Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire

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CMD : 22-M12

Date signed/Signé le : 7-MARCH-2022

Approve Regulatory Document

Approuver le document d'application de la réglementation

REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities*

REGDOC-2.4.4, *Analyse de la sûreté pour les installations de catégorie IB*

Public Meeting

Réunion publique

Scheduled for:

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Prévue pour le :

28 juin 2022

Submitted by:

CNSC Staff

Soumis par :

Le personnel de la CCSN

e-doc 6705671 (WORD)
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Summary

This CMD pertains to a request for a decision regarding:

- draft regulatory document REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities*

The following action is requested of the Commission:

- approve draft REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities*

The following items are attached:

- draft REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities*
- consultation report
- comments dispositioning table

Résumé

Ce document à l'intention des commissaires (CMD) concerne une demande de décision au sujet de :

- l'ébauche du document d'application de la réglementation REGDOC-2.4.4, *Analyse de la sûreté pour les installations de catégorie IB*

La Commission pourrait considérer prendre la mesure suivante :

- approuver l'ébauche du REGDOC-2.4.4, *Analyse de la sûreté pour les installations de catégorie IB*

Les pièces suivantes sont jointes :

- l'ébauche du REGDOC-2.4.4, *Analyse de la sûreté pour les installations de catégorie IB*
- le rapport de consultation
- le tableau des réponses aux commentaires reçus

Signed/signé le

March 7, 2022/ 7 mars 2022

DBeaton

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Director General

Regulatory Policy Directorate

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Direction de la politique de réglementation

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EXECUTIVE SUMMARY

Regulatory document REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities* clarifies requirements and provides guidance for applicants and licensees to demonstrate the safety of a Class IB nuclear facility, including:

- a safety analysis program (the managed process that governs conduct of a safety analysis)
- conduct of a safety analysis (a systematic evaluation of the potential hazards)
- safety analysis documents, records and reporting

CNSC staff developed this regulatory document taking into account international regulatory best practices and modern codes and standards including the International Atomic Energy Agency's safety standards. If approved for publication by the Commission, this will be the first document for safety analysis for Class IB nuclear facilities.

1 OVERVIEW

1.1 Background

Given the high level of interest on the subject of safety analysis for Class IB nuclear facilities, CNSC staff conducted extensive consultation during the development of the draft regulatory document. Staff engaged key stakeholders and selected licensees starting 2016 to understand best practices and elucidate a common consistent approach to safety analysis. Staff also reviewed current safety analysis reports of major licensees to confirm impact across a broad range of facility risk profiles that fall under a Class IB licences.

Section 2 of this Commission Member Document presents a list of the key comments received during public consultation. The attached detailed comments table provides all the comments received on the draft regulatory document as well as CNSC how the staff addressed each comment.

The draft regulatory document is intended to form part of the licensing basis for Class IB nuclear facilities. If the regulatory document is approved by the Commission, implementation plans will be established through discussions and consultations between CNSC staff and licensees, in accordance with the CNSC's process for the implementation of regulatory documents. As part of the implementation plan, licensees will adopt the requirements expressed in the regulatory document as part of their licensing basis, thereby providing the CNSC with the legal authority to enforce these requirements.

The International Atomic Energy Agency's Integrated Regulatory Review Service mission to Canada in 2019 commented that the CNSC has a comprehensive and robust regulatory framework. The mission noted that the CNSC regulatory framework does not entirely specify safety requirements for fuel cycle facilities. The publication of REGDOC-2.4.4 will establish relevant requirements for the facilities.

1.2 Highlights

Draft REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities*, provides requirements and guidance for safety analysis of Class IB nuclear facilities. Class IB nuclear facilities described in the draft document are defined in section 1 of the *Class I Nuclear Facilities Regulations* and paragraph 19(a) and (b) of the *General Nuclear Safety and Control Regulations*.

The post-closure safety assessment for Class IB disposal facilities is not include in the scope of this document. REGDOC-2.11.1, *Waste Management, Volume III: Safety Case for the Disposal of Radioactive Waste, Version 2* addresses the safety assessment for the post-closure phase of disposal facilities.

The draft document sets out to define the safety analysis report and to define the safety analysis program.

2 CONSULTATION

On August 28, 2020, a draft version of REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities* was issued for a 100-day public consultation period ending on December 5, 2020.

CNSC staff notified Indigenous Nations and communities as well as stakeholders, such as licensees, members of the public and Environmental Non-Government Organizations (NGOs) of the postings via the e-mail subscriber list and three social media platforms (Facebook, Twitter and LinkedIn). CNSC staff identified that this topic would not require engagement specifically with Indigenous peoples beyond the standard regulatory document notification and consultation process. However, the CNSC remains open to engaging with Indigenous peoples on this topic should an Indigenous Nation or community express an interest.

During the consultation period, the CNSC received 69 distinct comments from 14 respondents:

- Brian Beaton, Coalition for Responsible Energy Development in New Brunswick (Deceased)
- Bruce Power
- Cameco Corporation
- Canadian Nuclear Association (CNA)
- Canadian Nuclear Laboratories (CNL)
- Canadian Nuclear Workers Council
- Énergie New Brunswick Power (NBPower)
- P. Hader, consultant
- Nordion
- Nuclear Waste Management Organization (NWMO)
- Ontario Power Generation (OPG)
- Safety Probe International
- SRB Technologies
- M. Stephens, AECL (Deceased)

Following the public consultation period, submissions from respondents were posted on the CNSC's website, from December 6, 2020, to January 12, 2021, for feedback on the comments received. No additional feedback was received.

Following the initial disposition of comments by CNSC staff, the detailed comments table was sent to the commenters. Industry was satisfied with the most of CNSC staff responses, but requested clarification on a few, therefore staff held a workshop on December 13, 2021. Representatives from the following organizations attended:

- Bruce Power
- BWXT
- CANDU Owner's Group

- Cameco Corporation
- CNA
- CNL
- NB Power
- NWMO
- OPG
- SRB Technologies

The following comments raised during public consultation may be of particular interest:

Comment 1: Prescriptiveness of requirements

Some Class IB nuclear facility licence holders expressed a concern that draft REGDOC-2.4.4 is overly prescriptive with respect to the concepts of environmental qualification, minimum staff complement, credited operator action items and, to a lesser degree, the now-mandatory methodology in the application of defense-in-depth, particularly where nuclear substance processing facilities may intersect with the requirements. They also noted that not all Class IB facilities are “nuclear fuel cycle” facilities and do not play any role in the manufacture or processing of fuel for nuclear reactors.

CNSC staff response:

Changes have been made to address the broad range of Class IB facilities. CNSC staff agree that not all Class IB nuclear facilities are nuclear fuel cycle facilities. Staff took that into account in the development of REGDOC-2.4.4 and, also, in reviewing the existing safety analyses of these facilities.

The requirements in this regulatory document, which is consistent with other documents in the 2.4 series of regulatory documents, set the foundation on performing a safety analysis on a Class IB nuclear facility and promote consistency across the industry. CNSC staff expect that many licensees will apply a graded approach, which is consistent with how CNSC staff is currently assessing safety analysis for these facilities.

Comment 2: Graded approach

Stakeholders requested clarity on the application of a risk-informed graded approach to safety analysis. The reviewers commented that the requirements (“shall”) statements included in REGDOC-2.4.4 are inconsistent with a licensee’s ability to apply a risk-informed graded approach. In their opinion, REGDOC-2.4.4 is entirely prescriptive. While the risk-informed graded approach is described inREGDOC-3.5.3, *Regulatory Fundamentals*, they expressed that the information is of limited assistance because it merely defines a graded approach and states that the CNSC applies it, but does not provide any further guidance for licensees.

CNSC staff response:

Text in REGDOC-2.4.4 has been revised for clarity and to confirm the CNSC's risk-informed graded approach.

REGDOC-2.4.4 has been adapted to clarify the licensee's option to propose specific design measures, analysis or other measures that are commensurate with the level of risks posed, if they provide adequate justification. Text supporting this option is provided in the Preface, section 1.2 (Note 2) and in sections 4.1 and 7.

REGDOC-3.5.3, *Regulatory Fundamentals* is being revised to add information on the CNSC's risk-informed graded approach. Specifically, the CNSC is adding a new appendix on graded approach to REGDOC-3.5.3. Comments on the graded approach have been passed to the regulatory team working on that regulatory document. This document is expected to be provided to the Commission for approval shortly.

Comment 3: Postulated initiating events (PIEs)

Reviewers expressed concern about the treatment of external hazards and PIEs. They believe that external hazards/events should not be referred to as PIEs, similar to the approach in REGDOC-2.4.1, *Deterministic Safety Analysis* where they need to be considered, but they do not necessarily result in a PIE.

CNSC staff response:

It is the responsibility of the applicant or licensee to assess all potential hazards and select all appropriate ones for further safety analysis. However, the CNSC is not asking licensees to run safety analysis on events that, for that facility, could not lead to an accident.

The requirement is that "The applicant or licensee shall identify PIEs (both internally and externally initiated) that could lead to:

- radiation exposure to workers or to the public
- a release of significant amounts of nuclear substances
- a release of hazardous substances (such as hazardous chemicals) associated with the nuclear substances

External events are identified at the beginning of the process and identified by the licensee as "credible" or "not credible" for that facility. The licensee starts with a wider range and then decreases the range to "credible". This identification of the event as "credible" or "not credible" is the 2nd step of the licensee's 3-step analysis. It is the licensee's responsibility to systematically assess the events and provide analysis for those that can lead to a failure.

3 IMPLEMENTATION

REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities* is intended to form part of the licensing basis for applicable new and existing Class IB nuclear facility licensees. If approved, CNSC staff would contact licensees who should implement the regulatory document and formally request implementation plans and gap analyses. Once the request is sent, licensees are typically given 6 months to address the request.

Specific implementation plans and associated timelines are established through follow-up discussions between CNSC staff and individual licensees based on the size and significance of the gaps identified. Regulatory document implementation status is reported in an ongoing basis to the Commission through the appropriate Regulatory Oversight Report. Since 2016, CNSC staff have been promoting to the impacted licensees to follow the international guidance on safety reports. That guidance is consistent with the requirements and guidance found in this draft regulatory document, so most licensees already have safety analysis that meets the intent of the document.

