end of operation life.

4.1.9 Records management

The application should describe the adequate provisions for records management. Licensees are required to keep records relating to the licence submitted to the Commission.

4.1.10 Business continuity

The application should include a business continuity plan. This plan should provide procedures and information that guide the applicant to respond, recover, resume and restore to a predefined level following disruption. Some examples of disruptions are:

- natural disasters (such as hurricanes, floods, blizzards, earthquakes and fire)
- accidents
- sabotage, including cyber attacks and hacker activity
- labour actions
- loss of a key contractor
- power and energy disruptions
- communication, transport, safety and service sector failure
- health-related epidemic or pandemic events that have or could have a measurable impact
- environmental events (such as pollution and hazardous materials spills)

4.2 Human performance management

The human performance management SCA covers activities that enable effective human performance through the development and implementation of processes that ensure that a sufficient number of licensee personnel are in all relevant job areas and have the necessary knowledge, skills, procedures and tools in place to safely carry out their duties.

This section addresses the requirements of the following regulations made under the NSCA:

- *General Nuclear Safety and Control Regulations*, paragraphs 3(1)(k), and 12(1)(a), (b), (e) and (j), and section 17
- *Class I Nuclear Facilities Regulations*, paragraphs 3(f), 5(i), (l) and (m), 6(d), (h), (k), (l), (m), (n) and 7(f), (i) and (j) and subsection 14(2)
- *Nuclear Security Regulations*, section 48

4.2.1 General considerations

The application shall describe the qualifications, adequate numbers, skills and competencies required by workers at the facility. For the purposes of this document, the regulatory focus of this SCA for these types of facilities is personnel training. As applicable, the other specific areas are assessed as part of the licence application if requested.

The description shall include the measures to ensure a sufficient number of workers in all job areas and that workers have the necessary knowledge, skills, procedures and tools in place to safely carry out their duties.

The application should describe the measures to promote and support human performance at all levels in the organization. The application should demonstrate how the applicant's programs and processes interface to support continuous improvement of human performance. The application should demonstrate various measures to identify and monitor human performance weaknesses and to correct any organizational deficiencies to minimize human error.

The application should describe the workforce planning process, including measures for knowledge transfer, to ensure that workers are recruited and trained to fill each key role within the organization.

4.2.2 Human performance program

The application should describe how the human performance program addresses and integrates the range of human factors that influence human performance, including but not limited to:

- the adequate provision of qualified workers
- the reduction of human error
- organizational support for safe work activities
- the continuous improvement of human performance
- monitoring hours of work

4.2.3 Personnel training

The application shall describe a training system that is in accordance with REGDOC-2.2.2, *Personnel Training* [8].

4.2.4 Work organization and job design

The application should describe the minimum number of workers with specific qualifications required for normal operations and unusual conditions (minimum staff complement). The application should demonstrate that the minimum staff complement will be monitored and recorded.

The applicant should demonstrate that the adequacy of the minimum staff complement has been determined through a systematic analysis to identify the required number of workers and their qualifications. The applicant should demonstrate that the minimum staff complement can meet the performance requirements and support the safe operation of the facility.

For more information, refer to REGDOC-2.2.5, *Minimum Staff Complement* [9], and REGDOC-2.5.1, *General Design Considerations: Human Factors* [10].

4.2.5 Fitness for duty

High security sites are identified as a nuclear power plant or a nuclear facility where Category I or II nuclear material is processed, used or stored as per section 1 of the *Nuclear Security Regulations*. For sites subject to this designation, the application should identify the oversight requirements for supervisors of security personnel from the perspective of fitness for duty.

For more information regarding fitness for duty for high security sites, refer to:

- REGDOC-2.2.4, *Fitness for Duty: Managing Worker Fatigue* [11]
- REGDOC-2.2.4, *Fitness for Duty, Volume II: Managing Alcohol and Drug Use* [12]
- REGDOC-2.2.5, *Minimum Staff Complement* [9]

4.3 Operating performance

The operating performance SCA includes an overall review of the conduct of the licensed activities and the activities that enable effective performance.

This section addresses the requirements of the following regulations made under the NSCA:

- *General Nuclear Safety and Control Regulations*, paragraphs 3(1)(k) and 12(1)(c), (e) and (f), and sections 17, 29, 30, 31 and 32
- *Class I Nuclear Facilities Regulations*, paragraphs 4(a), 5(c), (i), (l) and (m), 6(c), (d), (e), (g), (h) and (k), 7(a), (c), (f) and (i) and subsection 14(2)
- *Radiation Protection Regulations*, subsection 1(3) and sections 13, 14 and 15

4.3.1 General considerations

The application shall include information on how the applicant will ensure that normal facility operations:

- are carried out safely, such that radiation doses to workers and members of the public—as well as any planned discharges or releases of radioactive material or hazardous substances from the facility—will be within the proposed limits and conditions
- adhere to any applicable provincial legislation or other applicable codes and standards

The application should describe how the operating principles, policies, processes and programs will confirm that the structures, systems and components (SSCs) will perform and function in accordance with the design specifications and regulatory requirements outlined in the safety analysis.

The application should include information regarding the development, verification, validation and implementation of programs and procedures related to commissioning, maintenance, operation and decommissioning.

For a new facility, the application should describe the processes used to ensure that the performance of the SSCs has been assured from site preparation to construction to operation and to the future, if major modifications are made to the facility.

4.3.2 Conduct of licensed activity

The application shall describe the proposed measures, policies, methods and procedures for carrying on the licensed activity at the nuclear facility. The application shall describe the means for preparation of equipment for maintenance and the monitoring of SSCs to confirm that they will continue to operate as required by the design.

The application shall also describe how the applicant will:

- exercise overall responsibility for safety in conducting licensed activities, including ongoing upgrades and modifications to the facility
- handle, store, load and transport nuclear and hazardous substances
- carry out effective oversight of these activities and procedural adherence

4.3.3 Procedures

The application shall describe the development, verification, validation and implementation of operating procedures for the activities to be licensed covering normal, unplanned and emergency conditions.

The application should describe how all normal, unplanned and emergency operating procedures will be validated. For more information, refer to REGDOC-2.5.1, *General Design Considerations: Human Factors* [10].

4.3.4 Reporting and trending

The application shall include the analysis of operating performance including the causes of events, accidents, injuries, unplanned shut downs and reportable events. For more information, refer to REGDOC-3.1.2, *Reporting Requirements, Volume I: Non-Power Reactor Class I Facilities and Uranium Mines and Mills* [13].

4.3.5 Operating limits and conditions

The application should state the safe operating limits and conditions. The information submitted should describe how the applicant will comply with limits imposed by the design and safety analysis assumptions. The application should clearly describe the actions to be taken if the limits and conditions are not met.

The information available on the set of limits and conditions and the accompanying design information for the facility should be sufficient to support the training and qualification of facility workers.

4.4 Safety analysis

The safety analysis SCA covers development and maintenance of the safety analysis that supports the overall safety case for the facility. Safety analysis is a systematic evaluation of the potential hazards associated with the conduct of a proposed activity or facility and considers the effectiveness of preventive measures and strategies in reducing the effects of such hazards.

This section addresses the requirements of the following regulations made under the NSCA:

- *General Nuclear Safety and Control Regulations*, paragraphs 3(1)(d), (e) and (i), and 12(1)(c) and (f)
- *Class I Nuclear Facilities Regulations*, paragraphs 3(b) and (d), 5(f), (i), (j) and (k), 6(a), (b), (c), (d), (h), (i), (j) and (k), and 7(f) and (g)
- *Radiation Protection Regulations*, subsection 1(3) and sections 4, 13, 14 and 15

4.4.1 General considerations

The application shall include a safety analysis program that is in accordance with REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities* [14]. It is required for licensees to submit a preliminary safety analysis report for a licence to construct and a final safety analysis report for a licence to operate.

4.4.2 Postulated initiating events

The safety analysis shall identify postulated initiating events (PIEs) using a systematic methodology (for example, hazard and operability studies). The scope and classification of PIEs in the application shall meet the requirements specified in REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities* [14]. The information provided should demonstrate that all credible events with the potential for serious consequences or with a significant frequency of occurrence are anticipated and considered.

The application should describe how the design and safety analyses have taken into account the potential for specific hazards from common cause events on the site.

4.4.3 Deterministic safety analysis

The application shall include a deterministic safety analysis to evaluate and justify facility safety, conducted in accordance with REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities* [14]. The level of conservatism of each deterministic safety analysis should be appropriate for the frequency of the event analyzed and the analysis objectives and should take into account operational experience/feedback from similar facilities.

4.4.4 Hazard analysis

The application should describe the analysis of all credible hazards (internal and external), both natural and human-induced. Some examples are:

- for natural external hazards: earthquakes, droughts, floods, high winds, tornadoes, abnormal surges in water level and extreme meteorological conditions
- for human-induced external hazards: those that are identified in the site evaluation, such as airplane crashes, ship collisions, and accidents at surrounding activities such as chemical explosion
- for internal hazards: internal fires, internal floods, turbine missiles, on-site transportation accidents and releases of hazardous substances from on-site storage facilities

The application should describe the analysis of any credible combinations of the external hazards and should consider maximum probable scenarios where applicable. It should also consider the potential interaction of external and internal hazards, such as external events that initiate internal fires or floods.

4.4.5 Criticality safety

Operations with fissionable materials shall meet the requirements of REGDOC 2.4.3, *Nuclear Criticality Safety* [15]. Operations with fissionable materials introduce risks of a criticality accident resulting in a release of radiation that can be lethal to nearby personnel. However, experience has shown that extensive operations can be performed safely and economically with a

combination of carefully considered engineered design features to prevent criticality and appropriate human performance measures. The few criticality accidents that have occurred show frequency and severity rates far below those typical of non-nuclear accidents.

4.5 Physical design

The physical design SCA relates to activities that impact the ability of SSCs to meet and maintain their design basis, given new information arising over time and taking changes in the external environment into account.

