



Waste Management
**Waste Management, Volume III:
Safety Case for the Disposal of
Radioactive Waste**

REGDOC-2.11.1, Waste Management, Volume III, Version 2

January 2021



Waste Management, Volume III: Safety Case for the Disposal of Radioactive Waste, Version 2

Regulatory document REGDOC-2.11.1, Volume III, Version 2

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Cat. No. CC172-190/3-2021E-PDF

ISBN 978-0-660-37032-3

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Également publié en français sous le titre : Gestion des déchets, tome III : Dossier de sûreté pour le stockage définitif des déchets radioactifs, version 2

Document availability

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LinkedIn: linkedin.com/company/cnsc-ccsn

Publishing history

May 2018

Assessing the Long-Term Safety of Radioactive Waste Management, Version 1

January 2021

Safety Case for the Disposal of Radioactive Waste, Version 2

Preface

This regulatory document is part of the CNSC's waste management series of regulatory documents, which also covers decommissioning. 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-2.11.1, *Waste Management, Volume III: Safety Case for the Disposal of Radioactive Waste, Version 2*, provides requirements and guidance to CNSC licensees and applicants for developing a safety case and supporting safety assessment for activities pertaining to a disposal facility, location or site.

This is the second version of this document and supersedes REGDOC-2.11.1, *Waste Management, Volume III: Assessing the Long-Term Safety of Radioactive Waste Management, Version 1*, published in May 2018.

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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Safety Case for the Disposal of Radioactive Waste

1. Introduction

1.1 Purpose

The purpose of this document is to provide requirements and guidance to licensees and applicants for developing a safety case and supporting safety assessment activities pertaining to the disposal of all classes of radioactive waste.

1.2 Scope

This regulatory document addresses the development of a safety case and supporting safety assessment for the post-closure phase of disposal facilities, which includes locations or sites, for all classes of radioactive waste. This document also applies to long-term radioactive waste management facilities, locations or sites where there is no intention to retrieve the waste. **Note:** In this regulatory document, the term “disposal facilities” also refers to disposal locations or sites, which are not classified as “nuclear facilities” under the NSCA.

The post-closure safety case considers information from the pre-closure phase (site preparation, construction, operation, decommissioning) insofar as this information impacts post-closure safety.

For disposal facilities that operated or that were decommissioned or closed before 2021, this document is to be considered as guidance.

This regulatory document is complemented by other [CNSC regulatory documents](#), such as REGDOC-2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures* [1].

The requirements and guidance in this regulatory document should also be adopted for the disposal of uranium mine and mill waste, as applicable. The licensee must provide a justification to the CNSC with respect to requirements that do not apply. Additional requirements and guidance for waste management at uranium mines and mills are provided in REGDOC-2.11.1, *Waste Management, Volume II: Management of Uranium Mine Waste Rock and Mill Tailings* [2].

1.3 Relevant legislation

The following provisions of the [Nuclear Safety and Control Act](#) (NSCA) and its associated regulations are relevant to this document:

- section 26 of the NSCA
- paragraphs 4(d) and 12(1)(c) of the [General Nuclear Safety and Control Regulations](#)
- paragraphs 3(k), 4(e), 5(f), (i), (j), (k), 6(c), (h), (i), (j), 7(f), (k) and 8(a) of the [Class I Nuclear Facilities Regulations](#)
- paragraph 4(t), 5(i) and 5(k) of the [Class II Nuclear Facilities and Prescribed Equipment Regulations](#)
- section 1 of the [Nuclear Substances and Radiation Devices Regulations](#)
- subparagraph 3(a)(viii), 3(c)(iii), 3(d)(i), 7(d) and 8(b) of the [Uranium Mines and Mills Regulations](#)

2. The CNSC's Waste Management Framework

In addition to this regulatory document, the CNSC's regulatory framework for waste management includes:

- REGDOC-2.11, *Framework for Radioactive Waste Management and Decommissioning in Canada*
- REGDOC-2.11.1, *Waste Management, Volume I: Management of Radioactive Waste*
- REGDOC-2.11.1, *Waste Management, Volume II: Management of Uranium Mine Waste Rock and Mill Tailings*
- REGDOC-2.11.2, *Decommissioning*

The following [CSA standards](#) complement the CNSC's regulatory framework:

- CSA N286, *Management System Requirements for Nuclear Facilities*
- CSA N288.4, *Environmental Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills*
- CSA N288.5, *Effluent Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills*
- CSA N288.6, *Environmental Risk Assessments at Class I Nuclear Facilities and Uranium Mines and Mills*
- CSA N288.7, *Groundwater Protection Programs at Class I Nuclear Facilities and Uranium Mines and Mills*
- CSA N292.0, *General Principles for the Management of Radioactive Waste and Irradiated Fuel*
- CSA N292.1, *Wet Storage of Irradiated Fuel and Other Radioactive Materials*
- CSA N292.2, *Interim Dry Storage of Irradiated Fuel*
- CSA N292.3, *Management of Low- and Intermediate-Level Radioactive Waste*
- CSA N292.5, *Guideline for the Exemption or Clearance From Regulatory Control of Materials That Contain, or Potentially Contain, Nuclear Substances*
- CSA N292.6, *Long-Term Management of Radioactive Waste and Irradiated Fuel*
- CSA N294, *Decommissioning of Facilities Containing Nuclear Substances*

3. Graded Approach

This regulatory document may be applied in a graded manner commensurate with risk. With a graded approach, all requirements apply, but to varying degrees depending upon the safety significance and complexity of the work being performed. The level of analysis, the depth of documentation and the scope of actions necessary to comply with regulatory requirements are commensurate with the nature and level of the hazards and complexity of the facility or activities, and with the characteristics of the waste.

Further information on the graded approach can be found in [REGDOC-3.5.3, Regulatory Fundamentals](#) [3].

4. Definition of Safety Case and Safety Assessment

A safety case is defined as an integrated collection of arguments and evidence to demonstrate the safety of a facility and the meeting of all applicable regulatory requirements. A safety case

