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Waste Management

Waste Management, Volume II: Assessing the Long-Term Safety of Radioactive Waste Management

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Waste Management, Volume II: Assessing the Long-Term Safety of Radioactive Waste Management

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Preface

This regulatory document is part of the Canadian Nuclear Safety Commission's (CNSC) waste management series of regulatory documents. The full list of regulatory document series is included at the end of this document and can also be found on the CNSC's website.

Regulatory document REGDOC-2.11.1, *Waste Management, Volume II: Assessing the Long-Term Safety of Radioactive Waste Management* is intended to assist applicants for new licences and for licence renewals in assessing the long-term safety of radioactive waste management. This document describes approaches for assessing the potential long-term impact that radioactive waste storage and disposal methods may have on the environment and on the health and safety of people.

This document replaces G-320, *Assessing the Long Term Safety of Radioactive Waste Management* published in December 2006, and P-290, *Managing Radioactive Waste* published in July 2004.

This regulatory document is intended to form part of the licensing basis for a regulated facility or activity within the scope of the document. It is intended for inclusion in licences as either part of the conditions and safety and control measures in a licence, or as part of the safety and control measures to be described in a licence application and the documents needed to support that application.

For proposed new facilities: This document will be used to assess new licence applications.

Guidance contained in this document exists to inform the applicant, to elaborate further on requirements or to provide direction to licensees and applicants on how to meet requirements. It also provides more information about how CNSC staff evaluate specific problems or data during their review of licence applications. Licensees are expected to review and consider guidance; should they choose not to follow it, they should explain how their chosen alternate approach meets regulatory requirements.

For existing facilities: The requirements contained in this document do not apply unless they have been included, in whole or in part, in the licence or licensing basis.

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. With a graded approach, the application of requirements is commensurate with the risks and particular characteristics of the facility or activity.

An applicant or licensee may put forward a case to demonstrate that the intent of a requirement is addressed by other means and demonstrated with supportable evidence.

The requirements and guidance in this document are consistent with modern national and international practices addressing issues and elements that control and enhance nuclear safety. In particular, they establish a modern, risk-informed approach to the categorization of accidents – one that considers a full spectrum of possible events, including events of greatest consequence to the public.

Important note: Where referenced in a licence either directly or indirectly (such as through licensee-referenced documents), this document is part of the licensing basis for a regulated facility or activity.

The licensing basis sets the boundary conditions for acceptable performance at a regulated facility or activity, and establishes the basis for the CNSC's compliance program for that regulated facility or activity.

Where this document is part of the licensing basis, the word "shall" is used to express a requirement 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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Assessing the Long-Term Safety of Radioactive Waste Management

1. Purpose

The purpose of this regulatory document is to assist applicants for new licences and for licence renewals in assessing the long-term safety of radioactive waste management.

2. Scope

This document describes approaches for assessing the potential long-term impact that radioactive waste storage and disposal methods may have on the environment and on the health and safety of people. This document addresses:

1. long-term care and maintenance considerations;
2. setting post-decommissioning objectives;
3. establishing assessment criteria;
4. assessment strategies and level of detail;
5. selecting time frames and defining assessment scenarios;
6. identifying receptors and critical groups; and
7. interpretation of assessment results.

This document addresses the assessment of long-term safety to support licence applications, and includes discussion of assessment methodologies, structures, and approaches. This document does not address other issues that are also taken into consideration in the licensing process, such as waste characterization[1], the assessment of facility operations, transportation of waste, or the social acceptability or economic feasibility of long-term waste management methods.

The guidance in this document is not applicable in its entirety to every assessment. The applicability of all or part of this document will be determined by the applicant, based on:

1. the nature and purpose of the assessment;
2. the hazard of the radioactive waste; and
3. the consequences of making an incorrect decision based on the assessment.

3. Relevant Legislation

3.1 Overview

The CNSC is the federal agency that regulates the development and use of nuclear energy and the production, possession, and use of nuclear substances, prescribed equipment, and prescribed information to prevent unreasonable risk to the health, safety, and security of persons and the environment, and to respect Canada’s international commitments on the peaceful use of nuclear energy.

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[1] For reference purposes, two informative annexes from CSA N292.0-14, *General principles for the management of radioactive waste and irradiated fuel* have been included as appendices to this document: Radioactive Waste Classification, Exemption, Clearance and Storage for Decay (appendix B), and, Methods of Waste Characterization (Appendix C).

Persons or organizations are required to be licensed by the CNSC to carry out the activities referred to in section 26 of the *Nuclear Safety and Control Act* (NSCA), subject to the associated regulations, which stipulate prerequisites for CNSC licensing, and the obligations of licensees and workers.

The regulations made under the NSCA identify the types of licences required throughout the lifecycle of various facilities. Licence types may include:

1. licence to prepare site;
2. licence to construct (sometimes combined with a licence to prepare site);
3. licence to operate;
4. decommissioning licence; and
5. licence to abandon.

The information required to obtain any type of licence includes an evaluation of the effects on the environment and the health and safety of persons that may result from the activities that are to be licensed. This evaluation enables the CNSC to determine whether the applicant will make adequate provision for the protection of the environment and the health and safety of persons.

As a time limit for this provision is not identified in the NSCA or the associated regulations, the evaluation must include assessment of potential long-term effects arising from radioactive waste or residual contamination. Therefore, evaluation of long-term safety is part of the information required in applications for every stage of the licensing cycle.

Since the NSCA and regulations specify protection of both the environment and persons, long-term assessments should address the impact on humans and on non-human biota from both radioactive and hazardous non-radioactive constituents of the radioactive waste, as reflected in appendix A, Principles for managing radioactive waste.

3.2 Legislated requirements

Requirements associated with long-term safety of radioactive waste management can be found in several portions of the NSCA and the regulations made pursuant to it. These include, but are not limited to, the following:

1. Paragraph 12(1)(c) of the *General Nuclear Safety and Control Regulations* requires that every licensee “take all reasonable precautions to protect the environment and the health and safety of persons and to maintain the security of nuclear facilities and nuclear substances;”

2. Paragraph 4(d) of the *General Nuclear Safety and Control Regulations* requires that an application for a licence to abandon a nuclear substance, nuclear facility, prescribed equipment or prescribed information contain, in addition to other information, shall contain information on “the effects on the environment and the health and safety of persons that may result from the abandonment, and the measures that will be taken to prevent or mitigate those effects;”

3. Paragraph 3(k) of the *Class I Nuclear Facilities Regulations* requires that an application for a licence for a Class I nuclear facility, other than a licence to abandon, include “the proposed plan for the decommissioning of the nuclear facility or of the site.”

4. Paragraph 4(e) of the *Class I Nuclear Facilities Regulations* requires that an application for a licence to prepare a site for a Class I facility contain, in addition to other information, information on “the effects on the environment and the health and safety of persons that may result from the activity to be licensed, and the measures that will be taken to prevent or mitigate those effects.”

5. Paragraph 5(f) of the *Class I Nuclear Facilities Regulations* requires that an application for a licence to construct a Class I nuclear facility include “a preliminary safety analysis report demonstrating the adequacy of the design of the nuclear facility;”

6. Paragraph 5(i) of the *Class I Nuclear Facilities Regulations* requires that an application for a licence to construct a Class I nuclear facility include information on “the effects on the environment and the health and safety of persons that may result from the construction, operation and decommissioning of the nuclear facility, and the measures that will be taken to prevent or mitigate those effects;”

7. Paragraph 5*(*j) of the *Class I Nuclear Facilities Regulations* requires that an application for a licence to construct a Class I nuclear facility include information on “the proposed location of points of release, the proposed maximum quantities and concentrations, and the anticipated volume and flow rate of releases of nuclear substances and hazardous substances into the environment, including their physical, chemical and radiological characteristics;”

8. Paragraph 5(k) of the *Class I Nuclear Facilities Regulations* requires that an application for a licence to construct a Class I nuclear facility include information on “the proposed measures to control releases of nuclear substances and hazardous substances into the environment;”

9. Paragraph 6(c) of the *Class I Nuclear Facilities Regulations* requires that an application for a licence to operate a Class I nuclear facility include “a final safety analysis report demonstrating the adequacy of the design of the nuclear facility;”

10. Paragraph 6(h) of the *Class I Nuclear Facilities Regulations* requires that an application for a licence to operate a Class I nuclear facility include information on “the effects on the environment and the health and safety of persons that may result from the operation and decommissioning of the nuclear facility, and the measures that will be taken to prevent or mitigate those effects;”

11. Paragraph 6*(*i) of the *Class I Nuclear Facilities Regulations* requires that an application for a licence to operate a Class I nuclear facility include information on “the proposed location of points of release, the proposed maximum quantities and concentrations, and the anticipated volume and flow rate of releases of nuclear substances and hazardous substances into the environment, including their physical, chemical, and radiological characteristics;”

12. Paragraph 6(j) of the *Class I Nuclear Facilities Regulations* requires that an application for a licence to operate a Class I nuclear facility include information on “the proposed measures to control releases of nuclear substances and hazardous substances into the environment;”

13. Paragraphs 7(f) and (k) of the *Class I Nuclear Facilities Regulations* require that an application for a licence to decommission a Class I facility contain, in addition to other information, “the effects on the environment and the health and safety of persons that may result from the decommissioning, and the measures that will be taken to prevent or mitigate

those effects;" and "a description of the planned state of the site on completion of the decommissioning."

14. Paragraph 8(a) of the *Class I Nuclear Facilities Regulations* stipulates that an application for a licence to abandon a Class I nuclear facility shall contain, in addition to the information required by sections 3 and 4 of the *General Nuclear Safety and Control Regulations*, "the results of the decommissioning;;
15. Subparagraph 3(a)(viii) of the *Uranium Mines and Mills Regulations* requires that an application for a licence in respect of a uranium mine or mill, other than a licence to abandon, contain, in addition to the information required by section 3 of the *General Nuclear Safety and Control Regulation*s, "the proposed plan for the decommissioning of the mine or mill;"
16. Subparagraph 3(c)(iii) of the *Uranium Mines and Mills Regulations* requires that an application for a licence in respect of a uranium mine or mill, other than a licence to abandon, contain information on "the effects on the environment that may result from the activity to be licensed, and the measures that will be taken to prevent or mitigate those effects;"
17. Subparagraph 3(d)(i) of the *Uranium Mines and Mills Regulations* requires that an application for a licence in respect of a uranium mine or mill, other than a licence to abandon, contain information on "the effects on the health and safety of persons that may result from the activity to be licensed, and the measures that will be taken to prevent or mitigate those effects;"
18. Paragraph 7(d) of the *Uranium Mines and Mills Regulations* requires that an application for a licence to decommission a uranium mine or mill contain "a description of the planned state of the site upon completion of the decommissioning work;"
19. Paragraph 8(b) of the *Uranium Mines and Mills Regulations* requires that an application for a licence to abandon a uranium mine or mill contain, in addition to other information, "the results of the decommissioning work;"
20. Paragraph 4(t) of the *Class II Nuclear Facilities Regulations* requires that an application for a licence to operate a Class II nuclear facility include "the proposed plan for the decommissioning of the nuclear facility;"
21. Paragraph 5(i) of the *Class II Nuclear Facilities Regulations* stipulates that an application for a licence to decommission a Class II nuclear facility shall include information on "the effects on the environment and the health and safety of persons that may result from the decommissioning, and the measures that will be taken to prevent or mitigate those effects;"
22. Paragraph 5(k) of the *Class II Nuclear Facilities Regulations* stipulates that an application for a licence to decommission a Class II nuclear facility shall include "a description of the planned state of the site upon completion of the decommissioning."

As a federal authority, the CNSC is also subject to certain obligations under the *Canadian Environmental Assessment Act, 2012* (CEAA 2012). The following excerpts from paragraph 15 of CEAA 2012 are directly relevant to the purpose of this document:

1. For the purposes of [CEAA 2012], the responsible authority with respect to a designated project that is subject to an environmental assessment is:

"(a) the Canadian Nuclear Safety Commission, in the case of a designated project that includes activities that are regulated under the *Nuclear Safety and Control Act* and that are linked to the Canadian Nuclear Safety Commission as specified in the regulations made under paragraph 84(a) or the order made under subsection 14(2);

(c) the federal authority that performs regulatory functions, that may hold public hearings and that is prescribed by regulations made under paragraph 83(b), in the case of a designated project that includes activities that are linked to that federal authority as specified in the regulations made under paragraph 84(a) or the order made under subsection 14(2);"

2. Paragraph 19(1) of CEAA 2012 states that the environmental assessment of a designated project must take into account the following factors:
   "(a) the environmental effects of the designated project, including the environmental effects of malfunctions or accidents that may occur in connection with the designated project and any cumulative environmental effects that are likely to result from the designated project in combination with other physical activities that have been or will be carried out."