This section addresses the requirements of the following regulations made under the NSCA:

- *General Nuclear Safety and Control Regulations*, paragraphs 3(1)(d), (e), (g), (h), (i) and (j), and 12(1)(c) and (f)
- *Class I Nuclear Facilities Regulations*, paragraphs 3(a), (b), (d) and (i), 4(a), (b), (c) and (d), 5(a), (b), (d), (e), (f), (g) and (j), 6(a), (b), (c), (g), (h), (i), (j), (k), (m) and (n), and 7(f), (g), (h) and (i)
- *Radiation Protection Regulations*, subsection 1(3) and sections 4, 13, 14 and 15

4.5.1 General considerations

The application shall include an appropriate level of detail about the description of the overall physical design of the facility, the design practices and the safety concepts commensurate with the activities being proposed in the licence. The application shall also describe the approach followed for the general design of and the performance of the SSCs.

For a new facility, the application shall include information showing that the facility's design, construction, commissioning and operation is consistent with prevailing national and international codes and standards. The facility design shall conform to the National Building Code of Canada, National Fire Code of Canada and CSA N393. Where appropriate, CNSC staff may require more stringent requirements with regards to seismic and fire protection. The IAEA suite of safety standards and safety guides are used as guidance in the technical assessment of fuel cycle facility design. These safety guides include:

- SSR-1, *Site Preparation for a Nuclear Facility* [16]
- SSR-4, *Safety of Nuclear Fuel Cycle Facilities* [1]
- SSG-5, *Safety of Conversion Facilities and Uranium Enrichment Facilities* [17]
- SSG-6, *Safety of Fuel Fabrication Facilities* [18] (for less than 6% enrichment)
- SSG-7, *Safety of Uranium and Plutonium Mixed-Oxide Fabrication Facilities* [19]
- SSG-42, *Safety of Nuclear Fuel Reprocessing Facilities* [20]
- SSG-43, *Safety of Nuclear Fuel Cycle Research and Development Facilities* [21]

For other radioisotope processing facilities, including processing of unsealed nuclear substances, REGDOC-2.5.6, *Design of Room where Unsealed Nuclear Substances are Used* [22] should be used as guidance.

Where there are multiple set of regulatory requirements for the same parameters, the most stringent requirement should be applied. Where there is a conflict between requirements, the applicant may propose alternate approaches and provide justification. The application should provide information that demonstrates compliance with the most recent national and international best practices as applicable.

For existing facilities, the application should address the information in this section to the extent practicable and provide references to past submissions. Any alternative approaches selected or mitigating measures applied should be identified and justified.

The application may refer to information that was submitted previously (for example, in the application for a licence to construct). The set of documents that address the requirements in this section should be submitted only once for the initial application, with few subsequent revisions.

Where appropriate, the application shall describe the radiation protection and environmental protection design principles and approaches adopted with the intent for facility operations to be carried out safely. The information submitted shall demonstrate that, in all operational states, radiation doses within the facility or any planned release of nuclear substances from the facility meet the requirements of REGDOC-2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures* [4], and REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities* [14]; are kept below regulatory limits; and are as low as reasonably achievable (ALARA). REGDOC-2.7.1, *Radiation Protection* [23], also provides guidance on design considerations for meeting CNSC regulatory requirements for the control of occupational exposures.

4.5.2 Design governance

The application shall describe how design governance and design change control are implemented for the proposed activities in consideration of factors described below.

Design change control and configuration management should be in accordance with CSA N286-12, *Management systems for nuclear facilities* [6]. For facilities processing radioisotopes used in medicinal applications, alternate standards, including ISO 13485, *Medical devices – Quality management systems – Requirements for regulatory purposes* [24], may be applied.

For more information please refer to REGDOC-2.5.1 *General Design Considerations: Human Factors* [10].

4.5.3 Site characterization

The application shall refer to, or summarize, the information previously submitted in any relevant environmental assessment or licensing documentation, such as environmental impact statements and any previous licence application. This information includes:

- geological, geotechnical, seismological, hydrological, hydrogeological and meteorological data
- site plan and description, and site reference data
- proximity of industrial, transport and military facilities

The site characterization should be developed in accordance with CSA N288.6, *Environmental risk assessments at Class I nuclear facilities and uranium mines and mills* [26]

4.5.4 Facility design

The application shall describe the overall conceptual design of the facility and the operation and interaction of all of the SSCs. To ensure that the facility will be reliable, robust and maintainable, the applicant shall ensure that the design:

- conforms to an acceptable quality assurance program
- incorporates the latest developments in knowledge and technology
- is resistant to the effects of common-cause events and, to the extent practicable, to severe accidents

The application shall identify the criteria used for determining the level of acceptable risk and demonstrates that the criteria meet general safety objectives.

The application should describe the decision-making methodology (for example, cost/benefit and best available technology) that was used to select the design option.

The application should include basic technical and schematic drawings of the main facility SSCs, including:

- details of the physical and geographical location of the facility
- means of access to the site by rail, road and water

The application should also include general layout drawings of the entire facility, accompanied by a brief description of the main systems and equipment, and their individual purposes and interactions. The application should refer to the confidential information on the adequate provisions made for the physical protection of the facility.

The applicant should provide information on the design of laboratories and Class II nuclear facilities within the facility and if included as a licensed activity under the Class I licence. The design of laboratories and Class II nuclear facilities shall meet the requirements of the *Class II Nuclear Facilities and Prescribed Equipment Regulations* and the *Nuclear Substances and Radiation Devices Regulations*, as applicable.

The applicant should provide information on the adequate provisions for storage of items such as, but not limited to, contaminated tooling and radiation sources.

For more information, refer to REGDOC-2.5.6, *Design of Room where Unsealed Nuclear Substances are Used*, [22].

4.5.5 System and component design

Commensurate with the activities being proposed in the licence application and safety importance of the system as it applies to the activities, the applicant shall provide, in detail, the characteristics and major components of the system and its design basis requirements (for example, the functional and performance requirements associated with the definition of design basis).

The application shall describe the basis for the design of the pressure-retaining SSCs and their supports. The application should also describe the pressure boundary standards and codes along with their editions and effective dates. It should also describe the overall pressure boundary program, including its implementation processes and procedures. In addition, the application should describe the service agreement with a recognized authorized inspection agency and the related pressure boundary quality assurance program.

The application shall clearly describe facility heating, ventilation and air conditioning (HVAC) systems when those systems are credited in the facility safety analysis. The description should

include areas such as control facilities, wet storage bays, the auxiliary and radioactive waste area and the ventilation systems for safety systems.

The safety significance of any HVAC system credited in the facility safety analysis should be clearly stated, including all common safety-related functionality dependencies such as the air conditioning system for an equipment room that may contain multiple divisions or groupings of support systems. Where applicable emergency ventilation may be required for personnel safety, and these areas and the associated requirements should be clearly identified and listed.

4.5.6 Waste treatment and control

The application should describe how the generation of radioactive and hazardous wastes is minimized, and how the wastes are characterized, controlled, handled, conditioned and disposed of.

The application should also describe how releases within the facility and to the environment will be monitored and controlled such that they remain within prescribed limits.

4.5.7 Control facilities

The applicant shall provide a description of the facility control facilities, including any control rooms.

The description should cover the habitability systems, equipment, supplies and procedures that are in place to ensure that essential facility workers, including those in the control rooms, can remain at their posts and operate the facility safely in all operational states considered in the safety analysis.

4.5.8 Structure design

The application shall include relevant information on the design of the site layout and on civil engineering works and structures associated with the nuclear facility. Site and facility layout information should include the buildings and structures (including the foundation) and access to all essential services required for both normal and emergency operation.

The application should describe the design principles, design basis requirements and criteria, and applicable codes and standards used in the design. The application should demonstrate that the safety margins are sufficient for the buildings and structures important to safety (for example, robustness against internal and external events). The application should clearly state and justify any deviation from applicable codes and standards or from other design requirements.

4.6 Fitness for service

The fitness for service SCA covers activities that affect the physical condition of SSCs to ensure that they remain effective over time. This area includes programs that ensure all equipment is available to perform its intended design function when called upon to do so.

This section addresses the requirements of the following regulations made under the NSCA:

- *General Nuclear Safety and Control Regulations*, paragraphs 3(1)(d), (e), (i) and (j), and 12(1)(c) and (f)

- *Class I Nuclear Facilities Regulations*, paragraphs 3(f), 5(d), (e), (f) and (m), and 6(a), (b), (c), (d), (m) and (n); and subsection 14(2)
- *Radiation Protection Regulations*, subsection 1(3); and sections 4, 13, 14 and 15

4.6.1 General considerations

The application should identify all facility-wide asset management programs that ensure fitness for service of all equipment and services are available as per its design intent and are functioning within the OLCs identified in the facility's safety analysis. The application should identify all SSCs important to safety. The applicant may use an acceptable risk assessment methodology (for example, Failure Mode and Effects Analysis or Mean Time Failure) in identifying frequency of maintenance and periodic inspection to ensure fitness for service of all equipment and SSCs.

4.6.2 Maintenance program

Maintenance activities include monitoring, inspecting, testing, assessing, calibrating, servicing, repairing and replacing parts. In general, maintenance programs should include: preventative maintenance, periodic maintenance based on inspections and corrective maintenance.

The application shall include a clearly defined maintenance program containing the proposed measures, policies, methods and procedures that provide direction for maintaining SSCs so that they remain capable of maintaining their functions, as described in design documents and safety analyses that are included in the facility licensing documentation.

The application should describe the processes for planning, monitoring, scheduling and executing work activities so that SSCs continue to perform the design intent and remain fit for service in the presence of degradation mechanisms.