If published, REGDOC-2.4.4 will be the first version of this type of document that will provide requirements and guidance including applying international guidance into Canadian context, for the safety analysis for Class IB nuclear facilities. As such, CNSC staff will continue to discuss implementation with impacted licensees after publication to ensure the requirements are well understood. CNSC Staff will also collect lessons learned during implementation and provide additional guidance as required.

4 OVERALL CONCLUSIONS AND RECOMMENDATIONS

4.1 Overall Conclusions

Draft REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities* was developed through consultation with stakeholders and is essential, especially for any new facilities, to communicating and formalizing the CNSC's requirements and guidance related to safety analysis.

CNSC staff conclude REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities*, is ready for final approval by the Commission for publication.

4.2 Overall Recommendations

CNSC staff recommend that the Commission approve REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities*.

Canada's Nuclear Regulator

CNSC CCSN

Safety Analysis

Safety Analysis for Class IB Nuclear Facilities

REGDOC-2.4.4

June 2022

Canadian Nuclear Safety Commission

Commission canadienne de sûreté nucléaire

Canada

Safety Analysis for Class IB Nuclear Facilities
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Publishing history

Preface

This regulatory document is part of the CNSC's safety analysis series of regulatory documents, which also covers deterministic safety analysis, probabilistic safety assessment and nuclear criticality safety. The full list of regulatory document series is included at the end of this document and can also be found on the CNSC's website.

Regulatory document REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities* clarifies requirements and provides guidance for applicants and licensees to demonstrate the safety of a Class IB nuclear facility, including:

- a safety analysis program (the managed process that governs conduct of a safety analysis)
- conduct of a safety analysis (a systematic evaluation of the potential hazards)
- safety analysis documents, records and reporting

This document is the first version of REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities*.

Class IB nuclear facilities have risk profiles that vary, significantly, depending on the particular characteristics of the activity or facility. The licensee may propose specific design measures, analyses or other measures that are commensurate with the level of risks posed, based on the CNSC's risk-informed graded approach, if they provide adequate justification.

For additional information on safety analysis for the post-closure phase of a disposal facility, see REGDOC-2.11.1, *Waste Management, Volume III: Safety Case for Disposal of Radioactive Waste*.

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

> The words "shall" and "must" are used to express requirements to be satisfied by the licensee or licence applicant. "Should" is used to express guidance or that which is advised. "May" is used to express an option or that which is advised or permissible within the limits of this regulatory document. "Can" is used to express possibility or capability.
>
> Nothing contained in this document is to be construed as relieving any licensee from any other pertinent requirements. It is the licensee's responsibility to identify and comply with all applicable regulations and licence conditions.

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Safety Analysis for Class IB Nuclear Facilities

1. Introduction

1.1 Purpose

This regulatory document clarifies requirements and provides guidance for applicants and licensees to demonstrate the safety of a Class IB nuclear facility, including:

- a safety analysis program (the managed process that governs conduct of a safety analysis)
- conduct of a safety analysis (a systematic evaluation of the potential hazards)
- safety analysis documents, records and reporting

Note: Throughout this regulatory document, the term "nuclear facility" means a Class IB nuclear facility.

1.2 Scope

This document provides requirements and guidance for safety analysis of the following Class IB nuclear facilities:

- a facility for the processing, reprocessing or separation of an isotope of uranium, thorium or plutonium
- a facility for the manufacture of a product from uranium, thorium or plutonium
- a facility, other than a Class II nuclear facility as defined in section 1 of the *Class II Nuclear Facilities and Prescribed Equipment Regulations*, for the processing or use, in a quantity greater than 10^{15} Bq per calendar year, of nuclear substances other than uranium, thorium or plutonium
- a facility for the disposal of a nuclear substance generated at another nuclear facility
  - note: this regulatory document applies for the operational phase, which includes the licensed activities conducted up to the closure of the disposal facility
- a facility prescribed by paragraph 19(a) or (b) of the *General Nuclear Safety and Control Regulations*:
  - a facility for the management, storage or disposal of waste containing radioactive nuclear substances at which the resident inventory of radioactive nuclear substances contained in the waste is 10^{15} Bq or more
    [**note:** for the scope of this regulatory document, some examples of these facilities include:
    - any facility for the storage of fissionable material before and after irradiation
    - any facility for associated waste conditioning, effluent treatment and facilities for storage of waste that allow for retrieval of the waste for later disposal]
  - a plant for the production of deuterium or deuterium compounds using hydrogen sulphide

For additional information on safety analysis for the post-closure phase of a disposal facility, see REGDOC-2.11.1, *Waste Management, Volume III: Safety Case for Disposal of Radioactive Waste* [1].

Note: Given the wide range of Class IB nuclear facilities, a graded approach may be proposed by the licensee in accordance with REGDOC-3.5.3, *Regulatory Fundamentals* [2].

1.3 Relevant legislation

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

- NSCA, subsections 24(4) and 24(5)
- *General Nuclear Safety and Control Regulations*, paragraph 3(1)(i)
- *Class I Nuclear Facilities Regulations*, paragraphs 5(f) and (i); paragraphs 6(c) and (h); and paragraph 7(f)

2. Safety Objectives

Safety analysis is a systematic evaluation of the potential hazards associated with the conduct of a proposed activity or facility and that considers the effectiveness of preventive measures and strategies in reducing the effects of such hazards.

A safety analysis program is designed, developed and maintained by the licensee, and is reviewed by CNSC staff. It is documented in a safety analysis report (SAR). As stated in paragraphs 5(f) and 6(c) of the *Class I Nuclear Facilities Regulations*:

- "An application for a licence to construct a Class I nuclear facility shall contain the following information... (f) a preliminary safety analysis report demonstrating the adequacy of the design of the nuclear facility;"
- "An application for a licence to operate a Class I nuclear facility shall contain the following information... (c) a final safety analysis report demonstrating the adequacy of the design of the nuclear facility;"

The SAR may reference other safety analysis documentation.

A facility's SAR forms an important part of the licensing basis for the facility. It is used to:

- establish limits for the safe operation of the facility
- assess proposed changes to the facility
- develop and maintain the licensee's policies, processes and procedures for the safe conduct of the licensed activities
- confirm that the design of the facility meets design and safety requirements

2.1 Defence in depth

Requirements

The licensee shall address the concept of defence in depth when developing a safety analysis for a nuclear facility.

Guidance

Five levels of defence in depth are normally defined for nuclear facilities, in accordance with the guidance provided in REGDOC-3.5.3, *Regulatory Fundamentals* [2]. Safety analysis plays a major role in demonstrating that levels 1 to 4 have been achieved. The applicability of safety analysis to these levels is as follows:

Level 1 The aim of the first level of defence is to prevent deviations from normal operation, and to prevent failures of structures, systems and components (SSCs) relied upon for safety.

Level 2 The aim of the second level of defence is to detect, intercept and control deviations from normal operation in order to prevent anticipated operational occurrences (AOOs) from escalating to accident conditions, and to return the facility to a state of normal operation.

Level 3 The aim of the third level of defence is to minimize the onsite consequences of accidents by providing inherent safety features, fail-safe design, additional equipment and mitigating procedures. The most important objective for this level is to prevent releases of nuclear and associated hazardous substances or radiation levels that require offsite protective actions.

Level 4 The aim of the fourth level of defence is to mitigate the consequences of accidents that result from failure of the third level of defence in depth. The most important objective for this level is to ensure that the containment function is maintained, thus ensuring that radioactive releases are kept as low as reasonably achievable.

Level 5 The aim of the fifth level of defence is to mitigate the radiological consequences and associated chemical consequences of releases or radiation levels that may result from accidents by means of adequately equipped emergency response facilities, emergency plans, and emergency procedures for onsite and offsite emergency response.

For more information on defence in depth, including means of achieving its aims (such as good design and proven engineering practices), see:

- REGDOC-3.5.3, *Regulatory Fundamentals* [2]
- IAEA SSR-4, *Safety of Nuclear Fuel Cycle Facilities* [3]

2.2 Safety analysis objectives

The objectives of a safety analysis are to:

- state the safety goals, objectives and acceptance criteria (the safety requirements) that the facility is designed to meet
- demonstrate that the safety goals, objectives and acceptance criteria are met
- derive or confirm operational limits and conditions (OLCs) that are consistent with the design and safety requirements of the facility
- identify the SSCs important to safety [4] (that is, the SSCs that are relied upon for the safety of the facility)
- provide results for use in establishing and validating operating and emergency procedures and guidelines

Requirements

The licensee shall maintain adequate capability to perform or procure safety analysis to:

- resolve technical issues that arise over the life of the nuclear facility
- ensure the safety analysis requirements are met (whether the safety analysis has been developed by the licensee or procured from a third party)

The licensee shall establish a process to assess and update the safety analysis to ensure that the safety analysis reflects:

- current configuration (for existing facilities)
- current operating limits and conditions (for existing facilities)
- operating experience, including experience from similar facilities and any applicable experience from other nuclear or industrial facilities
- if applicable to the specific Class IB nuclear facility, results from experimental research, improved theoretical understanding or new modelling capabilities to assess potential effects on the conclusions of safety analyses
- if applicable to the specific Class IB nuclear facility, considerations of human factors to ensure that credible estimates of human performance are used in the analysis

The licensee shall systematically review the safety analysis results to ensure they remain valid and continue to meet the safety goals, objectives and acceptance criteria.

Guidance

The licensee is responsible for the safety analysis whether it is performed by staff or by a service that is procured to do so. Supplier qualification requirements help to ensure adequate selection for the provision of a service, such as a safety analysis. Therefore, it is necessary for the licensee to possess the:

- ability to qualify the supplier
- ability to assess the sufficiency of the service provided

For more information on demonstrating the capability of a licensee's staff to perform safety analysis, or on procuring safety analysis as a service, see:

- CSA N286-12, *Management system requirements for nuclear facilities* [5]
- IAEA Safety Guide No. GS-G-3.5, *The Management System for Nuclear Installations* [6]

3. Safety Analysis Program

Requirements

The licensee shall develop, implement, conduct and maintain a safety analysis program for the nuclear facility.

In support of the program, the licensee shall establish one or more internal safety committees to advise management of the organization on safety issues related to the commissioning, operation and modification of the facility. The licensee shall ensure that committee has the necessary breadth of knowledge and experience to provide appropriate advice. The members shall, to the extent necessary, be independent of the operations management raising the safety issue.

