Canada's Nuclear Regulator

Reactor Facilities

Supplemental Information for Small Modular Reactor Proponents

REGDOC-1.1.5

August 2019

Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire

Canada

Supplemental Information for Small Modular Reactor Proponents
Regulatory document REGDOC-1.1.5

Cat. No. CC172-215/2019E-PDF
ISBN 978-0-660-31241-5

Également publié en français sous le titre : Renseignements supplémentaires pour les promoteurs de petits réacteurs modulaires

Document availability
This document can be viewed on the CNSC website. To request a copy of the document in English or French, please contact:

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Publishing history
August 2019 Version 1.0

Preface

This regulatory document is part of the CNSC's Reactor Facilities series of regulatory documents, which also covers licence application guides for licences to construct, operate and decommission nuclear power plants. 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-1.1.5, *Supplemental Information for Small Modular Reactor Proponents*, provides information in addition to three other CNSC regulatory documents (REGDOC-1.1.1, REGDOC-1.1.2, and REGDOC-1.1.3). REGDOC-1.1.5 is a new regulatory document and meant to be used in conjunction with these three other documents, which set out requirements and guidance for an applicant to consider prior to submitting a licence application to the CNSC for a small modular reactor. REGDOC-1.1.5 also identifies the CNSC's considerations in assessing the adequacy of a licence application.

A graded approach, commensurate with risk, may be defined and used when applying the requirements and guidance contained in this regulatory document. The use of a graded approach is not a relaxation of requirements, but rather the application of requirements in a manner commensurate with the risks and characteristics of a facility or activity. The information in this document is consistent with modern national and international practices addressing issues and elements that control and enhance nuclear safety. In particular, it establishes a modern, risk-informed approach to the licensing of SMRs.

A document that shows the changes made to REGDOC-1.1.5 since public consultation is available from the CNSC upon request.

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.

Table of Contents

Supplemental Information for Small Modular Reactor Proponents

1. Introduction

1.1 Purpose and scope

This document provides guidance on information to be provided to the Canadian Nuclear Safety Commission (CNSC) in support of an application for a licence to prepare site, to construct, to operate or to decommission a small modular reactor (SMR) facility.

REGDOC-1.1.5, *Supplemental Information for Small Modular Reactor Proponents*, provides information about CNSC safety and control areas as they apply to a licence application for an SMR facility. REGDOC-1.1.5 provides information that is additional to the licensing process documented in REGDOC-3.5.1, *Licensing Process for Class I Nuclear Facilities and Uranium Mines and Mills* [1], which provides an overview of the licensing process for Class I nuclear facilities.

In accordance with CNSC regulations, the CNSC has developed licence application guides that set out requirements and guidance for submitting a formal application to the CNSC to obtain a licence for reactor facilities, including SMRs, in Canada. The licence application guides also help identify information that should be included in an application. REGDOC-1.1.5 is intended to be used in conjunction with the following three licence application guides:

- REGDOC-1.1.1, *Site Evaluation and Site Preparation for New Reactor Facilities* [2]
- REGDOC-1.1.2, *Licence Application Guide: Licence to Construct a Nuclear Power Plant* [3]
- REGDOC-1.1.3, *Licence Application Guide: Licence to Operate a Nuclear Power Plant* [4]

For the purposes of this document, the term SMR includes:

- water-cooled reactors (smaller than traditional reactors)
- advanced reactors with alternative coolant technologies (i.e. non-water cooled)

SMRs may produce energy in the range of a few megawatts to a few hundred megawatts, and may be used for purposes beyond the generation of electricity. In some cases, an SMR facility could have multiple reactor units with a combined power output equivalent to that of a traditional nuclear power plant.

Protecting the environment is part of the CNSC's mandate. The CNSC requires the environmental effects of all licensed activities to be evaluated and considered when licensing decisions are made. This is a review of information used to support the Commission's determination on whether the licensee will make adequate provision for the protection of the environment and the health and safety of persons while carrying out a licensed activity. In addition to the information on environmental protection in the three licence application guides listed above, further information on this subject can also be found in REGDOC-2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures* [5], and REGDOC-3.5.1, *Licensing Process for Class I Nuclear Facilities and Uranium Mines and Mills* [1].

Section 2 of this document provides specific guidance for licence applications for SMRs.

Section 3 contains guidance on the application of the graded approach and the use of alternative approaches in the development of the licensing basis for SMR facilities.

Section 4 outlines the role of pre-licensing engagement. Pre-licensing engagement is optional, and can entail one or both of the following:

- A vendor Design Review (VDR)
- A defined CNSC process to determine an appropriate application assessment strategy for an SMR.