4. Background Information

The activities licensed by the CNSC generate different types of waste that are currently managed using the following methods:

1. Uranium mine waste rock and mill tailings are disposed of in above-ground facilities or in pits;
2. Low-level radioactive waste and radioactive waste that requires shielding (but does not generate heat), arising from uranium processing plants, nuclear power plants, nuclear research facilities, and industrial and medical applications, is stored in above-ground structures and in shallow in-ground structures; and
3. Highly radioactive nuclear fuel waste (spent fuel) that is stored in water-filled bays or in various types of dry storage structures (dry storage casks, concrete canisters, and modular above-ground vaults).

Additional approaches for long-term waste management that may be applicable include surface and near-surface facilities, and deep geological facilities for disposal or for long-term storage of the waste.

In addition to radioactive waste generated by licensed activities, legacy and historic waste from the early days of the nuclear industry now falls under CNSC regulatory oversight, and is subject to the licensing requirements of the CNSC.

4.1 Waste management systems for long-term storage and disposal

Waste management systems for long-term storage and disposal of waste refer to the combination of natural and engineered barriers and operational procedures that contribute to safely managing the waste. Long-term assessment of these systems can provide information that can be used when making decisions concerning:

1. Selection of an appropriate site (if more than one site is available);
2. Site characterization;
3. Selection of a suitable design option during planning;

4. Optimization of selected design(s), including the minimization of operational and post-operational impacts; and
5. Development of construction, operation, and decommissioning strategies and plans.

The approach, level of detail and degree of rigor used in long-term safety assessments is determined by the importance of long-term safety compared to the other factors considered in making a decision. When considering a licence application, the CNSC has an interest in how assessments of long-term safety have been considered, as discussed in section 7.2 of this document, Assessment context.

The CNSC's immediate concerns are that the long-term safety assessments satisfy:

1. CNSC licence application requirements for information on long-term impacts that may arise from the licensed activities; and
2. CEAA requirements (i.e., assessment of the environmental impact of constructing, operating and decommissioning the waste management system or facility) prior to licensing.

Assessment of long-term safety typically has two components:

1. Estimates of contaminants released and dispersal throughout the biosphere; and
2. Estimates of the resulting exposures and impacts.

A single approach can be used 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. However, because exposures of each of the various receptor organisms used as representative of the biosphere will occur by different pathways, and will be judged by different acceptance criteria than those applied to humans or to each other, multiple approaches may be needed to estimate the exposures and impacts, even when all receptors are present in the same environment at the same time.

4.2 Concepts for long-term management

The CNSC identifies the need for long-term management of radioactive waste and hazardous waste arising from licensed activities (refer to appendix A, Principles for managing radioactive waste). The principles that relate to the need for long-term management include the following:

1. The management of radioactive waste is commensurate with its radiological, chemical, and biological hazard to the health and safety of persons and the environment, and to national security;
2. The assessment of future impacts of radioactive waste on the health and safety of persons and the environment encompasses the period of time when the maximum impact is predicted to occur; and
3. The predicted impact on the health and safety of persons and the environment from the management of radioactive waste is no greater than the impact that is permissible in Canada at the time of the regulatory decision.

The concepts for long-term management are based on the containment and isolation of the waste, whether it is in a storage facility or a disposal facility. Containment can be achieved through a robust design based on multiple barriers providing defence in depth. Isolation is achieved through proper site selection and, when necessary, institutional controls to limit access and land use.

It is assumed that long-term storage facilities for radioactive waste will continue to be under licensed control until the waste is removed and the facility is decommissioned, or a decision is made to abandon the waste and the facility as in situ disposal. In either case, at that time a long-term assessment of the impact of the waste remaining at the site will be needed to support an application for a licence to abandon or an exemption by the Commission. The Commission may grant an exemption if doing so will not pose an unreasonable risk to the environment or the health and safety of persons; pose an unreasonable risk to national security; or result in a failure to achieve conformity with measures of control and international obligations to which Canada has agreed. A licence is no longer required if the activity or the activity concentration of the substance does not exceed its exemption quantity, its conditional clearance level, or its unconditional clearance level, as stipulated in the *Nuclear Substances and Radiation Devices Regulations*.

Long-term assessments of safety in support of decommissioning plans and activities must address not only the facilities to be used for long-term management of the waste, but also the residual contamination that will be left by decommissioning activities. Similarly, long-term assessments of safety are needed to support licence applications for lands that have been contaminated by legacy and historic waste from the early days of the nuclear industry.

4.3 Licensing considerations for long-term management

4.3.1 Determining methodology

An applicant for a CNSC licence should provide reasonable assurance that the proposed plans for the long-term management of radioactive waste that will arise from the licensed activities are consistent with all applicable requirements. It is up to the applicant to determine an appropriate methodology for achieving the long-term safety of radioactive waste based on their specific circumstances; however, applicants are encouraged to consult with CNSC staff throughout the pre-licensing period on the acceptability of their chosen methodology.

While the acceptability to CNSC staff of the methodology and its implementation influences recommendations on the licence application, it cannot and does not prejudge the final licensing decision that is made by the Commission.

4.3.2 Design optimization

The design of a nuclear facility should be optimized to exceed all applicable requirements. In particular, a radioactive waste management facility should more than meet the regulatory limits, remaining below those limits by a margin that provides assurance of safety for the long term. This expectation is necessitated by the uncertainty of long-term predictions, the uncertainty of future human actions, and the possibility that the waste management system being assessed may not be the only source of contaminants to which receptors will be exposed.

4.3.3 Assessment evaluation

CNSC evaluation of an assessment is based largely on information provided in written submissions, and any material referenced in those submissions. Reports on assessments should describe in an explicit and well-documented manner what is being assessed, as well as why and how it is being assessed. The level of detail and clarity of the report should enable a reviewer to easily follow the logic behind the assessment. Sufficient detail should be included to allow independent calculations to confirm assessment results, whether by means of simplified calculations or by complete reproduction of the results.

Claims of long-term safety submitted to support a licence application may be evaluated by the CNSC by way of:

1. Nationally and internationally accepted best practices;
2. The ‘weight of evidence’ and confidence-building arguments (i.e., scientific evidence, multiple lines of reasoning, reasoned arguments, and other complementary arguments) that support the assessment and its conclusions;
3. Expert judgement and the results of independent analysis performed by CNSC staff; and
4. Any third-party peer reviews of the submission.

5. Developing a Long-Term Safety Case

Demonstrating long-term safety consists of providing reasonable assurance that waste management will be conducted in a manner that protects human health and the environment. This is achieved through the development of a safety case, which includes a safety assessment complemented by various additional arguments based on:

1. Appropriate selection and application of assessment strategies;
2. Demonstration of system robustness;
3. The use of complementary indicators of safety; and
4. Any other evidence that is available to provide confidence in the long-term safety of radioactive waste management.

5.1 Safety assessment

The safety assessment is central to the safety case. It involves an analysis to evaluate the overall performance of the facility and its impact on human health and on the environment. A long-term safety assessment often uses a pathways analysis based on a scenario of expected evolution of a site or facility to predict:

1. Contaminant release;
2. Contaminant transport;
3. Receptor exposure; and
4. Potential effects resulting from the exposure.

The CNSC expects the safety assessment to demonstrate the applicant’s understanding of the waste management system through a well-structured, transparent, and traceable methodology. The assessment documentation should provide a clear and complete record of the decisions made and the assumptions adopted in developing the model of the waste management system. The parameters and variables used to run the model and to arrive at a given set of results should be reported and justified.

5.1.1 Additional arguments

Due to the uncertainty of predictions made far into the future, the reliability of quantitative predictions diminishes with increasing timescale. The demonstration of safety will rely less on quantitative predictions and more on qualitative arguments as the timescale increases. Long-term quantitative predictions should therefore not be considered as guaranteed impacts, but rather as safety indicators.

Accordingly, the long-term safety assessment should be supported within a safety case by additional arguments, as discussed in the following subsections.

5.2 Use of different assessment strategies

The strategy used to demonstrate long-term safety may include a number of approaches, including, without being limited to:

1. Scoping assessments to illustrate the factors that are important to long-term safety;
2. Bounding assessments to show the limits of potential impact;
3. Calculations that give a realistic best estimate of the performance of the waste management system, or conservative calculations that intentionally over-estimate potential impact; and
4. Deterministic or probabilistic calculations, appropriate for the purpose of the assessment, to reflect data uncertainty.

Any combination of these or other appropriate assessment strategies can be used in a complementary manner to increase confidence in the demonstration of long-term safety. For example, for low risk waste, a deterministic bounding assessment may be acceptable to demonstrate that there will be no unacceptable long-term impact. However, for higher risk waste, realistic best estimate or detailed conservative calculations based on either a deterministic or a probabilistic approach may be needed to demonstrate adequate understanding of the waste management system and the expectations for long-term safety. The choice of strategy should be discussed and justified in documentation demonstrating long-term safety. It is expected that the purpose of the assessment will also justify the modelling approach adopted and the level of confidence that is needed in the results.

5.2.1 Scoping and bounding assessments

Scoping assessments provide a general understanding of the overall waste management system, and help to identify the aspects of the system that are critical to safety. Scoping assessments tend to use mathematically simple models for the rapid assessment of many structural and parameter configurations. However, much care and consideration are often required to ensure that models are appropriate for the analysis of the entire spectrum of situations and conditions of interest.

Bounding assessments are designed to provide limiting estimates of waste management system performance. Such assessments can be mathematically simple models, or detailed process models that use limiting parameter values. As in the case of scoping models, a great degree of care and consideration is often required when developing bounding assessments.

Bounding or scoping assessments can complement the long-term safety assessment that is central to the safety case. The limiting values from bounding assessments and the identification of important aspects of the system from scoping assessments can provide useful checks on the long-term assessment calculations, improving confidence in the predictions of safety.

5.2.2 Realistic best estimates vs. conservative overestimations

In order to provide the best possible representation of reality, a realistic best-estimate assessment of the waste management system is expected to use real site and as-built facility data, site-specific scenarios, and accurate models of the processes being simulated. Such models give the best illustration of the waste management system, and are often used when the less realistic results of conservative overestimations cannot meet acceptance criteria.

Conservative calculations intentionally overestimate future consequences to provide an additional margin of safety for situations where assessment results cannot be considered accurate predictions, but merely indicators of safety. A conservative approach should be used when developing computer code and models, and assumptions and simplifications of processes to make them more amenable for inclusion in computer models 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.

5.2.3 Deterministic and probabilistic calculations

The mathematical approach to analyzing the scenarios in the safety case is guided by the purpose of the long-term assessment. A deterministic model uses single-valued input data to calculate a single-valued result that will be compared to an acceptance criterion. Variations in input data values are not taken into account in these calculations. 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) of deterministic models.

Probabilistic models can explicitly account for uncertainty arising from variability in the data used in assessment predictions. Such models may also be structured to take account of different scenarios (as long as they are not mutually exclusive) or uncertainty within scenarios. Probabilistic models 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 waste management system.

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 (see Section 8.1, “Comparing assessment results with acceptance criteria”). The results of a probabilistic assessment should be presented and discussed as the magnitude of the consequence and the likelihood of its occurrence, reflecting the probability that a scenario with those particular input data values will actually occur.

5.3 Robustness and natural analogues

The applicant should demonstrate that the waste management system will maintain its integrity and reliability under extreme conditions, disruptive events, or unexpected containment failure, including inadvertent human intrusion. This is achieved by adequate design of multiple engineered barriers, or favourable site characteristics, or both. The safety case should explain the relative role of the components that contribute to the overall robustness of the system.

System robustness can also be demonstrated using natural analogues. Natural analogue studies have been widely used internationally to build confidence in the ability of waste management systems to perform over the long term as predicted by safety assessment models.