The application should describe:

- preventive maintenance activities
- maintenance processes and record retention requirements
- corrective maintenance
- calibration of measuring and monitoring devices
- SSC monitoring, activity optimization
- work planning and scheduling
- work execution
- maintenance procedures
- post-maintenance verification and testing
- maintenance program assessment

4.6.3 Aging management program

The applicant shall identify end-of-life testing and a replacement plan for SSCs and major equipment (for example, calciners, flame reactors and sintering furnaces) and ensure that the equipment is performing as expected and that the equipment remains fit for service. The application should propose a plan to test for the structural integrity of major component to ensure fitness for service (ex. corrosion in pipes, wall thinning, stress cracks or fatigue). Regular monitoring, including any non-destructive testing, for common aging-related circumstances

corrosion-related should also be provided in the application. Where applicable, a replacement plan of major equipment must be provided.

4.6.4 Periodic inspection and testing programs

The application shall include periodic inspection and testing programs for SSCs relied upon for safety. Periodic inspection and testing programs require physical inspection and testing of SSCs to ensure availability and confirm that service-induced degradation has not increased the likelihood of a failure of a barrier against the release of radioactive or hazardous substances.

The application should state the codes and standards that the applicant intends to use as the basis of the design, inspection and testing programs. Regulatory acceptance of the proposed codes and standards will be considered as part of the application review process.

The application shall include a maintenance program for pressure boundary components as per a formal agreement with an authorized inspection agency. The authorized inspection agency should be recognized by the CNSC as authorized to register designs and procedures, perform inspections and other functions as defined by CSA B51, *Boiler pressure vessel and pressure piping code* [27].

Program documents should describe baseline inspection activities implemented to establish the condition of an SSC at the time it was placed into service and describe periodic inspection activities spanning the intended operating life of the facility.

4.7 Radiation Protection

The radiation protection SCA covers the implementation of a radiation protection program in accordance with the *Radiation Protection Regulations*. This program shall ensure that contamination levels and radiation doses received by individuals are monitored, controlled and maintained as low as reasonably achievable (ALARA).

This section addresses the requirements of the following regulations made under the NSCA:

- *General Nuclear Safety and Control Regulations*, paragraphs 3(1)(e) and (f), 12(1)(b), (c), (d), (e) and (f); and section 17
- *Class I Nuclear Facilities Regulations*, paragraphs 5(j) and (l), 6(d), (e), (h), (i), (k), (m) and (n), 7(e), (f), (g), (i) and (j); and section 14
- *Radiation Protection Regulations*, subsection 1(3) and sections 4-16 and 20-24

4.7.1 General considerations

The application shall describe the approaches for meeting the requirements of the *Radiation Protection Regulations*.

The application shall include a radiation protection program and should demonstrate how the design of the program is commensurate with the radiological hazards associated with the licensed activities, based on a thorough analysis of radiological hazards, radiation exposures and dose assessments, and an optimization of doses to conform to the ALARA principle.

The structure of a radiation protection program should include the policies and procedures for key elements of the radiation protection framework, including:

- application of the ALARA principle
- management control over work practices
- personnel qualification and training
- control of occupational and public exposure to radiation
- planning for unusual situations
- ascertaining the quantity and concentration of any nuclear substance released as a result of the licensed activity

The application should describe the proposed action levels, along with the supporting technical justification. Action levels are designed to alert licensees before regulatory dose limits are reached. Applicants are responsible for identifying the parameters of their program that represent timely indicators of potential losses of control of the radiation protection program, and providing rationale justifying the corresponding action levels.

REGDOC-2.7.1, *Radiation Protection* [23], provides detailed guidance for applicants and licensees on meeting regulatory expectations for radiation protection, including the development of radiation protection programs and action levels.

4.7.2 Application of ALARA

The application shall describe how the radiation protection program ensures that effective dose and equivalent dose received by and committed to persons are ALARA, taking into account social and economic factors. The application should describe the application of ALARA, in accordance with REGDOC-2.7.1, *Radiation Protection* [23].

4.7.3 Worker dose control

The application should describe how worker dose will be controlled, in accordance with the principles found in REGDOC-2.7.1, *Radiation Protection* [23]. Licensees should refer to REGDOC-2.7.2, *Dosimetry, Volume I: Ascertaining Occupational Dose* [25] for guidance on ascertaining worker dose.

4.7.4 Radiation protection program performance

The application should describe how radiation protection program performance will be evaluated, in accordance with the principles found in REGDOC-2.7.1, *Radiation Protection* [23].

4.7.5 Radiological hazard control

The application should describe how radiological hazards will be controlled, in accordance with the principles found in REGDOC-2.7.1, *Radiation Protection* [23].

4.8 Conventional health and safety

The conventional health and safety SCA covers the implementation of a program to manage workplace safety hazards and to protect workers.

This section addresses the requirements of paragraph 21(1)(a) of the NCSA and of the following regulations made under the NSCA:

- *General Nuclear Safety and Control Regulations*, subsection 12(1); section 17; and paragraphs 29(1)(d), (h), and (i)
- *Class I Nuclear Facilities Regulations*, paragraphs 3(e), (f) and (h), 4(e), 5(i), 6(e) and (h), and 7(f) and (i)

It also addresses the requirements of the *Canada Labour Code Part II* and the *Canada Occupational Health and Safety Regulations* or, where applicable, the provincial occupational health and safety legislation.

4.8.1 General considerations

The application shall describe the program and implementation of policies to minimize risk to the health and safety of workers posed by conventional (non-radiological) hazards in the workplace, including the management of workplace safety hazards and the protection of personnel and equipment.

The application shall provide information detailing compliance to all applicable requirements under the *Canada Labour Code*, including all occupational exposure limits for all chemical compounds listed under its regulations.

Where possible, the applicant shall indicate occupational exposure for acute exposure and chronic exposure.

For more information, see REGDOC-2.8.1, *Conventional Health and Safety* [28].

4.8.2 Practices

The application shall describe programs and policies in place to demonstrate compliance with *Canada Occupational health and safety Regulations*. The applicant should also list all hazardous substances used, produced, handled and stored for use in the workplace and list the recommended threshold limit values for the same as adopted by the American Conference of Government Industrial Hygienists (ACGIH). Where applicable, both short-term exposure limits and long-term exposure limits should be provided.

4.9 Environmental protection

The environmental protection SCA covers programs that identify, control and monitor all releases of radioactive and hazardous substances and effects on the environment from facilities or as the result of licensed activities.

This section addresses the requirements of the following regulations made under the NSCA:

- *General Nuclear Safety and Control Regulations*, paragraphs 3(1)(c) and (e), 12(1)(c) and (f), and 17(b), (c) and (e)
- *Class I Nuclear Facilities Regulations*, paragraphs 3(e), (g), and (h), 4(c) and (e), 5(b), (i), (j) and (k), 6(d), (h), (i), (j) and (k), and 7(f), (g), (h) and (i); and subsection 14(1)
- *Radiation Protection Regulations*, subsection 1(3) and paragraph 4(b)

These regulations include adequate provisions to ensure that licensees are meeting the CNSC's mandate to protect the environment and the health, safety and security of persons. Licensees shall demonstrate that their environmental protection measures consider the following:

- commensurate with the level of risk associated with the activity
- account for uncertainty by keeping all releases to the environment as low as reasonably achievable and apply the best available technology and techniques economically available
- implement corrective actions to eliminate the identified root causes and verify completion to prevent recurrence

4.9.1 General considerations

The application shall include a comprehensive set of environmental protection measures, including an environmental risk assessment, environmental management systems and environmental monitoring program that meet all requirements, as applicable, of REGDOC-2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures* [4]. Some supplemental information to REGDOC-2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures* [4] is set out in the following sections.

The release of hazardous substances is regulated by the CNSC and the applicable provincial authority for environmental protection. The application shall demonstrate compliance with the applicable provincial legislation.

4.9.2 Effluent and emissions control

The applicant shall propose licenced release limits and establish environmental action levels that are performance as per REGDOC-2.9.2, *Controlling Releases to the Environment* [29]. The effluent and emissions control measures in place are used to inform the development of the licenced release limits and environmental action levels for the facility or activity being licensed.

4.9.3 Environmental management system

The application shall describe the environmental management system established to ensure protection of the environment throughout operation.

4.9.4 Assessment and monitoring

The application shall describe the monitoring system established to cover all environmental monitoring activities on the site during as identified in the environmental risk assessment (ERA) licensed activities.

4.9.5 Protection of the public

The application shall identify and describe all of the radiological and non-radiological aspects of site activities that could have environmental effects, including exposure to members of the public during operation.

All applicants should submit the technical basis for calculating the dose to the public from licensed activities.

For existing facilities, the application should include the maximum effective doses to the public as a result of activities conducted at the facility during the current licence period.

This information may be submitted as part of the information addressing environmental protection.

4.9.6 Environmental risk assessment

The application shall include an ERA and review the ERA from previous submissions, if applicable, and update the information as necessary to reflect any changes to the site or the situation.

4.10 Emergency management and fire protection

The emergency management and fire protection SCA covers emergency plans and emergency preparedness programs that exist for emergencies and for non-routine conditions. This area also includes any results of participation in exercises.

Note: This SCA includes conventional emergency and fire response. Fire protection operations, design and analysis are discussed in the appropriate SCA of operating performance, safety analysis and physical design.

This section addresses the requirements of the following regulations made under the NSCA:

- *General Nuclear Safety and Control Regulations*, paragraphs 3(1)(d) and (i) [all requirements related to fire], and 12(1)(a), (b), (c), (d), (e), (f), (g) and (h)
- *Class I Nuclear Facilities Regulations*, paragraphs 3(a) and (f), 5(i) and (k), 6(h) and (k), and 7(f) and (i)
- *Radiation Protection Regulations*, section 15

4.10.1 General considerations

The application shall describe an emergency preparedness program that meets the requirements of REGDOC-2.10.1, *Nuclear Emergency Preparedness and Response* [30] and REGDOC-2.10.2, *Fire Protection* [31].