Pre-licensing review of a vendor's reactor design: This is commonly referred to as the VDR process. It is discussed briefly in section 4.1 of this document, and in depth in CNSC regulatory document REGDOC-3.5.4, *Pre-licensing Review of a Vendor's Reactor Design* [6]. This process involves a CNSC staff review of a vendor's design in order to identify and address potential regulatory or technical issues that could arise in the licensing process. A VDR is intended to help a vendor understand regulatory requirements while completing an SMR design, and usually takes place before an applicant submits a licence application. A VDR can also take place in parallel with a licence application; for example, a vendor may decide to engage in the VDR process in parallel with the CNSC's review of an application for a licence to prepare site. A VDR is not a licensing process: It does not necessarily involve a potential applicant for a project, does not involve any decision making by the Commission, and does not result in any decisions that could fetter the Commission's decision making concerning a potential project.

Process for establishing an appropriate application assessment strategy for risk-informed licensing: During the process for establishing an appropriate application assessment strategy for risk-informed licensing (detailed in section 4.2), the CNSC works with a potential applicant to provide clarification on preparing a licence application.

Both of these pre-licensing activities (VDR and the process for establishing an appropriate application assessment strategy for risk-informed licensing) are intended to provide regulatory clarity. These activities incorporate the risk considerations (described in section 3) that the CNSC uses when assessing how activities or SMR designs are measured against regulatory requirements.

2. Additional Guidance on Licence Applications for SMR Projects

The following information is presented to guide the proponent's licence application for an SMR:

- Section 2.1, Considerations by safety and control area (SCA): Addresses information specific to CNSC SCAs, with respect to the proposed SMR
- Section 2.2, Other regulatory areas: Addresses information not covered in the SCA-specific information presented in section 2.1

2.1 Considerations by safety and control area

SCAs are the technical topics that CNSC staff use across all regulated facilities and activities to assess, evaluate, review, verify and report on regulatory requirements and performance.

Consult the CNSC's regulatory documents Web page for a list of regulatory documents that may apply to SCAs addressed in a licence application, depending on the proposed activity and type of

Sections 2.1.1 to 2.1.14 provide SCA-specific information that a proponent should consider when determining the extent of the emphasis to give each SCA in a licence application. The list of considerations is not comprehensive.

2.1.1 Management system

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

This SCA covers the following specific areas:

- management system
- organization
- performance assessment, improvement, and management review
- operating experience
- change management
- safety culture
- configuration management
- records management
- management of contractors
- business continuity

REGDOC-2.1.1, *Management System* [7], consolidates CNSC expectations for the management system SCA, and also includes applicable legislative references. Consult the CNSC's regulatory documents Web page for a full list of regulatory documents and CSA standards that may be applicable to the management system SCA, depending on the proposed activity and type of licence being applied for.

When describing the management system and the emphasis it should be given, the applicant should address the following considerations:

1. complexity of the facility or activity, elements of which may include:
    a. complexity of required managed processes
    b. complexity of the organization
    c. number and size of radioactive or nuclear sources present
    d. number of radioactive sources being used at any one time
    e. degree of automation
2. structure of the operating organization
3. the need for effectively managed processes to control identified hazards, elements of which may include:
    a. change control
    b. design control
    c. document control
    d. work planning and control
    e. corrective action
    f. maintenance
    g. configuration management
    h. operations

   i. operating experience
4. safety culture
5. extent of activities involving risk (to health, safety and the environment) and requiring managed processes and controls
6. frequency, extent and need for critical human involvement in the activities of the facility
7. remote or local operation
8. number and type of barriers to accident progression or radioactive release
9. access control to process or equipment
10. the relative significance of integration points between process and programs

2.1.2 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 that these personnel have the necessary knowledge, skills, procedures and tools to safely carry out their duties.

Note: The human performance management SCA does not need to be included in an application for a licence to prepare site. This SCA is included in applications for a licence to construct, for a licence to operate and for a licence to decommission. For an application for a licence to prepare site, basic human performance management aspects are addressed under the management system SCA.

This SCA covers the following specific areas:

- human performance program
- personnel training
- personnel certification
- initial certification examinations and requalification tests
- work organization and job design
- fitness for duty

Consult the CNSC's regulatory documents Web page for a list of regulatory documents and CSA standards that may be applicable to the human performance management SCA, depending on the proposed activity and type of licence being applied for.

When assessing human performance management and the emphasis it should be given, the applicant should address the following considerations:

1. complexity of the facility or activity, elements of which may include:
   a. complexity of required managed processes
   b. complexity of the organization
   c. operating model
   d. number and size of radioactive or nuclear sources present
   e. number of radioactive sources being used at any one time
   f. degree of automation
2. the need for effective managed processes to control identified hazards, elements of which may include:
   a. change control

b. design control
c. document control
d. work planning and control
e. corrective action
f. maintenance
g. configuration management
h. operations
i. operating experience

3. workers, elements of which may include:

   a. complexity of job tasks
   b. competence of management, technical and other staff
   c. risk of not having qualified, trained and experienced personnel
   d. number of staff
   e. type, education and disciplines

4. extent of activities involving risk (to health, safety and the environment) and requiring managed processes and control
5. frequency, extent and need of critical human involvement in the activities of the facility
6. probability and potential impact of human error
7. number and type of barriers to accident progression or radioactive release
8. access control to process or equipment

2.1.3 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 SCA covers the following specific areas:

- conduct of licensed activity
- procedures
- reporting and trending
- outage management performance
- safe operating envelope
- severe accident management and recovery
- accident management and recovery

Consult the CNSC's regulatory documents Web page for a list of regulatory documents and CSA standards that may be applicable to the operating performance SCA, depending on the proposed activity and type of licence being applied for.