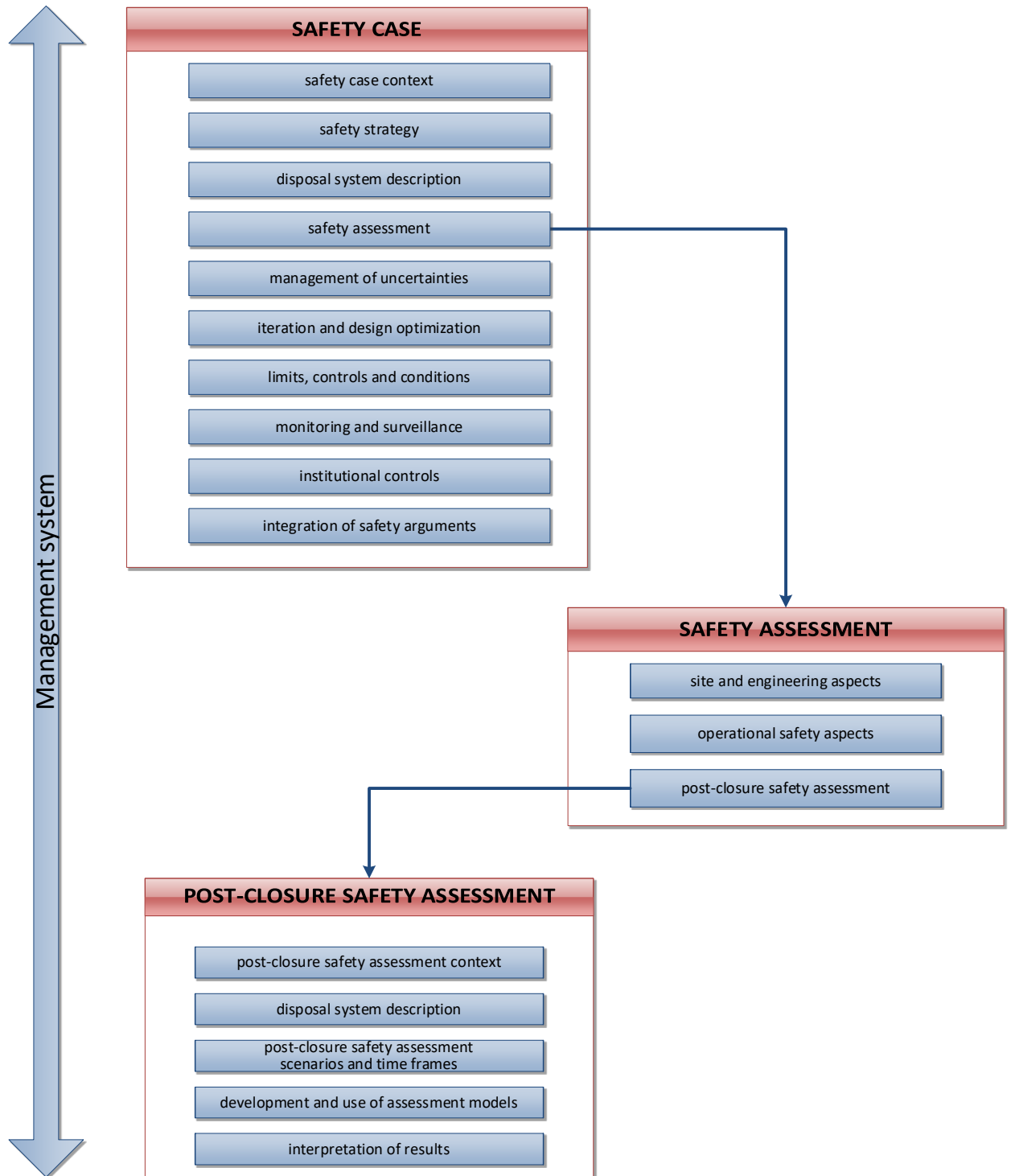
normally includes a safety assessment, but could also typically include information (such as supporting evidence and reasoning) on the robustness and reliability of the safety assessment and the assumptions made therein.

For a disposal facility, the safety case may support the decision to proceed to a specific stage of development. In such instances, the safety case should acknowledge the existence of any remaining uncertainties and should provide guidance for work to manage these uncertainties in future development stages.

A safety assessment is defined as an assessment of all aspects relevant to safety of a nuclear facility. It is a systematic process that includes quantitative analyses and the interpretation of the results of those analyses. The safety assessment follows an iterative approach that carries on throughout the design process and over the lifecycle of the facility or the activity, to ensure that all the relevant safety requirements are met. Safety assessment is often used interchangeably with safety analysis.

Figure 1 provides an outline of the components of a safety case and safety assessment.

Figure 1. Components of a safety case and safety assessment



5. Role and Development of the Safety Case

5.1 Role of the safety case

The safety case relates to all hazards and is the main tool used to document and demonstrate that a facility will adequately protect people and the environment during its entire lifecycle (site preparation, construction, operation and decommissioning) and in the post-closure period. For a post-closure safety assessment, the emphasis is on the performance of the disposal facility and the assessment of its impact after closure. The safety case is a structured framework for documenting and presenting all of the safety-related information for a disposal facility in a consolidated manner.

The safety case supports the regulatory process, including decision making, and is a means of communicating and consulting with interested parties at different points throughout the facility's lifecycle.

The safety case can be used to:

- verify a concept
- support the selection of a site
- perform design optimization
- establish limits, controls and conditions
- design the monitoring program
- guide operation, decommissioning and closure
- prioritize research and development programs

5.2 Development of the safety case

A post-closure safety case is required for a disposal facility throughout its entire lifecycle – at the start of each major licensing stage, from site preparation through to decommissioning (which includes closure and decommissioning of ancillary facilities) – and post-closure period until release from regulatory control. The post-closure safety case evolves throughout the lifecycle of the disposal facility using an iterative approach.

In the pre-licensing phase, assumptions may need to be made regarding concept development and site selection. These activities do not require licensing from the CNSC; however, due to their very long time spans, typically several decades, early engagement with the CNSC during the pre-licensing period is encouraged. As concept development and site selection proceed, empirical site-specific data is necessary and details of the proposed design, construction, operation, decommissioning, closure and post-closure, as appropriate, need to be developed. This will allow specific issues to be addressed in more detail in the safety case.

The safety case is updated progressively throughout the lifecycle of the disposal facility by the systematic collection, analysis, and interpretation of the necessary scientific and technical data. The scope and level of technical detail will depend on the stage of development of the disposal facility. Data used in the safety case can be obtained from a variety of sources, including site-specific sampling, regional field investigations, scientific literature and analogous examples. Updates to the safety case consider comments from technical and regulatory reviews, increased knowledge, and operational experience, as well as results from monitoring programs and research activities. The lifecycle approach to the development of the safety case enables ongoing

engagement with the public and Indigenous groups and the incorporation of stakeholder feedback.

At closure of the disposal facility, the safety case will contain information that future generations may require (e.g., institutional control plans, long-term monitoring plan).

6. General Requirements for the Safety Case

In support of a licence application for activities pertaining to a disposal facility, the licensee or applicant shall submit a safety case to the CNSC for acceptance. The safety case must:

- demonstrate that all safety requirements will be met
- be detailed and comprehensive so as to provide the necessary technical input for informing the decisions required
- include clearly written documentation, including arguments justifying the approaches in the safety case, based on information that is traceable and credible
- assess the safety of the facility using a graded approach
- describe all relevant safety aspects of the site, and design, construction, operation, decommissioning, closure and post-closure (including institutional control), as applicable, of the facility or site in the safety case
- be periodically reviewed and updated at all licensing stages and whenever there are significant changes to the disposal facility
- include the implementation of management system principles; additional requirements and guidance for management systems is provided in REGDOC-2.1.1, *Management System* [4]

7. Components of the Safety Case

The safety case shall include the following components, as illustrated in figure 1:

- safety case context
- safety strategy
- disposal system description
- safety assessment
- management of uncertainties
- iteration and design optimization
- limits, controls and conditions
- monitoring and surveillance
- safety features during the period of institutional control
- integration of safety arguments

Note: There are many possible ways of structuring and documenting the safety case.

7.1 Safety case context

The licensee or applicant shall ensure that the safety case:

- defines its scope and purpose
- states the requirements to be met to demonstrate safety

Boundaries and interfaces with facilities and activities in close proximity, both within and outside the site, should be considered in the safety case.

The scope of the safety case should provide a clear description of the relevant stage in the facility's lifecycle; how the safety case has changed from previous revisions; and, how it will support future revisions.

Safety requirements are those that ensure that the proposed licensed activities do not incur unreasonable risk, to the environment and to the health and safety of persons. Requirements typically include acceptance criteria (see section 8.1.1.1) for selected safety indicators (such as dose, risk, radionuclide concentration), in addition to principles of containment, isolation, defence in depth, and robustness. Safety requirements should be developed in consultation with the CNSC and other stakeholders.

7.2 Safety strategy

The licensee or applicant shall develop and adopt a safety strategy that describes the integrated approach that will be taken to meet the safety requirements. The strategy should be established early in the development of the safety case.

The strategy shall identify and describe a number of key elements to provide confidence in safety, such as:

- containment and isolation of the waste
- multiple safety functions, defence in depth, and passive safety features
- robustness
- demonstrability and feasibility
- the interdependencies of the various steps in waste management
- other elements that contribute to and provide confidence in safety

The safety strategy should identify the time frames associated with the key elements of the strategy.