An effective emergency preparedness program is based on the following components:

- planning basis
- program management
- response plan and procedures
- preparedness

The application should describe the preparations that have been made to ensure that on-site and off-site emergencies will be dealt with safely and effectively. The application should reference population studies and emergency planning considerations related to the site.

4.10.2 Nuclear emergency preparedness and response

The application should describe how the nuclear emergency program encompasses both emergency preparedness and emergency response measures as per REGDOC-2.10.1, *Nuclear Emergency Preparedness and Response* [30].

4.10.3 Conventional emergency preparedness and response

The application shall describe all non-radiological, non-routine conditions at the facility for which the emergency preparedness program has been established. The description shall include details about which adequate provisions exist on-site and which provisions involve off-site response support. The application shall include information that determines the need for an emergency response facility, on or near the site, from which the on-site response to an emergency can be coordinated.

4.10.4 Fire emergency preparedness and response

The applicant shall describe a comprehensive fire protection program that ensures the licensed activities do not result in unreasonable risk to the health and safety of persons and the environment due to fire. The application shall include information on arrangements with first responders, provisions for mutual support or aid, and interagency communication requirements. If a memorandum of understanding is established with the first responders' agency, the same shall be provided as part of the application.

4.11 Waste management

The waste management SCA covers internal waste-related programs that form part of the facility's operations up to the point where the waste is removed from the facility to a separate waste management facility. This area also covers the planning for decommissioning.

This section addresses the requirements of the following regulations made under the NSCA:

- *General Nuclear Safety and Control Regulations*, paragraphs 3(1)(c) and (j), and 12(1)(c)
- *Class I Nuclear Facilities Regulations*, paragraphs 3(e), (f) and (k), 4(e), 5(i), (j) and (k), 6(e), (h), (i) and (j); section 7; and subsection 14(2)
- *Radiation Protection Regulations*, subsection 1(3); and sections 4, 13, 14, 15, 20, 21, 22 and 23

4.11.1 General considerations

The application should demonstrate compliance with the six principles of radioactive waste management set out in REGDOC-2.11, *Framework for Radioactive Waste Management and Decommissioning in Canada* [32].

The application should contain a waste management program that meets the requirements of REGDOC-2.11.1, *Waste Management, Volume I: Management of Radioactive Waste* [33].

The application should demonstrate that the licensee will implement and maintain associated programs and procedures to support the waste management program (e.g. waste characterization). These programs and procedures should be commensurate with the risk of the waste streams being managed.

4.11.2 Waste characterization

The application shall demonstrate that waste characterization will be performed at appropriate intervals during the management of radioactive waste. The application should meet the requirements of REGDOC-2.11.1, *Waste Management, Volume I: Management of Radioactive Waste* [33].

4.11.3 Waste minimization

The application shall demonstrate how the waste hierarchy will be considered in the management of radioactive waste.

4.11.4 Waste management practices

The application shall demonstrate that the licensee will:

- be responsible for the safe management of its radioactive waste, taking into consideration the health and safety of persons, the environment and national security
- optimize the steps in radioactive waste management and practices to ensure the protection of the health and safety of people and the environment
- take into account interdependencies among all steps in radioactive waste management, as appropriate; each step shall be evaluated as an individual step in the process and as part of an integrated radioactive waste management system

The application should contain the waste classification plan and the waste acceptance criteria, if applicable, that meet the requirements of REGDOC-2.11.1, *Waste Management, Volume I: Management of Radioactive Waste* [33].

4.11.5 Decommissioning plans

The application shall contain the proposed plan for the decommissioning of the nuclear facility or of the site. Planning for decommissioning is an ongoing process that is considered at each lifecycle stage of the facility. Requirements and guidance on decommissioning are provided in REGDOC-2.11.2, *Decommissioning* [34].

A Preliminary Decommissioning Plan (PDP) is required for the siting, construction (including the design) and operation lifecycle stages of the facility. The PDP shall document:

- the selected decommissioning strategy
- main decontamination, dismantling and/or clean-up activities
- end-state objectives
- an overview of the principal hazards and protection strategies
- a waste management strategy
- a cost estimate
- financial guarantee arrangements

A Detailed Decommissioning Plan (DDP) shall be developed for the decommissioning lifecycle stage. The DDP shall document:

- the decommissioning strategy
- decontamination, dismantling and/or clean-up activities

- final end-state objectives
- the principle hazards and protection plans
- a waste management plan; a cost-estimate
- financial guarantee arrangements

A safety assessment shall be developed for the decommissioning lifecycle stage to identify any radiological or non-radiological hazards to workers, the environment and the public from both routine decommissioning activities and credible potential accidents during decommissioning. The safety assessment may be a stand-alone document or may be included in the detailed decommissioning plan.

4.12 Security

The security SCA covers the programs required to implement and support the security requirements stipulated in the regulations, the licence, orders, or expectations for the facility or activity.

This section addresses the requirements of the following regulations made under the NSCA:

- *General Nuclear Safety and Control Regulations*, paragraph 3(1)(d), (e), (g), (h) and (i), 12(1)(c), (g), (h) and (j), 17(c) and (e); sections 21, 22, and 23; subsection 28(1); and sections 29 and 30
- *Class I Nuclear Facilities Regulations*, paragraphs 3(a), (b) and (i), 5(h), (i), 6(h), (k) and (l) and 7(f)
- *Nuclear Security Regulations*
- *Nuclear Substances and Radiation Devices Regulations*, paragraphs 36(1)(a) and (d)

4.12.1 General considerations

An applicant who intends on processing, using or storing Category I or II nuclear material should consult with CNSC staff to identify additional relevant requirements for the site prior to submitting an application. Applications involving this material will be subject to Part 1 of the *Nuclear Security Regulations* and its associated prescribed regulatory documents. Additional relevant requirements include implementing a nuclear response force and addressing the Design Basis Threat document for example. For all other facilities, Part 2 of the *Nuclear Security Regulations* apply.

Note: Any information that is considered classified, protected, proprietary or personal, or that is designated as prescribed information should be clearly identified and submitted in accordance with the CNSC's *Guidance Document on Confidential Filings* [35].

For facilities requesting a licence in respect of Category III Nuclear Material, an application for licence (other than a licence to transport) shall contain the information required by section 3 of the *Nuclear Substances and Radiation Devices Regulations*. Further, it shall include a description of the measures to be taken to ensure compliance with subsection 7(3) and sections 7.1 and 7.2 of the *Nuclear Security Regulations*.

The application shall describe the general design approach and adequate provisions in place to control access and security at the facility.

For facilities with nuclear substances meeting or exceeding the thresholds of Category 3 or higher as identified in REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material* [5], the licensee shall submit a site security plan. This site security plan shall provide detail on how the licensee has met the requirements defined in that REGDOC, including the technical and administrative measures incorporated by the licensee.

The application should describe a security program that meets the requirements of REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material* [5].

4.12.2 Response arrangements

For licensees subject to Part 2 of the *Nuclear Security Regulations*, the application shall describe how the security program ensures that off-site response arrangements effectively respond to the unauthorized removal of nuclear or radioactive material. The application should provide details regarding the licensee's arrangements for annual familiarization visits to the nuclear facility by members of the off-site response force. These arrangements should provide detail on the joint development of a contingency plan by the licensee and the off-site response force to facilitate the off-site response force's effective intervention.

For licensees that process, use, store or transfer nuclear substances that meet or exceed the threshold of Category 3 nuclear substances, the application should include details regarding the notification of a local law enforcement agency as required in REGDOC-2.12.3, *Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material* [5].

4.12.3 Security practices

The application shall describe the measures in the security program that ensure administrative and technical measures are implemented, maintained and documented in a security program.

The applicant shall describe how access to prescribed assets is limited to those workers having the appropriate security clearance, facility site access clearance, or trustworthiness and reliability verification. Further, the application should identify a process to determine how a valid need-to-know basis will be utilized to determine access to prescribed assets as applicable to the site.

4.12.4 Security training and qualification

The application shall include adequate provisions indicating all persons with authorized access to sealed sources or prescribed information at the licensee's location are made aware of the facility's security policies, protocols and practices. These provisions shall identify how the security awareness program is documented and how it will be annually reviewed. The application shall also include details on the development of an assured process for ensuring new employees participate in security awareness training, and refresher training is conducted on a regular basis (every three years or less) for existing employees.

The application shall describe the duties of any security officers employed or contracted on-site. The applicant should demonstrate that the security officers are adequately equipped to perform their assigned duties and tasks.

This shall include the proposed measures for written procedures and instructions specific to:

- measures for controlling access to the licensed area
- surveillance foot and vehicle patrols
- assessment and response to alarms
- apprehension and detainment of unarmed intruders
- reporting of suspicious activities, including armed intruders, to the local law enforcement agency
- security equipment operation
- security training relating to assigned duties

For licensees subject to Part 2 of the *Nuclear Security Regulations*, the applicant shall describe their supervisory awareness program identifying that supervisors are trained to recognize behavioural changes in all personnel, including contractors, that could pose a risk to security at a facility at which it carries on licensed activities.

4.12.5 Cyber security

The application should describe a cyber security program. The application should address internal and external cyber threats.

The application should describe how the cyber security program is designed, implemented and maintained as an effective program. The application should provide information on the following program elements, including:

- defensive strategy and security architecture
- policies and procedures
- asset identification and classification
- roles and responsibilities of the involved parties
- security controls
- awareness and training
- configuration management
- coordination with other programs
- incident response, reporting and recovery plan
- program review and maintenance
- lifecycle approach to cyber assets

4.13 Safeguards and non-proliferation

The safeguards and non-proliferation SCA covers the programs and activities required for the successful implementation of the obligations arising from the Canada/International Atomic Energy Agency (IAEA) safeguards agreements as well as other measures arising from the *Treaty on the Non-Proliferation of Nuclear Weapons* (IAEA INFCIRC/140) [36].

