



Regulatory
Guide

G-320

**Assessing the Long Term Safety of
Radioactive Waste Management**

December 2006

TYPES OF REGULATORY DOCUMENTS

Regulatory documents support the Canadian Nuclear Safety Commission (CNSC) regulatory framework. By expanding on expectations set out in general terms in the *Nuclear Safety and Control Act* and associated regulations, regulatory documents provide one of the core management tools upon which the CNSC relies to fulfill its legislated obligations.

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Regulatory Guide (G): The regulatory guide informs licensees about how they can meet CNSC expectations and requirements. It provides licensees with a recommended approach for meeting particular aspects of the requirements and expectations associated with their respective licensed activities.

Regulatory Notice (N): The regulatory notice notifies licensees and other stakeholders about significant matters that warrant timely action.

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WASTE MANAGEMENT**

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Canadian Nuclear Safety Commission
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Office of Communications and Regulatory Affairs
Canadian Nuclear Safety Commission
P.O. Box 1046, Station B
280 Slater Street
Ottawa, Ontario, CANADA, K1P 5S9

Telephone: 613-995-5894 or 1-800-668-5284 (Canada only)
Facsimile: 613-992-2915
E-mail: info@cnsccsn.gc.ca

TABLE OF CONTENTS

| | | |
|------------|--|-----------|
| 1.0 | PURPOSE..... | 1 |
| 2.0 | SCOPE..... | 1 |
| 3.0 | RELEVANT LEGISLATION | 2 |
| 3.1 | Overview | 2 |
| 3.2 | Legislated Requirements..... | 3 |
| 4.0 | BACKGROUND INFORMATION | 6 |
| 4.1 | Waste Management Systems for Long Term Storage and Disposal..... | 6 |
| 4.2 | Concepts for Long Term Management..... | 7 |
| 4.3 | Licensing Considerations for Long Term Management..... | 8 |
| 4.3.1 | Determining Methodology | 8 |
| 4.3.2 | Design Optimization..... | 8 |
| 4.3.3 | Assessment Evaluation..... | 9 |
| 5.0 | DEVELOPING A LONG TERM SAFETY CASE | 9 |
| 5.1 | Safety Assessment..... | 10 |
| 5.1.1 | Additional Arguments..... | 10 |
| 5.2 | Use of Different Assessment Strategies..... | 10 |
| 5.2.1 | Scoping and Bounding Assessments | 11 |
| 5.2.2 | Realistic Best Estimates vs. Conservative Over-Estimates..... | 11 |
| 5.2.3 | Deterministic and Probabilistic Calculations | 12 |
| 5.3 | Robustness and Natural Analogues..... | 13 |
| 5.4 | Use of Complementary Indicators of Safety..... | 14 |
| 6.0 | DEFINING ACCEPTANCE CRITERIA..... | 14 |
| 6.1 | Overview | 14 |
| 6.2 | Criteria for Protection of Persons and the Environment | 15 |
| 6.2.1 | Radiological Protection of Persons..... | 15 |
| 6.2.2 | Protection of Persons from Hazardous Substances..... | 17 |
| 6.2.3 | Radiological Protection of the Environment..... | 18 |
| 6.2.4 | Protection of the Environment from Hazardous Substances..... | 18 |
| 7.0 | PERFORMING LONG TERM ASSESSMENTS..... | 19 |
| 7.1 | Selection of Appropriate Methodology | 19 |
| 7.1.1 | The Canadian Environmental Assessment Act | 20 |
| 7.1.2 | Environment Canada | 20 |
| 7.1.3 | Health Canada | 20 |
| 7.1.4 | The Canadian Council of Ministers of the Environment | 21 |
| 7.1.5 | The International Atomic Energy Agency | 21 |
| 7.2 | Assessment Context | 21 |
| 7.2.1 | Terms of Reference | 21 |
| 7.2.2 | Regulatory Requirements to be Met..... | 22 |
| 7.2.3 | Criteria to be Met..... | 22 |
| 7.2.4 | Approach Used to Demonstrate Safety | 22 |