Containment and isolation

Containment and isolation shall be demonstrated by presenting evidence that the overall barrier system retains its safety functions during the safety case time frame. For each barrier, the safety functions, the expected performance, and design life shall be provided. Degradation of these safety functions under normal evolution or disruptive events shall be taken into account. It must be demonstrated that, despite this degradation, containment and isolation and all other safety requirements including acceptance criteria (such as dose, risk, or contaminant concentration) will be met.

Multiple safety functions and defence in depth

The principle of defence in depth shall be applied so that the performance of the disposal facility, described in section 7.3, does not unduly rely on a single barrier. The principle of defence in depth is usually applied in disposal facilities by the provision of a system of multiple barriers with multiple safety functions that contribute to the containment and isolation of the waste.

The safety functions of the individual barrier, as well as the time frames over which the barrier is expected to perform should be identified and justified. Each safety function should be independent of the others, to the extent possible, in order to ensure that they are complementary and that barriers are unlikely to fail through a single failure mode. The number and extent of the barriers necessary should be commensurate with the hazards of the waste to be disposed of.

Safety functions shall be provided by passive means, to the extent possible. Active controls, such as monitoring, can contribute to the confidence in passive barriers and safety functions although shall not be solely relied on to ensure defence in depth. The multiple barrier system should provide resistance, primarily by passive means, to radionuclide migration.

Robustness

The overall disposal system as well as each individual barrier shall be shown to be robust. The overall disposal system is robust if it can be demonstrated that none of the safety requirements would be jeopardized if one or more barriers or safety functions were to fail. Barrier robustness is demonstrated with evidence that the barrier would fulfill its safety functions under the effects of the expected natural processes or anthropogenic disturbances.

The effect of long time frames on robustness should be considered. For disposal facilities with long time frames, there is an increased likelihood that natural processes or disturbances could affect the performance of individual barriers or the overall disposal facility.

Time frames

The licensee or applicant shall define the time frame, which is the period covered by the safety assessment. Time frames establish boundary conditions for the longevity and performance of barriers to isolate and contain the waste.

The licensee or applicant shall justify the time frame associated with the required performance of the overall disposal facility and of its individual components, as part of the safety strategy. This justification shall be commensurate with the class of waste to be stored or emplaced and with the time frame associated with hazards imposed by the waste.

The time frame shall consider the following, at a minimum:

- time of the peak radiological impact predicted by the safety assessment
- normal (expected) evolution of the disposal system, in consideration of the decay of the radiological substances associated with the waste and of the stability of the host medium or site
- type and severity of events considered in the safety assessment

The licensee or applicant should also consider the following to provide additional evidence to support the determination of the time frame:

- use of appropriate natural analogs (e.g., geological, hydrogeological and geochemical characteristics similar to those of the site)
- site-specific natural background levels of radiological and non-radiological contaminants

It may be necessary to define several different time frames within one safety case in order to deal with different scenarios and to demonstrate containment. For example, additional time frames, in addition to the reference time frame used in the normal evolution scenario, may be used to

illustrate the robustness of the disposal facility for time periods beyond when the maximum impact is predicted to occur. The licensee or applicant should define additional time frames to illustrate the performance of particular barriers in response to disruptive events (e.g., earthquakes, glaciation, climate change) that are predicted to occur in the future. The design of the disposal facility should be based on disruptive events that are consistent with the time frame of the normal evolution scenario. In some other situations (e.g., for the deep geological disposal of high-level or intermediate-level waste), impact predictions using very long time frames up to tens of millions of years could illustrate the containment capabilities of the barriers, despite significant environmental or geological perturbations. The evolution of the disposal facility shall be considered when deriving the time frame, and the normal evolution scenario used in the safety assessment would be defined accordingly.

7.3 Disposal system description

The licensee or applicant shall describe the disposal system in the safety case. The disposal system is defined as the integrated collection of properties of the site for a disposal facility; design of the disposal system; physical structures and items; procedures for control; and characteristics of the waste and other elements that contribute in different ways and over different time frames to the fulfilment of safety functions for disposal. The description should also include both quantitative and qualitative information. As applicable, the following shall be included:

- specific understanding of features, events and processes (FEPs) associated with the site and the disposal facility
- waste information (e.g., quantities and properties of the waste and the radionuclide inventory)
- waste acceptance criteria at the disposal facility
- description of the biosphere including human and non-human biota and the surface environment
- site characteristics including, as applicable, the deep and near-surface geological units at the site, including:
 - the description of surface and subsurface characteristics (e.g. geology, hydrogeology, hydrology, geochemistry, tectonics, seismicity, geomorphology, climate, ecology)
 - current and foreseeable land use
 - the identification and description of expected natural evolution and disruptive events
- the design and assumptions upon which the design is based
- description of the structure, systems and components (SSCs) of the disposal system, which includes the engineered and natural barriers, their safety functions, interfaces, associated uncertainties and performance as a function of time¹
- radiological, thermal, hydraulic, mechanical, chemical and biological processes that may affect the disposal system and its components as well as the possible interaction among those components

The licensee or applicant shall demonstrate that nuclear criticality safety has been considered as applicable. Nuclear criticality safety analysis for the post-closure phase shall utilize waste acceptance criteria and technical practices that are provided in REGDOC-2.4.3, *Nuclear Criticality Safety* [5].

¹ For disposal, the performance should take into consideration the degradation of the barriers during the time frame associated with the disposal facility.

Following a graded approach to safety, the level of rigour and completeness in the description of the system and its components should be commensurate with the hazards imposed by the waste, and with the development and licensing stage of the facility. For example, in the concept development stage, generic data might be sufficient, but it is expected that an increasing level of site-specific data would be available at later stages such as site selection, construction and operation. The safety case should be updated by taking into account improved knowledge of the behaviour of the disposal system obtained through a systematic research and development program.

The licensee or applicant shall identify the safety functions of both the overall disposal system and the individual SSCs and assess the safety performance in terms of their ability to fulfill the safety functions. The safety case and its supporting safety assessment should explain and justify the safety functions of the overall disposal system and of each individual barrier.

Guidance on the site characterization of a deep geological repository is found in REGDOC-1.2.1, *Guidance on Deep Geological Repository Site Characterization* [6].

7.4 Safety assessment

The licensee or applicant shall perform a safety assessment that addresses impacts to people and the environment that may arise from normal evolution of the site and from potential disruptive events identified in an FEPs analysis. The FEPs analysis may consider the Nuclear Energy Agency's International FEP List.

7.4.1 Components of the safety assessment

The safety assessment shall include the following components, as applicable:

- site and engineering aspects
- operational safety aspects
- post-closure safety assessment

7.4.1.1 Site and engineering aspects

The licensee or applicant shall use data obtained from the disposal system description as inputs to the safety assessment, and provide boundary conditions for the quantitative assessment models (discussed in section 8.1.1.2).

The licensee or applicant should use the results of the safety assessment to provide confidence in the adequacy of the site and engineering design.

Passive safety

The licensee or applicant shall take passive safety means into account in the design of the facility to minimize the dependence of safety on active means.

Multiple safety functions

The licensee or applicant shall assess defence in depth in the context of the site and engineering aspects. This entails a demonstration that multiple safety functions are provided at the facility.

Scientific and engineering principles

The licensee or applicant should make use of established construction techniques and materials, and should give due consideration to feedback from experience gained. If the licensee or applicant uses other techniques and materials, these should be justified.

Quality of site characterization

The licensee or applicant shall ensure that the safety assessment describes and/or references the approach and criteria used in site selection and demonstrate that the site selected is in accordance with the safety strategy and any criteria that have been established.

For disposal facilities, site characterization activities will take place over many years and should be carried out under a formal site characterization plan that includes quality assurance / quality control protocols to verify the data.

7.4.1.2 Operational safety aspects

While operational safety aspects are outside the scope of this document, the licensee shall ensure that the impacts of pre-closure activities on post-closure safety are assessed and minimized.