Essential elements of a safety analysis program are the statements made by the licensee about the licensee's safety, health and environmental policies [3]. The licensee shall provide these statements in the licence application as a declaration of the organization's objectives and the public commitment of corporate management. To put these statements into effect, the licensee shall also specify and put in place organizational structures, standards and management arrangements capable of meeting the organization's objectives and public commitments.

The licensee shall demonstrate that the safety analysis program is governed by the licensee's management system and is consistent with the applicable requirements of CSA N286-12, *Management System Requirements for Nuclear Facilities* [5].

Guidance

For more information on establishing internal safety committees, see IAEA SSR-4, *Safety of Nuclear Fuel Cycle Facilities* [3].

The licensee is not required to create a separate document for the safety analysis program – neither a standalone document nor within the SAR.

The CNSC accepts that the licensee's safety analysis program may not map exactly onto the CNSC's requirements and expectations for this area. However, the licensee should be able to demonstrate how all the requirements and expectations are addressed by various programs under the overall management system.

In establishing internal safety committees, the licensee should involve staff with a variety of perspectives; for example, employee representatives.

4. Safety Analysis

Requirements

The licensee shall perform a safety analysis for normal operation, and for internal and external events that deviate from normal operation and belong to a category of credible abnormal events [7].

4.1 Classification of events into facility states

Requirements

The licensee shall classify events into one of the facility states: AOO, design-basis accident (DBA), beyond-design-basis accident (BDBA) and specific ranges within BDBA referred to as design extension conditions (DEC), or equivalent classification scheme.

The licensee shall ensure that the safety analysis examines the following facility states:
- normal operational modes (including maintenance and shutdown)
- AOO
- DBA
- DEC

For additional information on classification and ranges of events, refer to appendix C.

Guidance

The licensee may use an alternative classification scheme, provided the classifications meet the same risk-based intent.

4.2 Safety analysis assumptions

Safety analysis assumptions depend on a number of factors:
- the overall risk profile of the nuclear facility

- the event being analyzed (AOO, DBA or DEC)
  - for AOO and DBA, use conservative assumptions (to demonstrate the effectiveness of the safety systems)
  - for DEC, use best-estimate approach and assumptions
- state of knowledge of the event progression and consequences

Requirements

The licensee shall not credit systems that are not qualified to operate in a post-accident environment.

To credit operator action, the licensee shall demonstrate that the following are in place:
- clear, well-defined, validated and readily available operating procedures that identify the necessary actions
- instrumentation at the control location to provide clear and unambiguous indications of the need for operator action
- a credible, protected and accessible path for the operator to safely carry out the actions required in the procedures
- training for any person who may be expected to perform the operator actions

The licensee shall set operator action times. The licensee shall add additional time to include, as appropriate, dressing in protective equipment; accessing remote equipment; and transporting, connecting and operating temporary equipment. The safety analysis report (SAR) shall justify the operator action time.

Guidance

After an indication of the need for operator action, the operator action credited in the safety analysis report should be delayed by:
- at least 15 minutes at the control location
- at least 30 minutes outside the control location

These operator action times are for the start of the action.

For more information on crediting SSCs important to safety, see REGDOC-2.5.2, *Design of Reactor Facilities* [8]. **Note:** This reference is provided only as a source of information; the licensee does not need to apply the requirements or other guidance in REGDOC-2.5.2 to their safety analysis for a Class IB nuclear facility.

4.3 Postulated initiating events

Guidance

A postulated initiating event (PIE) is not necessarily an accident itself. A PIE is the event that initiates a sequence that may lead to an AOO, a DBA, or a BDBA, depending on the additional failures that occur.

The primary causes of PIEs may be credible equipment failures and worker errors, human-induced events or natural events.

The safety analysis and design for the nuclear facility shall consider not only the facility itself but also the interfaces with other facilities and installations that may affect its safety. For more information, refer to IAEA SSR-4, *Safety of Nuclear Fuel Cycle Facilities* [3].

For additional information on types of PIEs and ranges of conditions, refer to appendix C.

4.3.1 Identification of postulated initiating events

Requirements

The licensee shall identify PIEs (both internally and externally initiated) that could lead to:

- radiation exposure to workers or to the public
- a release of significant amounts of nuclear substances
- a release of hazardous substances (such as hazardous chemicals) associated with the nuclear substances

The licensee shall describe the methods used to identify the PIEs.

The licensee shall document and maintain the resulting list of PIEs. With input from technical specialists and experts in safety analysis, the licensee shall conduct a review of the list of PIEs:

- initially, to determine that the list is comprehensive and that the events include:
  - all credible failures of the facility's structures, systems and components (SSCs)
  - all credible human errors that could occur in any of the operating conditions of the facility
- regularly, to confirm the relevance of the current list and revise it as necessary, given that relevant PIEs may change as the facility goes through different phases of its lifecycle (for example, as a result of aging effects)

Guidance

The list of PIEs should be developed through a comprehensive assessment of credible failures of the facility's SSCs and documentation of credible human errors that could occur in any of the operating conditions of the facility.

The list of PIEs may take many forms, depending on the complexity of the activity or facility. The licensee should develop a list that is specific to their situation, and takes into account the nuclear and associated hazardous substances of the specific activity or facility.

On their initial list, the licensee should include as many PIEs as have been identified. If additional PIEs are subsequently identified, the licensee should revise their safety analysis to include those PIEs.

4.3.2 Classification of postulated initiating events

Requirements

During the safety assessment as described in section 4.4, the licensee shall classify PIEs and event sequences upon identification, for the purpose of demonstrating that the acceptance criteria and the safety goals are met.

Guidance

The licensee should group PIEs with similar characteristics (in particular, those that make similar demands on the mitigating measures) into event groups. For the safety assessment, the licensee should identify bounding events from each event group.

4.4 Safety assessment

Safety assessment includes an evaluation of the risk associated with the hazards of a nuclear facility. The assessment can be either quantitative, or qualitative, or a mix of both (semi-quantitative).

4.4.1 Assessment of consequences

Requirements

The licensee shall perform a deterministic safety analysis (that is, an assessment of the consequences) to identify the physical process occurring in the nuclear facility during an event and to assess the consequences. The licensee shall justify the assumptions and the actions of qualified mitigating measures (such as safety systems and operator actions) used in the deterministic analysis.

When the deterministic analysis is quantitative, the licensee shall develop models of the physical processes to calculate the consequences of the event. The licensee shall validate the computational tools used to calculate the consequences.

Guidance

The licensee should ensure that the level and rigour of validation of the computational tools is commensurate with the level of risk for the activity or facility (that is, apply a graded approach).

Applicants or licensees may use commercially-available modelling software and data analysis software; to demonstrate validation of these tools, the licensee may submit the software vendor's validation of the software for this application.

For more information on demonstrating validation of software tools, see:
- section 6 of this regulatory document
- CSA N286.7-16, *Quality assurance of analytical, scientific and design computer programs* [9]

4.4.2 Assessment of likelihood

Requirements

The licensee shall perform an assessment of likelihood to establish the likelihood of PIEs or event sequences to occur.

Guidance

Typically for Class IB nuclear facilities, the licensee performs a qualitative or semi-quantitative assessment of the likelihood of PIEs or event sequences using one of the following methods:

- deterministic safety analysis methods are published in IAEA SSG-5, *Safety of Conversion Facilities and Uranium Enrichment Facilities* [10] and IAEA SSG-6, *Safety of Uranium Fuel Fabrication Facilities* [11]
- methods for assessment of likelihood are published in IAEA TECDOC No. 1267, *Procedures for Conducting Probabilistic Safety Assessment for Non-Reactor Nuclear Facilities* [12]; numerous methods may be used, either in a quantitative or qualitative manner; some examples are:
    - hazard and operability studies (HAZOPs)
    - failure mode and effects analysis
    - fault tree / event tree analysis
    - operational feedback; for example, through the fuel incident notification and analysis system (FINAS) database and locally recorded events for each facility
    - what-if technique
    - check lists (for example, ergonomics check lists)
    - master logic diagram

4.5 Identification of structures, systems and components important to safety

Requirements

The licensee shall use a safety assessment, or an equivalent methodology, to identify event sequences that may lead to an AOO, DBA, DEC or BDBA. For additional information, see IAEA SSR-4, *Safety of Nuclear Fuel Cycle Facilities* [3].

For each event sequence, the licensee shall identify the safety functions, the corresponding SSCs important to safety [4], and the administrative safety requirements that are used to implement the defence in depth concept.

To be consistent with the safety analysis results, the licensee shall ensure that [3]:

- SSCs important to safety are designed to withstand the effects of extreme loadings and environmental conditions (such as extremes of temperature, humidity, pressure and radiation levels) that may be encountered in operational states and in accident conditions
- the required intervals for periodic testing and inspection of SSCs important to safety are defined
- the codes and standards applicable to SSCs important to safety are identified, and their use is justified
- the necessary levels of availability and reliability of SSCs important to safety, as established in the safety analysis, are attained

In protecting against potential hazards, the licensee shall ensure that the following hierarchy of design and administrative measures is used to the extent practicable [3]:

1. selection of the process (to eliminate the hazard)
2. passive design features
3. active design features
4. administrative controls

4.6 Operational limits and conditions

Requirements

The licensee shall derive the OLCs from the safety analysis. The licensee shall document the OLCs before starting operation of the facility.

Guidance

OLCs include limiting conditions for safe operation (values, conditions), monitoring systems and associated alarm settings, and surveillance and administrative requirements.

Staff availability and competency are an important component of the operational conditions. The OLCs should set minimum requirements for the availability of staff and equipment. For more information on the availability of staff, see REGDOC-2.2.5, *Minimum Staff Complement* [13].

Where it is not practicable to define precisely the safe limits of all relevant parameters, OLCs should be set to define the limits of the assessment in order to prevent operation in the unanalyzed or unanalyzable conditions.

Appendix B provides examples of parameters that may be managed through OLCs across the broad range of facilities.

4.7 Acceptance criteria

Requirements

The licensee shall establish explicit criteria for the level of safety to be achieved to demonstrate that the licensee is making adequate provision for the protection of the environment and the health and safety of persons [3].

The licensee shall set limits on the radiological consequences and associated chemical consequences for the workers and the public of direct exposures to radiation or discharges of radionuclides to the environment. These limits shall:

- be set equal to, or below:
  - the provisions of the *Radiation Protection Regulations*, when applicable and as far as practicable; otherwise
  - criteria established by national or international standards as triggers for protective measures during radiological or chemical emergencies (for example, for sheltering or for distribution of iodine pills)
- apply to the consequences of operational states and the possible consequences of AOO and DBA at the facility
- apply at the site boundaries of the licensed facility when offsite consequences to the public are considered

For new designs, the licensee shall consider targets that are below these limits.