This section addresses the requirements of the following regulations made under the NSCA:

- *General Nuclear Safety and Control Regulations*, subsection 3(2), paragraphs 3(1)(g) and (h), 10(b) and 12(1)(i), 20(d), and 21(1)(a) and (b); and subsection 23(2)
- *Class I Nuclear Facilities Regulations*, paragraphs 5(h), 6(f) and 7(d)
- *Nuclear Non-Proliferation Import and Export Control Regulations*

It also addresses the requirements of the following safeguard agreements:

- IAEA INFCIRC/164, *Agreement between Government of Canada and IAEA for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons* [37]
- IAEA INFCIRC/164/Add.1, *Protocol Additional to the Agreement between Canada and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons* [38]

4.13.1 General considerations

Note: Either before or concurrent with applying for a licence to construct a Class IB processing facility, the applicant shall complete and submit to the CNSC the IAEA safeguards design information questionnaire (available upon request from the CNSC International Safeguards Division). The CNSC encourages applicants to submit the completed questionnaire early, particularly for novel technologies where safeguards measures have not yet been developed. For more information, see REGDOC 2.13.1, *Safeguards and Nuclear Material Accountancy* [39].

The application shall describe how the arrangements address the requirements in REGDOC-2.13.2, *Import and Export* [40] and REGDOC-2.13.1, *Safeguards and Nuclear Material Accountancy* [39].

The application should describe measures related to site buildings and structures, operational parameters and the flow and storage of nuclear material, from the facility's design and commissioning phases through to its decommissioning and eventual abandonment.

For processing facilities, the non-proliferation program is limited to the tracking and reporting of foreign obligations and origins of nuclear material.

For the purposes of the application and its review, document ownership will vary between the IAEA, the CNSC and the applicant:

- the IAEA is responsible for the generic safeguards approach
- the CNSC is responsible for:
 - coordinating with the IAEA in developing the generic safeguards approach
 - negotiating the safeguards arrangements with the IAEA for the applicant facility
 - monitoring the applicant's compliance with safeguards documents, requirements and obligations
- the applicant is responsible for establishing and implementing the safeguards program

Where applicable, the export of nuclear material covered under the non-proliferation regs (spell out), an separate import/export licence must be obtained for the specific circumstances and destination.

4.13.2 Nuclear accountancy and control

The application should describe how the program ensures the collection, storage and reporting of information to the CNSC and IAEA. The application should describe measures to ensure that:

- nuclear materials are tracked
- reports are submitted to the CNSC on:

- the inventory and transfer of nuclear material
- the application of IAEA safeguards

The application should describe adequate provisions for timely submission of accurate reports and information on nuclear material. Further information is available in REGDOC-2.13.1, *Safeguards and Nuclear Material Accountancy* [39].

4.13.3 Access and assistance to the IAEA

The application should describe how the program ensures that the IAEA is able, upon request, to access the facility for inspections and other verification activities. Additionally, the application should describe how the program ensures that such activities are supported by facility workers and resources.

The application should describe how the effectiveness of safeguards procedures, and assistance to the IAEA for site access and inspections, are reviewed.

4.13.4 Operational and design information

The application should describe:

- the processes that collect, store and report relevant operational information to the CNSC and the IAEA
- how the program ensures that the facility's design information questionnaire is complete and accurate
- how the program ensures that updates provided under the *Additional Protocol* are reported to the CNSC

The application should also describe methods of development and implementation of an appropriate safeguards approach based on the facility's specific designs.

The application should describe how the program engages both the CNSC and the IAEA to ensure a suitable safeguards approach is taken for its purpose.

The application should describe adequate provisions for the submission of:

- annual operational information
- accurate design information of facility structures
- processes and procedures

4.13.5 Safeguards equipment, containment and surveillance

The applicant should demonstrate that adequate resources (for example, power and lighting) are provided to IAEA equipment and that measures are in place for the protection of IAEA equipment and seals.

4.14 Packaging and transport

The packaging and transport SCA covers programs for the safe packaging and transport of nuclear substances to and from the licensed facility.

This section addresses the requirements of the following regulations made under the NSCA:

- *General Nuclear Safety and Control Regulations*, paragraphs 3(1)(e) and 20(a)
- *Class I Nuclear Facilities Regulations*, paragraphs 5(i), 6(e) and (h) and 7(f)
- *Packaging and Transport of Nuclear Substances Regulations, 2015*

It also addresses the requirements of the *Transportation of Dangerous Goods Regulations*.

4.14.1 Package design and maintenance

The application shall describe how the program ensures that all shipping packages are designed and maintained for the protection and containment of the quantities transported, as per the *Packaging and Transport of Nuclear Substances Regulations, 2015*, where applicable.

The application shall describe elements such as package certification, package testing, inspection and maintenance.

4.14.2 Packaging and transport program

The applicant shall describe the measures in place to ensure compliance with all requirements of the *Packaging and Transport of Nuclear Substances Regulations, 2015* and the *Transportation of Dangerous Goods Regulations*.

The application shall describe the measures to ensure that appropriate training is provided for workers involved in the handling, preparation for transport, and transport of dangerous goods, and that training certificates are issued to workers.

4.14.3 Registration for use

The application shall describe the measures in place to ensure that certified packages are registered for use prior to transport.

5. Other Regulatory Areas

This section addresses the requirements of the following regulations made under the NSCA:

- *General Nuclear Safety and Control Regulations*, paragraphs 3(1)(l) and (m), and sections 29 to 32
- *Class I Nuclear Facilities Regulations*, paragraphs 3(j) and (k)
- *Canadian Nuclear Safety Commission Cost Recovery Fees Regulations*

5.1 Public information and disclosure program

The applicant shall describe how their proposed public information and disclosure program (required for all licensees) meets the requirements in REGDOC-3.2.1, *Public Information Disclosure* [41].

The description shall include how and with what tools the licensee will communicate with the public, particularly with those persons living in the vicinity of the site, and the general nature and

characteristics of the anticipated effects on the environment and the health and safety of persons that may result from the operation of the facility.

For new facilities, the applicant should demonstrate that ongoing engagement with appropriate parties has been continued from construction activities and integrated into operational activities.

5.2 Indigenous engagement

The CNSC, as an agent of the Crown, has the responsibility for fulfilling Canada's legal duty to consult and, where appropriate, to accommodate Indigenous peoples when the CNSC's decisions may have had adverse effect on potential or established Indigenous or treaty rights. The CNSC is committed to meaningful ongoing engagement and consultation with Indigenous groups who have an interest in facilities and activities regulated by the CNSC.

REGDOC-3.2.2, *Indigenous Engagement* [42] provides guidance for licensees whose proposed projects may raise the Crown's duty to consult. While the CNSC cannot delegate its obligation, it can delegate procedural aspects of the consultation process to licensees, where appropriate. To meet CNSC obligations for consultation, the CNSC may use the information collected and measures proposed by licensees regarding avoiding, mitigating or offsetting adverse effects.

5.3 Cost recovery and financial guarantees

Each facility licensee in Canada has the primary responsibility for ensuring the safety of its facility, including providing adequate financial resources to support the safety of each facility throughout its life.

5.3.1 Cost recovery

An operating licence for a processing facility is subject to the requirements of Part 2 of the *Canadian Nuclear Safety Commission Cost Recovery Fees Regulations*. Any application shall be accompanied by the prescribed fee, as per the NSCA subsection 24(2). Applicants are responsible for payment of the annual fees determined by CNSC. Payments are normally requested on a quarterly basis and are due to the Receiver General of Canada.

The applicant should discuss the details of the amount and payment plan with the CNSC.

For additional information, refer to the *Canadian Nuclear Safety Commission Cost Recovery Fees Regulations*.

5.3.2 Financial guarantees

The application shall describe the financial guarantees for the costs of decommissioning the facility according to the NSCA and the *General Nuclear Safety and Control Regulations*. The applicant should also provide a cross-reference to the supporting document regarding the value and form of the financial guarantee.

For more information about financial guarantees and licensing, consult REGDOC-3.3.1, *Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities* [43].

Appendix A: Legislative Clauses

The information submitted by an applicant for a licence to prepare a site, construct, operate and/or decommission a Class IB processing facility is based on the relevant clauses from legislation, including the *Nuclear Safety and Control Act* (NSCA) and the regulations made under the NSCA. Table A.1 lists select relevant sections; however, applicants are responsible for ensuring that all requirements under the NSCA and regulations for the proposed activities are addressed in an application.

Table A.1: Clauses in the NSCA and the regulations made under the NSCA, mapped to the relevant sections of this licence application guide

Legislation	Clause(s)	Section(s) in this document	Licenced Activity
NSCA	24(4)	Every SCA (sections 4.1 through 4.14) 5, Other Matters of Regulatory Interest	All
	26(a), (e)	Every SCA (sections 4.1 through 4.14) 5, Other Matters of Regulatory Interest	All
<i>General Nuclear Safety and Control Regulations</i> (GNSCR)	3(1)(a)	3.1.2, Applicant's name and business address	All
	3(1)(b)	3.2.2, Statement of the main purpose	All
	3(1)(c)	3.2.5, Nuclear substances 4.9, Environmental protection 4.11, Waste management	All
	3(1)(d)	3.2.2, Statement of the main purpose 4.4, Safety analysis 4.5, Physical design 4.6, Fitness for service 4.10, Emergency management and fire protection 4.11, Waste management 4.12, Security	All
	3(1)(e)	4.4, Safety analysis 4.5, Physical design 4.6, Fitness for service 4.7, Radiation protection 4.9, Environmental protection 4.11, Waste management 4.12, Security 4.14, Packaging and transport	All
	3(1)(f)	4.7, Radiation protection	All
	3(1)(g)	4.5, Physical design 4.12, Security 4.13, Safeguards and non-proliferation	All
	3(1)(h)	4.5, Physical design 4.12, Security 4.13, Safeguards and non-proliferation	All