When assessing the operating performance SCA and the emphasis it should be given, the applicant should address the following considerations:

1. availability and applicability of operational experience for similar facilities or activities
2. frequency and type of activities to be performed
3. complexity of operation
4. number and type of barriers to accident progression or radioactive release
5. access control to process or equipment

2.1.4 Safety analysis

The safety analysis SCA covers 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 SCA covers the following specific areas:

- deterministic safety analysis
- hazard analysis
- probabilistic safety analysis
- criticality safety
- severe accident analysis
- management of safety issues (including R&D programs)

Consult the CNSC's regulatory documents Web page for a list of regulatory documents and CSA standards that may be applicable to the safety analysis SCA, depending on the proposed activity and type of licence being applied for.

When assessing the safety analysis SCA and the emphasis it should be given, the applicant should address the following considerations:

1. the number of provisions in the design to reduce risk
2. the number of process systems
3. the number of active safety systems and their interdependence
4. the number of passive safety systems
5. dependence on human performance/administrative controls to limit risk
6. total activities involving risk (to health, safety and the environment)
7. required managed process controls
8. extent and need for critical human involvement in the activities of the facility
9. probability of failure of structures, systems and components
10. consequences of failure of structures, systems and components
11. ability to manage change in facility design and/or operation as a result of events, operating experience, new knowledge, production or regulatory requirements
12. potential for undesirable chemical, physical and nuclear reactions
13. nature and complexity of safety systems to prevent accidents
14. degree of automation (as it relates to mitigation of potential initiating events or to address consequences thereof)

2.1.5 Physical design

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

This SCA covers the following specific areas:

- design governance
- site characterization
- facility design

- structure design
- system design
- component design

Consult the CNSC's regulatory documents Web page for a list of regulatory documents and CSA standards that may be applicable to the physical design SCA, depending on the proposed activity and type of licence being applied for.

When assessing the physical design SCA and the emphasis it should be given, the applicant should address the following considerations:

1. number of provisions in the design to reduce risk
2. number of process systems
3. number of active safety systems and their interdependence
4. number of passive safety systems
5. dependence on human performance/administrative controls to limit risk
6. total activities involving risk (to health, safety and the environment)
7. required managed process controls
8. extent and need for critical human involvement in the activities of the facility
9. probability of failure of structures, systems and components multiplied by consequences
10. ability to manage change in facility design and/or operation as a result of events, OPEX, new knowledge, production or regulatory requirements
11. requirements for cooling radioactive material or sources
12. number and diversity of equipment and systems
13. nature and complexity of safety systems to prevent accidents
14. degree of automation (as it relates to mitigation of potential initiating events or to address consequences thereof)

2.1.6 Fitness for service

The fitness for service SCA covers activities that impact the physical condition of structures, systems and components 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.

Note: The fitness for service SCA is not included in an application for a licence to prepare site. This SCA is only included in an application for a licence to construct, and an application for a licence to operate.

This SCA covers the following specific areas:

- equipment fitness for service / equipment performance
- maintenance
- structural integrity
- aging management
- chemistry control
- periodic inspection and testing

Consult the CNSC's regulatory documents Web page for a list of regulatory documents and CSA standards that may be applicable to the fitness for service SCA, depending on the proposed activity and type of licence being applied for.

When assessing the fitness for service SCA and the emphasis it should be given, the applicant should address the following considerations:

1. number of provisions in the design to reduce risk
2. number of process systems
3. number of active safety systems and their interdependence
4. number of passive safety systems
5. technical and administrative maintenance requirements to keep structures, systems and components functioning as designed

2.1.7 Radiation protection

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

This SCA covers the following specific areas:

- application of ALARA
- worker dose control
- radiation protection program performance
- radiological hazard control
- estimated dose to public

Consult the CNSC's regulatory documents Web page for a list of regulatory documents and CSA standards that may be applicable to the radiation protection SCA, depending on the proposed activity and type of licence being applied for.

When assessing the radiation protection SCA and the emphasis it should be given, the applicant should address the following considerations:

1. number of provisions in the design to reduce risk
2. number of process systems
3. number of active safety systems and their interdependence
4. number of passive safety systems
5. magnitude of projected worker doses in relation to regulatory limits and action levels (application of ALARA in reducing doses)
6. consequence of failure of program from a worker dose/health perspective
7. potential pathways of exposure (ingestion, absorption and inhalation)
8. number of sources of radiation
9. type of radiation present
10. longest decay time of the sources
11. mobility of sources
12. expected number of workers who may be exposed to radiation
13. expected releases that may affect members of the public or the environment

2.1.8 Conventional health and safety

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

This SCA covers the following specific areas:

- performance
- practices
- awareness

Consult the CNSC's regulatory documents Web page for a list of regulatory documents and CSA standards that may be applicable to the conventional health and safety SCA, depending on the proposed activity and type of licence being applied for.