The licensee shall establish derived acceptance criteria to demonstrate that the barriers to prevent the release of nuclear or associated hazardous substances are effective; that is, the barriers:

- avoid the potential for consequential failures resulting from an initiating event
- maintain SSCs important to safety in a configuration that prevents releases of nuclear or associated hazardous substances to the environment or in the facility
- prevent consequences that extend beyond the site boundaries of the licensed facility
- are consistent with the design requirements for the facility's SSCs

For acceptance criteria for nuclear criticality safety, see REGDOC-2.4.3, *Nuclear Criticality Safety* [14].

4.8 Safety goals

Requirements

The licensee shall demonstrate that the offsite consequences, as calculated at the site boundaries of the licensed facility, of a BDBA included in the DEC do not exceed criteria established as a trigger for temporary evacuation, for long-term relocation of the local population, or for both temporary evacuation and long-term relocation in:

- Health Canada, *Canadian Guidelines for Intervention During a Nuclear Emergency* [15]
- IAEA GSR Part 7, *Preparedness and Response for a Nuclear or Radiological Emergency* [16]

In addressing the concept of defence in depth, the licensee shall include events from BDBA in the DEC. As a minimum, the licensee shall include the following events in the DEC [7]:

- an extended loss of AC power (ELAP)
- PIEs and event sequences, including those that are specific or unique to the facility, that belong to a category of credible abnormal events [7]

For naturally occurring PIEs (for example, seismic events, flooding and severe weather), when selection of credible abnormal events is not practical, the licensee shall include in the DEC events that are more severe than considered in analyses of DBA consistent with the guidance of national or international standards (see appendix C)

The classification shall be based on likelihood, as specified in section 4.4.2.

5. Safety Analysis Documents and Records

The safety analysis documents describe the methods used in performing analyses, and record the results of each analysis. They support the siting, design, commissioning, operation and decommissioning of a nuclear facility. They demonstrate that any risks to the health and safety of persons are managed and mitigated, and also help to demonstrate that defence in depth has been achieved.

5.1 Purpose and scope of safety analysis documents and records

Guidance

The safety analysis documents and records provide information on the safety analysis, as follows:

- demonstrate that the safety goals, objectives and acceptance criteria are met
- assist in deriving or confirming operational limits and conditions that are consistent with the design and safety requirements of the facility
- assist in establishing and validating operating and emergency procedures and guidelines

The scope of safety analysis documents and records covers internal and external events that could lead to a release of nuclear or associated hazardous substances, to a criticality accident, or to an accidental exposure to high radiation fields.

5.2 Content of safety analysis documents and records

Requirements

The licensee shall report the safety analysis results in sufficient detail to permit review by CNSC staff.

The licensee shall ensure that the content of the safety analysis documents and records for a facility includes, as a minimum, the SAR and the OLCs (or equivalent) [3].

The SAR shall contain a representative summary of the safety analysis documents and records. The SAR shall:

- describe the site characteristics
- identify nuclear and associated hazardous substances and their locations
- identify applicable acceptance criteria for offsite consequences to the public of pertinent accidents (some examples of pertinent accidents are radiological, nuclear criticality, fire and chemical accidents, including explosions)
- identify SSCs that prevent or mitigate release of nuclear or associated hazardous substances, or prevent accidental exposure to high radiation fields (to the extent appropriate for the facility, in accordance with a graded approach)
- classify SSCs in accordance with their importance to safety
- identify operating and emergency procedures and actions that prevent or mitigate release of nuclear or associated hazardous substances
- identify the safety analysis assumptions (some examples are boundary conditions, facility configuration, and time for operator actions); many of these assumptions may be documented in the operational limits and conditions
- identify credible initiating events that may affect the licensee's control of nuclear or associated hazardous substances, including:
  - internal events (for example, component failures, human error, fire or flood)
  - external events (for example, earthquake, fire, flood or extreme weather)
- group together all initiating events that have similar characteristics and identify bounding events for analysis
- provide the results of the analysis of the consequences of the analyzed events
- when applicable, include uncertainty and sensitivity analysis results
- compare the results to acceptance criteria

- provide results and conclusions
- be independently reviewed as per the management system of the licensee
- provide references to detailed analyses that support the safety analysis results

Guidance

The licensee may incorporate information by reference. For example, many of the safety analysis assumptions may be documented in the licensee's operational limits and conditions and may be incorporated into the SAR by reference.

The licensee should ensure that staff with a variety of perspectives (for example, employee representatives) have an opportunity to review the SAR and to provide independent comments.

Risks to the environment as a result of routine releases (which are considered part of normal operation) are considered in the licensee's environmental risk assessment (ERA) for the facility, and therefore are not considered in the SAR.

For more information on:
- validation and verification of safety analysis tools, see section 6
- a sample structure and content for a SAR, see appendix A

5.3 Documenting and recording postulated initiating events and design-basis accidents

Requirements

The licensee shall describe the facility's behaviour following a PIE and compare it to the analysis acceptance criteria.

Guidance

For DBAs, the licensee should describe each event in the SAR as follows:
- the timing of the main events, including:
  - the initial event and any subsequent failures
  - times at which mitigating equipment is actuated
  - times of operator actions
  - time at which a safe long-term stable state is achieved
- graphical presentation of key parameters as functions of time during the event (the parameters should be selected so that a full understanding of the event's progression can be obtained within the context of the acceptance criterion being considered)
- comparison with acceptance criteria
- the conclusion of the event

5.4 Maintaining safety analysis documents and records

The SAR and other safety analysis documents and records are updated periodically throughout the lifecycle of the facility. The period for SAR updates is stated in each facility's licence conditions handbook (LCH). Five years is the recommended period, but different periods may be set; for example, based on the overall safety impact of the facility or on significant changes to the facility.

Requirements

The licensee shall perform an ongoing site evaluation. If the ongoing site evaluation identifies new information about the site characteristics (that is, changing the results of the identification and classification of PIEs), then safety precautions (such as engineering controls and emergency arrangements) may need to be reviewed and revised.

Guidance

The process for updates should meet the requirements of the safety analysis program and should include:

- identification of sections to be revised due to:
    - changes to initiating events
    - changes to the facility equipment or procedures
    - extension of the facility operating life
    - changes to regulatory requirements
    - new knowledge from research or operating experience
    - aging of SSCs
- performance of analysis
- independent review
- documents and records in the SAR

Items of safety analysis may be performed at various times, for a variety of reasons. Normal practice is that any updated safety analysis performed in mid-cycle is included with the next scheduled update of the SAR.

6. Validation and Verification of Safety Analysis Tools

Guidance

The safety analysis tools should be validated and verified. For more information, see:

- REGDOC-3.5.3, *Regulatory Fundamentals* [2]
- CSA Group N286, *Management System Requirements for Nuclear Facilities* [5]
- CSA Group N292.0, *General Principles for the Management of Radioactive Waste and Irradiated Fuel* [17]
- CSA Group N292.1, *Wet Storage of Irradiated Fuel and Other Radioactive Materials* [7]
- CSA Group N292.2, *Interim Dry Storage of Irradiated Fuel* [18]

7. Graded Approach

Guidance

For information on the CNSC’s risk-informed graded approach, see REGDOC-3.5.3, *Regulatory Fundamentals* [2].

Class IB nuclear facilities have risk profiles that vary, significantly, depending on the particular characteristics of the activity or facility. The licensee may propose, with adequate justification, specific design measures, analyses or other measures that commensurate with the level of risks.

Some examples of elements of the safety analysis that may be considered using the graded approach include:

- frequency boundaries for facility states (AOO, DBA, and DEC)
- rigour of validation and verification of safety analysis tools
- rigour of uncertainty evaluation
- extent of sensitivity studies
- quantity and quality of supporting evidence for analysis

Appendix A: Sample Structure and Content for a Safety Analysis Report

This appendix provides a sample structure for an SAR. The licensee is under no obligation to follow this format; however, as described in sections 2 through 5 of this regulatory document, the report shall include all information as applicable.

Table of contents

Chapter 1: Introduction

Chapter 2: General facility description

- applicable regulations, codes and standards
- basic technical characteristics
- facility layout
- operating modes
- additional referenced analyses
- a summary of significant modifications or changes to the site or facility since the previous safety analysis report, including modifications to any facility buildings, processes, equipment, procedures, programs or organizational structure

Chapter 3: Management of safety

- organizational structure
- operational management philosophy
- safety culture
- quality assurance
- monitoring and review of safety performance

Chapter 4: Site evaluation

- site reference data (area under the control of the licensee and the surrounding area)
- hydrology
- hydrogeological characteristics
- meteorology
- seismology
- present and projected surrounding population distribution
- present and projected surrounding land use
- evaluation of site specific hazards
- proximity of industrial, transport and military facilities
- activities at the facility site that may influence the facility's safety
- radiological conditions due to external sources
- site related issues in emergency planning and accident management
- monitoring of site related parameters

Chapter 5: General design aspects

- safety objectives, design principles and criteria
- conformance with the design principles and criteria
- classification of structures, systems and components
- civil engineering aspects of facility design
- equipment qualification and environmental factors
- human performance program
- protection against internal and external hazards

Chapter 6: Description of facility systems and components

- nuclear systems and components
- non-nuclear systems and components
- instrumentation and control
- electrical systems
- auxiliary systems
- fire protection systems
- radioactive waste treatment system
- other SSCs important to safety

Chapter 7: Safety analyses

- safety objectives and acceptance criteria
- identification and classification of PIEs
- human actions
- deterministic approach
- probabilistic approach
- summary of results of the safety analyses

Chapter 8: Commissioning (for new facilities)

Chapter 9: Operational aspects

- organization
- administrative procedures
- operating procedures
- emergency operating procedures
- guidelines for accident management
- maintenance, surveillance, inspection and testing
- management of aging
- control of modifications
- qualification and training of personnel
- human factors
- feedback of operational experience
- documents and records

Chapter 10: Operational limits and conditions

Chapter 11: Radiation protection

- application of the ALARA principle
- sources of radiation
- design features for radiation protection
- radiation monitoring
- radiation protection program