In *Natural Analogs in Performance Assessments for the Disposal of Long Lived Radiological Wastes* (IAEA 1989), the International Atomic Energy Agency (IAEA) notes that:

"The natural analogue is often regarded as one of the very few means by which it may be possible to demonstrate to the public that safety assessments are based on a realistic understanding of how nature works over time periods longer than the existence of mankind."

Natural analogues can be employed in a variety of ways, and can be used to demonstrate that waste management concepts actually work in nature. For example, in Canada, the Cigar Lake uranium ore deposit has been used as a natural analogue for the long-term stability of a spent nuclear fuel repository that could be constructed deep in the Precambrian shield. Natural analogues can also be the subject of complementary assessments of long-term safety, and can be included in the safety case to provide confidence in the conclusions drawn from the waste management system assessment models, as discussed in Section 7.6.3, "Confidence in assessment models."

Information from natural analogue studies can be used to develop and test detailed process models that may be incorporated into the assessment models in an abbreviated or simplified manner. Natural analogues can also provide data for verifying and validating both detailed process and simplified assessment models (see Section 7.6.2, "Confidence in computing tools), and for developing generic site descriptive models in the absence of site-specific characterization data, as discussed in Section 7.3.1, "Site characteristics."

5.4 Use of complementary indicators of safety

The long-term safety of radioactive waste management is usually demonstrated by directly comparing predictions with current regulatory limits, such as dose and contaminant concentrations.

Several other safety indicators, such as those that reflect containment barrier effectiveness or site-specific characteristics that can be directly related to contaminant release and transport phenomena, can also be presented to illustrate the long-term performance of a waste management system. Some examples of additional parameters include:

1. container corrosion rates;
2. waste dissolution rates;
3. groundwater age and travel time;
4. fluxes of contaminants from a waste management facility;
5. concentrations of contaminants in specific environmental media (for example, concentration of radium in groundwater); or
6. changes in toxicity of the waste.

The acceptance criteria by which these complementary safety indicators are to be judged should be derived from the relationship between the complementary indicators and the more direct indicators of safety. For example, if the environmental concentration of a hazardous substance is directly related to groundwater velocity near a waste facility, then predicted groundwater velocity could be used as an indicator of long-term safety to complement a more complete assessment of the environmental concentration. Assessments that use complementary indicators should present justification for their use, along with the acceptance criteria derived for them.

6. Defining Acceptance Criteria

6.1 Overview

Acceptance criteria are the numerical values used to judge the results of assessment model calculations. The parameters that are calculated to compare with the acceptance criteria should provide reasonable assurance that the regulatory requirements imposed by the NSCA and its associated regulations, and by other applicable legislation, will be met. Given that the principal regulatory requirements are those that address radiological dose and environmental concentrations, it is expected that these parameters will be used in long-term assessments as the primary indicators of safety.

Additional model parameters that further indicate waste management system performance should also be calculated. These complementary indicators can be derived from the regulatory requirements, from objectives and benchmarks specified in guidelines, or from performance expectations that relate to safety.

Current values of regulatory limits, standards, objectives, and benchmarks may be used as acceptance criteria. CNSC licensees operate under both federal and provincial jurisdictions, and the guidelines, objectives, and benchmarks can vary between these jurisdictions. In keeping with the non-prescriptive approach to regulation, the applicant is expected to propose justified and scientifically defensible benchmarks and acceptance criteria for the assessment.

In deriving acceptance criteria, benchmarks can also be reduced by applying an additional margin of safety, such as a dose constraint or a safety factor. The adoption of a fraction of a currently applied value as an acceptance criterion for a long-term assessment can provide additional assurance that the uncertainty in the predictions and in future human actions will not result in unreasonable risk in the future. CNSC staff is available for consultation on the suitability of the acceptance criteria, and on the balance between conservatism in the assessment and conservatism in the acceptance criteria.

6.2 Criteria for protection of persons and the environment

The regulatory requirements for protection of persons and the environment from both radiological and non-radiological hazards of radioactive wastes lead to four distinguishable sets of acceptance criteria for a long-term assessment:

1. Radiological protection of persons;
2. Protection of persons from hazardous substances;
3. Radiological protection of the environment; and
4. Protection of the environment from hazardous substances.

6.2.1 Radiological protection of persons

Long-term safety assessments of a facility or contaminated site should provide reasonable assurance that the regulatory radiological dose limit for public exposure (currently 1 mSv/a) will not be exceeded. However, to account for the possibility of exposure to multiple sources and to help ensure that doses resulting from the facility being assessed are as low as reasonably achievable (ALARA), an acceptance criterion that is less than the regulatory limit should be used.

For example, for design optimization, the International Commission on Radiological Protection (ICRP) recommends a design target, referred to as a ‘dose constraint,’ of no more than about 0.3 mSv/a. While the dose constraint is used as a design target in the optimization process, it is not used as a limit for compliance. The dose constraint should therefore not be used to account for uncertainties in assessment model predictions.

Uncertainties in the modeling should instead be addressed by conservatism built into:

1. the assessment model;
2. the scenario design; and
3. parameter choice.

Radiological exposure can be expressed as a radiological dose or as a radiological risk that reflects the probability of developing a health or genetic effect from the exposure. The effects of radiological exposure are classified as and “deterministic effects” or as “stochastic effects,” depending on the likelihood that an effect will develop. Deterministic effects will occur if the dose exceeds a threshold, whereas the likelihood of stochastic effects is directly proportional to the magnitude of the dose. Since the acceptable dose limit (1 mSv/a) for individuals who are not nuclear energy workers is orders of magnitude less than the threshold for any deterministic effect, only stochastic effects are discussed further in this document.

The probability of stochastic effects is evaluated as the product of the dose and a probability coefficient for stochastic effects. This probability coefficient is commonly referred to as a “risk conversion factor,” and reflects the likelihood of developing a health or genetic effect from a radiological exposure at low doses and dose rates.

The probability coefficient for stochastic effects currently recommended by the ICRP is 0.073 per sievert for the general public (ICRP 1991). The probability of stochastic effects corresponding to the 1 mSv/a statutory effective dose limit for members of the public is about 7×10^{-5} per year. Similarly, the probability of stochastic effects corresponding to a dose constraint of 0.3 mSv/a is about 2×10^{-5} per year.

Because the probability of stochastic effects is directly proportional to the dose, the risk conversion factor is a constant value. Use of either radiological dose or the associated probability of stochastic effects in long-term safety assessments may be acceptable. The consequence of any assessment scenario, then, can be expressed as a dose or as a probability of stochastic effect.

The form of radiological acceptance criteria should be consistent with the approach and strategy chosen for the long-term assessment. The dose calculated by deterministic assessments can be compared directly to radiological acceptance criteria expressed as dose, or both the assessment results and the acceptance criteria can be expressed as probability of stochastic effects by applying the risk conversion factor.

Probabilistic assessments calculate a potential risk based on the likelihood of an exposure occurring and the consequence of each exposure (whether expressed as a dose or as a probability of stochastic effect). The result of the assessment is the sum over all significant scenarios of the product of the probability of the scenario and the probability of stochastic effects. Each radiological acceptance criterion must be expressed as risk (i.e., the probability of stochastic effects) for direct comparison to probabilistic assessment results.

In probabilistic assessments, high-consequence scenarios with low probability can have the same potential risk as low-consequence scenarios with high probability. If a probabilistic approach is adopted in addition to a direct comparison of calculated potential risk and the risk acceptance criterion, the assessment results should be evaluated as the distribution of doses compared to dose acceptance criteria, including discussion of the probability of the doses occurring.

6.2.2 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 Council of Ministers of the Environment's (CCME's) *Canadian Environmental Quality Guidelines* (CCME 2002) 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 provincial guidelines should be used. For example, *Canadian Drinking Water Quality Guidelines* (CCME 2002) should be used for contaminants in potable water, including groundwater; however, for non-potable water, provincial guidelines, such as those of the Ontario Ministry of Environment and Energy (MOEE 1997), may be used as appropriate.

Safety factors are used in establishing the benchmarks. These safety factors vary with the contaminant, but generally a safety factor of 100 is used, resulting in a benchmark that corresponds to a low level of risk. For generic Canadian soil quality guidelines, the CCME regards a 10^{-6} level of risk as essentially negligible to humans (CCME 1996). Health Canada has established that a cancer risk in the range of 10^{-5} to 10^{-6} is negligible for carcinogenic substances in drinking water, and that only exposure to adults needs to be determined (HC 2012a). A 10^{-5} incremental increase in the incidence of cancer risk represents a 0.0025% increase over the background cancer incidence.

Where Canadian jurisdiction has not established human health-based guidelines, benchmarks may be based on those of the United States Environmental Protection Agency (USEPA 2008).

Benchmarks that are proposed based on sources of information other than those identified above may need additional justification for their use. Other sources of information include the USEPA *Integrated Risk Information System*, the World Health Organization, the Netherlands National Institute of Public Health and the Environment, and the U.S. Agency for Toxic Substances and Disease Registry.

6.2.3 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. The development of benchmarks for radiation protection of non-human biota is not as mature as the development of benchmarks for hazardous substances, due to the historic assumption that protecting humans from radiation is sufficient to protect the environment. However, benchmark values for mean radiation doses to non-human biota have been derived for various types of organisms (National Council on Radiation Protection and Measurements (NCRP) 1991, IAEA 1992, EC 2003).

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

6.2.4 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* (CCME 2002) for water, sediment, and soil are appropriate benchmarks for conservative assessments. 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 the toxicity literature, or studies can be performed to assess toxicity. The protocols for developing criteria for the protection of the environment include determining critical toxicity values such as an effects concentration for 25% response (EC25), lowest observable adverse effects level (LOAEL), or no observable adverse effects level (NOAEL), from studies of chronic exposure to the most sensitive species.

Expected no effects values (ENEVs) are derived from identified critical toxicity values using appropriate safety or application factors. Safety factors are applied to the critical toxicity values in determining the benchmark to account for data uncertainties and natural variability amongst individuals in a species. In general, larger safety factors of 10 to 1,000 are used in benchmarks for conservative assessments, whereas smaller values are used in benchmarks for realistic assessments.

For metal contaminants that are a natural component of the environment, the upper end (95th or 97.5th percentile) of the distribution of background concentration may be used as the benchmark; however, the use of the maximum background concentration is not acceptable.

Although guidance is provided in the use of safety factors, their use is somewhat subjective and the derived benchmarks must be environmentally protective and scientifically defensible. Justification must be provided for the use of any derived benchmark.

7. Performing long-term assessments

The CNSC expects the applicant to use a structured approach to assess the long-term performance of a waste management system. Although long-term assessments are done with different levels of detail and rigour for different purposes, the overall methodology for performing them should include the following elements:

1. Selection of appropriate methodology;
2. Assessment context;
3. System description;
4. Timeframes;
5. Assessment scenarios; and
6. Development of assessment models.

7.1 Selection of appropriate methodology

No single methodology is appropriate for all long-term assessments. Applicants are encouraged to consult with CNSC staff on issues concerning the appropriate methodologies for long-term assessments of their particular circumstances, and are expected to document and justify the methodology they have used.

Limited guidance on how to conduct an assessment for specific purposes is available from several sources, including the following:

1. The *Canadian Environmental Assessment Act*, 2012;
2. Environment Canada;
3. Health Canada;
4. The Canadian Council of Ministers of the Environment; and
5. The International Atomic Energy Agency.

7.1.1 The Canadian Environmental Assessment Act, 2012

The *Canadian Environmental Assessment Act, 2012* (CEAA 2012) is a planning tool that is used by federal authorities to ensure that adverse environmental effects are identified and mitigated before a project is carried out. The result of an environmental assessment under the CEAA 2012 is a decision about whether there are adverse environmental effects of the project that are likely to be significant. This decision is taken into account when determining whether the proposed project should proceed to the licensing phase.

The methodology used by the CNSC to conduct an environmental assessment under the CEAA 2012 is posted on the CNSC website (CNSC 2017).

7.1.2 Environment Canada

Environment Canada's assessment approach subdivides the key elements of the assessment as follows:

1. Framework and overview;
2. Data collection and generation;
3. Problem formulation;
4. Entry characterization;
5. Exposure characterization;
6. Effects characterization; and
7. Risk characterization.