When assessing the conventional health and safety SCA and the emphasis it should be given, the applicant should address the following considerations:

1. number, severity and nature of hazards
2. type and toxicity of materials
3. amount of time hazards will exist
4. physical work conditions
5. type of operation (fuelling onsite, waste storage, etc.)
6. chemical or biological hazards associated with possession and use of nuclear substances

2.1.9 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 SCA covers the following specific areas:

- effluent and emissions control (releases)
- environmental management system
- assessment and monitoring
- protection of the public
- environmental risk assessment

Consult the CNSC's regulatory documents Web page for a list of regulatory documents and CSA standards that may be applicable to the environmental protection SCA, depending on the proposed activity and type of licence being applied for.

When assessing the environmental protection SCA and the emphasis it should be given, the applicant should address the following considerations:

1. proximity to sensitive habitat and the public
2. environmental pathways (air, water, ground conditions, tailings)
3. type of operation (fuelling onsite, waste storage, etc.)
4. chemical characteristics (types and concentration) of releases
5. volume of releases
6. types of facilities
7. age of the facility
8. environmental risk assessment results (if available)

2.1.10 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: The emergency management and fire protection SCA includes conventional emergency and fire response. Operations, design and analysis in the context of fire protection for a nuclear facility are discussed in the appropriate SCAs of operating performance, safety analysis and physical design.

This SCA covers the following specific areas:

- conventional emergency preparedness and response
- nuclear emergency preparedness and response
- fire emergency preparedness and response

Consult the CNSC's regulatory documents Web page for a list of regulatory documents and CSA standards that may be applicable to the emergency management and fire protection SCA, depending on the proposed activity and type of licence being applied for.

When assessing the emergency management and fire protection SCA and the emphasis it should be given, the applicant should address the following considerations:

1. onsite consequences
2. types and toxicity of materials
3. quantity of accidental radiological/nuclear and/or hazardous substance releases (above or below threshold)
4. ability of the applicant and/or municipality (if known) to respond to an emergency
5. location, elements of which include:
    a. distance and density of population
    b. nearby infrastructure (facilities)
    c. sensitive environments

2.1.11 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 planning for decommissioning.

The waste management SCA covers the following specific areas:

- waste characterization
- waste minimization
- waste management practices
- decommissioning plans

Consult the CNSC's regulatory documents Web page for a list of regulatory documents and CSA standards that may be applicable to the waste management SCA, depending on the proposed activity and type of licence being applied for.

When assessing the waste management SCA and the emphasis it should be given, the applicant should address the following considerations:

1. categories of waste (liquid, solid, mixed waste)
2. waste classes (low, intermediate and high)
3. volume of waste
4. onsite waste processing
5. onsite storage
6. financial guarantees

2.1.12 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.

The security SCA covers the following specific areas:

- facilities and equipment
- response arrangements
- security practices
- drills and exercises
- cyber security

Consult the CNSC's regulatory documents Web page for a list of regulatory documents and CSA standards that may be applicable to the security SCA, depending on the proposed activity and type of licence being applied for.

When assessing the security SCA and the emphasis it should be given, the applicant should address the following considerations:

1. theft of material (highly enriched uranium, low enriched uranium, slightly enriched uranium, plutonium, tritium, other nuclear substances or prescribed equipment and/or information)
2. sabotage (risk to facility and/or public)
3. location

2.1.13 Safeguards and non-proliferation

The safeguards and non-proliferation SCA covers the programs and activities required for the successful implementation of the safeguards agreement[1] between Canada and the International Atomic Energy Agency (IAEA), as well as all other measures arising from the *Treaty on the Non-Proliferation of Nuclear Weapons*.

[1] Canada signed a comprehensive safeguards agreement with the IAEA in 1972 (IAEA INFCIRC/164, *Agreement Between the Government of Canada and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non Proliferation of Nuclear Weapons*). In 2000, an additional protocol (IAEA INFCIRC/164/Add.1, *Protocol Additional to INFCIRC/164*) was brought into force.

The safeguards and non-proliferation SCA covers the following specific areas:

- nuclear material accountancy and control
- access and assistance to the IAEA
- operational and design information
- safeguards equipment, containment and surveillance
- import and export

Consult the CNSC's regulatory documents Web page for a list of regulatory documents and CSA standards that may be applicable to the safeguards and non-proliferation SCA, depending on the proposed activity and type of licence being applied for.

When assessing the safeguards and non-proliferation SCA and the emphasis it should be given, the applicant should address the following considerations:

1. types, quantity and form of nuclear materials
2. measures taken to report, contain, verify and provide other information required by Canada's international obligations

2.1.14 Packaging and transport

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

The packaging and transport SCA is not included in an application for a licence to prepare site. This SCA is only included in an application for a licence to construct, and an application for a licence to operate.

The packaging and transport SCA covers the following specific areas:

- package design and maintenance
- packaging and transport
- registration for use

Consult the CNSC's regulatory documents Web page for a list of regulatory documents and CSA standards that may be applicable to the packaging and transport SCA, depending on the proposed activity and type of licence being applied for.