Chapter 12: Emergency preparedness

- emergency management
- emergency response facilities
- fire protection program

Chapter 13: Environmental aspects associated with credible abnormal events (such as spills)

- radiological effects
- non-radiological effects

Chapter 14: Radioactive waste management

- control of waste
- handling of radioactive waste
- minimizing the accumulation of waste
- conditioning of waste
- storage of waste
- disposal of waste

Chapter 15: Decommissioning and end of life aspects

- decommissioning plan
- financial guarantee

Chapter 16: Public information program

Appendix B: Sample Parameters for Operational Limits and Conditions

This appendix provides some examples of limiting conditions for safe operation of the facility, applying requirements for:

- nuclear substances (type, chemical and physical form, maximum capacity in the facility, isotopic composition)
- associated hazardous substances (such as chemicals) inside the facility and its equipment
- minimum availability requirements for:
  - SSCs important to safety
  - requirements on testing values of the SSCs

  Note: in some cases, OLCs relating to the availability of SSCs may include requirements for their testing, including:
    - initial and periodic tests
    - type of tests
    - verification
    - calibration or inspection
    - required intervals for inspections
    - time between two successive tests
- means of confinement:
  - air flows (and where appropriate, temperatures and humidity) within the facility and its processes
  - target pressure drops across filters
  - pressures within the facility buildings (rooms, cells or boxes as appropriate) relative to the atmosphere (under normal and emergency conditions)
  - isolation of means of confinement and starting of emergency ventilation
  - operations that require confinement
  - configuration and minimum equipment for ventilation system
  - leak rate from the means of confinement
  - efficiency of filters
- radiation protection and management of radioactive waste:
  - alarm setting for criticality alarm systems and for radiation detection and monitoring instrumentation and equipment
  - limits on the airborne concentration of nuclear substances
  - radiation exposure control levels for operation, including radiation dose action levels
  - limits for controlling surface contamination
  - storage capacity for liquid and solid nuclear waste
- material handling, including requirements for:
  - movements of nuclear and associated hazardous substances, including onsite transfer and offsite transportation
  - the material handling tools and equipment including cranes (maximum allowable loads and testing requirements)

    - storage containers
- electrical systems, including requirements for:
    - emergency power supply
    - testing frequency
    - availability and reliability of uninterruptable power supply and diesel generators
- other systems; some examples are:
    - fire protection systems
    - process auxiliaries
    - communications systems
    - emergency lighting systems
- monitoring system and associated alarm settings:
    - values of the settings for instrumentation in the facility
    - values of the settings for process equipment necessary for safety
- administrative requirements:
    - staffing (for example, minimum staffing and hours of work)
    - prerequisites for activities important to safety (such as transport of radioactive or fissile material (both onsite and offsite))

Appendix C: Postulated Initiating Events

This appendix describes the types of PIEs and the ranges of conditions to be considered for applicability at Class IB nuclear facilities.

C.1 Selected postulated initiating events

Some examples of PIEs are:

1. incorrect specification of incoming and transferred material
2. loss of services
   - loss of electrical power
   - loss of compressed air
   - loss of inert atmosphere
   - loss of coolant
   - loss of ultimate heat sink
3. loss of criticality safety controls
   - drop of fuel during handling
   - loss of geometry
   - flooding
   - loss of neutron poison
   - excess reflection or moderation
   - unintentional change of phase
   - failure or collapse of structural components
   - maintenance error
   - control system error
   - over (double) batching
4. processing errors
   - incorrect facility configuration
   - insufficient reagent or coolant, added too fast or too early
   - incorrect pressure or gas flow, rupture
   - incorrect or extreme temperature
   - unexpected phase changes leading to criticality or loss of confinement
   - function required for safety not applied
   - safety function applied too late
5. facility and equipment failures
   - failure of confinement or leak
   - inadequate isolation of process fluids
   - blockage or bypass of filter or column
   - spurious actuation of an SSC important to safety
   - structural failures
6. handling errors
   - hazardous load dropped
   - heavy load dropped on SSC(s) important to safety
   - safety interlocks failure on demand
   - brakes, overspeed or overload protection inadequate

- obstructed pathway leading to collision
- failure of lifting component (for example, hook, beam, or cable)
- load fixed to floor

7. special internal events
   - internal fires or explosions
   - internal flooding (for example, from sprinkler systems or other water pipes)
   - malfunction in experiment
   - improper access by persons to restricted areas
   - criticality event
   - fluid jets, pipe whip, internal missiles
   - exothermic chemical reaction
   - ignition of accumulated combustible gases (for example, hydrogen)
   - failure due to corrosion
   - loss of neutron absorption
   - accidents on internal transport routes (including collisions into the facility building)
8. external events
   - external fires or explosions
   - earthquakes (including seismically induced faulting and landslides)
   - flooding (including failure of an upstream/downstream dam; blockage of a river; or damage due to storm surges or high waves)
   - tornados and tornado missiles
   - extreme meteorological phenomena (including precipitation, sandstorms, hurricanes, storms and lightning
   - aircraft crashes
   - toxic spills
   - effects from adjacent facilities (for example, nuclear facilities, chemical facilities and waste management facilities)
   - biological hazards such as microbial corrosion, structural damage or damage to equipment by rodents or insects
   - power or voltage surges on the external supply line
9. human errors
   - worker error or omission
   - maintenance error or omission

C.2 Range of selected events to be considered for applicability

The following classification and ranges of internal events are to be considered for applicability:

- **anticipated operational occurrence (AOO):** an event with a likelihood of occurrence that is greater than 10^{-2} per year
- **design basis accident (DBA):** an event with a likelihood of occurrence that is less than 10^{-2} per year and greater than 10^{-5} per year
- **design extension conditions (DEC):** an event with a likelihood of occurrence that is less than 10^{-5} per year and greater than 10^{-6} per year

The following ranges of selected external events are to be considered for applicability.

Wind and tornado loading

For assessment of design basis accidents (DBA):
The potential for the occurrence of tornadoes in the region of interest shall be assessed on the basis of detailed historical and instrumentally recorded data for the region. For example, wind design for an existing facility if prescribed by an applicable building code would have an annual exceedance probability of greater than or equal to 2×10^{-2}. For more information, see *Standard Review Plan for Fuel Cycle Facilities Licence Applications (NUREG-1520)* [19].

For assessment of design extension conditions (DEC):
Depending on the geographical location of the facility, the effects of a tornado with an annual exceedance probability of 10^{-5} or greater may need to be considered if a potential exists at the facility for offsite consequences of DEC that may lead to offsite emergency mitigation measures.

Flooding hazards

For assessment of DBA:
Existing facilities are generally to be sited above the 100-year flood plain.

For assessment of DEC:
Maximum probable flood plain should be used if a potential exists at the facility for offsite consequences of DEC that may lead to offside emergency mitigation measures.

Seismic hazards

Near regional studies should include a geographical area typically not less than 25 km in radius. Site vicinity studies should cover a geographical area typically not less than 5 km in radius. Site area studies should include the entire area covered by the facility. For more information, see IAEA SSG-9, *Seismic Hazards in Site Evaluation for Nuclear Installations* [20].

Information on prehistorical, historical and instrumentally recorded earthquakes in the region should be collected and documented. For more information, see IAEA NS-R-3 (Rev. 1), *Site Evaluation for Nuclear Installations* [21].

For assessment of DBA:
Structures at existing nuclear fuel cycle facilities are built to a building code. Guidance in CSA N289.5, *Seismic instrumentation requirements for nuclear power plants and nuclear facilities* [22] should be used if a potential exists at the facility for offsite consequences of DBA that may lead to offsite emergency mitigation measures.

For assessment of DEC:
CSA N289.5, *Seismic instrumentation requirements for nuclear power plants and nuclear facilities* [22] provides guidance that includes meeting a design-basis earthquake having an exceedance probability of 10^{-3} per year to less than 10^{-4} per year. CSA N289.5 [22] should be used if a potential exists at the facility for offsite consequences of DEC that may lead to offsite emergency mitigation measures.

Aircraft crashes

The potential for aircraft crashes, including impacts, fires and explosions on site, should be considered with account taken of:

- the foreseeable characteristics of air traffic, the locations and types of airports
- the characteristics of aircraft, including those with special permission to fly over or near the facility such as firefighting aircraft and helicopters

For more information, see IAEA NS-R-3 (Rev. 1), *Site Evaluation for Nuclear Installations* [21].

For assessment of both DBA and DEC:
The potential hazards arising from aircraft crashes are taken into account if:

- airways or airport approaches pass within 4 km of the site
- airports are located within 10 km of the site for all but the biggest airports
- for large airports, if the distance (d) in kilometers to the proposed site is less than 16 km and the number of projected yearly flight operations is greater than $500d^2$

Where the distance (d) is greater than 16 km, the hazard is considered if the number of projected yearly flight operations is greater than $1000d^2$.

For military installations or air space usage such as practice bombing or firing ranges, which might pose a hazard to the site, the hazard is considered if there are such installations within 30 km of the proposed site.

For more information, see IAEA NS-G-3.1, *External Human Induced Events in Site Evaluation for Nuclear Power Plants* [23].

Glossary

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

The following terms are either new terms being defined, or include revisions to the current definition for that term. Following public consultation, the final terms and definitions will be submitted for inclusion in the next version of REGDOC-3.6, *Glossary of CNSC Terminology*.

credible abnormal event *(événement anormal crédible)*
As defined in the CSA Group publication CSA N292.1, *Wet storage or irradiated fuel and other radioactive materials* [7], a naturally occurring or human-generated event or event sequence that has a frequency of occurrence equal to or greater than 10^{-6} per year.

control location *(lieu de commande)*
A location that is permanently staffed during periods when the event in question may occur; for example, a control room.

safety analysis program *(programme d'analyse de la sûreté)*
Activities to plan, execute, verify and document safety analyses; to identify and act upon research and experience; to train analysts; and to preserve knowledge. The safety analysis program includes interfaces with other programs to ensure that safety analysis is initiated when needed and that the results of the safety analysis are used appropriately.