The assessment should explicitly address the rationale for model selection, and the benefits, weaknesses, and limitations of the models used. Key assumptions and rationales, the extent of scientific consensus and uncertainties, and the effect of reasonable alternative assumptions on the assessment conclusions and estimates, should be clearly identified. Information about data variability and uncertainty, parameter sensitivities and model uncertainty should be included as well.

7.1.3 Health Canada

Health Canada provides national guidance on the assessment of hazardous substances with respect to human health in documents prepared to support the Federal Contaminated Sites Accelerated Action Plan. This material includes soil quality and drinking water guidelines, toxicological reference values, contaminant bioavailability, human characteristics and exposure factors, and other aspects of risk assessment (HC 2012a, HC 2010b).

7.1.4 The Canadian Council of Ministers of the Environment

A CCME guidance document titled *A Framework for Ecological Risk Assessment: General Guidance* gives advice on planning an ecological risk assessment (ERA) and describes its major components (CCME 1996). Planning should include site characterization, problem identification and identification of valued ecosystem components (VECs), establishment of objectives, development of a conceptual model, selection of assessment endpoints and measurement endpoints, and establishment of level of effort. Other major components of an ERA include the following:

1. Receptor characterization;
2. Exposure assessment;
3. Hazard assessment; and
4. Risk characterization.

7.1.5 The International Atomic Energy Agency

The IAEA's Research Coordinated Project on Improvement of Safety Assessment Methodologies (ISAM) for Near Surface Disposal Facilities has published useful recommendations on a structured and iterative methodology for performing and documenting assessments (IAEA 2004). This methodology could be applied to any type of waste management system.

Other IAEA publications that offer guidance focused on specific types of radioactive waste to be managed are included in the references at the end of this document.

7.2 Assessment context

The assessment context defines the terms of reference for the assessment, the regulatory requirements that are to be met, the criteria that are to be used, and the approach adopted to demonstrate that the safety criteria can be met in the long term.

7.2.1 Terms of reference

The terms of reference should present the purpose and rationale for the assessment, answering the following questions:

1. Why is the assessment being conducted?
2. What is the intended audience for the assessment? and
3. What decision is the assessment supporting?

7.2.2 Regulatory requirements to be met

The assessment context should describe the regulatory framework under which the assessment will be conducted. This description should demonstrate understanding of the federal and provincial regulatory requirements, as well as any international obligations that apply to the project. The description of a relatively complex assessment might also include a cross-reference table, or "road map," that identifies which part of the documentation discusses how each regulatory requirement is being met.

7.2.3 Criteria to be met

The criteria by which the assessment results will be judged should be identified in the assessment context. These criteria can be based on regulatory limits and objectives, other scientifically justifiable benchmarks (Section 6, "Defining Acceptance Criteria"), or complementary safety indicators, such as barrier performance or groundwater travel time, that indicate system performance (Section 5.4, "Use of complementary indicators of safety").

7.2.4 Approach used to demonstrate safety

The assessment context should also include a description of the approach used to demonstrate safety over the long-term and gain confidence in the results, and how that approach addresses the principles of radioactive waste management put forward in appendix A. The approach used to demonstrate safety can be based on combinations of complementary assessments at various levels of detail, as discussed in Section 5, “Developing a Long-Term Safety Case.”

7.3 System description

The system description should present both the characteristics of the site and the design of the waste management system. The waste management system and the way its components function should be described in sufficient detail to provide a clear understanding of how safety and environmental protection will be achieved. The system description should also include a description of the type of waste to be managed and the management system to be employed (i.e., disposal or storage on surface or at depth using combinations of engineered containment barriers and natural isolation barriers).

The required information varies with the assessment requirements for the system, and therefore varies between types of facilities.

It is recognized that the system description may be less complete and rigorous early in the licensing lifecycle, and that the information used in long-term assessments of safety for the purpose of design optimization or to support an environmental assessment or a licence application may therefore need to use some default or generic data. As licensing progresses through the facility’s lifecycle, as-built information and operational data are acquired, and the site characteristics become better understood. It is expected that assessments of long-term safety that are made later in the licensing lifecycle will be based on updated and refined models and data, with less reliance on default, generic, or assumed information, resulting in more reliable model results.

Applicants are encouraged to consult the regulatory authorities for specific guidance on the appropriate balance between generic and site-specific information for their particular circumstances and licensing stages.

7.3.1 Site characterizations

Site characterization should include a description of the environment of the site, such as the ecological, geological, hydrological, and climatic conditions. This description should include sufficient information on the baseline conditions to allow thorough assessment of the impact of the licensed activities.

Site characteristics must be sufficiently defined to produce an accurately descriptive model. For long-term waste management 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 (QA/QC) protocols to verify the data. The evaluation and characterization plan also should include:

1. Subsurface characterization (geology, hydrogeology, geochemistry, seismicity, etc.);
2. Surface characterization (ecology, hydrology, geomorphology, climate, etc.);
3. Monitoring systems;
4. Current and foreseeable land use;

5. Data integration, analysis, and incorporation into the site descriptive model; and
6. Program and management quality assurance plans.

The resulting information should be sufficient to develop site-specific models that will reliably simulate the response of the site to the perturbation caused by the licensed activities. Geoscientific modelling and initial assessment modelling can identify information gaps and later be used to guide on-going site characterization activities.

As the site is investigated over time, additional information will result in a more detailed understanding of the subsurface site characteristics. The improved site-specific information is expected to allow refinement of the initial site model by replacing generic or default data and reducing the reliance on assumptions.

7.3.2 Waste management systems

The waste management system and the way that its components function should be described in sufficient detail to provide a clear understanding of how safety and environmental protection will be achieved, and how the different components of the system will interact with each other and with the environment in the long term.

The description of the waste management system should include the design and characteristics of at least the following:

1. Waste forms (type, inventories, and characteristics of nuclear and hazardous substances, packaging, etc.);
2. Engineered barriers (waste containers, buffer and backfill materials, liners and constructed covers, reactive barriers, containment structures, pervious surrounds, etc.);
3. Natural barriers, including the geosphere (for underground facilities) and water covers (if used); and
4. Active and passive institutional controls to limit access and exposure to the waste.

Early in the licensing lifecycle, it may be necessary to rely on design specifications, waste acceptance criteria, generic or default data, and assumptions to describe the waste management system in sufficient detail that its performance can be predicted. At later stages in the facility's development, as-built information and operational data should be used to refine the model of the system for assessment purposes. As with the site model, the model of the waste management system should evolve to become more realistic, and less conservative, based on real data.

7.4 Assessment time frames

There is no time limit associated with the statutory objective to "prevent unreasonable risk, to the environment and to the health and safety of persons..," (NSCA, 9(a)(i)), or with the principle that the predicted impact on the health and safety of persons and the environment from the management of radioactive waste are no greater than the impacts that are permissible in Canada at the time of the regulatory decision (as discussed in appendix A).

Assessments of the future impact that may arise from the radioactive waste are expected to include the period of time during which the maximum impact is predicted to occur. In some cases, only the magnitude of the maximum impact, independent of time, may be sufficient for the assessment (e.g., in bounding assessments using calculations based on solubility constraints).

The assessment should provide a rationale for the assessment time frame. The approach taken to determine respective periods of time used in the assessment should take into account the following elements:

1. Hazardous lifetime of the contaminants associated with the waste;
2. Duration of the operational period (before the facility reaches its end state);
3. Design life of engineered barriers;
4. Duration of both active and passive institutional controls; and
5. Frequency of natural events and human-induced environmental changes (e.g., seismic occurrence, flood, drought, glaciation, climate change, etc.).

The assumed performance time frames of engineered barriers and the evolution of their safety function with time should be documented and justified, with reference to current national or international standards where appropriate.

7.5 Assessment scenarios

A scenario is an assumed set of future conditions or events to be modelled in an assessment. A long-term assessment scenario should be sufficiently comprehensive to account for all of the potential future states of the site and the biosphere. It is common for a safety assessment to include a central scenario of the normal, or expected, evolution of the site and the facility over time, and additional scenarios that examine the potential impact of disruptive events or modes of containment failure.

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

1. The timeframe on which the assessment is based;
2. The duration (start to finish) during which institutional controls are relied upon as a safety feature; and
3. 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 features, events, and processes (FEPs) that are based on current and 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 assessment, taking into consideration the purpose of the assessment, the hazard of the waste, and the nature of the decision for which the assessment is being undertaken. Accordingly, scenario development can range from “brainstorming” to formal analysis of FEPs and extrapolation of current lifestyle information.

A great deal of work has been done globally on assembling lists of FEPs that have been used in past assessments, particularly through the Nuclear Energy Agency and the BIOMOVS project (NEA 2000, NEA 2003, BIOMOVS 1996). These lists not only provide a basis for comparison with site-specific scenarios, they can also be used to develop initial generic scenarios in the absence of site-specific data, or as default FEPs for developing stylized scenarios.

Stylized scenarios are generic representations of a group of scenarios, where part of the waste management system is treated in a standardized or simplified way. Stylized scenarios based on default information and data have been developed for the biosphere, climate change and glaciation, and exposure pathways (NEA 2001, IAEA 2003, SKI 1995, OPG 2001). The application of stylized scenarios may be useful where site-specific information is lacking, or where the purpose of the assessment does not require detailed site-specific information. As assessment time scales become longer, the use of stylized scenarios for distant future conditions becomes more important.

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 there is an extremely low likelihood that they would occur, or if they would have trivial impact. Considering the range of scenarios that can be developed for different waste management systems at different stages in their life cycles, applicants are expected to propose the criteria for excluding FEPs and scenarios and consult with CNSC staff as to their acceptability. The approach and screening criteria used to exclude or include scenarios should be justified and well documented.

7.5.1 Normal evolution scenario

A normal evolution scenario should be based on reasonable extrapolation of present day site features and receptor lifestyles. It should include expected evolution of the site and degradation of the waste 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 safety assessment.

Depending on site-specific conditions and the timeframe for the assessment, a normal evolution scenario may need to include extreme conditions such as climate shifts or the onset of glaciation. Similarly, periodic natural disruptive events such as floods or forest fires may be part of the normal evolution scenario for a particular site and timeframe, but may have to be analyzed separately.

The decision about which natural disruptive events should be included is based on the probability of their occurrence within the timeframe of the 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 unpredictable disruptive events that might be expected to occur once or more during the assessment period, including penetration of the barriers by intrusion.

Intrusion by burrowing animals or plant roots may be considered part of the normal evolution of some types of waste management systems. While thicker covers, rip-rap armouring and other barriers can be designed to prevent such intrusion, human intrusion cannot be easily prevented by barrier design. Institutional controls may be placed on some facilities as a safety feature to prevent human intrusion. In such cases, assessment of the impact of human intrusion may have to assume scenarios in which institutional controls fail.

7.5.2 Disruptive event scenarios, including human intrusion

Disruptive event scenarios postulate the occurrence of unlikely events 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 usually cannot be integrated directly into the normal evolution scenario where barriers are assumed to remain intact for their entire design life. Such events, even those that can be predicted to occur once or more during the assessment period, may have to be assessed separately and included in the interpretation of the normal evolution scenarios.

Intrusion not only breaches containment barriers, but may result in waste being redistributed outside the barriers, potentially exposing the public and the environment. Assessments of human intrusion therefore need 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, assessment of intentional human intrusion, in which the intruder is assumed to be aware of the hazard of the waste, need not consider the exposure of the intruder.

Scenarios assessing the risk from inadvertent intrusion should be case-specific, based on the type of waste and the design of the facility, and should consider both the probability of intrusion and its associated consequences. Surface and near-surface facilities (e.g., tailings sites) are more likely to experience intrusion than deep geological facilities.

Scenarios concerning inadvertent human intrusion into a waste facility could predict 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 risk from the intrusion should therefore be reported.

Reasonable efforts should be made to limit the dose from a high-consequence intrusion scenario, and to reduce the probability of the intrusion occurring. The consequences of intrusion could be reduced by controlling the form and properties of the waste accepted at the facility. Design modifications to reduce the likelihood of inadvertent intrusion should be undertaken. This may include the choice of site for the facility (where site selection options are feasible), siting the 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.

7.5.3 Institutional controls

A submission from a licence applicant should identify the role that institutional controls play in waste management system safety, and how that role is taken into account in the safety assessment. Institutional controls can include active measures that require on-site activities such as monitoring, surveillance, and maintenance, and passive measures that do not require activities on the site, such as land use restrictions, markers, etc. Institutional controls may be part of the design of a radioactive waste management system as a necessary safety measure or to enhance the confidence in the system.