Legislation	Clause(s)	Section(s) in this document	Licensed Activity
	3(1)(i)	4.4, Safety analysis 4.5, Physical design 4.6, Fitness for service 4.7, Radiation protection 4.9, Environmental protection 4.10, Emergency management and fire protection (all requirements related to fire) 4.11, Waste management 4.12, Security	All
	3(1)(j)	4.5, Physical design 4.6, Fitness for service 4.11, Waste management	All
	3(1)(k)	3.1.7, Identification of persons responsible for management and control of the licensed activity 4.1, Management system 4.2, Human performance 4.3, Operating performance	All
	3(1)(l)	5, Other matters of regulatory interest	All
	3(1)(m)	5, Other matters of regulatory interest	All
	3(2)	4.13, Safeguards and non-proliferation	All
	10(b)	4.13, Safeguards and non-proliferation	All
	12(1)(a)	4.1, Management system 4.2, Human performance management 4.7, Radiation protection 4.10, Emergency management and fire protection	All
	12(1)(b)	4.2, Human performance management 4.7, Radiation protection 4.10, Emergency management and fire protection	All
	12(1)(c)	4.3, Operating performance 4.4, Safety analysis 4.5, Physical design 4.6, Fitness for service 4.7, Radiation protection 4.8, Conventional health and safety 4.9, Environmental protection 4.10, Emergency management and fire protection 4.11, Waste management 4.12, Security	All
	12(1)(d)	4.7, Radiation protection 4.10, Emergency management and fire protection	All

Legislation	Clause(s)	Section(s) in this document	Licensed Activity
	12(1)(e)	4.2, Human performance management 4.3, Operating performance 4.7, Radiation protection 4.10, Emergency management and fire protection	All
	12(1)(f)	4.3, Operating performance 4.4, Safety analysis 4.5, Physical design 4.6, Fitness for service 4.7, Radiation protection 4.9, Environmental protection 4.10, Emergency management and fire protection	All
	12(1)(g)	4.10, Emergency management and fire protection 4.12, Security	All
	12(1)(h)	4.10, Emergency management and fire protection 4.12, Security	All
	12(1)(i)	4.13, Safeguards and non-proliferation	All
	12(1)(j)	4.2, Human performance management 4.12, Security	All
	15	3.1.7, Identification of persons responsible for management and control of the licensed activity 4.1, Management system	All
	15(a)	3.1.4, All persons who have authority to interact for the applicant with the CNSC 3.1.9, Legal signing authority	All
	15(b)	3.1.4, All persons who have authority to interact for the applicant with the CNSC 3.1.7, Identification of persons responsible for management and control of the licensed activity	All
	17(a)	4.2, Human performance management 4.3, Operating performance 4.7, Radiation protection 4.8, Conventional health and safety 4.9, Environmental protection	All
	17(b)	4.2, Human performance management 4.3, Operating performance 4.7, Radiation protection 4.8, Conventional health and safety 4.9, Environmental protection	All

Legislation	Clause(s)	Section(s) in this document	Licensed Activity
	17(c)	4.1, Management system 4.2, Human performance management 4.3, Operating performance 4.7, Radiation protection 4.8, Conventional health and safety 4.9, Environmental protection 4.12, Security	All
	17(d)	4.2, Human performance management 4.3, Operating performance 4.7, Radiation protection 4.8, Conventional health and safety	All
	17(e)	4.1, Management system 4.2, Human performance management 4.3, Operating performance 4.7, Radiation protection 4.8, Conventional health and safety 4.9, Environmental protection 4.12, Security	All
	20(a)	4.14, Packaging and transport	All
	20(d)	4.13, Safeguards and non-proliferation	All
	21	4.12, Security	All
	21(1)(a)	4.13, Safeguards and non-proliferation	All
	21(1)(b)	4.13, Safeguards and non-proliferation	All
	22	4.12, Security	All
	23	4.12, Security	All
	23(2)	4.13, Safeguards and non-proliferation	All
	27	[...keep a copy of all info relating to the licence that is submitted by the licensee to the Commission... see section 3] 4.1, Management system	All
	28	4.1, Management system	All
	28(1)	4.12, Security	All
	29	4.3, Operational performance 4.7, Radiation protection 4.12, Security 5.1, Reporting requirements	All
	30	4.3, Operating performance 4.12, Security 5.1, Reporting requirements	All
	31	4.3, Operating performance 5.1, Reporting requirements	All
	32	4.3, Operating performance 5.1, Reporting requirements	All

Legislation	Clause(s)	Section(s) in this document	Licensed Activity
<i>Canadian Nuclear Safety Commission Cost Recovery Fees Regulations</i>	all	5.4, Cost recovery, financial guarantees and insurance	All
<i>Class I Nuclear Facilities Regulations</i>	3(a)	3.2.3, Description of site 4.5, Physical design 4.10, Emergency management and fire protection 4.12, Security	All
	3(b)	3.2.3, Description of site 4.4, Safety analysis 4.5, Physical design 4.12, Security	All
	3(c)	3.1.6, Evidence that the applicant is the owner of the site...	All
	3(d)	4.1, Management system 4.4, Safety analysis 4.5, Physical design	All
	3(e)	3.2.5, Nuclear and hazardous substances 4.8, Conventional health and safety 4.9, Environmental protection 4.11, Waste management	All
	3(f)	4.1, Management system 4.2, Human performance management 4.6, Fitness for service 4.8, Conventional health and safety 4.10, Emergency management and fire protection 4.11, Waste management	All
	3(g)	4.9, Environmental protection	All
	3(h)	4.8, Conventional health and safety 4.9, Environmental protection	All
	3(i)	4.5, Physical design 4.12, Security	All
	3(j)	5, Other matters of regulatory interest	All
	3(k)	4.11, Waste management	All
	4(a)	4.3, Operating performance 4.5, Physical design	To prepare site
	4(b)	4.5, Physical design	To prepare site

Legislation	Clause(s)	Section(s) in this document	Licensed Activity
	4(c)	4.5, Physical design 4.9, Environmental protection	To prepare site
	4(d)	4.1, Management system 4.5, Physical design	To prepare site
	4(e)	4.8, Conventional health and safety 4.9, Environmental protection	To prepare site
	5(a)	4.5, Physical design	To construct
	5(b)	4.5, Physical design 4.9, Environmental protection	To construct
	5(c)	4.1, Management system 4.3, Operating performance	To construct
	5(d)	4.5, Physical design 4.6, Fitness for service	To construct
	5(e)	4.5, Physical design 4.6, Fitness for service	To construct
	5(f)	4.4, Safety analysis 4.6, Fitness for service	To construct
	5(g)	4.1, Management system	To construct
	5(h)	4.12, Security 4.13, Safeguards and non-proliferation	To construct
	5(i)	4.1, Management system 4.2, Human performance management 4.3, Operating performance 4.4, Safety analysis 4.7, Radiation protection 4.8, Conventional health and safety 4.9, Environmental protection 4.10, Emergency management and fire protection 4.11, Waste management 4.12, Security 4.14, Packaging and transport	To construct
	5(j)	4.4, Safety analysis 4.5, Physical design 4.7, Radiation protection 4.9, Environmental protection 4.11, Waste management	To construct
	5(k)	4.4, Safety analysis 4.7, Radiation protection 4.9, Environmental protection 4.10, Emergency management and fire protection 4.11, Waste management	To construct

Legislation	Clause(s)	Section(s) in this document	Licensed Activity
	5(l)	4.1, Management system 4.2, Human performance management 4.3, Operating performance 4.7, Radiation protection	To construct
	5(m)	4.2, Human performance management 4.3, Operating performance 4.6, Fitness for service 4.7, Radiation protection	To construct
	6(a)	4.4, Safety analysis 4.5, Physical design 4.6, Fitness for service	To operate
	6(b)	4.4, Safety analysis 4.5, Physical design 4.6, Fitness for service	To operate
	6(c)	4.4, Safety analysis	To operate
	6(d)	4.1, Management system 4.3, Operating performance 4.6, Fitness for service	To operate
	6(e)	4.1, Management system 4.3, Operating performance 4.7, Radiation protection 4.8, Conventional health and safety 4.11, Waste management 4.14, Packaging and transport	To operate
	6(f)	4.13, Safeguards and non-proliferation	To operate
	6(g)	4.1, Management system 4.3, Operating performance 4.5, Physical design	To operate
	6(h)	4.1, Management system 4.2, Human performance 4.3, Operating performance 4.4, Safety analysis 4.5, Physical design 4.7, Radiation protection 4.8, Conventional health and safety 4.9, Environmental protection 4.10, Emergency management and fire protection 4.11, Waste management 4.12, Security 4.14, Packaging and transport	To operate

Legislation	Clause(s)	Section(s) in this document	Licensed Activity
	6(i)	4.4, Safety analysis 4.5, Physical design 4.7, Radiation protection 4.9, Environmental protection 4.11, Waste management	To operate
	6(j)	4.4, Safety analysis 4.5, Physical design 4.9, Environmental protection 4.11, Waste management	To operate
	6(k)	4.1, Management system 4.2, Human performance management 4.3, Operating performance 4.4, Safety analysis 4.5, Physical design 4.7, Radiation protection 4.9, Environmental protection 4.10, Emergency management and fire protection 4.12, Security	To operate
	6(l)	4.1, Management system 4.2, Human performance management 4.12, Security	To operate
	6(m)	4.1, Management system 4.2, Human performance management 4.5, Physical design 4.6, Fitness for service 4.7, Radiation protection	To operate
	6(n)	4.1, Management system 4.2, Human performance management 4.5, Physical design 4.6, Fitness for service 4.7, Radiation protection	To operate
	7(a)	4.3, Operating performance 4.11, Waste management	To decommission
	7(b)	4.11, Waste management	To decommission
	7(c)	4.1, Management system 4.3, Operating performance 4.11, Waste management	To decommission
	7(d)	4.13, Safeguards and non-proliferation	To decommission
	7(e)	4.7, Radiation protection 4.11, Waste management	To decommission