To be added to "Appendix A: Acronyms and abbreviations" in REGDOC-3.6:

ELAP *(PPACA)*	extended loss of AC power
FINAS *(FINAS)*	fuel incident notification and analysis system
SAR *(RAS)*	safety analysis report

References

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

1. Canadian Nuclear Safety Commission (CNSC), REGDOC-2.11.1, *Waste Management, Volume III: Safety Case for Disposal of Radioactive Waste*, Ottawa, Canada
2. CNSC, REGDOC-3.5.3, *Regulatory Fundamentals*, Ottawa, Canada
3. International Atomic Energy Agency (IAEA), SSR-4, *Safety of Nuclear Fuel Cycle Facilities*, Vienna, Austria, 2017
4. CNSC, REGDOC-3.6, *Glossary of CNSC Terminology*, Ottawa, Canada
5. CSA Group, CSA N286-12, *Management system requirements for nuclear facilities*, reaffirmed in 2017
6. IAEA, Safety Guide No. GS-G-3.5, *The Management System for Nuclear Installations*, Vienna, Austria, 2009
7. CSA Group, CSA N292.1, *Wet storage of irradiated fuel and other radioactive materials*, 2016
8. CNSC, REGDOC-2.5.2, *Design of Reactor Facilities*, Ottawa, Canada
9. CSA Group, CSA N286.7-16, *Quality assurance of analytical, scientific and design computer programs*, 2016
10. IAEA, Safety Guide SSG-5, *Safety of Conversion Facilities and Uranium Enrichment Facilities*, Vienna, Austria, 2010
11. IAEA, Safety Guide SSG-6, *Safety of Uranium Fuel Fabrication Facilities*, Vienna, Austria, 2010
12. IAEA, TECDOC No. 1267, *Procedures for Conducting Probabilistic Safety Assessment for Non-Reactor Nuclear Facilities*, Vienna, Austria, 2002
13. CNSC, REGDOC-2.2.5, *Minimum Staff Complement*, Ottawa, Canada
14. CNSC, REGDOC-2.4.3, *Nuclear Criticality Safety*, Ottawa, Canada
15. Health Canada, H46-2/03-326E, *Canadian Guidelines for Intervention During a Nuclear Emergency*, Ottawa, Canada, 2003
16. IAEA, General Safety Requirements No. GSR Part 7, *Preparedness and Response for a Nuclear or Radiological Emergency*, Vienna, Austria, 2015
17. CSA Group, CSA standard N292.0, *General principles for the management of radioactive waste and irradiated fuel*, 2019

18. CSA Group, CSA standard N292.2, *Interim dry storage of irradiated fuel*, 2013 (reaffirmed in 2018)

19. United States Nuclear Regulatory Commission (NUREG), *Standard Review Plan for Fuel Cycle Facilities License Applications (NUREG-1520)*, Revision 2, 2015

20. IAEA, Specific Safety Guide SSG-9, *Seismic Hazards in Site Evaluation for Nuclear Installations*, Vienna, Austria, 2010

21. IAEA, Safety Standard No. NS-R-3 (Rev. 1), *Site Evaluation for Nuclear Installations*, Vienna, Austria, 2016

22. CSA Group, CSA standard N289.5, *Seismic instrumentation requirements for nuclear power plants and nuclear facilities*, reaffirmed in 2017

23. IAEA, Safety Guide NS-G-3.1, *External Human Induced Events in Site Evaluation for Nuclear Power Plants*, Vienna, Austria, 2002

Additional Information

The CNSC may recommend additional information on best practices and standards such as those published by CSA Group. With permission of the publisher, CSA Group, all nuclear-related CSA standards may be viewed at no cost through the CNSC webpage "How to gain free access to all nuclear-related CSA standards".

The following documents provide additional information that may be relevant and useful for understanding the requirements and guidance provided in this regulatory document:

- CSA Group, CSA standard N291, *Requirements for nuclear safety-related structures*, 2019
- International Atomic Energy Agency (IAEA) General Safety Requirements GSR Part 4 (Rev. 1), *Safety Assessment for Facilities and Activities*, Vienna, Austria, 2016
- IAEA Safety Guide GS-G-4.1, *Format and Content of the Safety Analysis Report for Nuclear Power Plants*, Vienna, Austria, 2004
- United States Nuclear Regulatory Commission (U.S. NRC), *Integrated Safety Analysis Guidance Document (NUREG-1513)*, 2001

CNSC Regulatory Document Series

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

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

1.0 Regulated facilities and activities

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

2.0 Safety and control areas

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

3.0 Other regulatory areas

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

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L'organisme de réglementation
nucléaire du Canada

Analyse de la sûreté

Analyse de la sûreté pour les installations de catégorie IB

REGDOC-2.4.4

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Canadian Nuclear Safety Commission

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Analyse de la sûreté pour les installations de catégorie IB
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Préface

Ce document d'application de la réglementation fait partie de la série de documents d'application de la réglementation de la CCSN intitulée Analyse de la sûreté, qui porte également sur l'analyse déterministe de la sûreté, les études probabilistes de sûreté et la sûreté-criticité nucléaire. La liste complète des séries figure à la fin de ce document et elle peut être consultée à partir du site Web de la CCSN.

Le document d'application de la réglementation REGDOC-2.4.4, *Analyse de la sûreté pour les installations de catégorie IB*, précise les exigences et fournit l'orientation que doivent suivre les demandeurs et les titulaires de permis pour démontrer la sûreté d'une installation nucléaire de catégorie IB, notamment :

- un programme d'analyse de la sûreté (le processus géré qui régit la conduite d'une analyse de la sûreté)
- la réalisation d'une analyse de la sûreté (une évaluation systématique des dangers potentiels)
- les documents, dossiers et rapports d'analyse de la sûreté

Le présent document est la première version du REGDOC-2.4.4, *Analyse de la sûreté pour les installations de catégorie IB*.

Les installations nucléaires de catégorie IB ont des profils de risque qui varient considérablement en fonction des caractéristiques particulières de l'activité ou de l'installation. S'il fournit une justification adéquate, le titulaire de permis peut proposer des mesures de conception particulières, des analyses ou d'autres mesures qui sont proportionnelles au niveau de risque posé, selon l'approche graduelle tenant compte du risque de la CCSN.

Pour obtenir de plus amples renseignements sur l'analyse de la sûreté pour la phase de post-fermeture d'une installation de stockage définitif, veuillez consulter le REGDOC-2.11.1, *Gestion des déchets, tome III : Dossier de sûreté pour la gestion à long terme des déchets radioactifs*.

Pour en savoir plus sur la mise en œuvre des documents d'application de la réglementation et sur l'approche graduelle, consultez le REGDOC-3.5.3, *Principes fondamentaux de réglementation*.

> Le terme « doit » est employé pour exprimer une exigence à laquelle le titulaire ou le demandeur de permis doit se conformer; le terme « devrait » dénote une orientation ou une mesure conseillée; le terme « pourrait » exprime une option ou une mesure conseillée ou acceptable dans les limites de ce document d'application de la réglementation; et le terme « peut » exprime une possibilité ou une capacité.
>
> Aucune information contenue dans le présent document ne doit être interprétée comme libérant le titulaire de permis de toute autre exigence pertinente. Le titulaire de permis a la responsabilité de prendre connaissance de tous les règlements et de toutes les conditions de permis applicables et d'y adhérer.

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1. Introduction

1.1 Objet

Le présent document précise les exigences et fournit l’orientation que doivent suivre les demandeurs et les titulaires de permis pour démontrer la sûreté d’une installation nucléaire de catégorie IB, notamment :

- un programme d’analyse de la sûreté (le processus géré qui régit la conduite d’une analyse de la sûreté)
- la réalisation d’une analyse de la sûreté (une évaluation systématique des dangers potentiels)
- les documents, dossiers et rapports d’analyse de la sûreté

Remarque : Dans ce document d’application de la réglementation, le terme « installation nucléaire » désigne une installation nucléaire de catégorie IB.

1.2 Portée

Ce document décrit les exigences et l’orientation relatives à l’analyse de la sûreté pour les installations nucléaires de catégorie IB ci-dessous :

- une usine de traitement, de retraitement ou de séparation d’isotopes d’uranium, de thorium ou de plutonium
- une usine de fabrication de produits à partir d’uranium, de thorium ou de plutonium
- une usine, autre qu’une installation nucléaire de catégorie II au sens de l’article 1 du Règlement sur les installations nucléaires et l’équipement réglementé de catégorie II, qui traite ou utilise, par année civile, plus de 1015 Bq de substances nucléaires autres que l’uranium, le thorium et le plutonium
- une installation de stockage définitif de substances nucléaires provenant d’une autre installation nucléaire
    - Remarque : le présent document d’application de la réglementation s’applique à la phase opérationnelle, qui comprend les activités autorisées menées jusqu’à la fermeture de l’installation de stockage définitif.
- une installation visée aux alinéas 19a) ou b) du Règlement général sur la sûreté et la réglementation nucléaires :
    - une installation pour la gestion, le stockage, temporaire ou permanent, l’évacuation ou l’élimination des déchets qui contiennent des substances nucléaires radioactives et dont l’inventaire fixe en substances nucléaires radioactives est d’au moins 10^{15} Bq (**remarque :** voici quelques exemples de ce type d’installation qui cadrent dans la portée du présent document d’application de la réglementation :
        - toute installation servant au stockage de matières fissiles avant et après irradiation
        - toute installation de conditionnement des déchets associés, de traitement des effluents et de stockage des déchets qui permet de récupérer les déchets en vue de leur évacuation ou élimination ultérieure)
    - une usine produisant du deutérium ou des composés du deutérium à l’aide d’hydrogène sulfuré

Pour obtenir de plus amples renseignements sur l’analyse de la sûreté pour la phase de post-fermeture d’une installation de stockage définitif, veuillez consulter le

REGDOC-2.11.1, *Gestion des déchets, tome III : Dossier de sûreté pour la gestion à long terme des déchets radioactifs* [1].

Remarque 2 : Compte tenu du large éventail d’installations nucléaires de catégorie IB, le titulaire de permis peut proposer une approche graduelle conformément au REGDOC-3.5.3, *Principes fondamentaux de réglementation* [2].

1.3 Législation pertinente

Les dispositions législatives de la *Loi sur la sûreté et la réglementation nucléaires* (LSRN) et des règlements pris en vertu de celle-ci qui s’appliquent au présent document sont les suivants :

- les paragraphes 24(4) et 25(5) de la LSRN
- l’alinéa 3(l)i) du *Règlement général sur la sûreté et la réglementation nucléaires*
- les alinéas 5f) et i), 6c) et h), et 7f) du *Règlement sur les installations nucléaires de catégorie I*

2. Objectifs en matière de sûreté

Une analyse de la sûreté est une évaluation systématique des dangers possibles associés au fonctionnement d’une installation ou à la réalisation d’une activité proposée. Elle sert à examiner l’efficacité des mesures et des stratégies de prévention qui visent à réduire les effets de ces dangers.