When assessing the packaging and transport SCA and the emphasis it should be given, the applicant should address the following considerations:

1. frequency of shipments
2. number of packages
3. type and category of packages transported
4. activity and physical form of radioactive material
5. consignor vs consignee functions
6. potential package contamination events
7. type of region through which the shipment travels, if known (i.e., rural area versus a populated area)

2.2 Other regulatory areas

The following other regulatory areas are relevant to an application for a licence to prepare site for, to construct, to operate or to decommission an SMR:

- reporting
- public information and disclosure program
- engagement with Indigenous peoples of Canada
- intergovernmental consultation
- financial guarantees

Consult the CNSC's regulatory documents Web page for a list of regulatory documents that articulate CNSC expectations and guidance on how to comply with regulatory requirements, and on content of licensing submissions, in the above-mentioned areas.

3. Development of the Licensing Basis for an SMR Facility

When applying for a licence, the applicant is to address CNSC requirements in a manner that is commensurate with the novelty, complexity and potential for harm that the activity represents.

The CNSC's regulatory framework is an evolving set of requirements based on more than 70 years of operating experience, and is intended to be technology-neutral. Many requirements reflect experience from water-cooled reactor designs. As a result, the CNSC recognizes that a graded approach may be applied or that alternative approaches may be used to meet the intent of some requirements.

3.1 Applying a graded approach

The graded approach is a method or process by which elements such as the level of analysis, the depth of documentation and the scope of actions necessary to comply with requirements are commensurate with the following:

1. the relative risks to health, safety, security, the environment, and the implementation of international obligations to which Canada has agreed
2. the characteristics of a facility or activity

The Commission makes independent and objective decisions to ensure that unreasonable risks are prevented, taking into consideration regulatory requirements, best available information from regulatory or credible third-party research, and all information provided by applicants/licensees, Indigenous peoples, other stakeholders and staff. CNSC staff make recommendations to the Commission based on thorough assessments of factual evidence, measured against regulatory requirements.

The Commission recognizes the role of professional judgment, particularly in areas where no objective standards exist. Its independence and transparency in decision making are supported by fair, open, transparent and predictable regulatory processes.

Understanding risks, including associated uncertainties, and ensuring that these risks are mitigated plays a significant role in making regulatory recommendations and decisions. The risks and mitigation approaches need to be clearly described and well understood in order for the

Commission to make an informed decision. Supporting evidence and the quality of that evidence are critical.

The Commission and CNSC staff apply a risk-informed approach to all SCAs in order to place an appropriate amount of regulatory scrutiny on activities, depending on the level of risk. Primary considerations for the extent and depth of application are the degree of novelty, complexity and potential harm posed by the proposed activity or facility. The degree of scrutiny, which may vary upward or downward, is further informed by:

- technical assessments of submissions
- safety performance history of the licensee (if applicable)
- relevant research
- information supplied through the Commission's public processes
- national and international activities that advance knowledge in nuclear and environmental safety
- cooperation with other regulatory bodies

When the Commission assesses applications that reflect a graded approach, its primary consideration is to ensure that risk is demonstrated to be at a reasonable level. This includes ensuring that:

1. regulatory requirements will be met
2. fundamental safety functions are adequate
3. defence in depth is demonstrated
4. safety margins are appropriate and in line with specific hazards over the facility's lifecycle

Regulatory requirements and expectations provide a starting point for regulatory review, but each case will be reviewed on its own merits.

More detailed information on risk-informed techniques and other methodologies can be found in CAN/CSA-IEC/ISO 31010-10, *Risk management – Risk assessment techniques* [8], and CSA N290.19, *Risk-informed decision making for nuclear power plants* [9].

3.2 Proposing alternative approaches

The CNSC will consider alternative approaches to meeting the requirements in its regulatory framework.

Any alternative approach shall demonstrate that safety and security protections are maintained or improved. Where risk characteristics contain uncertainties, the amount of evidence required for the applicant to demonstrate a credible decision increases. Suitable evidence may include results of research and development, computer modelling and consideration of operating experience, and the evidence must be demonstrated to be relevant to the specific proposal. All of these types of evidence should be documented, traceable and quality-assured. A proponent that is considering a licence application for an SMR is encouraged to engage with the CNSC early on, well in advance of submitting the application, in order to understand CNSC expectations for management systems and quality assurance. This will inform research and development work, with a view to supporting a potential future licence application.