Legislation	Clause(s)	Section(s) in this document	Licensed Activity
	7(f)	4.1, Management system 4.2, Human performance 4.3, Operating performance 4.4, Safety analysis 4.5, Physical design 4.7, Radiation protection 4.8, Conventional health and safety 4.9, Environmental protection 4.10, Emergency management and fire protection 4.11, Waste management 4.12, Security 4.14, Packaging and transport	To decommission
	7(g)	4.4, Safety analysis 4.5, Physical design 4.7, Radiation protection 4.9, Environmental protection 4.11, Waste management	To decommission
	7(h)	4.5, Physical design 4.9, Environmental protection 4.11, Waste management	To decommission
	7(i)	4.1, Management system 4.2, Human performance management 4.3, Operating performance 4.5, Physical design 4.7, Radiation protection 4.8, Conventional health and safety 4.9, Environmental protection 4.10, Emergency management and fire protection	To decommission
	7(j)	4.1, Management system 4.2, Human performance management 4.7, Radiation protection	To decommission
	7(k)	4.11, Waste management	To decommission
	14(1)	4.1, Management system 4.9, Environmental protection 4.11, Waste management	All

Legislation	Clause(s)	Section(s) in this document	Licensed Activity
	14(2)	4.1, Management system 4.2, Human performance management 4.3, Operating performance 4.5, Physical design 4.6, Fitness for service 4.7, Radiation protection 4.9, Environmental protection 4.11, Waste management	To operate
	14(3)	4.1, Management system 4.2, Human performance management 4.3, Operating performance 4.7, Radiation protection 4.11, Waste management	To decommission
	14(4)	4.1, Management system	To operate To decommission
	14(5)	4.1, Management system 4.2, Human performance management	To operate To decommission
<i>Nuclear Non-proliferation Import and Export Control Regulations</i>	all	4.13, Safeguards and non-proliferation	To construct To operate To decommission
<i>Nuclear Security Regulations</i>	all	4.5, Physical design 4.12, Security	All
	3(b)	3.2.3, Description of site	All
	16	3.2.3, Description of site	All
	37(1), (2) and (3)	4.1, Management system	All
	38	4.1, Management system 4.2, Human performance management	All
<i>Nuclear Substances and Radiation Devices Regulations</i>	5	4.7, Radiation protection	All
	8	4.7, Radiation protection	All
	20	4.7, Radiation protection	All
	23	4.7, Radiation protection	All
	36(1)(a)	4.1, Management system 4.12, Security	All
	36(1)(b)	4.1, Management system	All
	36(1)(c)	4.1, Management system	All
	36(1)(d)	4.1, Management system 4.12, Security	All
	36(1)(e)	4.1, Management system	All

Legislation	Clause(s)	Section(s) in this document	Licensed Activity
<i>Packaging and Transport of Nuclear Substances Regulations, 2015</i>	all	4.14, Packaging and transport	All
<i>Radiation Protection Regulations</i>	1(3)	4.3, Operating performance 4.4, Safety analysis 4.5, Physical design 4.6, Fitness for service 4.7, Radiation protection 4.9, Environmental protection 4.11, Waste management	All
	4	4.4, Safety analysis 4.6, Fitness for service 4.7, Radiation protection 4.9, Environmental protection 4.11, Waste management	All
	5-12	4.7, Radiation protection	All
	13	4.3, Operating performance 4.4, Safety analysis 4.6, Fitness for service 4.7, Radiation protection 4.11, Waste management	All
	14	4.3, Operating performance 4.4, Safety analysis 4.6, Fitness for service 4.7, Radiation protection 4.11, Waste management	All
	15	4.3, Operating performance 4.4, Safety analysis 4.6, Fitness for service 4.7, Radiation protection 4.11, Waste management	All
	16	4.7, Radiation protection	All
	20	4.7, Radiation protection 4.11, Waste management	All
	21-23	4.7, Radiation protection 4.11, Waste management	All

Appendix B: Safety and Control Areas

The CNSC's regulatory requirements and expectations for the safety performance of programs are grouped into three functional areas and 14 safety and control areas (SCAs). The SCAs are further divided into specific areas that define the key components of each SCA. Table A shows a list of the functional areas, SCAs and the specific areas that define the key components of each SCA.

Table A: The CNSC's functional areas, safety and control areas, and specific areas

Functional area	Safety and control area (SCA)	Specific area
Management	1. Management system	Management system
		Organization
		Performance assessment, improvements and management review
		Operating experience (OPEX)
		Change management
		Safety culture
		Configuration management
		Records management
		Management of contractors
	Business continuity	
	2. Human performance management	Human performance program
		Personnel training
		Personnel certification
		Initial certification examinations and requalification tests
Work organization and job design		
3. Operating performance	Fitness for duty	
	Conduct of licensed activities	
	Procedures	
	Reporting and trending	
	Outage management performance	

Functional area	Safety and control area (SCA)	Specific area
		Safe operating envelope
		Severe accident management and recovery
		Accident management and recovery
Facility and equipment	4. Safety analysis	Deterministic safety analysis
		Hazard analysis
		Probabilistic safety assessment
		Criticality safety
		Severe accident analysis
		Management of safety issues (including R&D programs)
	5. Physical design	Design governance
		Site characterizations
		Facility design
		Structure design
		System design
		Components design
	6. Fitness for service	Equipment fitness for service / equipment performance
		Maintenance
		Structural integrity
		Aging management
		Chemistry control
		Periodic inspections and testing
Core control processes	7. Radiation protection	Application of ALARA
		Worker dose control
		Radiation protection program performance
		Radiological hazard control

Functional area	Safety and control area (SCA)	Specific area
	8. Conventional health and safety	Performance
		Practice
		Awareness
	9. Environmental protection	Effluent and emissions control (releases)
		Environmental management system (EMS)
		Assessment and monitoring
		Protection of the public
		Environmental risk assessment
	10. Emergency management and fire protection	Conventional emergency preparedness and response
		Nuclear emergency preparedness and response
		Fire emergency preparedness and response
	11. Waste management	Waste characterization
		Waste minimization
		Waste management practices
		Decommissioning plans
	12. Security	Facilities and equipment
		Response arrangements
		Security practices
		Drills and exercises
		Cyber Security
	13. Safeguards and non-proliferation	Nuclear material accountancy and control
		Access and assistance to the IAEA
		Operational and design information
		Safeguards equipment, containment and surveillance
		Import and export

Functional area	Safety and control area (SCA)	Specific area
	14. Packaging and transport	Package design and maintenance
		Packaging and transport
		Registration for use

Appendix C: Regulatory Documents and Industry Standards

C.1 Regulatory documents and industry standards to be applied as requirements for all applicants

Licensees are required to meet these requirements, codes and standards. The application shall include a description of how these documents and standards will be met.

Document source	Document number	Document title	Related SCAs
CNSC	REGDOC-2.1.2	<u>Safety Culture</u>	1
CNSC	REGDOC-2.2.2	<u>Personnel Training</u>	2, 10
CNSC	REGDOC-2.2.4	<u>Fitness for Duty, Volume III: Nuclear Security Officer Medical, Physical and Psychological Fitness</u>	2, 12
CNSC	REGDOC-2.3.2	<u>Accident Management</u>	3, 10
CNSC	REGDOC-2.4.4	<u>Safety Analysis for Class IB Nuclear Facilities</u>	3, 4
CNSC	REGDOC-2.7.1	<u>Radiation Protection</u>	7
CNSC	REGDOC-2.9.1	<u>Environmental Protection: Environmental Policy, Assessments and Protection Measures</u>	3, 9
CNSC	REGDOC-2.10.1	<u>Nuclear Emergency Preparedness and Response</u>	10
CNSC	REGDOC-2.11.1	<u>Waste Management, Volume I: Management of Radioactive Waste</u>	11
CNSC	REGDOC-2.11.2	<u>Decommissioning</u>	11
CNSC	REGDOC-2.13.1	<u>Safeguards and Nuclear Material Accountancy</u>	3, 13
CNSC	REGDOC-3.2.1	<u>Public Information and Disclosure</u>	N/A
CSA Group	N286	<i>Management system requirements for nuclear facilities</i>	1, 3
CSA Group	N288.1	<i>Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities</i>	3, 9
CSA Group	N288.4	<i>Environmental monitoring programs at Class I nuclear facilities and uranium mines and mills</i>	3, 9

Document source	Document number	Document title	Related SCAs
CSA Group	N288.5	<i>Effluent monitoring programs at Class I nuclear facilities and uranium mines and mills</i>	3, 9
CSA Group	N288.6	<i>Environmental risk assessments at Class I nuclear facilities and uranium mines and mills</i>	3, 9
CSA Group	N292.3	<i>Management of low- and intermediate-level radioactive waste</i>	3, 11
CSA Group	N393	<i>Fire protection for facilities that process, handle or store nuclear substances</i>	5, 6, 10
CSA Group	N294	<i>Decommissioning of facilities containing nuclear substances</i>	3, 11
CSA Group	B51	<i>Boiler, Pressure Vessel, and Pressure Piping Code</i>	3, 5, 6

C.2 Regulatory documents and industry standards to be applied as requirements for new facilities and addressed as guidance for existing facilities

In addition to the documents listed in Table C.1, applicants for new facilities are required to meet the requirements, codes and standards listed in Table C.2. The application shall include a description of how these documents and standards will be met. For any licence renewals for existing facilities, the application shall address these documents and standards to the extent practicable (for example, in a periodic safety review).