Long-term management options should not rely on long-term institutional controls as a safety feature unless they are absolutely necessary. However, for some waste types in certain site-specific situations, there may be no realistic alternative to long-term institutional controls as a safety feature, even after optimizing the facility design (as discussed in Section 4.3.2, “Design optimization).

As a result of the uncertainties associated with future human activities and the evolution and stability of societies, current international practice generally limits the reliance on institutional controls as a safety feature to a few hundred years. However, it is recognized that in spite of design optimization, some facilities, such as surface impoundments for tailings, may need to rely on institutional controls for a more extended period of time. Any intention of relying on institutional controls to ensure long-term safety should be documented and justified in the long-term assessment.

7.5.4 Identification of critical groups and environmental receptors

The development of assessment scenarios should include identification of humans and environmental receptors that may be exposed to radioactive and hazardous substances. These receptors may be identified through the FEP analysis or from evaluation of valued ecosystem components (VECs). Each scenario that is analyzed may have different critical groups and environmental receptors for radiological protection and for environmental protection.

The approach taken to protect the environment is fundamentally different from the approach taken to protect persons. Protecting persons from both radiological and non-radiological hazards is based on protecting the individual, whereas environmental protection is based on protecting populations of species, communities, and ecosystems; not necessarily individual organisms.

Assessments usually predict the impact on representative individual organisms, and then evaluate the significance of that impact to the affected population.

The human receptors in a scenario may be based on the International Commission on Radiological Protection (ICRP) concept of a critical group for radiological protection of persons. It is reasonably assumed that the critical group for radiological protection will also be a conservative receptor for exposure to hazardous substances. The critical group is a group of people representative of those individuals in the population that are expected to receive the highest annual radiological dose. Such a group would be small enough to be relatively homogeneous with respect to age, diet, and those aspects of behaviour that affect the annual doses received (ICRP 1998; paragraph 43). The habits and characteristics that are assumed for the human critical group should be based on reasonably conservative and plausible assumptions that consider current lifestyles and available site-specific or region-specific information. When such specific information is not available, default or generic information may be adequate to meet the purpose of the assessment (ICRP 1998; paragraph 44). CNSC staff should be consulted if there is a question of the suitability of using generic data.

The identification of non-human receptors can be more complex than the identification of human critical groups, even when all receptors are present in the same environment at the same time. This is due to the large variety of organisms with different life cycles, habitats, exposure pathways, and sensitivities. Non-human receptors usually include a range of different plants and animals occurring at various levels of biological organization (e.g., organism, population, community, or ecosystem). Among other criteria, the receptors should represent the taxonomic groups most likely to receive a higher exposure from a particular pathway.

The 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 (discussed in Section 7.3.1, “Site characteristics”). 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 assessment. Specific species or generic receptors can be used to represent non-human receptors, but the assessment should be clear about which is being assessed. A stylized approach to biosphere modelling is presently under development by the IAEA (IAEA 2003). CNSC staff should be consulted on the suitability of using a stylized biosphere or generic data in any particular assessment.

7.6 Developing and using assessment models

Long-term assessments usually employ a variety of computational tools to predict future conditions for comparison to acceptance criteria that indicate safety. Computer models are used to solve the mathematical equations that represent the understanding of the inter-relationships among the major features, processes, and characteristics of the waste management system in its particular environment. To be amenable to this treatment, the conceptual models of the site and the waste management system that have been developed often need to be simplified to correspond to the limitations of the mathematical equations and the capabilities of computer models to solve them.

For long-term assessment models, the level of accuracy needed in the model, and the degree of conservatism desired in the results, are determined by the purpose of the assessment and the importance of the model results with respect to indicating expected performance and safety.

The accuracy of predictions made in long-term assessments cannot be checked, making it necessary to rigorously test and evaluate the assessment models to the extent determined by the purpose of the assessment.

7.6.1 Developing assessment models

An assessment model should be consistent with the site description, waste properties, and receptor characteristics, and with the quality and quantity of data available to characterize the site, waste, exposure pathways, and receptors. A systematic process should be used to ensure that the set of data used for developing the assessment model is accurate and representative. Complex models should not be developed if there is not sufficient data to support them. The use of generic or default data in place of site-specific data in developing the conceptual and computer models may be acceptable when there is no site-specific data available, such as in early stages of development; however, with the acquisition of as-built information and operational data, and increased understanding of site characteristics throughout the facility lifecycle, site-specific data should be used.

A conceptual model of the waste management system should be developed to the rigour and level of detail that are appropriate for the purpose of the assessment. The conceptual model should account for uncertainties, incomplete information in the system description, and simplifications and assumptions adopted during interpretation of the site characterization data. These simplifications and assumptions, and any resulting restrictions or limitations in the model, should be identified and discussed in the assessment. Data and information that is inconsistent with the conceptual model of the site and the waste management system should also be identified, and justification for rejecting alternate interpretations should be discussed.

Mathematical representation of the conceptual model usually requires additional simplification to make the equations amenable to solution. Further simplification and assumptions may be necessary to structure the mathematical equations so that they can be solved for the conditions defined by each scenario. These simplifications may include assumptions about the homogeneity of site characteristics, the adoption of fixed boundary conditions, the imposition of steady-state conditions, and assumptions about future lifestyles. All simplifications and assumptions should be discussed in the assessment.

The necessity of simplifying the processes and conditions included in an assessment model may impose some restrictions on what can and cannot be addressed by that model. The entire set of assumptions and limitations that accumulate throughout development of the conceptual, mathematical, and computer models should be internally consistent. That is, there should be no contradictory or mutually exclusive assumptions or limitations. The sets of input data that define the scenarios being analyzed by the assessment model should be consistent with the conceptual model of the site, the limitations of the analysis tools, and the restrictions imposed by the assumptions and simplifications on which each scenario is based.

7.6.2 Confidence in computing tools

The computing tools used to solve the equations in the assessment model can range from commercially available software packages to computer programs that are developed specifically for the given assessment. All software used in an assessment should conform to accepted quality assurance (QA) standards. Commercial software packages developed for market typically follow standard software development QA practices. Software developed specifically for the assessment should also be developed in compliance with an acceptable QA standard.

Some assessment models use generic tools such as spreadsheets or commercial finite difference or finite element software. Documentation of the QA process applied to such tools during their development should be available from the software distributor. The equations used to construct the model using such generic tools should also be subject to QA protocols. Alternatively, the equations should be justified for use in the given assessment.

Calibration of computer models and verification and validation of software are the main processes involved in software QA. 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.

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. All computer software used for long-term assessments should be verified.

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.

Data that is used to calibrate a model cannot be subsequently used to validate that model.

7.6.3 Confidence in assessment models

Confidence in the computing tools alone is not generally sufficient for regulatory purposes. The assessment model should be shown to use those tools correctly and within their limitations, and input data for the model should be verified according to an acceptable QA standard, to an extent consistent with the rigor of the assessment. The input data, the scenarios analyzed, and the resulting predictions, should all be shown to be consistent with the assumptions and limitations of the assessment model. In addition, the assessment model as a whole (scenario, conceptual model, input data, and mathematical model) should be validated to the extent possible.

The need to evaluate the uncertainty in the assessment model through deterministic sensitivity analyses or through probabilistic calculations is determined by the level of confidence needed in the model results. The acceptable level of confidence is governed by the purpose of the assessment, the safety factor built into the acceptance criteria for safety indicators, and the importance of the assessment model results to the safety case.

Although models of individual processes or phenomena can sometimes be validated by experiments and blind predictions, the long-term predictions made by assessment models cannot be confirmed. Similarly, a perfect match between the measured data from an experiment and blind predictions does not guarantee that the model will be a good predictor for performance assessment, since different processes can dominate performance and safety on different space and time scales, and under different conditions. The space and time scales for any experiment, as well as other test conditions, will likely be different from the scales or conditions for which long-term performance assessment calculations are made. In addition, experience in international computer model testing projects has shown that, due to the complexity and spatial variability of the natural environment, an unambiguous description or model of a system cannot generally be attained.

As a result, the model evaluation process should concentrate on identifying and understanding the key physical, chemical, and biological processes that are important to safety at the various space and time scales of concern in the assessment. Sophisticated detailed models of processes can be used to determine if those processes are sufficiently influential to include them in the long-term assessment model, or if they can be 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 values. 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 and mechanisms being simulated. The results obtained from these analyses should be shown to conform to the limitations and restrictions of the assumptions in the assessment model.

One useful check on the results of the model is to perform a mass balance of the contaminants. Discrepancies in mass balance should be explainable, such as decisions to assume no decay or to assume a constant source concentration to be conservative.

Neither sensitivity studies nor uncertainty analyses of deterministic or probabilistic models can inherently account for uncertainties in the underlying conceptual model, or 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 assessment model can be enhanced through a number of activities, including (without being limited to):

1. performing independent predictions using entirely different assessment strategies and computing tools;
2. demonstrating consistency between the results of the long-term assessment model and complementary scoping and bounding assessments;
3. applying the assessment model to an analog of the waste management system;
4. performing model comparison studies of benchmark problems;
5. scientific peer review by publication in open literature; and
6. widespread use by the scientific and technical community.

8. Interpretation of Results

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

The results of the 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 investigated and explained.

8.1 Comparing assessment results with acceptance criteria

Comparison of the assessment results with acceptance criteria to provide a reasonable assurance of future safety should include discussion of the conservatism of the model results, and the conservatism built into the acceptance criteria for the safety indicators.

While in most cases acceptance criteria are expressed as single values, both deterministic and probabilistic assessment results have an associated uncertainty. It is expected that the comparison between the assessment results and the acceptance criteria will explicitly take the uncertainty in the assessment results into account, as follows:

1. For deterministic 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; and
2. For probabilistic assessments, the likelihood of exceeding the acceptance criterion should be determined from the calculated results distribution, if the criterion is expressed as a single value of consequence.

Analysis of uncertainties is discussed in further detail in Section 8.2, “Analyzing uncertainties.”

For assessment results that are significantly less than the acceptance criteria, taking the uncertainty and conservatism into account in the interpretation can add to the confidence that the acceptance criteria is unlikely to be exceeded in reality and there will be no impact.

If the range of 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 assessment calculations and the likelihood of the circumstances leading to these results.

8.2 Analyzing uncertainties

A formal uncertainty analysis of the predictions should be performed to identify the sources of uncertainty. This analysis should distinguish between uncertainties arising from:

1. Input data;
2. Scenario assumptions;
3. The mathematics of the assessment model; and
4. The conceptual models.

Appendix A: Principles for Managing Radioactive Waste

A.1 Purpose

These principles are intended to promote:

- the implementation of measures to manage radioactive waste so as to
    - protect the health and safety of persons and the environment
    - provide for the maintenance of national security
    - achieve conformity with measures of control and international obligations to which Canada has agreed
- consistent national and international standards and practices for the management and control of radioactive waste

A.2 Scope

These principles describe the philosophy that underlies the CNSC's approach to regulating the management of radioactive waste and the principles that are taken into account when making a regulatory decision concerning radioactive waste management. These principles are relevant to all waste management phases, practices and considerations, including the generation, handling, processing, controlled release, storage, disposal and abandonment of radioactive waste.

These principles also express the CNSC's commitment to consulting and cooperating with provincial, national and international agencies on matters concerning harmonization of the regulation of radioactive waste management in Canada.

A.3 Definition

The term "radioactive waste" means any material (liquid, gaseous or solid) that contains a radioactive "nuclear substance," as defined in section 2 of the *Nuclear Safety and Control Act* (NSCA) and which the owner has declared to be waste. In addition to containing nuclear substances, radioactive waste may also contain non-radioactive "hazardous substances," as defined in section 1 of the *General Nuclear Safety and Control Regulations*.

A.4 Background

The CNSC regulates the use of nuclear energy and materials to protect the health and safety of persons, the environment and national security and to respect Canada's international commitments on the peaceful use of nuclear energy. Under section 26 of the NSCA, subject to exemptions authorized by the regulations, no person may possess, transfer, import, export, use, abandon, mine, produce, refine, convert, enrich, process, reprocess, package, transport, manage, store or dispose of a nuclear substance, except in accordance with a licence issued by the CNSC.