In their assessment of alternatives proposed by an applicant (see section 3.2), CNSC staff evaluate if the alternatives:

- meet the objectives of the requirements
- meet high-level safety objectives
- meet fundamental safety functions of "control, cool, contain"

At the same time, the alternatives need to demonstrate:

- defence in depth
- safety margins in view of the uncertainties in the safety case and of specific hazards over the facility's lifecycle

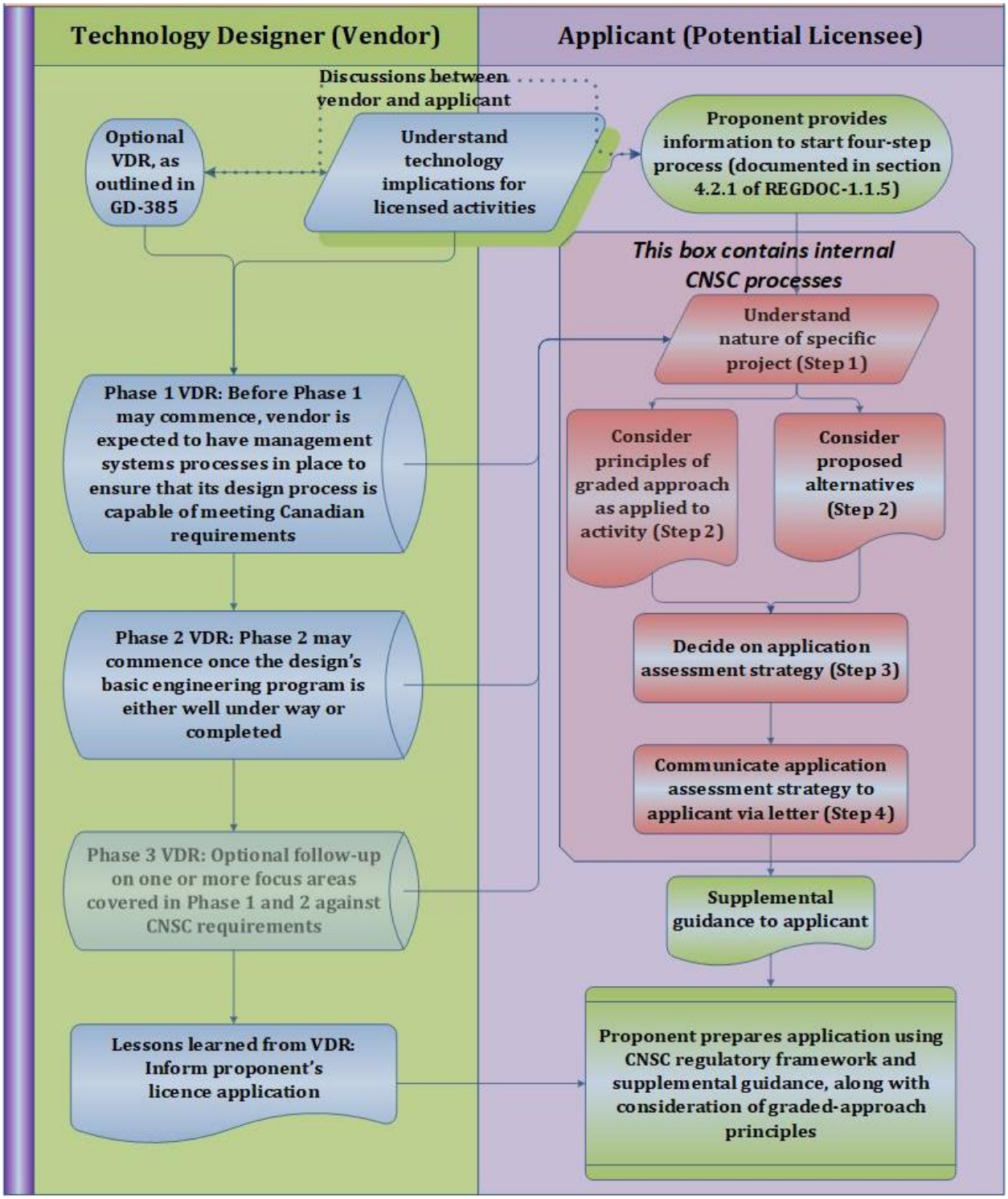
4. Role of Pre-Licensing in Establishing the Licensing Basis for an SMR Facility

There are two types of pre-licensing engagement with the CNSC:

- the VDR process
- the process for establishing an appropriate application assessment strategy for risk-informed licensing

Figure 1 illustrates these two types of pre-licensing activities at a conceptual level, including how the two processes can overlap while incorporating graded-approach considerations.

Figure 1: Pre-licensing engagement activities in establishing the licensing basis for an SMR facility



4.1 The role of the VDR process

SMRs differ greatly in size, design, and operation. Each SMR design also has varying degrees of uncertainty, which SMRs of similar types may address differently. In light of this variability, a

vendor may wish to consult with the CNSC prior to licensing to ensure that its design meets high-level Canadian requirements. The CNSC offers an optional VDR service in this regard.

A VDR is separate from the licensing process, and its primary purpose is to inform the vendor of the design's overall acceptability. This review provides early identification and resolution of potential regulatory or technical issues in the design process, particularly those that could result in significant changes to the design or safety case.

In a VDR, the CNSC enters into a service agreement with the vendor that is based on a fixed scope of work, under which the vendor can gain a comprehensive grasp of Canadian regulatory requirements and how its design, as it is evolving, would be capable of meeting those requirements. Similarly, this agreement helps CNSC develop a better understanding of the specific technology being presented.