7.4.1.3 Post-closure safety assessment

The licensee or applicant shall perform a post-closure safety assessment. The post-closure safety assessment forms the core of the safety assessment for a disposal facility. It involves an analysis of the expected normal evolution of the disposal system, possible disruptive events, and the potential radiological and non-radiological impacts on people and the environment, as well as the interpretation of results. Scenarios are used to describe possible evolutions of the disposal system and its environment as well as the impacts.

The impacts are determined quantitatively by means of mathematical models. This includes an analysis of the potential migration of radioactive and hazardous substances from the disposal facility, their movement in the environment and resulting impacts. Requirements and guidance on how to perform a post-closure safety assessment can be found in section 8 of this document.

7.5 Management of uncertainties

The licensee or applicant shall characterize uncertainties in the safety case with respect to their source, nature and degree using quantitative methods as well as professional judgment.

The licensee or applicant shall ensure that the safety case demonstrates how uncertainties are managed; for example by:

- modifying the safety strategy to reduce the uncertainties
- showing that the uncertainties do not have implications on safety
- using conservative assumptions to bound the uncertainties and showing that there remains a sufficient margin for safety requirements to be met

The licensee or applicant should reduce uncertainties throughout the different stages of the development of the safety case. The licensee or applicant should identify the remaining uncertainties within the safety case and how the safety case is still supported despite these uncertainties.

Uncertainties that remain in the safety case and that have implications on safety should be addressed through uncertainty and sensitivity analyses. In addition, the development of monitoring and research and development programs could be used to further reduce the uncertainties.

7.6 Iteration and design optimization

The licensee or applicant should ensure that the disposal system design and its components are optimized using a well-defined and iterative process. As the project proceeds and additional information is gained, initial results should be refined and should replace the generic or default data, reducing the reliance on assumptions.

The licensee or applicant should demonstrate within the safety case how the selected design and its components have been optimized. The design process should include a comparison between the design options considered, an assessment of their advantages and disadvantages, and a justification for the preferred option. Optimization may be demonstrated through a comparison of previous design iterations to the final design.

7.7 Limits, controls and conditions

The licensee or applicant shall establish limits, controls and conditions using the safety case. These shall be applied to all activities that have an influence on the post-closure safety of the facility and to the waste that will be disposed of at the facility.

The limits, controls and conditions derived from the safety assessment for the waste shall include the waste acceptance criteria for individual packages as well as for the entire facility, and the acceptable waste inventory and/or the allowable concentration levels of radionuclides in the waste.

The licensee or applicant shall use the established limits, controls and conditions as an input to the development of operational programs and procedures in consideration for the post-closure phase. For example, the safety case and established limits, controls and conditions should be used to inform the development of the monitoring and surveillance program for the site and of the surrounding area appropriate to the specific facility.

7.8 Monitoring and surveillance

REGDOC 2.11.1, *Waste Management, Volume I: Management of Radioactive Waste* [7], provides requirements for the monitoring and surveillance of waste management facilities.

7.9 Institutional controls

The licensee or applicant shall identify the role that institutional controls play in disposal facility safety, and how that role is taken into account in the safety case and its supporting safety assessment. The presence of institutional controls should not be used to justify a reduction in the level of design of the containment and isolation system.

While long-term safety of the disposal facility should not be dependent on institutional controls, these should be used to the extent practicable to confirm that the disposal system is performing as designed.

Given the uncertainties associated with future human activities and the evolution and stability of societies, licensees or applicants should limit reliance on institutional control as a safety feature to a few hundred years. For uranium mine and mill waste, the large volume of the waste and the longevity of some of the radionuclides might necessitate longer periods of institutional control as a means of providing safety. Reliance on such longer-term institutional control (beyond a few hundred years) should be justified in the safety case through an optimization process taking into account technical and socio-economic factors.

REGDOC 2.11.1, *Waste Management, Volume I: Management of Radioactive Waste* [7], provides guidance on institutional control.

7.10 Integration of safety arguments

The licensee or applicant should ensure that the safety case provides a synthesis of available evidence, arguments and analyses. This synthesis should be provided in a well-structured, transparent and traceable manner.

The licensee or applicant should:

- provide evidence that all safety requirements have been met
- provide complementary safety indicators, such as radionuclide concentrations and fluxes through individual barriers
- provide additional safety arguments, for example from the study of paleohydrogeological information on the site, and the study of natural analogs to the overall disposal system, and /or its individual components
- address how hazardous substances contained in the radioactive waste could affect the environment

In addition, the licensee or applicant should:

- describe the treatment of uncertainty in the safety case and supporting assessment
- provide evidence on the quality and reliability of the science and design work that form the basis of the safety case
- provide evidence of the quality and reliability of the safety assessment with respect to the derivation of scenarios; the adequacy of methods, models, computer codes and databases; and quality of the calculations
- provide findings that contradict the arguments made in the safety case
- acknowledge any limitations of currently available evidence, arguments and analyses
- document any third-party peer review of the safety case, showing how the outcomes of the peer review have been taken into consideration
- provide management system requirements for the performance of safety assessment calculations to provide assurance of their quality

Following the integration of safety arguments, the licensee or applicant should provide justification for the continuation of the project.

7.10.1 Comparison with acceptance criteria

The licensee or applicant shall compare the selected assessment end points for the assessment to acceptance criteria (such as dose and contamination concentrations). It should be noted that meeting the acceptance criteria is not sufficient for making a safety case acceptable, since other

safety requirements (e.g., isolation, containment) also have to be met. In addition, it should be demonstrated that the proposed disposal system has been optimized.

7.10.2 Complementary safety indicators

In addition to comparing safety assessment end points with the acceptance criteria, the licensee or applicant should use complementary safety indicators (i.e., the calculation of values other than the end points of the assessment) to provide additional confidence in the conclusions of the safety case. Assessments that use complementary safety indicators as additional arguments for safety should present justification for their use.

Complementary indicators from the safety assessment can also be used to inform the monitoring program. In many instances, however, those indicators cannot be directly or practically monitored (e.g., container corrosion rates), but must be inferred by a set of sub-indicators that are easily measured or quantified. For example, corrosion rates depend on temperature and the geochemical composition of the groundwater, and the former parameters can be included in a monitoring program.

7.10.3 Additional arguments (multiple lines of reasoning)

The licensee or applicant should use multiple lines of reasoning to provide confidence in the safety case; for example, from natural or anthropogenic analogs or from paleohydrogeological information.

Natural analogs can be used to demonstrate that components of a disposal system remain effective over extended temporal and spatial scales considered in post-closure safety assessment models, which cannot be replicated in laboratory studies. Natural analogs can provide data for verifying and validating both detailed process and simplified assessment models, and for developing generic models that describe the site in the absence of site-specific characterization data. Anthropogenic analogs, if relevant, may also be used in addition to natural analogs. Site-specific paleohydrogeological information can build confidence in the site's geological stability and containment capability. Natural analogs and paleohydrogeological information can provide complementary assessments of long-term safety, and be included in the safety case to provide confidence in the conclusions drawn from the safety assessment.

8. Post-Closure Safety Assessment

The licensee or applicant shall ensure that the post-closure safety assessment for a disposal system includes a systematic quantitative analysis of the evolution of the disposal system and its environment, possible disruptive events, and the potential resulting radiological and non-radiological impacts on people and the environment. The interpretation of the quantitative results should be clear.

The licensee or applicant shall develop and use scenarios to describe possible evolutions of the facility and its environment as well as the potential impact of the identified FEPs on safety.

The licensee or applicant should apply models to each given scenario to assess:

- evolution of the waste form and associated contaminant activity/concentrations over time
- contaminant release rates
- evolution of the engineered barriers
- evolution of the natural barriers

- contaminant transport through the engineered barriers, the geosphere and the biosphere
- receptor exposure
- potential effects resulting from the exposure

The licensee or applicant shall ensure that the post-closure safety assessment demonstrates their understanding of the disposal system through a well-structured, transparent and traceable methodology.