Un programme d’analyse de la sûreté est conçu, élaboré et tenu à jour par le titulaire de permis et est examiné par le personnel de la CCSN. Il est documenté dans un rapport d’analyse de la sûreté (RAS). Comme le prescrivent les alinéas 5f) et 6c) du *Règlement sur les installations nucléaires de catégorie I* :

- « La demande de permis pour construire une installation nucléaire de catégorie I comprend les renseignements suivants... f) un rapport préliminaire d’analyse de la sûreté démontrant que la conception de l’installation nucléaire est adéquate;
- La demande de permis pour exploiter une installation nucléaire de catégorie I comprend les renseignements suivants... c) un rapport final d’analyse de la sûreté démontrant que la conception de l’installation nucléaire est adéquate. »

Le RAS peut faire référence à d’autres documents d’analyse de la sûreté.

Le RAS d’une installation constitue une partie importante du fondement d’autorisation de l’installation. Ce rapport est utilisé aux fins suivantes :

- établir les limites pour l’exploitation sûre de l’installation
- évaluer les changements proposés à l’installation
- élaborer et tenir à jour les politiques, les processus et les procédures du demandeur ou du titulaire de permis pour la réalisation sûre des activités autorisées
- confirmer que la conception de l’installation respecte les exigences en matière de conception et de sûreté

2.1 Défense en profondeur

Exigences

Le titulaire de permis doit tenir compte du concept de défense en profondeur lorsqu'il élabore une analyse de la sûreté pour une installation nucléaire.

Orientation

Cinq niveaux de défense en profondeur sont normalement définis pour les installations nucléaires, conformément à l'orientation fournie dans le REGDOC-3.5.3, *Principes fondamentaux de réglementation* [2]. L'analyse de sûreté joue un rôle de premier plan afin de démontrer que les niveaux 1 à 4 ont été atteints. L'analyse de sûreté s'applique comme suit à ces niveaux :

Niveau 1 L'objectif du premier niveau de défense est de prévenir des écarts par rapport à l'exploitation normale, et de prévenir les défaillances des structures, des systèmes et des composants (SSC) importants pour la sûreté.

Niveau 2 Le deuxième niveau de défense sert à détecter, à intercepter et à contrôler les écarts par rapport à l'exploitation normale afin d'empêcher les incidents de fonctionnement prévue (IFP) de dégénérer en conditions d'accident, et à ramener l'installation nucléaire dans l'état d'exploitation normale.

Niveau 3 L'objectif du troisième niveau de défense est de minimiser les conséquences sur le site des accidents en prévoyant des caractéristiques de sûretés inhérentes, une conception à sûreté intégrée, de l'équipement additionnel et des procédures d'atténuation. À ce niveau, l'objectif le plus important consiste à prévenir les rejets de substances nucléaires et de substances dangereuses connexes ou des niveaux de rayonnement qui nécessiteraient des mesures de protection hors site.

Niveau 4 L'objectif du quatrième niveau de défense est de s'assurer que le rejet de matières radioactives causé par des accidents graves demeure au niveau le plus bas qu'il soit raisonnablement possible d'atteindre. À ce niveau, l'objectif le plus important consiste à s'assurer que la fonction de confinement est maintenue afin que les rejets de matières radioactives demeurent au niveau le plus bas qu'il soit raisonnablement possible d'atteindre.

Niveau 5 L'objectif du cinquième niveau de défense est d'atténuer les conséquences radiologiques des rejets possibles de matières radioactives et les conséquences chimiques connexes pouvant résulter d'accidents en utilisant des installations d'intervention adéquatement équipées et en mettant en œuvre des plans et des procédures d'urgence pour assurer une intervention d'urgence sur le site et hors site.

Pour obtenir de plus amples renseignements sur le principe de la défense en profondeur, y compris les moyens d'atteindre les objectifs de ce principe (comme une bonne conception et des pratiques d'ingénierie éprouvées), veuillez consulter les documents suivants :

- REGDOC-3.5.3, *Principes fondamentaux de réglementation* [2]
- AIEA SSR-4, *Sûreté des installations du cycle du combustible nucléaire* [3]

2.2 Objectifs de l'analyse de la sûreté

Les objectifs d'une analyse de la sûreté sont les suivants :

- énoncer les buts, les objectifs et les critères d'acceptation en matière de sûreté (les exigences de sûreté) que l'installation doit satisfaire par sa conception
- démontrer que les buts, les objectifs et les critères d'acceptation en matière de sûreté sont atteints
- déterminer ou confirmer les limites et conditions d'exploitation (LCE) qui sont compatibles avec les exigences de conception et de sûreté de l'installation
- indiquer les SSC importants pour la sûreté [4] (c.-à-d. les SSC dont dépend la sûreté de l'installation)
- fournir des résultats permettant d'établir et de valider les procédures et lignes directrices d'exploitation et d'urgence

Exigences

Le titulaire de permis doit maintenir une capacité adéquate pour effectuer ou faire effectuer des analyses de la sûreté afin de :

- résoudre les problèmes techniques qui se posent pendant la durée de vie de l'installation nucléaire
- s'assurer que les exigences en matière d'analyse de la sûreté sont respectées (peu importe que l'analyse de la sûreté ait été élaborée par le titulaire de permis ou qu'elle ait été obtenue d'un tiers)

Le titulaire de permis doit établir un processus d'évaluation et de mise à jour de l'analyse de la sûreté afin de garantir que celle-ci reflète :

- la configuration actuelle (pour les installations existantes)
- les LCE actuelles (pour les installations existantes)
- l'expérience en exploitation acquise, y compris celle tirée de l'exploitation d'installations similaires et toute expérience applicable provenant d'autres installations nucléaires ou industrielles
- s'ils s'appliquent à l'installation nucléaire de catégorie IB visée, les résultats disponibles provenant de la recherche expérimentale, les connaissances théoriques améliorées ou les nouvelles capacités de modélisation afin d'évaluer les impacts possibles sur les conclusions des analyses de la sûreté
- s'ils s'appliquent à l'installation nucléaire de catégorie IB visée, les facteurs humains, afin que l'on tienne compte des estimations crédibles de la performance humaine dans le processus d'analyse

Le titulaire de permis doit systématiquement examiner les résultats de l'analyse de la sûreté pour s'assurer qu'ils restent valables et continuent de répondre aux buts, objectifs et critères d'acceptation en matière de sûreté.

Orientation

Le titulaire de permis est responsable de l'analyse de la sûreté, qu'elle soit réalisée par son personnel ou par une entreprise qui fournira ce service. Des exigences en matière de qualification des fournisseurs aident à assurer une sélection adéquate pour l'obtention d'un service comme la réalisation de l'analyse de la sûreté. Par conséquent, le titulaire de permis doit avoir :

- la capacité de vérifier les qualifications du fournisseur
- la capacité d'évaluer la justesse du service fourni

Pour obtenir plus d'information sur la façon de démontrer la capacité du personnel d'un titulaire de permis à réaliser l'analyse de la sûreté ou la capacité à obtenir un service pour réaliser une analyse de sûreté, veuillez consulter les documents suivants :

- CSA N286-12, *Exigences relatives au système de gestion des installations nucléaires* [5]
- AIEA, Guide de sûreté n° GS-G-3.3,5, *The Management System for Nuclear Installations* [6]

3. Programme d'analyse de la sûreté

Exigences

Le titulaire de permis doit élaborer, mettre en œuvre, exécuter et tenir à jour un programme d'analyse de la sûreté pour l'installation nucléaire.

À l'appui de ce programme, le titulaire de permis doit créer un ou plusieurs comités internes de sûreté pour conseiller la direction de l'organisation en ce qui concerne les questions de sûreté touchant la mise en service, l'exploitation et la modification de l'installation. Il doit veiller à ce que les membres de ces comités possèdent les connaissances et l'expérience nécessaires pour fournir des conseils judicieux. Les membres doivent, dans la mesure nécessaire, être indépendants de la direction de l'exploitation qui soulève les questions de sûreté.

Les éléments essentiels d'un programme d'analyse de la sûreté sont les déclarations faites par le titulaire de permis au sujet de ses politiques en matière de sûreté, de santé et d'environnement [3]. Le titulaire de permis doit fournir ces déclarations dans la demande de permis, sous forme d'une déclaration des objectifs de l'organisation et de l'engagement public de la direction de l'entreprise. Afin de mettre en œuvre ces déclarations, il doit également préciser et mettre en place des structures organisationnelles, des normes et des dispositions de gestion pouvant répondre aux objectifs de l'organisation et à ses engagements publics.

Le titulaire de permis doit démontrer que le programme d'analyse de la sûreté est régi par son système de gestion et qu'il est conforme aux exigences applicables de la norme CSA N286-12, *Exigences relatives au système de gestion des installations nucléaires* [5].

Orientation

Pour obtenir de plus amples renseignements sur l'établissement de comités internes de sûreté, veuillez consulter le document SSR-4 de l'AIEA, *Sûreté des installations du cycle du combustible nucléaire* [3].

Le titulaire de permis n'est pas obligé de créer un document distinct pour le programme d'analyse de la sûreté (ni un document indépendant ou un document dans le cadre du RAS).

La CCSN accepte que le programme d'analyse de la sûreté du demandeur ou du titulaire de permis ne corresponde pas exactement aux exigences et aux attentes de la CCSN dans ce domaine. Cependant, le titulaire de permis devrait être en mesure de démontrer comment toutes les exigences et les attentes sont prises en compte par les différents programmes du système de gestion global.

Lorsqu'il établit un comité interne de sûreté, le titulaire de permis devrait inclure des employés de diverses perspectives, par exemple, des représentants des employés.

4. Analyse de la sûreté

Exigences

Le titulaire de permis doit effectuer une analyse de la sûreté portant sur l'exploitation normale et sur les événements internes et externes qui s'écartent de l'exploitation normale et qui appartiennent à la catégorie des événements anormaux crédibles [7].

4.1 Classification des événements en fonction des états de l'installation

Exigences

Le titulaire de permis doit classer les événements dans l'un des états de l'installation : IFP, accident de dimensionnement (AD), accident hors dimensionnement (AHD) et plages spécifiques à l'intérieur des AHD appelées conditions additionnelles de dimensionnement (CAD), ou utiliser un système de classification équivalent.