Document source	Document number	Document title	Related SCAs
CNSC	REGDOC-2.10.1	<i>Nuclear Emergency Preparedness and Response</i>	10
ASME	B31.1	<i>Power Piping</i>	3, 5, 6
ASME	BPVC	<i>Boiler and Pressure Vessel Code</i>	3, 5, 6
CSA Group	N1600	<i>General requirements for nuclear emergency management programs</i>	10

C.3 Regulatory documents and industry standards to be addressed as guidance

For all facilities, the application should demonstrate that the guidance in the following regulatory documents and industry standards has been considered

Document source	Document number	Document title	Related SCAs
CNSC	REGDOC-3.2.2	<i>Aboriginal Engagement</i>	N/A

Document source	Document number	Document title	Related SCAs
CNSC	REGDOC-3.3.1	<i>Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities</i>	3, 11
CNSC	REGDOC-2.12.3	<i>Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material</i>	12, 14
CNSC	REGDOC-2.5.1	<i>General Design Considerations: Human Factors</i>	2, 4, 5
CNSC	REGDOC-2.2.5	<i>Minimum Staff Complement</i>	2, 3
CNSC	REGDOC-2.13.1	<i>Safeguards and Nuclear Material Accountancy</i>	3, 13
ASME	ASME/ANS RA-Sa-2009	<i>Addenda to ASME/ANS RA-S-2880 Standard for Level 1/ Large Early Release Frequency Probabilistic Risk Assessment for Nuclear Power Plant Applications</i>	4
ASME	B31.3	<i>Process Piping Guide</i>	3, 5, 6
ASME	B31.5	<i>Refrigeration Piping and Heat Transfer Components</i>	3, 5, 6
EPRI	TR-1019194	<i>Guidelines for Performance of Internal Flooding Probabilistic Risk Assessment</i>	4
IAEA	INSAG-4	<i>Safety Series No. 75: Safety Culture</i>	4
U.S. DOD	UFC 3-340-02	<i>Structures to Resist the Effects of Accidental Explosions</i>	12
U.S. NRC	NUREG-0700	<i>Human-System Interface Design Review Guidelines</i>	2, 3, 5
U.S. NRC	NUREG-0711 Rev. 3	<i>Human Factors Engineering Program Review Model</i>	2, 4, 5

Glossary

For definitions of terms used in this document, see [REGDOC-3.6, *Glossary of CNSC Terminology*](#), which includes terms and definitions used in the [Nuclear Safety and Control Act](#) and the regulations made under it, and in CNSC regulatory documents and other publications. REGDOC-3.6 is provided for reference and information.

References

The CNSC may include references to information on best practices and standards such as those published by CSA Group. With permission of the publisher, CSA Group, all nuclear-related CSA standards may be viewed at no cost through the CNSC Web page “[How to gain free access to all nuclear-related CSA standards](#)”.

1. International Atomic Energy Agency (IAEA), Specific Safety Requirements No. SSR-4 [Safety of Nuclear Fuel Cycle Facilities](#), Vienna, Austria, 2017.
2. CNSC, [REGDOC-3.5.3, Regulatory Fundamentals](#), Ottawa, Canada, 2018.
3. CNSC, [REGDOC-3.5.1, Licensing Process for Class I Nuclear Facilities and Uranium Mines and Mills](#), Ottawa, Canada, 2017.
4. CNSC, [REGDOC-2.9.1, Environmental Protection: Environmental Principles, Assessments and Protection Measures](#), Ottawa, Canada, 2017.
5. CNSC, [REGDOC-2.12.3, Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Materials](#), Ottawa, Canada, 2019.
6. CSA Group, CSA N286, [Management system requirements for nuclear facilities](#), Toronto, Canada, 2014.
7. CNSC, [REGDOC-2.1.2, Safety Culture](#), Ottawa, Canada, 2018.
8. CNSC, [REGDOC-2.2.2, Personnel Training](#), Ottawa, Canada, 2016.
9. CNSC, [REGDOC-2.2.5, Minimum Staff Complement](#), Ottawa, Canada, 2019.
10. CNSC, [REGDOC-2.5.1, General Design Considerations: Human Factors](#), Ottawa, Canada, 2019.
11. CNSC, [REGDOC-2.2.4, Fitness for Duty: Managing Worker Fatigue](#), Ottawa, Canada, 2017.
12. CNSC, [REGDOC-2.2.4, Fitness for Duty, Volume II: Managing Alcohol and Drug Use](#), Ottawa, Canada, 2017.
13. CNSC, [REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Facilities and Uranium Mines and Mills](#), Ottawa, Canada, 2018.
14. CNSC, [REGDOC-2.4.4, Safety Analysis for Class IB Nuclear Facilities](#), (under development).
15. CNSC, [REGDOC-2.4.3, Nuclear Criticality Safety](#), Ottawa, Canada, 2019.
16. IAEA, Specific Safety Requirements No. SSR-1 [Site Evaluation for Nuclear Installations](#), Vienna, Austria, 2019.
17. IAEA, Specific Safety Guide No. SSG-5, [Safety of Conversion Facilities and Uranium Enrichment Facilities](#), Vienna, Austria, 2010.
18. IAEA, SSG-6, [Safety of Uranium Fuel Fabrication Facilities](#), Vienna, Austria, 2010.

19. IAEA, Specific Safety Guide No. SSG-7, [*Safety of Uranium and Plutonium Mixed Oxide Fuel Fabrication Facilities*](#), Vienna, Austria, 2010.
20. IAEA, Specific Safety Guide No. SSG-42, [*Safety of Nuclear Fuel Reprocessing Facilities*](#), Vienna, Austria, 2017.
21. IAEA, Specific Safety Guide No. SSG-43, [*Safety of Nuclear Fuel Cycle Research and Development Facilities*](#), Vienna, Austria, 2017.
22. CNSC, [REGDOC-2.5.6, *Design of Rooms Where Unsealed Nuclear Substances Are Handled*](#), Ottawa, Canada, (under development).
23. CNSC, [REGDOC-2.7.1, *Radiation Protection*](#), Ottawa, Canada, 2021.
24. International Organization for Standardization, ISO 13485, [*Medical devices – Quality management systems – Requirements for regulatory purposes*](#), London, United Kingdom, 2016.
25. CNSC, [REGDOC-2.7.2, *Dosimetry, Volume I: Ascertaining Occupational Dose*](#), Ottawa, Canada, 2021
26. CSA Group, CSA N288.6, [*Environmental risk assessments at Class I nuclear facilities and uranium mines and mills*](#), Toronto, Canada, 2017.
27. CSA Group, CSA B51, [*Boiler, pressure vessel, and pressure piping code*](#), Toronto, Canada, 2019.
28. CNSC, [REGDOC-2.8.1, *Conventional Health and Safety*](#), Ottawa, Canada, 2019.
29. CNSC, [REGDOC-2.9.2, *Controlling Releases to the Environment*](#), Ottawa, Canada, (under development).
30. CNSC, [REGDOC-2.10.1, *Nuclear Emergency Preparedness and Response*](#), Ottawa, Canada, 2017.
31. CNSC, [REGDOC-2.10.2, *Fire Protection*](#), Ottawa, Canada, (under development).
32. CNSC, [REGDOC-2.11, *Framework for Radioactive Waste Management and Decommissioning in Canada*](#), Ottawa, Canada, 2021.
33. CNSC, [REGDOC-2.11.1, *Waste Management, Volume I: Management of Radioactive Waste*](#), Ottawa, Canada, 2021.
34. CNSC, [REGDOC-2.11.2, *Decommissioning*](#), Ottawa, Canada, 2021.
35. CNSC, [*Guidance Document on Confidential Filings*](#), Ottawa, Canada, 2014.
36. IAEA, *Treaty on the Non-Proliferation of Nuclear Weapons*, IAEA INFCIRC/140, 1970.
37. IAEA, *Agreement between Government of Canada and IAEA for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons* IAEA, INFCIRC/164, Vienna, Austria, 1972.

38. IAEA, *Protocol Additional to the Agreement between Canada and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons*, IAEA INFCIRC/164/Add 1, Vienna, Austria, 2000.
39. CNSC, [REGDOC-2.13.1, *Safeguards and Nuclear Material Accountancy*](#), Ottawa, Canada, 2018.
40. CNSC, [REGDOC-2.13.2, *Import and Export*](#), Ottawa, Canada, 2018.
41. CNSC, [REGDOC-3.2.1, *Public Information and Disclosure*](#), Ottawa, Canada, 2018.
42. CNSC, [REGDOC-3.2.2, *Indigenous Engagement*](#), Ottawa, Canada, 2018.
43. CNSC, [REGDOC-3.3.1, *Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities*](#), Ottawa, Canada, 2021.

CNSC Regulatory Document Series

Facilities and activities within the nuclear sector in Canada are regulated by the CNSC. In addition to the *Nuclear Safety and Control Act* and associated regulations, these facilities and activities may also be required to comply with other regulatory instruments such as regulatory documents or standards.

CNSC regulatory documents are classified under the following categories and series:

1.0 Regulated facilities and activities

- Series
- 1.1 Reactor facilities
 - 1.2 Class IB facilities
 - 1.3 Uranium mines and mills
 - 1.4 Class II facilities
 - 1.5 Certification of prescribed equipment
 - 1.6 Nuclear substances and radiation devices

2.0 Safety and control areas

- Series
- 2.1 Management system
 - 2.2 Human performance management
 - 2.3 Operating performance
 - 2.4 Safety analysis
 - 2.5 Physical design
 - 2.6 Fitness for service
 - 2.7 Radiation protection
 - 2.8 Conventional health and safety
 - 2.9 Environmental protection
 - 2.10 Emergency management and fire protection
 - 2.11 Waste management
 - 2.12 Security
 - 2.13 Safeguards and non-proliferation
 - 2.14 Packaging and transport

3.0 Other regulatory areas

- Series
- 3.1 Reporting requirements
 - 3.2 Public and Indigenous engagement
 - 3.3 Financial guarantees
 - 3.4 Commission proceedings
 - 3.5 CNSC processes and practices
 - 3.6 Glossary of CNSC terminology

Note: The regulatory document series may be adjusted periodically by the CNSC. Each regulatory document series listed above may contain multiple regulatory documents. Visit the CNSC's website for the latest [list of regulatory documents](#).