The VDR process is divided into three phases, each requiring increasingly detailed technical information, and is fully described in CNSC regulatory document REGDOC-3.5.4, *Pre-licensing Review of a Vendor's Reactor Design* [6].

While the VDR process is separate from the process for determining an appropriate application assessment strategy (described in section 4.2), outputs from each VDR phase can inform the determination of such a strategy. VDR results may also be used by an applicant in the licensing process.

4.2 Scope of the process to establish an appropriate application assessment strategy for an SMR project

All licence applications are presented to the Commission for approval. When applying for a license, the proponent should provide clearly articulated descriptions of how proposed activities would be conducted safely and would meet all applicable requirements. Clearly documented intentions facilitate fair and informed decisions. With this in mind, the purpose of establishing an application assessment strategy is to enable potential proponents to understand:

- the overall licensing process
- the specific licensing process for the proposed activity
- regulatory framework tools available to support the licensing process (e.g., regulations, licence application guides and other regulatory documents) and how they are used to establish the licensing basis
- licensee obligations (should the licence application be approved)

The CNSC has a process for determining an appropriate application assessment strategy for an innovative activity or facility that uses technology that is new to Canada. This process ensures that a risk-informed approach is systematically and consistently applied.

While establishing an appropriate application assessment strategy is optional, it could be especially beneficial for a proponent whose application includes one or more of the following:

- new organizational models for conducting a project
- a proposal for new types of activities, for which there is little or no past experience (e.g., potential demonstration activities to be performed in a demonstration facility)
- new ways to conduct activities (e.g., construction approaches)
- new technological approaches that require extensive interpretation of requirements

This optional process is carried out prior to any licence application. It begins via early CNSC engagement with a potential SMR applicant to reach a common understanding of the nature of the proposed design and of the specificities of the approach to operation.

The establishment of an application assessment strategy begins with a high-level analysis of the proposed project, including applicable regulations and regulatory process. Applicable regulatory documents and practices, with recommendations on their risk-informed application, are also identified. Pre-licensing engagement and review of proposed activities may indicate that no license is required. For example, the testing of a thermal hydraulic loop (without the use of nuclear substances) is not subject to sections 24 or 26 of the NSCA and therefore would not require a licence application to the CNSC.

The outcome of this process is an appropriate risk-informed application assessment strategy, which CNSC staff will ultimately use in developing supplemental guidance for an applicant on how to prepare a licence application for a given project. The process is expected to be iterative, with several interactions between the CNSC and an applicant before the CNSC develops this supplemental guidance.

4.2.1 Process for determining an appropriate application assessment strategy for a novel nuclear technology

In the interest of providing clarity to potential proponents, this section describes the process for determining an appropriate application assessment strategy for a novel nuclear technology. The process is divided into the following four activities:

- Activity A: Prepare for and establish preliminary description of activities and hazards
- Activity B: Conduct risk assessment and document proposed strategy for novel nuclear technology
- Activity C: Decide on application assessment strategy
- Activity D: Communicate application assessment strategy via letter

The following text provides detailed descriptions of activities A, B, C and D.

Activity A: Prepare for and establish preliminary description of activities and hazards

The proponent provides conceptual information about the technology design to the CNSC. The proponent may also choose to submit information resulting from an optional VDR. See section 4.2.3 for additional guidance on what should be included in the preliminary description.

A discussion is facilitated with the proponent to understand what activities are being planned and the associated time frames. This communication with the proponent allows the CNSC to gain the required preliminary information about the activity or facility being proposed in Canada.

Activity B: Conduct risk assessment and document proposed strategy for novel nuclear technology

CNSC staff discuss the applicant’s proposal and document a risk-informed application assessment strategy report. This report documents the CNSC’s understanding of the proposal and the key areas where risks influence the nature of the provisions (or safety and control measures) to satisfy the requirements of the relevant SCA.

This activity involves:

- evaluating risks and technical challenges
- requesting additional information from the proponent where necessary
- making a recommendation on whether a licence is required under section 26 (a–f) of the NSCA
- identifying applicable regulations and recommended application guides, regulatory documents and technical criteria that would be most appropriate

Activity C: Decide on application assessment strategy

CNSC staff finalize the application assessment strategy and prepare a letter for the proponent.

Activity D: Communicate application assessment strategy via letter

Following Activity C, the letter is sent to the proponent. An applicant can then use this guidance in conjunction with section 2 of this document to prepare a licence application.

The letter:

- includes an overview of applicable regulations, licence application guides and information to be submitted in support of a licence application
- identifies a CNSC single point of contact
- may also provide additional information, including the following:
  - applicability of an environmental assessment
  - public and Indigenous consultation
  - considerations with respect to nuclear liability, security and safeguards
  - potential licensing timelines

Once the application assessment strategy is communicated via a letter, an applicant can then use the letter, in conjunction with section 2 of this document, to prepare a licence application. While the supplemental guidance in the letter can provide clarity to a proponent, it does not provide an endorsement of a project by CNSC staff. This letter does not, in any way, bind the Commission in its consideration of the application.