The post-closure safety assessment documentation should provide a clear and complete record of the decisions made and the assumptions adopted in developing the model of the disposal system. The parameters and variables used to run the model and to arrive at a given set of results should be reported and justified. This input data should be obtained from site-specific studies and research results.

The assumptions and data of the post-closure safety assessment shall be supported by an assessment of the current and future conditions of the disposal system.

Due to the uncertainty of assumptions made about future events, the reliability of quantitative estimates diminishes with increasing time scale. The demonstration of safety will therefore rely less on quantitative estimates and more on qualitative arguments as the time scale increases. The licensee or applicant should not consider long-term quantitative estimates as guaranteed impacts, but rather as safety indicators. To build confidence, the post-closure safety assessment should be performed using an approach that combines multiple lines of reasoning (additional arguments) and safety indicators within the context of the safety case.

8.1 Components of the post-closure safety assessment

The licensee or applicant should use a structured approach to perform the post-closure safety assessment of a disposal system that includes the following components:

- post-closure safety assessment context
- disposal system description
- post-closure safety assessment scenarios and time frames
- development and use of safety assessment models
- interpretation of results

8.1.1 Post-closure safety assessment context

The licensee or applicant shall ensure that the safety assessment context:

- defines the scope and purpose
- states the assessment criteria used in the assessment
- outlines the approach adopted to demonstrate safety
- states the end points for the assessment (i.e. the modelling output that needs to be compared to the acceptance criteria; see section 8.1.1.1)

8.1.1.1 Acceptance criteria used in the assessment

The licensee or applicant shall ensure that the safety assessment context contains the criteria by which the safety assessment results will be deemed acceptable. These criteria shall be based on regulatory requirements and/or derived from other scientifically justifiable benchmarks or safety

indicators that indicate system performance. The licensee should establish explicit criteria for the level of safety to be achieved.

Radiological protection of persons

The post-closure safety assessment of a disposal facility shall provide reasonable assurance that the regulatory radiological dose limit for public exposure (currently 1 mSv/year) will not be exceeded for the normal evolution scenario. To account for the possibility of exposure to multiple sources, and their potential cumulative effects, and to help ensure that doses resulting from the disposal system are as low as reasonably achievable (ALARA), a dose constraint should be established as a fraction of the regulatory dose limit. The dose constraint is not a limit, but rather a design tool in the optimization process. For example, for optimization, the International Commission on Radiological Protection (ICRP) [8] recommends a dose constraint of 0.3mSv/year.

The dose constraint should not be used to account for uncertainties in safety assessment model predictions. The achievement of a design constraint does not, in itself, demonstrate that a design satisfies the optimization principle. A dose should be reduced below a constraint if this can be done at a justifiable cost, taking into consideration social and economic factors. The form of the radiological design target should be consistent with the approach and strategy chosen for the post-closure safety assessment.

The IAEA's SSR-5, *Disposal of Radioactive Waste* [9], proposes the following criteria, according to ICRP recommendations:

- (a) The dose limit for members of the public for doses from all planned exposure situations is an effective dose of 1 mSv in a year. This and its risk equivalent are considered criteria that are not to be exceeded in the future.
- (b) To comply with this dose limit, a disposal facility (considered as a single source) is so designed that the calculated dose or risk to the representative person who might be exposed in the future as a result of possible natural processes affecting the disposal facility does not exceed a dose constraint of 0.3 mSv in a year or a risk constraint of the order of 10^{-5} per year.
- (c) In relation to the effects of inadvertent human intrusion after closure, if such intrusion is expected to lead to an annual dose of less than 1 mSv to those living around the site, then efforts to reduce the probability of intrusion or to limit its consequences are not warranted.
- (d) If human intrusion were expected to lead to a possible annual dose of more than 20 mSv to those living around the site, then alternative options for waste disposal are to be considered; for example, disposal of the waste below the surface, or separation of the radionuclide content giving rise to the higher dose.
- (e) If annual doses in the range of 1 to 20 mSv are indicated, then reasonable efforts are warranted, at the facility development stage, to reduce the probability of intrusion or to limit its consequences by means of optimization of the facility's design.
- (f) Similar considerations apply where the relevant thresholds for deterministic effects in organs may be exceeded.

Protection of persons from hazardous substances

Benchmark values for protection from hazardous substances can be found in federal and provincial environmental objectives and guidelines. Where available, the *Canadian Environmental Quality Guidelines* [10], established by the Canadian Council of Ministers of the Environment (CCME) for protection of human health, should be used for benchmark or toxicological reference values. Where the CCME's human health guidelines are not available, human health-based federal or provincial guidelines should be used. If none are available, benchmarks can be derived from the toxicity literature or other regulatory agencies, or from CCME protocols for the derivation of criteria.

Radiological protection of the environment

For the protection of non-human biota from radiation exposure, the primary concern is the total radiation dose to the organisms resulting in deterministic effects. Radiation dose benchmarks for a quantitative effects analysis should follow the guidance of the United Nations Scientific Committee on the Effects of Atomic Radiation [11]. For species identified to be in need of special protection (e.g., those named on the Government of Canada's List of Wildlife Species at Risk), a more conservative screening dose rate criterion [8] should be considered. Other benchmark values for mean radiation doses to non-human biota have been derived for various types of organisms [12, 13, 14, 15, 16, 17].

Development of criteria for ensuring radiological protection of the environment should follow the protocols established for hazardous substances, as discussed below.

Protection of the environment from hazardous substances

Non-radiological acceptance criteria for protection of the environment can include concentration or flux of hazardous substances. The *Canadian Environmental Quality Guidelines* [10] for water, sediment and soil are appropriate benchmarks for conservative safety analyses. Provincial guidelines can be used, where appropriate, for substances for which federal guidelines have not been established.

Alternatively, benchmarks for hazardous substances can be derived from toxicity literature, or other regulatory agencies (e.g., the U.S. Environmental Protection Agency). The CCME provides protocols for the derivation of air, soil and water quality criteria. The protocols for developing criteria for the protection of the environment include determining critical toxicity values – such as an effects concentration for a 10% or 20% response, lowest observable adverse effects level, or no observable adverse effects level – from studies of chronic exposure to the most sensitive species. The assessment of risks of hazardous substances to non-human biota is done at the population level, but for species identified to be in need of special protection (e.g., those identified under the *Species at Risk Act*), the assessment should focus on protection at an individual level.

8.1.1.2 Approach adopted to demonstrate safety

A licensee or applicant should use risk-informed approaches to estimate the release and dispersal of contaminants and resulting concentrations in water, sediment, soil and air based on waste characteristics, release mechanisms and rates, and contaminant transport rates. This may be a combination of modelling supported by monitoring data.

A licensee or applicant should assess post-closure safety using a number of quantitative approaches, including, without being limited to:

- a scoping assessment to illustrate the factors that are important to post-closure safety and a bounding assessment to show the limits of potential impact
- calculations that give a realistic best estimate of the performance of the disposal facility or system, or conservative calculations that intentionally over-estimate potential impact
- deterministic or probabilistic calculations, appropriate for the purpose of the safety assessment, to reflect data uncertainty

The licensee or applicant may use any combination of these or other appropriate assessment strategies in a complementary manner to increase confidence in the demonstration of the safety of the facility.

The licensee or applicant should discuss and justify the choice of approach in the documentation demonstrating post-closure safety. It is expected that the purpose of the safety assessment will also justify the assessment model used (section 8.1.5) and the level of confidence that is needed in the results.

Scoping and bounding assessment

The licensee or applicant may use a scoping assessment to provide a general understanding of the overall disposal facility, and to help identify the aspects of the system that are critical to safety.

The licensee or applicant may use a bounding assessment to provide limiting estimates of disposal facility performance. Such assessment may be performed with simple mathematical models, or detailed models that use limiting parameter values.