Since all radioactive waste contains nuclear substances, radioactive waste is subject to the NSCA and its regulations. Stated explicitly, all of the exclusions, prohibitions, requirements, exemptions and limitations imposed by the NSCA, the *General Nuclear Safety and Control Regulations*, the *Radiation Protection Regulations*, the *Class I Nuclear Facilities Regulations*, the *Class II Nuclear Facilities and Prescribed Equipment Regulations,* the *Uranium Mines and Mills Regulations, the Nuclear Substances and Radiation Devices Regulations*, the *Packaging and Transport of Nuclear Substances Regulations*, the *Nuclear Security Regulations*, and the *Nuclear Non-Proliferation Import and Export Control Regulations* apply to radioactive waste.

Licensed activities produce many types of radioactive waste, such as uranium mill tailings, medical isotope waste, spent nuclear fuel, and cleaning material contaminated with low levels of nuclear substances; each presenting its own level of hazard. Since all nuclear substances associated with licensed activities will eventually become waste, the safe long-term management of that waste is taken into consideration during the review process for any licensed activity.

A.5 Policy statement

When making regulatory decisions concerning the management of radioactive waste, it is the policy of the CNSC to consider the extent to which the owners of the waste have addressed the following principles:

a) The generation of radioactive waste is minimized to the extent practicable by the implementation of design measures, operating procedures and decommissioning practices;
b) The management of radioactive waste is commensurate with its radiological, chemical and biological hazard to the health and safety of persons and the environment and to national security;
c) The assessment of future impacts of radioactive waste on the health and safety of persons and the environment encompasses the period of time when the maximum impact is predicted to occur;
d) The predicted impacts on the health and safety of persons and the environment from the management of radioactive waste are no greater than the impacts that are permissible in Canada at the time of the regulatory decision;
e) The measures needed to prevent unreasonable risk to present and to future generations from the hazards of radioactive waste are developed, funded and implemented as soon as reasonably practicable; and
f) The trans-border effects on the health and safety of persons and the environment that could result from the management of radioactive waste in Canada are not greater than the effects experienced in Canada.

It is also CNSC policy to consult and cooperate with provincial, national and international agencies to:

g) promote harmonized regulation and consistent national and international standards for the management of radioactive waste; and
h) achieve conformity with the measures of control and international obligations to which Canada has agreed concerning radioactive waste.

Appendix B: Radioactive Waste Classification, Exemption, Clearance and Storage for Decay

Note: This appendix is informative and is not a mandatory part of this regulatory document. It has been extracted from CSA N292.0-14, *General principles for the management of radioactive waste and irradiated fuel*.

B.1 General

B.1.1 Waste characterization methods

Waste characterization methods are generalized in this Annex for waste organizations. Further description of the methods specified in this Annex can be found in the LLRWMO's *Management of Low-Level Radioactive Waste Produced on an Ongoing Basis: The Characterization of Radioactive Waste for Disposal*.

B.1.2 Classification system – Purpose

A radiological classification system groups radioactive waste into categories in order to specify the needs for the safe management of different types of waste. Classification assists in:

a) devising waste management strategies;
b) planning, designing, licensing, and operating waste management facilities;
c) identifying the hazards associated with a particular waste;
d) determining the type and degree of radiological protection required for a specific waste and choosing the appropriate management process; and
e) facilitating communication between waste generators, regulators, and other stakeholders by providing a common framework.

B.1.3 Waste classification system

The radioactive waste classification system recognizes four main classes of radioactive waste.

a) low-level radioactive waste;
b) intermediate-level radioactive waste;
c) high-level radioactive waste; and
d) uranium mine and mill tailings.

Note: These waste classes are defined in Clauses B.4 to B.7.

Subclasses for low-level wastes are also identified to provide further guidance on waste management needs.

B.2 Exemption and clearance

Two processes are available to determine if an activity that manages a radioactive nuclear substance, or materials that contain or potentially contain radioactive nuclear substances, is subject to regulatory control. These are:

a) exemption; and
b) clearance.

The exemption process is used to determine if a licence is required initially for an activity and the clearance process is used to determine if a material can be released or removed from a licensed activity (i.e., determine if a licence is still required to manage the material).

See CSA N292.5 for guidance on the requirements for exemption and clearance.

Notes:
1. The term "manage" includes possess, transfer, import, export, use, mine, produce, refine, convert, enrich, process, reprocess, manage, store, abandon, or dispose.
2. Materials that satisfy the conditions for exemption or clearance can still be subject to other regulatory control [e.g., TDGR (SOR/2001-286); PTNSR (SOR/2000-208)].

B.3 Decay storage

B.3.1

Decay storage should ensure the proper handling and segregation of mixed or hazardous waste and mitigate the generation of gases as necessary.

Notes:
1. Decay storage is used to lower the activity and dose rate of radioactive waste.
2. Decay storage can have the goal of lowering doses to workers handling the waste, or lowering the waste packaging requirements.
3. Decay storage can have the goal of allowing for sufficient decay so that the waste no longer requires a licence
4. in accordance with the AHJ.

B.3.2

Decay storage periods that intend to lower activities to permit reclassification as non-radioactive waste should consider not only the primary radionuclide but also radioactive impurities and the possibility of unknown radionuclides in the waste (these may be inferred if the production method of the radionuclides is well understood).

Note: Simple rules like monitoring the waste to ensure it is not above background after decaying it for 10 half lives might not be sufficient to ensure that the requirements of the AHJ are met. Removal or defacing of labels is required for disposal if waste can be documented to be classified as non-radioactive after sufficient decay storage.

B.4 Classification system — Organization

B.4.1 General

The main consideration for defining waste classes is safety. The classification scheme is not intended to and cannot substitute for the specific safety assessment required for a waste management activity or facility.

Waste is classified according to the degree of containment and isolation required to ensure its safety, with consideration given to the hazard potential of different types of waste. This reflects a graded approach towards the achievement of safety, as the classification of waste is on the basis of the characteristics of the practice or source, with account taken of the magnitude and likelihood of exposures. The criteria according to which waste is assigned to a particular waste class will depend on the specific situation in relation to the nature of the waste and the disposal options available or under consideration.

B.4.2 Parameters for classification

The following radiological properties are important characteristics of radioactive waste that may be used as parameters for waste classification:

a) half-lives of radionuclides;
b) heat generation;
c) intensity of penetrating radiation;
d) activity concentration of radionuclides;
e) dose factors of relevant radionuclides; and
f) decay products.

B.5 Low-level radioactive waste

B.5.1 General

Low-level radioactive waste (LLW) contains material with radionuclide content above established clearance levels and exemption quantities, but generally has limited amounts of long-lived activity. For orientation purposes only, a limit of 400 Bq/g on the average (and up to 4000 Bq/g for individual packages) for long lived alpha emitting radionuclides can be considered in the classification process. For long lived beta and/or gamma emitting radionuclides, such as 14C, 36Cl, 63Ni, 93Zr, 94Nb, 99Tc and 129I, the allowable average activity concentrations can be considerably higher (up to tens of kBq/g) and can be specific to the site and disposal facility. However, detailed classification should be distinguished using the characteristics specified in Clause C.3. LLW requires isolation and containment for periods of up to a few hundred years. LLW does not generally require significant shielding during handling and interim storage.

Note: Exemption quantity is defined as the quantity of a radioactive nuclear substance as specified in section 1 of the NSRDR.

B.5.2 Very-short-lived low-level radioactive waste

Very-short-lived low-level radioactive waste (VSLLW) is waste that can be stored for a decay period of not more than a few years (a time frame of two years is commonly used) and subsequently cleared for release. VSLLW includes radioactive waste containing only short half-life radionuclides typically used for research and biomedical purposes. Examples of such radioactive waste are Ir-192 and Tc-99m sources and radioactive waste containing similar short half-life radionuclides from industrial and medical applications.

The main criterion for VSLLW is the half-life of the predominant radionuclides. In general, the management of very-short-lived radioactive waste should only be applied to radionuclides with a half-life of 100 d or less.

B.5.3 Very-low-level radioactive waste

Very-low-level radioactive waste (VLLW) has a low hazard potential but is above the criteria for exemption. Long-term waste management facilities for VLLW do not need a high degree of containment and/or isolation; near-surface repository with limited regulatory control is generally suitable. Typical VLLW includes bulk material such as low-activity soil and rubble as well as some uranium wastes.

B.6 Intermediate-level radioactive waste

B.6.1 General

Intermediate-level radioactive waste (ILW) typically exhibits levels of penetrating radiation sufficient to require shielding during handling and interim storage. A precise boundary between LLW and intermediate level waste (ILW) cannot be provided, as limits on the acceptable level of activity concentration will differ between individual radionuclides or groups of radionuclides. For orientation purposes only, a contact dose rate of 2 mSv/h and thermal power below 2 kW/m3 can be used in some cases to distinguish between low- and intermediate-level radioactive waste class. However, detailed classification should be distinguished using the characteristics specified in Clause C.3. ILW generally requires little or no heat dissipation during its handling, transportation, and long-term management.

However, because of its total radioactivity level, ILW might require consideration of the implications of short-term heat generation.

Because of its long-lived radionuclides, ILW generally requires a higher level of containment and isolation than can be provided in near-surface repositories.

B.6.2 Identification

ILW generally contains long-lived radionuclides in concentrations that require isolation and containment for periods greater than several hundred years (i.e., more than 300 to 500 years). ILW includes alphabearing radioactive waste (i.e., wastes containing one or more alpha-emitting radionuclides, usually actinides) in quantities greater than the levels acceptable for near-surface repositories. ILW also includes waste that exhibits levels of penetrating radiation sufficient to require shielding during handling and interim storage.

ILW is sometimes subdivided into predominantly short-lived (ILW-SL) and predominantly long lived (ILW-LL) categories depending upon the ratio of the two categories in the wastes.

B.7 High-level radioactive waste

High-level radioactive waste (HLW) is used (i.e., irradiated) nuclear fuel that has been declared as radioactive waste and/or is waste that generates significant heat (typically more than 2kW/m3) via radioactive decay. HLW typically has levels of activity concentration in the range of 10^4 to 10^6 TBq/m3. However, detailed classification should be distinguished using the characteristics specified in Clause C.3.

Used nuclear fuel is associated with penetrating radiation; thus, shielding is required. Used nuclear fuel also contains significant quantities of long-lived radionuclides, necessitating long-term isolation. Waste forms derived from used nuclear fuel (e.g., nuclear fuel reprocessing wastes) can also exhibit similar characteristics and thus are considered HLW.

Placement in deep, stable geological formations is recommended for the long-term management of HLW.

Note: The interim dry storage of used nuclear fuel is covered in CSA N292.2.

B.8 Uranium mine and mill tailings

Uranium mine and mill tailings are a specific type of radioactive waste generated during the mining and milling of uranium ore and the production of uranium concentrate. In addition to tailings, mining activities typically result in the production of large quantities of waste rock, as workings are excavated to access the ore body. The wastes contain long-lived activity that do not decrease significantly over extended time periods. In general, long-term management in near-surface facilities adjacent to mines and mills is the only practical option for these wastes, given the large volumes of waste generated in mining and milling operations.

Uranium mine and mill tailings are not included in the scope of this Standard.

Appendix C: Methods of Waste Characterization

Note: This appendix is informative and is not a mandatory part of this regulatory document. It has been extracted from CSA N292.0-14, *General principles for the management of radioactive waste and irradiated fuel*.

C.1 General

C.1.1 Waste characterization methods

Waste characterization methods are generalized in this appendix for waste organizations. Further description of the methods specified in this appendix can be found in the LLRWMO’s *Management of Low- Level Radioactive Waste Produced on an Ongoing Basis: The Characterization of Radioactive Waste for Disposal*.