| | | |
|------------|---|-----------|
| 7.3 | System Description | 22 |
| 7.3.1 | Site Characteristics | 23 |
| 7.3.2 | Waste Management System..... | 24 |
| 7.4 | Assessment Time Frames..... | 24 |
| 7.5 | Assessment Scenarios | 25 |
| 7.5.1 | Normal Evolution Scenario | 26 |
| 7.5.2 | Disruptive Event Scenarios, Including Human Intrusion..... | 27 |
| 7.5.3 | Institutional Controls | 28 |
| 7.5.4 | Identification of Critical Groups and Environmental Receptors | 28 |
| 7.6 | Developing and Using Assessment Models | 30 |
| 7.6.1 | Developing Assessment Models..... | 30 |
| 7.6.2 | Confidence in Computing Tools..... | 31 |
| 7.6.3 | Confidence in Assessment Models..... | 32 |
| 8.0 | INTERPRETATION OF RESULTS | 33 |
| 8.1 | Comparing Assessment Results with Acceptance Criteria..... | 34 |
| 8.2 | Analyzing Uncertainties | 34 |
| | GLOSSARY | 35 |
| | ASSOCIATED DOCUMENTS..... | 39 |

ASSESSING THE LONG TERM SAFETY OF RADIOACTIVE WASTE MANAGEMENT

1.0 PURPOSE

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

2.0 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 guide 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 guide addresses the assessment of long term safety to support licence applications, and includes discussion of assessment methodologies, structures, and approaches. This guide does not address other issues that are also taken into consideration in the licensing process, such as waste characterization, 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 guide 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.

3.0 RELEVANT LEGISLATION

3.1 Overview

The Canadian Nuclear Safety Commission (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.

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. Site preparation licence;
2. Licence to construct (sometimes combined with a site preparation licence);
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 regulatory policy P-290, *Managing Radioactive Waste* (CNSC 2004).

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 a licensee, “take all reasonable precautions to protect the environment and the health and safety of persons and to maintain security”;
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, “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, “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 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 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 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 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 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 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, contains, in addition to the information required by section 3 of the *General Nuclear Safety and Control Regulations*, “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, contains 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, contains 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 contains, “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 contains, 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”; and
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* (Canada 1992). The following excerpts from the CEAA are directly relevant to the purpose of this guide:

1. Paragraph 5 (1) (d) stipulates that an environmental assessment of a project is required before the CNSC (as the federal authority), “issues a permit or licence, grants an approval, or takes any other action for the purpose of enabling the project to be carried out in whole or in part”; and
2. Paragraph 16 (1) states that every screening or comprehensive study of a project, and every mediation or assessment by a review panel, shall include consideration of a number of factors, including, (a) the environmental effects of the project, including the environmental effects of malfunctions or accidents that may occur in connection with the project and any cumulative environmental effects that are likely to result from the project in combination with other projects or activities that have been or will be carried out.”

4.0 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) 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. CEEA 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

CNSC regulatory policy P-290, *Managing Radioactive Waste*, identifies the need for long term management of radioactive waste and hazardous waste arising from licensed activities. The principles espoused by P-290 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.

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.

5.0 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 is 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 Over-Estimates

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 over-estimates cannot meet acceptance criteria.

Conservative calculations intentionally over-estimate 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 under-estimation 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 over-estimate 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 over-estimate.

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.

6.0 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 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 or 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 2004a). 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 2002).

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 nonhuman 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 nonhuman 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 nonhuman 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 (EC_{25}), lowest observable adverse effects level (LOAEL), or no observable adverse effects level (NOAEL), from studies of chronic exposure of 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 1000 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.

7.0 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 rigor 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:

1. The *Canadian Environmental Assessment Act*;
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

The *Canadian Environmental Assessment Act* (CEAA) 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 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.

An environmental assessment under the CEAA does not require the same level of detail and rigor that would, for example, be required to licence a radioactive waste management facility under the NSCA. The methodology used by the CNSC to conduct an environmental assessment under the CEAA is posted on the CNSC website (CNSC 2006).

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 2004a, HC 2004b).

7.1.4 The Canadian Council of Ministers of the Environment

A CCME guidance document entitled *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:

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 "Reference Documents" list provided 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 6.0, “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 CNSC regulatory policy P-290, *Managing Radioactive Waste*. The approach used to demonstrate safety can be based on combinations of complementary assessments at various levels of detail, as discussed in Section 5.0, “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 Characteristics

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 System

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 CNSC regulatory policy P-290, *Managing Radioactive Waste*).

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 modeled 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 rigor 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 modeling 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 rigor and level of detail that is 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.

8.0 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.

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.).

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 guide, 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 guide 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 (VEC)

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 guide 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.

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