Realistic best estimates vs. conservative overestimations assessment

The licensee or applicant may use a realistic best-estimate assessment to provide the most likely behavior of the disposal facility. The licensee or applicant should use real site and as-built facility data, site-specific scenarios and accurate models of the processes being simulated in the realistic estimate.

The licensee or applicant may use conservative assessments to intentionally overestimate future consequences to provide an additional margin of safety for situations where the assessment results cannot be considered accurate estimates, but indicators of safety. A conservative approach should be used when developing computer codes and models. Assumptions and simplifications of processes should not result in underestimation of the potential risks or impacts. It may not be necessary for every assumption to be conservative; however, the net effect of all assumptions should be a conservative representation of long-term impact and risk.

Conservative values of boundary and initial conditions of an assessment model, as well as input data, can be used to overestimate future consequences. Because models do not necessarily have a linear response to input data, conservative input values are not necessarily upper or lower limits of the data. It is the value of the computed result that determines whether the model structure and input data have given a conservative overestimation.

If the assessment results are to be used for compliance with a numerical measure or standard of performance, it may be appropriate to undertake a conservative approach based on relatively

simple models. Such an approach will be feasible if there is a large margin of safety. Caution is necessary because if misused, results from overly conservative or worst case representations of the facility or activity may lead to poor decision making based on assessment results that bear little resemblance to the actual disposal system.

Deterministic and probabilistic approach

The licensee or applicant may use a deterministic model to illustrate the impact of specific individual uncertainties or alternative model assumptions. The deterministic model uses single-valued input data to calculate a single-valued result that will be compared to an acceptance criterion. To account for data variability, individual deterministic calculations must be done using different values of input parameters.

This is the approach used for performing sensitivity analyses (determining the response of model predictions to variations in input data) and importance analyses (calculating the range of predicted values that corresponds to the range of input values).

The licensee or applicant may use probabilistic models which typically perform repeated deterministic calculations based on input values sampled from parameter distributions, with the set of results expressed as a frequency distribution of calculated consequences. Frequency multiplied by consequence is interpreted as the overall potential risk of harm from the disposal. Probabilistic models can explicitly account for uncertainty arising from variability in the data used in safety assessment predictions. Such models may also be structured to take account of different scenarios or uncertainty within scenarios.

The potential risk calculated by a probabilistic model cannot be compared directly to an acceptance criterion unless that criterion is also expressed as a risk. The results of a probabilistic model should be presented and discussed. When risk is calculated as the magnitude of the consequence and the likelihood of its occurrence, the model will reflect the probability that a scenario with those particular input data values will actually occur.

8.1.1.3 Assessment end points

The licensee or applicant shall demonstrate that the selected assessment end points are consistent with the purpose of the assessment and with relevant regulatory requirements, such as requirements related to radiological dose.

Other safety indicators, complementary safety indicators, such as those that reflect containment barrier effectiveness or impacts on non-human species, can also be presented to illustrate the long-term performance of a disposal system. Some examples of complementary safety indicators include:

- container corrosion rates
- waste degradation rates
- groundwater age and travel time
- fluxes of contaminants from a disposal facility
- impacts of the system on site-specific flora and fauna
- concentrations of contaminants in specific environmental media (for example, concentration of radium in groundwater)
- changes in toxicity of the waste

The licensee or applicant should derive and justify the acceptance criteria by which these complementary safety indicators are to be judged from the relationship between the complementary safety indicator and the more direct assessment end-points. For example, if the environmental concentration of a hazardous substance is directly related to groundwater velocity near a disposal facility, then groundwater velocity could be used as a criterion to demonstrate post-closure safety to complement a more complete safety assessment that uses impact on the environment, such as environmental concentration, as end points.

Identification of human and environmental receptors

The licensee or applicant shall develop scenarios to include the identification of human and environmental receptors that may be exposed to radioactive and hazardous substances. The exposures of persons and the various receptor organisms can occur by different pathways and will be judged by different acceptance criteria even when all receptors are present in the same environment at the same time.

Human and environmental receptors should be identified based on the guidance of CSA N288.1, *Guidelines for Calculating Derived Release Limits for Radioactive Material in Airborne and Liquid Effluents for Normal Operations* [18], and CSA N288.6, *Environmental Risk Assessment for Class I Facilities and Uranium Mines and Mills* [19].

IAEA-TECDOC-1077, *Critical Groups and Biospheres in the Context of Radioactive Waste Disposal* [20], provides guidance for assessing exposures to critical groups throughout the time frame of the normal evolution scenario. For long time frames, the proponent may elect to use a reference biosphere for the critical group. Additional guidance on the use of reference biospheres can be found in the 2003 IAEA's BIOMASS-6, *Reference Biospheres for Solid Radioactive Waste Disposal* [21].

8.1.2 Disposal system description

The licensee shall include the disposal system description, a component of the overall safety case, which should be reiterated to show that the features are relevant to the safety assessment. The disposal system description should present both the characteristics of the site and the design of the SSCs important to safety, as well as a description of the waste to be managed.

As licensing progresses through the facility's lifecycle, as-built information and operational data are acquired. Both of these sources of information will enhance the understanding of the site characteristics. It is expected that safety assessments that are made later in the facility's lifecycle will be based on updated and refined models and data. There should be less reliance on default, generic or assumed information, resulting in more reliable model results.

8.1.2.1 Site characterization

The licensee or applicant shall include site characterization data in the safety assessment.

The licensee or applicant should ensure that the site characteristics are sufficiently defined to support an accurate description of the current site conditions and a credible projection of their future evolution.

Guidance on the site characterization of a deep geological repository is found in REGDOC-1.2.1, *Guidance on Deep Geological Repository Site Characterization* [6].

8.1.3 Post-closure safety assessment scenarios and time frames

The licensee shall develop and use scenarios to describe possible evolutions of the disposal system and its environment as well as the potential impact of identified FEPs on safety.

The licensee or applicant shall ensure that assessment scenarios are sufficiently comprehensive to account for all of the present and potential future states of the site and the biosphere.

The safety assessment shall include a base case scenario of the normal, expected or anticipated evolution of the site and the disposal system over time, and additional scenarios that examine the potential impact of disruptive events with a low probability of occurrence.

Each scenario presented in a safety assessment shall include specific information about:

- the time frame on which the assessment is based
- the length of time (start to finish) that institutional controls are relied upon as a safety feature
- the identity and characteristics of the assumed receptors and critical groups

A safety assessment should present and justify the techniques and criteria used to develop the scenarios that are analyzed. Scenarios should be developed in a systematic, transparent, and traceable manner through a structured analysis of relevant FEPs that are based on current and predicted future conditions of site characteristics, waste properties, and receptor characteristics and their lifestyles. The approach to scenario development should be consistent with the rigour of the safety assessment, taking into consideration the purpose of the assessment, the hazards of the waste, and the nature of the decision for which the assessment is being undertaken.

For the demonstration of the robustness of a disposal system, the assessment should consider disruptive event scenarios in which the total or partial failure of one or several barriers or safety functions is assumed. These disruptive event scenarios should show that the safety of the overall disposal system is still valid.

“What if” scenarios should be used to exhibit the robustness and performance of various natural and engineered barriers under extreme conditions. It can be instructive to assign parameter values or other properties to parts of the barrier system such that the barrier under consideration is influenced in an exaggerated way. This may show that such exaggerated conditions are impractical, do not negatively impact safety or that they can be avoided by design.

Stylized scenarios are generic representations of a group of scenarios, where part of the disposal system is treated in a standardized or simplified way. The application of stylized scenarios may be useful where site-specific information is lacking, or where the purpose of the safety assessment does not require detailed site-specific information.

The safety assessment should demonstrate that the set of scenarios developed is credible and comprehensive. Some FEPs or scenarios may be excluded from the assessment if these are extremely unlikely or would have trivial impact.