C.1.2 Parameters for classification

The following are important characteristics of radioactive waste that may be used as parameters for waste classification:

a) origin;

b) criticality;

c) chemical properties, including
   i. chemical composition;
   ii. solubility and chelating agents;
   iii. potential chemical hazard;
   iv. corrosion resistance/corrosiveness;
   v. organic content;
   vi. combustibility and flammability;
   vii. chemical reactivity and swelling potential;
   viii. gas generation;
   ix. sorption of radionuclides; and
   x. presence of complexing agents;

d) physical properties, including
   i. physical state (solid, liquid, or gaseous);
   ii. size and weight;
   iii. compactability;
   iv. dispersibility;
   v. volatility;
   vi. miscibility; and
   vii. free liquid content;

e) biological properties, including
   i. potential biological hazards; and
   ii. bioaccumulation;

f) radiological properties, including
    i. half-lives of radionuclides;
    ii. heat generation;
    iii. intensity of penetrating radiation;
    iv. activity concentration of radionuclides;
    v. surface contamination;
    vi. dose factors of relevant radionuclides; and
    vii. decay products; and

g) other factors, including
    i. volume;
    ii. amount arising per unit time; and
    iii. physical distribution.

C.2 Characterization of physical properties

C.2.1 General

C.2.1.1 Physical properties

Physical properties include:

a) the physical characteristics of the waste;
b) a general description of the waste type; and
c) the identification of those items that constitute the waste.

C.2.1.2 Characterization methods

Methods for the characterization of physical properties include:

a) non-invasive (i.e., non-destructive) techniques, such as visual examination of the outside of the container or the use of radiographic techniques; and
b) invasive (i.e., destructive) techniques that require opening the container and removing some or all of the contents for examination and measurement.

C.2.2 Non-invasive methods

C.2.2.1 Physical characteristics

The density of waste can be determined by measuring the weight and volume of waste packages. Higher than normal density can suggest the presence of unusual materials in the waste, whereas low density can indicate the presence of voids or a partially filled container. Package weight can also be useful in the application of scaling factors; that is, the activity of a waste package might be proportional to its weight

C.2.2.2 Visual examination

Visual examination may be used to observe the waste contents in cases where the container is transparent (e.g., clear plastic bags) to ensure that no restricted objects (e.g., unprotected sharp objects) or substances (e.g., free liquids) are present.

The outside of waste packages may be visually examined for identification marks, leakage of liquids, and container damage in the form of corrosion, deformation, abrasion, cracking, puncturing, and tearing.

C.2.2.3 Audible examination

Audible examination may be used to determine whether a waste package contains a significant amount of free liquid; moving the package back and forth will produce a sloshing sound consistent with the movement of liquid inside the container.

C.2.2.4 Radiographic examination

Radiographic techniques may be used to examine the contents of opaque containers for restricted substances (e.g., free liquids) or obscuring objects (e.g., small lead flasks). These techniques can involve film radiography or electronic radiography, including real time radiography, digital radiography, and computed tomography.

C.2.3 Invasive methods

C.2.3.1 Visual examination

The contents of waste packages may be visually examined by opening the container and removing the contents. This operation is usually conducted in a controlled environment (e.g., a ventilation hood, fume hood, glove box, or shielded cell) to protect the health and safety of the workers involved.

C.2.3.2 Puncture test for free liquid

A container may be checked for the presence of free liquid by puncturing the bottom of the container and collecting and measuring the liquid that drains out.

C.3 Characterization of radiological properties

C.3.1 General

The identification of radionuclides and the estimation or measurement of their activity in the waste placed in a repository is important for the safety of a facility.

C.3.2 Non-invasive characterization methods

C.3.2.1 Inference

C.3.2.1.1 General

Inference is a process of using known information about the generation of a waste item or waste stream to infer certain properties that are not known directly. Identification of waste streams is a vital part of the inference method. Inference may be used by the facility operator, provided that:

a) an appropriate method for inferring the waste inventory is used; and
b) a validated alternative method for confirming the inferred inventory is available (e.g., by radiochemical analysis).

C.3.2.1.2 Methods

The four basic inference methods specified in Clauses C.3.2.1.3 to C.3.2.1.6 may be used individually or in combination to infer waste properties.

C.3.2.1.3 Knowledge of source

If the source of the waste is known, it can provide sufficient information to identify some of the properties of the waste. For example, if it is known that the waste was in contact with primary reactor coolant, contamination by both fission products and activation products can be expected.

C.3.2.1.4 Knowledge of process

This method can allow a reasonable estimation of some of the properties of waste. It involves:

a) a thorough understanding of the material input to a process;
b) how the process functions; and
c) how the waste is generated.

The knowledge-of-process method can involve flow-sheet work, undertaken as part of process development, using the results of research and development and analogues with existing processes.

C.3.2.1.5 Material balance

This bookkeeping method uses the difference between the material input to a process and the amount that ends up in the product, taking into account quantities known to be consumed, converted, and remaining on process surfaces. This method is often used by industrial waste generators (e.g., isotope generators).

C.3.2.1.6 Scaling factors

This method is used to estimate some or all of the radionuclide inventory in waste packages of a given waste stream. The inventory is inferred from an easily measured radionuclide concentration or content and a scaling factor that relates the measured value to the unknown value(s). The scaling factor and its variability are initially established using radiochemical analysis of representative samples from the waste stream. Three common types of scaling factors are employed, based on dose rate, weight, and gamma spectrometry.

C.3.2.2 Gross radiation measurements

Gross radiation measurements can provide information on the radiation dose rate produced by the waste package as well as providing data for scaling factors as described in Clause C.3.2.1.6. Initial measurements are usually done with a hand-held monitor, but more accurate measurements can be obtained using cavity monitors, which surround all or part of the waste package with solid state detectors and shielding to reduce background radiation that might interfere with the measurements.

C.3.2.3 Nuclide-specific measurements

C.3.2.3.1 General

Spectrometry or spectroscopic analysis refers to a process of measuring the radiation spectrum and the relative intensities of the radiation emanating from a waste item. The radiation can be alpha, beta, gamma, or neutrons, with gamma spectrometry being the most common.

C.3.2.3.2 Gamma spectrometry

Generally, the detection device used for gamma spectrometry is a high-purity germanium solid-state detector coupled to a multi-channel analyzer and a personal computer. The usual configuration is that of a drum scanner or barrel monitor where the whole waste package is rotated on a turntable as it is scanned by the detector. Collimators may be used to scan the package in a series of vertical segments as the package rotates, a process referred to as “segmented scanning”. Many of the detector systems are either fully or partially automated.

C.3.2.3.3 Alpha and beta spectrometry

Non-invasive spectrometry of alpha and beta particles is not practical in the field because of the limited range of these particles.

C.3.3 Invasive characterization methods

C.3.3.1 General

Invasive methods involve opening the waste container and disturbing the contents by taking samples of the waste for examination, testing, and radiochemical analysis or by emptying the container for visual examination and monitoring of the contents.

C.3.3.2 Inspection of waste contents

Dry active waste consists of a wide variety of materials and objects that make sampling difficult. Often, much of this waste contains little measurable activity, and in many cases only a few items contain most of the activity. By visually examining and monitoring the individual items removed from a waste container, it can be possible to identify the items that are contributing most to the activity in the container. These items can then be removed for examination and measurement using, for example, gamma spectrometry, the sensitivity of which is improved with the removal of less radioactive items.

C.3.3.3 Radiochemical analysis

C.3.3.3.1 General

Waste characterization by radiochemical analysis consists of extracting samples from the waste, usually in the field, and analyzing them for radioactive constituents in a laboratory.

A variety of analytical techniques are available to determine radionuclide concentrations. The choice of technique depends on the particular radionuclide and the sensitivity required as well as other factors that might be specified in the waste acceptance criteria. Radiochemical analysis is used sparingly because it:

a) is often costly to perform (it is time consuming and labour intensive or it requires very expensive equipment, or both); and
b) can lead to increased radiation exposures of sampling and analytical personnel.

C.3.3.3.2 Sampling

Critical to the accuracy of radiochemical analyses is the requirement that the samples being analyzed be representative of the waste from which they are taken. The sample, which is usually a very small fraction of the total amount of waste, must be representative of the entire bulk, or of the average if the waste is not homogeneously mixed. Elaborate procedures can be required to homogenize the waste prior to taking the samples. The other approach, as specified in Clause C.3.3.2, is to separate out the more radioactive items, analyze them, and then average the activity over the whole waste package to arrive at an average radionuclide concentration.

C.3.3.3.3 Analytical methods

Analysis of gamma-emitting radionuclides is relatively straightforward, but analysis of radionuclides that do not emit gamma rays, or only emit low energy gamma rays, has historically been a difficult task.

Where a complex mixture of radionuclides is present, extensive chemical separations usually have to be performed prior to measurement of the radionuclides. This is done to eliminate interference from other radionuclides in order to ensure proper identification and quantitative analysis of the radionuclide of interest. This elimination is particularly important where short-lived radionuclides are masking the longer-lived ones.

C.3.3.3.4 Wet chemistry techniques

Many analysis methods require samples to be in solution and this can require the optimization of techniques such as fusion, acid digestion, and solvent extraction. In addition, other wet chemistry techniques are required for specific radionuclide analyses. Control of yield is essential in choosing an appropriate method.

C.3.3.3.5 Instrumentation

Instrumentation that may be used for radiochemical analysis includes:

a) gamma spectrometry;
b) liquid scintillation counting (beta counting);
c) alpha counting;
d) alpha spectrometry;
e) neutron activation analysis;
f) mass spectrometry;
g) thermal-emission negative-ion mass spectrometry;
h) accelerator mass spectrometry;
i) high-performance liquid chromatography;
j) inductively coupled plasma mass spectrometry; and
k) neutron counting devices.

C.4 Characterization of chemical and biological properties

C.4.1 General

The principal concern regarding the chemical and biological properties of radioactive waste is whether the waste contains chemical or biological hazardous substances in addition to the radioactive component. Where waste does contain such substances, it is generally referred to as “mixed waste”. Although the radioactive component decays away over time, many hazardous substances do not decay but remain a health risk forever (e.g., heavy metals, arsenic, asbestos).

Another concern is that certain substances, while they might not be regarded as hazardous, can adversely impact the performance of the repository. Chelating and complexing agents are examples of this, as they can mobilize or accelerate the rate of release of radionuclides and heavy metals from the waste. Reactive and corrosive substances can also have similar effects. Waste acceptance criteria often restrict such chemicals from waste management facilities.

C.4.2 Sampling

Invasive sampling of mixed wastes for hazardous and restricted substances is similar to the sampling for radioactive materials and involves many of the same problems (see Clause C.3). There are also added complications; principal among these is the possible presence of volatile organic compounds or highly infectious biological agents. When a waste container is opened to take samples or to homogenize the contents, volatile organic compounds or infectious agents can be released. Thus, special procedures must be used to sample such wastes.

C.4.3 Analytical methods

There are a number of methods available for the analysis of hazardous substances in mixed wastes. Selection of the appropriate method depends on the physical state of the component (gas, liquid, or solid), the type of waste (homogeneous or heterogeneous), the nature of the hazardous substances (inorganic, organic, or biological) and their concentrations, the presence of interfering substances, and the sensitivity required.

Analytical instrumentation that may be used to measure hazardous substances in the waste includes:

a) mass spectrometry;
b) gas chromatography;
c) liquid chromatography;
d) organic vapour analyzers with photo-ionization detector;
e) atomic emission spectrometry;
f) atomic absorption spectrometry; and
g) UV-visible spectrometry.

For organic compounds, a solvent extraction or a volatilization and trapping step might precede many analytical methods. Some biological agents might first have to be cultured in a nutrient medium, highlighted with specific reagents, and identified under a microscope.

C.5 Characterization of stabilized waste forms

C.5.1 General

Where a particular waste type or stream has characteristics that prevent or limit its acceptability for a particular repository (e.g., liquid wastes), the waste might have to be excluded from that facility or be made acceptable by suitable processing and/or packaging. This can require improving the durability (e.g., the leach resistance) of the waste to restrict the future release of radionuclides to a level consistent with the design requirements of the overall repository system. Such durability may be achieved by stabilizing the waste in a solid form (e.g., cement, bitumen, or a polymer) or by placing the waste in a more durable container, or both. The new waste form or package is then characterized to provide confidence that it will perform as required.

Characterization of solidified waste forms and packages may take the form of special tests, such as tests for leach resistance, mechanical stability, immersion resistance, radiation stability, thermal cycling resistance, biodegradation resistance, and tests for free liquid inside solidified wastes.

C.5.2 Leach tests

Some repositories require a leach test to assess the leach resistance of solidified waste forms. Samples (cores or whole waste packages) are exposed to specified leach solutions for exposure periods ranging from 90 d to 1 year. High early radionuclide concentrations can give an indication of surface contamination; later concentrations measure the leaching rate of the bulk of the waste. At the end of the exposure period, the radionuclide concentrations in the leach solutions must be below specified limits for the waste form to be acceptable.