The Commission is the final arbitrator of what represents reasonable risk when it comes to the development and use of nuclear energy and sources. The Commission makes the determination as to whether a project can be developed in a manner that meets the CNSC's requirements and protects the health, safety, security and the environment of Canadians and ultimately uses this determination to decide whether or not to issue a licence.

4.2.2 Information required for the preliminary description of activities and hazards

The applicant's preliminary description should include enough details of the proposed activities and hazards over the life of a potential project. This allows CNSC staff to initiate a technical assessment in order to document regulatory considerations and propose an application assessment strategy.

The preliminary description should be of sufficient detail to allow CNSC staff to:

- understand the nature of the activities, including the hazards they may present to workers, the public and the environment
- proceed to Activity B (conduct risk assessment and document proposed strategy for novel nuclear technology), which documents regulatory considerations and proposes the requirements applicable to the proposal and a draft application assessment strategy

The three topics of specific criteria are as follows:

- description of the purpose of the project and key activities to be conducted
- description of the nuclear facility or activity
- estimate of quantity, form, origin and volume of any radioactive waste or hazardous waste

The three topics are covered in further detail in the following sections.

Description of the purpose of the project and key activities to be conducted

The project should encompass the entire lifecycle up to and including decommissioning. Specific project dates are not required. Instead, relative times for conduct of each phase and sets of key activities should be provided.

The purpose of the project and key activities to be conducted should, at a conceptual level, describe:

- the ultimate purpose of the project, including primary objectives to be achieved as a result of performance of the project. (for example, a facility for the purpose of conducting research to support a safety case for a future demonstration facility)
- operating experience that exists from similar types of projects (if applicable)
- the preliminary timelines of key project phases which have been identified, for example:
  - licence submissions
  - preparation of the site
  - construction/installation
  - commissioning
  - operational phase
  - decommissioning
  - site closure
- key project activities that have been identified for each project phase

Description of the nuclear facility or activity

The section should describe, as applicable, the following information at a conceptual level:

- the proposed plans for the nuclear facility, showing its layout, location, the location of its components and the location of adjacent areas that may be occupied by persons
- where the facility may be located (e.g., on a university campus, near a populated region as an industrial facility, in a sparsely populated region)
- the key structures and systems such that their operation by persons can be understood by CNSC staff for the purpose of understanding the proponent’s description of potential hazards under all facility operating states
- the proposed organizational arrangements for the conduct of the activities to be licensed

- an estimate of quantity, form, origin and volume of any radioactive waste or hazardous waste that may result from the activity to be licensed, including waste that may be stored, managed, processed or disposed of at the site of the activity to be licensed
- how the environment could adversely affect the project (e.g., overview of key external natural or human induced events of concern being considered)
- key evolutions or configuration changes planned for the facility that could impact the safety case
- a description of radiological and non-radiological malfunctions and accidents that may occur at the facility in connection with each phase of the project as well as:
    - preventive measures being considered and mitigation measures such as monitoring, contingency, cleanup or restoration work in the surrounding environment that would be required during or immediately following the postulated malfunction and accident scenarios
    - the source, quantity, mechanism, pathway, rate, form and characteristics of contaminants and other materials (physical and chemical) likely to be released to the surrounding environment during the postulated malfunctions and accidents
    - potential consequences to health of workers, the public and environment
- the conceptual environmental releases

Estimate of quantity, form, origin and volume of any radioactive waste or hazardous waste

The preliminary description should describe, at a conceptual level, the radioactive and/or hazardous wastes that will be generated:

- during normal operation
- as a result of major configuration changes planned for the facility over its lifecycle
- as a result of decommissioning

For each type of waste that will be produced, the following should be described:

- where and how waste will originate
- estimates of quantities of each form to be generated
- hazards associated with handling and storage
- methods being considered for managing and disposing of the waste

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. CNSC. REGDOC-3.5.1, *Licensing Process for Class I Nuclear Facilities and Uranium Mines and Mills*. Ottawa, 2017.

2. CNSC. REGDOC-1.1.1, *Site Evaluation and Site Preparation for New Reactor Facilities*. Ottawa. 2018.

3. CNSC. REGDOC-1.1.2, *Licence Application Guide: Licence to Construct a Nuclear Power Plant*. Ottawa, 2019.

4. CNSC. REGDOC-1.1.3, *Licence Application Guide: Licence to Operate a Nuclear Power Plant*. Ottawa, 2017.

5. CNSC. REGDOC-2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures*. Ottawa, 2017.

6. CNSC. REGDOC-3.5.4, *Pre-licensing Review of a Vendor's Reactor Design*. Ottawa, 2018.

7. CNSC. REGDOC-2.1.1, *Management System*. Ottawa, 2019.

8. International Organization for Standardization. CAN/CSA-IEC/ISO 31010-10, *Risk management – Risk assessment techniques*. Switzerland, 2010.

9. CSA Group. CSA N290, *Risk-informed decision making for nuclear power plants*. Mississauga, 2018.

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

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