An alternative method for developing scenarios is based on an analysis of how the safety functions are influenced by possible FEPs. This may be followed by a process of auditing the scenarios developed against an appropriate list of the FEPs.

The approach and screening criteria used to exclude or include scenarios should be justified and well documented.

8.1.3.1 Normal evolution scenario

The licensee or applicant shall present a normal evolution scenario in the post-closure safety assessment. The normal evolution scenario should be based on reasonable extrapolation of current site features and receptor lifestyles. It should include the expected evolution of the site and the degradation of the disposal system (gradual or total loss of barrier function) as it ages. Evolution scenarios are not expected to include biological evolution of individual receptor species, which can be assumed to be static for the purposes of the post-closure safety assessment.

Depending on site-specific conditions and the time frame for the safety assessment, a normal evolution scenario should include expected conditions or events such as, earthquakes, climate shifts or the onset of glaciation. Similarly, periodic natural events such as floods or forest fires, if they are expected to occur during the time frame, should be part of the normal evolution scenario. Their effects on barrier performance should be considered. These scenarios may be analyzed separately as variants of the normal evolution scenario.

The decision about which natural events should be included is based on the assessment of FEPs and the probability of their occurrence within the time frame of the safety assessment.

Normal evolution scenarios should also take into account the failure modes of the containment and isolation systems. These failures can result not only from natural degradation of barriers, but from events that might be expected to occur once or more during the assessment time frame, including penetration of the barriers by intrusion.

The safety assessment should model the biosphere, which will be the receiving environment for the contaminants, based as much as possible on the site specific information in the system description. Alternatively, when-site specific information is not adequate to make reasonable or conservative extrapolations from the characteristics of the current biosphere, a stylized approach to defining the biosphere may meet the purpose of the safety assessment.

8.1.3.2 Disruptive event scenarios, including human intrusion

The licensee or applicant shall postulate disruptive event scenarios leading to possible penetration of barriers and abnormal loss of containment. The occurrence of events such as fire, flood, seismic activity, volcanism and human intrusion cannot be predicted accurately, even in cases where they can be associated with an annual probability of occurrence or a return period. Disruptive events – that are more severe than the events considered in normal evolution scenarios to which barriers are designed and assumed to resist – should be considered. The inclusion of disruptive event scenarios will demonstrate the principle of defence in depth and the robustness of the overall disposal system.

Intrusion not only breaches containment barriers, but also may result in waste being redistributed outside the barriers, potentially exposing the public and the environment. Assessment of human intrusion therefore needs to estimate the exposure of persons and the environment that would result from waste redistribution. Scenarios of inadvertent intrusion, where the intruder is not aware of the hazards of the waste, should estimate the exposure of the intruder. However, intentional human intrusion, where the intruder is assumed to be aware of the hazard of the waste, need not be considered.

Scenarios for inadvertent intrusion should be case-specific, based on the class of waste and the design of the disposal system, and should consider both the probability of intrusion and its associated consequences. Surface and near-surface disposal facilities (e.g., tailings sites) are more likely to experience intrusion than deep geological repositories. Acceptance criteria for human intrusion should be defined. In case the criteria cannot be met, even after optimization of the design and siting, management of the waste at greater depths should be considered.

Reasonable efforts should be made to limit the dose from a high-consequence intrusion scenario and to reduce the probability of the intrusion. The consequences of intrusion could be reduced by controlling the form and properties of the waste accepted. Design modifications to reduce the likelihood of inadvertent intrusion should be undertaken. This may include the choice of site (where site selection options are feasible), siting the disposal facility at a depth that discourages intrusion, incorporating robust design features that make intrusion more difficult, and implementing active or passive institutional controls, as appropriate.

For near-surface disposal, in addition to design and optimization, assessment of human intrusion scenarios also contributes to the development of waste acceptance criteria, to the development of the time frames necessary for institutional controls, and to the determination of whether specific waste streams require deeper disposal.

For deep geological repositories – where the site characteristics, and the depth and the design of the facility have already been optimized to reduce the likelihood of the intrusion – the assessment results of human intrusion scenarios should be used for illustrative purposes. Scenarios concerning inadvertent human intrusion into such repositories could estimate doses that are greater than the regulatory limit. Such results should be interpreted in light of the degree of uncertainty associated with the assessment, the conservatism in the dose limit, and the likelihood of the intrusion. Both the likelihood and the consequences from the intrusion should therefore be reported.

8.1.3.3 Assessment time frames

The licensee or applicant shall ensure that future impact that may arise from the radioactive waste includes the period of time during which the maximum impact is predicted to occur.

A rationale for the time frame associated with the safety assessment shall be given. The approach taken to determine respective periods of time used in the safety assessment should take into account the following elements:

- hazardous lifetime of the contaminants associated with the waste
- duration of the operational period (before the disposal facility reaches its end state)
- design life of engineered barriers
- duration of both active and passive institutional controls
- frequency of natural events and human-induced environmental changes (e.g., seismic occurrence, flood, drought, glaciation, climate change)
- the degree of protection and isolation required against inadvertent intrusion over the long term

The licensee or applicant should document and justify the assumed performance time frames of engineered barriers and the evolution of their safety functions over time. Depending on the purpose of the assessment, it might be convenient to divide the overall time frame into several

shorter time windows for modelling or presentational reasons. Different end points can also be used for different time windows.

With long time frames, more severe events (associated with lower annual probability of exceedance) should be considered in the design of the disposal system and its components. For example, the design earthquake to be chosen for a system or its component depends on the likelihood and consequences of failure should a more severe earthquake occur during the time frame. If the consequences are high, the design earthquake should be chosen such as its probability of exceedance during the time frame would be smaller. A design earthquake is often associated with a return period (in years), which is the inverse of its annual probability of exceedance. For example an earthquake with a return period of 10,000 years has an annual probability of exceedance of 1/10,000. Therefore, for any given year, there is a probability of 1/10000 (0.01%) that a more severe earthquake might occur. For a time frame of 10,000 years, that probability increases to 63% and for a time frame of 100,000 years, this probability is near 100%.

8.1.4 Development and use of assessment models

In developing assessment models, the licensee or applicant should employ a variety of computational tools (conceptual and mathematical models) to predict future conditions for comparison to acceptance criteria.

The licensee or applicant should develop a conceptual model, which is a representation of the behaviour of the disposal system that includes the description of the components of the system and the interactions between these components. It should also include a set of assumptions concerning the geometry of the system and the chemical, physical, biological, mechanical and geological behavior of the facility or activity, consistent with the information and knowledge available.

The conceptual models of the site and the disposal system often need to be simplified to correspond to the limitations of the mathematical equations and the capabilities of computer models. A mathematical model is a representation of the features and processes included in the conceptual model in the form of mathematical equations.

The level of accuracy needed in the post-closure safety assessment models, and the degree of conservatism desired in the results, are determined by:

- the purpose of the safety assessment
- the importance of the model results with respect to indicating expected performance and safety

8.1.4.1 Confidence in safety assessment models

The licensee or applicant should ensure that safety assessment models are fit for purpose. The input parameters, the scenarios analyzed, and the results should be shown to be consistent with the assumptions and limitations of the model.

The licensee or applicant should keep records of how site-specific and system-specific characterization data have been used to derive input parameters.

The safety assessment model evaluation process should concentrate on identifying and understanding the key radiological, physical, chemical and biological processes that are important to safety at the various spatial and temporal scales of concern in the safety assessment. Sophisticated detailed models of processes can be used to determine if those processes are sufficiently influential to include them in the post-closure safety assessment model, or if they can be simplified or ignored with no detriment to the reliability of the predictions.

Model evaluation should include sensitivity analyses to show whether the model output responds as expected to variations in the model input parameter. Model evaluation should also include uncertainty and importance analyses to show which parameters control the variability in model output. These analyses should demonstrate how well the model replicates what is known and understood about the processes being simulated. The results obtained from these analyses should be shown to conform to the limitations and restrictions of the assumptions in the safety assessment model.