Leach tests can also be required to determine the leaching rate of hazardous substances in solidified mixed wastes. In this case, the concentration of hazardous substances in the leachate solution must be below specified values for the waste form to be acceptable.

Glossary

Assessment
The process, and the result, of systematically evaluating the hazards associated with sources and practices, and associated protection and safety measures, aimed at quantifying performance measures for comparison with criteria. Assessment should be distinguished from analysis. Assessment is aimed at providing information that forms the basis of a decision whether something is satisfactory or not. Various kinds of analysis may be used as tools in doing this. Hence an assessment may include a number of analyses.

Best practice
An industry accepted way of doing something (process or procedure) that consistently produces superior results.

Boundary conditions
The values of variables in a mathematical model that are assumed at the spatial bounds of the model.

Bounding assessment
An assessment designed to provide limiting or worst-case predictions, based on simplification of the processes being simulated or the use of data limits (such as maximum possible precipitation, or thermodynamic solubility limits).

Calibration
The process in which model simulations are compared with field observations or experimental measurements from the system being modeled, and the model adjusted if necessary to achieve a best fit to the measured/observed data. A model may be calibrated by using data obtained from a particular location or for a limited range of conditions. It may then be considered valid for use in those circumstances but not necessarily in all circumstances.

Complementary indicator
A performance or safety indicator that is not specified by legislation or regulation and is not a direct measure of performance or safety, but is used to complement the use of these more direct indicators (see ‘safety indicator’). Complementary indicators are often intermediate parameters from which performance or safety indicators can be derived, but are more amenable to calculation and monitoring (for example, concentration of contaminant releases as a complementary indicator to human exposure to that contaminant). Complementary indicators can be useful in scoping calculations.

Conservative calculations
Calculations that are designed to over-predict a parameter with the intention that the reality will not be greater than the prediction. These calculations can be based on simplifications of the processes being simulated (the structure of a model) or on limits of data values used in the model.

Critical group
A group of members of the public that is reasonably homogeneous with respect to its exposure for a given radiation source and given exposure pathway, and is typical of individuals receiving the highest effective dose or equivalent dose (as applicable) by the given exposure pathway from the given source.

Deterministic effect
A radiation effect in which a threshold level of dose exists above which the severity of the effect is greater for a higher dose. The level of the threshold dose is characteristic of the particular health effect but

may also depend, to a limited extent, on the exposed individual. Examples of deterministic effects include erythema and acute radiation syndrome (radiation sickness).

Defence in depth
The application of more than one protective measure for a given safety objective, such that the objective is achieved even if one of the protective measures fails.

Disposal
Placement of radioactive waste without the intention of retrieval.

Hazardous substance
A substance, other than a nuclear substance, that is used or produced in the course of carrying on a licensed activity and that may pose a risk to the environment or the health and safety of persons.

Initial conditions
The values of variables in a mathematical model that are assumed at the beginning of the time period considered in the model.

Institutional controls
The control of residual risks at a site after it has been decommissioned. Institutional controls can include active measures (requiring activities on the site such as water treatment, monitoring, surveillance and maintenance) and passive measures (that do not require activities on the site, such as land use restrictions, markers, etc.).

licensing basis
A set of requirements and documents for a regulated facility or activity comprising:

- the regulatory requirements set out in the applicable laws and regulations
- the conditions and safety and control measures described in the facility's or activity's licence and the documents directly referenced in that licence
- the safety and control measures described in the licence application and the documents needed to support that licence application

Long term
In radioactive waste disposal, any period of time after active institutional controls can be expected to cease.

Natural analogues
Natural conditions or processes, occurring over long periods of time, that are the same or similar to those known or predicted to occur in some part of the waste management system. Natural analogue information should be used to build confidence that the system will perform as predicted by demonstrating that natural processes will limit the long-term release of contaminants to the biosphere to levels well below target criteria. The success of natural analogues in confidence building depends mainly on the degree of similarity between the natural conditions or processes to those of the system, and the level of detail and confidence in the data obtained from the analogue investigation.

Radioactive waste
For the purposes of this document, any material (liquid, gaseous, or solid) that contains a radioactive "nuclear substance," as defined in section 2 of the NSCA, and which the owner has declared to be waste. In addition to containing nuclear substances, radioactive waste may also contain non-radioactive "hazardous substances," as defined in section 1 of the General Nuclear Safety and Control Regulations.

Receptor
Any person or environmental entity that is exposed to radiation, or a hazardous substance, or both. A receptor is usually an organism or a population, but it could also be an abiotic entity such as surface water or sediment.

Risk
A multi-attribute quantity expressing hazard, danger or chance of harmful or injurious consequences associated with actual or potential exposures. It relates to quantities such as the probability that specific deleterious consequences may arise and the magnitude and character of such consequences.

Risk assessment
An assessment of the radiological risks associated with normal operation and potential accidents involving a source or practice. This will normally include consequence assessment and associated probabilities.

Safety
'Safety' in this document is taken to mean freedom from unreasonable risk to persons or the environment arising from the generation and management of radioactive waste and all of its constituents.

Safety assessment
An analysis to evaluate the performance of an overall system and its impact, where the performance measure is radiological impact or some other global measure of impact on safety.

Safety case
An integrated collection of arguments and evidence to demonstrate the safety of a facility. This will normally include a safety assessment, but could also typically include information (including supporting evidence and reasoning) on the robustness and reliability of the safety assessment and the assumptions made therein.

Safety indicator
A quantity used in assessments as a measure of the performance of provisions for protection and safety. These are normally either (a) illustrative calculations of dose or risk quantities, used to give an indication of the possible magnitude of doses or risks for comparison with criteria, or
(b) other quantities, such as concentrations or fluxes of radionuclides or hazardous substances, that are considered to give a more reliable indication of impact, and that can be compared with protective limits set by legislation or regulation.

Scenarios
A postulated or assumed set of conditions or events. They are most commonly used in analysis or assessment to represent possible future conditions or events to be modeled, such as possible accidents at a nuclear facility, or the possible future evolution of a repository and its surroundings.

Scoping assessment
An assessment using simplified mathematical models to quickly estimate the likely results that will be predicted by more detailed assessment models, also can be used to provide a first-order examination of whether the model sensitivity to changes in input values is a reasonable simulation of reality.

Sensitivity analysis
A quantitative examination of how the behaviour of a system varies with change, usually in the value of the governing parameters.

Stochastic effect
In contrast to a deterministic effect, a stochastic effect is a radiation-induced health effect, the probability of occurrence of which is greater for a higher radiation dose and the severity of which (if it occurs) is independent of dose. Stochastic effects may be somatic effects or hereditary effects, and generally occur without a threshold level of dose. Examples include cancer and leukaemia.

Storage
The holding of radioactive waste in a facility that provides for its containment with the intention of retrieval.

Validation
In radioactive waste management, the process of building confidence that a model adequately represents a real system for a specific purpose.

Valued ecosystem component
The environmental element of an ecosystem that is identified as having scientific, social, cultural, economic, historical, archaeological or aesthetic importance.

Verification
The process of determining whether a computational model correctly implements the intended conceptual model or mathematical model.

Associated Documents

A number of documents are referred to in this regulatory document and listed below for the assistance of licensees and licence applicants. This reference does not signify that the CNSC has necessarily adopted those publications as its own criteria for its regulatory functions.

1 BIOMOVS 1996, *BIOMOVS II Technical Report No. 6, Development of a Reference Biospheres Methodology for Radioactive Waste Disposal*, BIOMOVS II Steering Committee, Stockholm, 1996.

2 Canada 2012, *Canadian Environmental Assessment Act*, S.C. 2012, c. 37.

3 Canada 2000a, *Nuclear Safety and Control Act*, S.C. 1997, c. 9.

4 Canada 2000b, *General Nuclear Safety and Control Regulations,* SOR/2000-202.

5 Canada 2000c, *Radiation Protection Regulations*, SOR/2000-203.

6 CCME 1996, *A Framework for Ecological Risk Assessment: General Guidance. The National Contaminated Sites Remediation Program*, Canadian Council of Ministers of the Environment, Winnipeg, Manitoba, 1996.

7 CCME 2002, *Canadian Environmental Quality Guidelines*, Canadian Council of Ministers of the Environment (CCME), Ottawa, 2002.

8 CNSC 2017, *Fact Sheet: Environmental Assessments at the CNSC*, Canadian Nuclear Safety Commission, Ottawa, 2017, http://nuclearsafety.gc.ca/eng/pdfs/Fact_Sheets/Factsheet-EA-at-the-CNSC-eng.pdf.

9 EC 1997, *Environmental Assessments of Priority Substances under the Canadian Environmental Protection Act*, Guidance Manual Version 1.0, Environment Canada, 1997.

10 EC 2006, *Priority Substances List Assessment Report. Releases of radionuclides from nuclear facilities (Impact on Non-human Biota)*, Environment Canada, Ottawa, 2006.

11 HC 2012a, *Contaminated Sites Program, Federal Contaminated Site Risk Assessment in Canada, Part I: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA Version 2)*, Environmental Health Assessment Services, Safe Environments Program, Health Canada, Ottawa, 2012.

12 HC 2010b, *Contaminated Sites Program, Federal Contaminated Site Risk Assessment in Canada, Part II: Health Canada Toxicological Reference Values (TRVs) and Chemical-Specific Factors, Version 2*, Environmental Health Assessment Services, Safe Environments Program, Health Canada, Ottawa, 2010.

13 IAEA 1989, *Natural Analogues in Performance Assessments for the Disposal of Long Lived Radioactive Wastes, IAEA Technical Report Series No. 304*, International Atomic Energy Agency, Vienna, 1989.

14 IAEA 1992, *Effects of Ionizing Radiation on Plants and Animals at Levels Implied by Current Radiation Protection Standards*, *IAEA Technical Report Series No. 332*, International Atomic Energy Agency, Vienna, 1992.

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17 IAEA 2003, *"Reference Biospheres" for solid radioactive waste disposal*, *IAEABIOMASS-6*, International Atomic Energy Agency, Vienna, 2003.

18 IAEA 2004, *IAEA ISAM, Safety Assessment Methodologies for Near Surface Disposal Facilities –Results of a Co-ordinated Research Project,* 2 Volumes, International Atomic Energy Agency, Vienna 2004.

19 ICRP 1991, *ICRP Publication 60: 1990 Recommendations of the International Commission on Radiological Protection*, International Commission on Radiological Protection, 1991.

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21 MOEE 1997, *Guideline for Use at Contaminated Sites in Ontario*, Ontario Ministry of the Environment and Energy (MOEE), 1997.

22 NCRP 1991, *NCRP Report No. 109, Effects of Ionizing Radiation on Aquatic Organisms*, National Council on Radiation Protection and Measurement, Washington, 1991.

23 NEA 2000, *Features, Events and Processes (FEPs) for Geologic Disposal of Radioactive Waste—An International Database*, OECD Nuclear Energy Agency, Paris, 2000.

24 NEA 2001, *Scenario Development Methods and Practice*, OECD Nuclear Energy Agency, Paris, 2001.

25 NEA 2003, *Features, Events and Processes Evaluation Catalogue for Argillaceous Media*, NEA 4437, OECD Nuclear Energy Agency, Paris, 2003.

26 OPG 2001, *A Design Basis Glacier Scenario*, W. R. Peltier, OPG Report No. 06819-REP-01200-10069-R00, Ontario Power Generation, Toronto, 2001.

27 SKI 1995, *SKI Report 95:42, The Central Scenario for SITE-94: A Climate Change Scenario,* Swedish Nuclear Power Inspectorate, Stockholm, 1995.

28 USEPA 2008, *Child-Specific Exposure Factors Handbook, Interim Report*. United States Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, Washington Office, Washington DC, EPA-600/R-06/096F, 2008.

CNSC Regulatory Document Series

Facilities and activities within the nuclear sector in Canada are regulated by the Canadian Nuclear Safety Commission (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.

Effective April 2013, the CNSC's catalogue of existing and planned regulatory documents has been organized under three key categories and twenty-five series, as set out below. Regulatory documents produced by the CNSC fall under one of the following 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 Aboriginal 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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