The need to evaluate the uncertainty in the safety assessment models is determined by the level of confidence needed in the modelling results. The acceptable level of confidence is governed by the purpose of the safety assessment, the safety factor built into the acceptance criteria for safety indicators, and the importance of the safety assessment model results to the safety case.

Neither sensitivity studies nor uncertainty analyses of deterministic or probabilistic models can inherently account for uncertainties in the underlying conceptual model, or for uncertainties resulting from limitations of the mathematical model used to describe the processes. Investigation of such uncertainties would require the use of different mathematical and computer models based on alternate conceptual models.

Confidence in the safety assessment model can be enhanced through a number of activities, including (without being limited to):

- performance of independent predictions using entirely different safety assessment strategies and computing tools
- demonstration of consistency between the results of the post-closure safety assessment model and complementary scoping and bounding safety assessment
- application of the safety assessment model to an analog of the disposal system
- performance of model comparison studies of benchmark problems
- scientific peer review by publication in open literature
- other practices in widespread use by the scientific and technical community
- demonstration of consistency between the model results and site-specific field studies

8.1.4.2 Confidence in computing tools

The licensee or applicant should ensure that computer programs are suitable for the given assessment; these may include commercially available software packages or software specifically developed for the assessment in question.

The computer software used for assessment calculations should be qualified in accordance with applicable standards.

Calibration of computer models and verification and validation of software are the main processes involved in software quality assurance. Calibration involves setting adjustable

parameters within the mathematical equations to minimize the differences between the calculated and measured responses of the system, with the prior knowledge of the latter.

The licensee or applicant should verify and validate all computer software used for the safety assessment or provide reference to existing validation. Verification ensures that the program functions as designed and intended (i.e., that the mathematical equations in the computer model are solved correctly). This can be tested using benchmark problems specific for the type of model being assessed. Validation is meant to ensure that the mathematical equations in the computer model simulate, with reasonable accuracy, the processes and conditions they are supposed to represent.

8.1.5 Interpretation of results

When interpreting the safety assessment results, the applicant should demonstrate a thorough understanding of the underlying science and engineering principles that are controlling the safety assessment results. Interpretation should include evaluation of compliance with the acceptance criteria and analysis of the uncertainties associated with the safety assessment.

The results of the safety assessment should also be analyzed to show consistency with system performance expectations and with the complete set of assumptions and simplifications used in developing the models and scenarios. Any unexpected results or discrepancies should be documented, investigated and explained.

8.1.5.1 Comparing safety assessment results with acceptance criteria

One of the aims of the safety assessment is to compare the safety assessment end points with acceptance criteria. Comparison of the safety assessment results with acceptance criteria should include discussion of the conservatism of the model results, and of the conservatism built into the acceptance criteria for the assessment end points.

If the safety assessment results do not demonstrate compliance with the acceptance criteria, the safety assessment shall be revised. Sufficient detail should be provided to enable the CNSC to verify the results.

However, compliance with the acceptance criteria, in itself, is not sufficient for acceptance of a safety case since additional safety requirements must also be shown to be met.

8.1.5.2 Analyzing uncertainties

An uncertainty analysis of the assessment results should be performed to identify the sources and significance of uncertainty. This analysis should distinguish between uncertainties arising from:

- input data or parameters
- scenario assumptions
- the imprecision in the mathematical model
- the conceptual models

Sensitivity analysis is used to identify the relative importance of the uncertainty of each input parameter to the results of the safety assessment.

While acceptance criteria are usually expressed as single values, both deterministic and probabilistic safety assessment results have an associated uncertainty. It is expected that the

comparison between the safety assessment end points and the acceptance criteria will explicitly take the uncertainty in the safety assessment into account, as follows:

- for deterministic safety assessments, the range of uncertainty in the calculated result as determined by a sensitivity analysis (or importance analysis) is expected to be explicitly included in the comparison
- for probabilistic safety assessments, the likelihood of exceeding the acceptance criteria should be determined from the calculated results distribution; if the range of safety assessment results from deterministic uncertainty analysis or from the probabilistic results distribution shows that part of the results may exceed the acceptance criteria, the applicant should demonstrate that these results will not represent unreasonable risk to the environment or to the health and safety of persons, taking into account the conservatism built into the safety assessment calculations and the likelihood of the circumstances leading to these results

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.

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16. Environment and Climate Change Canada. [Priority Substances List Assessment Report: Releases of Radionuclides From Nuclear Facilities \(Impact on Non-Human Biota\)](#). Ottawa, 2003.
17. ICRP. ICRP Publication 108, [Environmental Protection – the Concept and Use of Reference Animals and Plants](#), United Kingdom, 2008.

18. CSA Group. CSA N288.1, [Guidelines for Calculating Derived Release Limits for radioactive Material in Airborne and Liquid Effluents for Normal Operations](#). Mississauga, 2014.
19. CSA Group. CSA N288.6, [Environmental Risk Assessments at Class I Nuclear Facilities and Uranium Mines and Mills](#). Mississauga, 2012.
20. IAEA. [IAEA TECDOC No. 1077, Critical Groups and Biospheres in the Context of Radioactive Waste Disposal](#). Vienna, 1999.
21. IAEA. [IAEA BIOMASS-6, "Reference Biospheres" for Solid Radioactive Waste Disposal](#). Vienna, 2003.

Additional Information

The CNSC may recommend additional 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 Webpage on its "[How to gain free access to all nuclear-related CSA standards](#)" Web page.

The following documents are not referenced in this regulatory document but contain information that may be useful to the reader:

- CNSC. [REGDOC-2.11, Framework for Radioactive Waste Management and Decommissioning in Canada](#). Ottawa, 2018.
- CNSC. [REGDOC-2.11.2, Decommissioning](#). Ottawa, 2021.
- CSA Group. CSA N286, *Management System Requirements for Nuclear Facilities*. Mississauga, 2012.
- CSA Group. CSA N288.4, *Environmental Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills*. Mississauga, 2019.
- CSA Group. CSA N288.5, *Effluent Monitoring programs at Class I Nuclear Facilities and Uranium Mines and Mills*. Mississauga, 2011.
- CSA Group. CSA N288.7, *Groundwater Protection Programs at Class I Nuclear Facilities and Uranium Mines and Mills*. Mississauga, 2015.
- CSA Group. CSA N292.0, *General Principles for the Management of Radioactive Waste and Irradiated Fuel*. Mississauga, 2014.
- CSA Group. CSA N292.1, *Wet Storage of Irradiated Fuel and Other Radioactive Materials*. Mississauga, 2016.
- CSA Group. CSA N292.2, *Interim Dry Storage of Irradiated Fuel*. Mississauga, 2013.
- CSA Group. CSA N292.3, *Management of Low- and Intermediate-Level Radioactive Waste*. Mississauga, 2014.
- CSA Group. CSA N292.5, *Guideline for the Exemption or Clearance From Regulatory Control of Materials that Contain, or Potentially Contain, Nuclear Substances*. Mississauga, 2011.
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- CSA Group. CSA N294, *Decommissioning of Facilities Containing Nuclear Substances*. Mississauga, 2019.
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- IAEA. [IAEA Technical Reports Series No. 389, Radiological Characterization of Shut Down Nuclear Reactors for Decommissioning Purposes](#). Vienna, 1998.
- International Organization for Standardization. [ISO 21238: 2007, Nuclear Energy – Nuclear fuel Technology – Scaling Factor Method to Determine the Radioactivity of Low- and Intermediate-Level Radioactive Waste Packages Generated at Nuclear Power Plants](#). Geneva, 2007.

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.

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| | 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

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| | 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 |
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3.0 Other regulatory areas

- | | | |
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| Series | 3.1 | Reporting requirements |
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