Le titulaire de permis doit veiller à ce que l'analyse de la sûreté examine les états suivants de l'installation :

- les modes de fonctionnement normal (y compris les entretiens et les arrêts)
- les IFP
- les AD
- les CAD

Pour obtenir de plus amples renseignements sur la classification et les plages des événements, veuillez consulter l'annexe C.

Orientation

Le titulaire de permis peut utiliser un système de classification différent tant que les classifications respectent la même intention fondée sur le risque.

4.2 Hypothèses de l'analyse de la sûreté

Les hypothèses de l'analyse de la sûreté dépendent d'un certain nombre de facteurs :

- le profil de risque global de l'installation nucléaire
- l'événement analysé (IFP, AD ou CAD)
  - dans le cas des IFP et des AD, on utilisera des hypothèses prudentes (pour démontrer l'efficacité des systèmes de sûreté)
  - dans le cas des CAD, on utilisera l'approche et les hypothèses de la meilleure estimation
- l'état des connaissances sur la progression et les conséquences de l'événement

Exigences

Le titulaire de permis ne doit pas créditer les systèmes qui ne sont pas qualifiés pour fonctionner dans un environnement post-accident.

Pour créditer les interventions de l'opérateur, le titulaire de permis doit démontrer que les éléments suivants sont en place :

- des procédures opérationnelles claires, bien définies, validées et immédiatement accessibles décrivant les interventions nécessaires
- des instruments au lieu de commande pour fournir des indications claires et non ambiguës sur la nécessité d'une intervention de l'opérateur

- un plan crédible, protégé et accessible que peut suivre l'opérateur pour exécuter les interventions requises dans les procédures
- la formation de toute personne susceptible d'exécuter des interventions de l'opérateur

Le titulaire de permis doit établir les temps d'intervention de l'opérateur. Le titulaire de permis doit ajouter un délai supplémentaire pour inclure, selon le cas, le temps requis pour enfiler un équipement de protection, accéder à l'équipement à distance, et transporter, raccorder et faire fonctionner l'équipement temporaire. Le délai d'intervention de l'opérateur crédité dans le rapport d'analyse de la sûreté (RAS) doit être justifié.

Orientation

Lorsqu'il y a indication que l'intervention de l'opérateur est nécessaire, l'intervention de l'opérateur créditée dans la simulation de l'accident et documentée dans le rapport d'analyse de la sûreté devrait comporter un délai d'au moins :

- 15 minutes sur le lieu de commande
- 30 minutes à l'extérieur du lieu de commande

Ces délais d'intervention de l'opérateur correspondent au début de l'intervention.

Pour obtenir de plus amples renseignements sur l'attribution de crédits aux SSC importants pour la sûreté, veuillez consulter le REGDOC-2.5.2, *Conception d'installations dotées de réacteur* [8]. **Remarque :** Cette référence est fournie à titre informatif seulement. Le titulaire de permis n'est pas tenu d'appliquer les exigences ou l'orientation contenues dans le REGDOC-2.5.2 à son analyse de la sûreté pour une installation nucléaire de catégorie IB.

4.3 Événements initiateurs hypothétiques

Orientation

Un événement initiateur hypothétique (EIH) n'est pas nécessairement un accident en soi. Un EIH est l'événement qui déclenche une séquence pouvant mener à un IFP, un AD ou un AHD, selon les défaillances supplémentaires qui se produisent.

Les principales causes des EIH peuvent être des défaillances crédibles de l'équipement et des erreurs du travailleur, des événements d'origine humaine ou des événements naturels.

L'analyse de la sûreté et la conception de l'installation nucléaire doivent tenir compte non seulement de l'installation elle-même, mais également des interfaces avec d'autres installations et équipements qui peuvent avoir une incidence sur sa sûreté. Pour obtenir de plus amples renseignements, veuillez consulter le document SSR-4 de l'AIEA, *Sûreté des installations du cycle du combustible nucléaire* [3].

Pour obtenir de plus amples renseignements sur les types d'EIH et les plages de conditions, veuillez consulter l'annexe C.

4.3.1 Détermination des événements initiateurs hypothétiques

Exigences

Le titulaire de permis doit déterminer les EIH (autant internes qu'externes) qui pourraient mener aux conditions suivantes :

- une exposition aux rayonnements des travailleurs ou du public
- un rejet de quantités importantes de substances nucléaires
- un rejet de substances dangereuses (p. ex., des produits chimiques dangereux) associées aux substances nucléaires

Le titulaire de permis doit décrire les méthodes utilisées pour déterminer les EIH.

Le titulaire de permis doit documenter et tenir à jour la liste des EIH. Avec l'aide de spécialistes techniques et d'experts en analyse de la sûreté, il doit procéder à un examen de la liste des EIH :

- dans un premier temps, pour déterminer si la liste est complète et si les événements comprennent :
  - toutes les défaillances crédibles des structures, systèmes et composants (SSC) de l'installation
  - toutes les erreurs humaines crédibles qui pourraient se produire dans l'une ou l'autre des conditions d'exploitation de l'installation
- régulièrement, pour confirmer la pertinence de la liste en vigueur et la réviser au besoin, car les EIH pertinents peuvent changer au fur et à mesure que l'installation passe par les différentes phases de son cycle de vie (p. ex., en raison des effets du vieillissement)

Orientation

La liste des EIH devrait être établie à partir d'une évaluation complète des défaillances crédibles des SSC de l'installation et de la documentation des erreurs humaines crédibles qui pourraient se produire dans n'importe quelle condition d'exploitation de l'installation.

La liste des EIH peut prendre plusieurs formes, selon la complexité de l'activité ou de l'installation. Le titulaire de permis devrait dresser une liste propre à sa situation, qui tienne compte des substances nucléaires et des substances dangereuses connexes de l'activité ou de l'installation en question.

Sur sa liste initiale, le titulaire de permis devrait inclure autant d'EIH qu'il en a recensé. Si d'autres EIH sont relevés par la suite, le titulaire de permis devrait réviser son analyse de la sûreté pour les inclure.

4.3.2 Classification des événements initiateurs hypothétiques

Exigences

Au cours de l'évaluation de la sûreté, qui est décrite à la section 4.4, le titulaire de permis doit classer les EIH et les séquences d'événements dès leur identification, afin de démontrer que les critères d'acceptation et les objectifs de sûreté sont respectés.

Orientation

Le titulaire de permis devrait regrouper les EIH présentant des caractéristiques similaires (en particulier, ceux qui exigent des mesures d'atténuation similaires) dans différents groupes d'événements. Pour l'évaluation de la sûreté, il devrait déterminer les événements limitatifs de chaque groupe d'événements.

4.4 Évaluation de la sûreté

L'évaluation de la sûreté comprend une évaluation du risque associé aux dangers d'une installation nucléaire. L'évaluation peut être soit quantitative, soit qualitative, soit une combinaison des deux (semi-quantitative).

4.4.1 Évaluation des conséquences

Exigences

Le titulaire de permis doit effectuer une analyse déterministe de la sûreté (c.-à-d. une évaluation des conséquences) afin de déterminer le processus physique se déroulant dans l'installation nucléaire lors d'un événement et d'en évaluer les conséquences. Il doit justifier les hypothèses et les actions des mesures d'atténuation qualifiées (p. ex., les systèmes de sûreté et les interventions de l'opérateur) utilisées dans l'analyse déterministe.

Lorsque l'analyse déterministe est quantitative, le titulaire de permis doit élaborer des modèles des processus physiques pour calculer les conséquences de l'événement. Il doit valider les outils informatiques utilisés pour calculer les conséquences.

Orientation

Le titulaire de permis devrait s'assurer que la portée et la rigueur de la validation des outils informatiques sont proportionnelles au niveau de risque de l'activité ou de l'installation (c'est-à-dire, appliquer une approche graduelle).

Les demandeurs ou les titulaires de permis peuvent utiliser des logiciels de modélisation et d'analyse de données disponibles sur le marché. Afin de démontrer la validation de ces outils, le titulaire du permis peut soumettre la validation du logiciel par le vendeur du logiciel pour cette application.

Pour plus d'information sur la démonstration de la validation des outils logiciels, veuillez consulter :

- la section 6 de ce document d'application de la réglementation
- CSA N286.7-16, *Assurance de la qualité des programmes informatiques scientifiques, d'analyse et de conception* [9]

4.4.2 Évaluation de la probabilité

Exigences

Le titulaire de permis doit procéder à une évaluation de la probabilité pour établir la probabilité d'un EIH ou d'une séquence d'événements.

Orientation

En règle générale, pour les installations nucléaires de catégorie IB, le titulaire de permis procède à une évaluation qualitative ou semi-quantitative de la probabilité d'occurrence des EIH ou de séquences d'événements, à l'aide de l'une des méthodes suivantes :

- les méthodes d'analyse déterministe de la sûreté sont publiées dans les documents SSG-5 de l'AIEA, *Safety of Conversion Facilities and Uranium Enrichment Facilities* [10] et SSG-6, *Safety of Uranium Fuel Fabrication Facilities* [11]
- les méthodes d'évaluation de la probabilité sont publiées dans le document TECDOC Nº 1267 de l'AIEA, *Procedures for Conducting Probabilistic Safety Assessment for Non-Reactor Nuclear Facilities* [12]; de nombreuses méthodes peuvent être utilisées, de manière quantitative ou qualitative. En voici quelques exemples :
    - les études de danger et d'exploitabilité (HAZOP)
    - les analyses des modes de défaillance et de leurs effets
    - les analyses de l'arbre des défaillances et de l'arbre des événements
    - la rétroaction fondée sur l'expérience en exploitation; p. ex., par le biais de la base de données des systèmes de notification et d'analyse des incidents relatifs au cycle du combustible (FINAS) et des événements enregistrés localement pour chaque installation
    - la technique des scénarios (que se passerait-il si…)
    - les listes de contrôle (p. ex., les listes de contrôle de l'ergonomie)
    - le schéma logique principal

4.5 Détermination des structures, systèmes et composants importants pour la sûreté

Exigences

Le titulaire de permis doit procéder à une évaluation de la sûreté, ou employer une méthode équivalente, pour déterminer les séquences d'événements qui peuvent conduire à un IFP, un AD, des CAD ou un AHD. Pour obtenir de plus amples renseignements, veuillez consulter le document SSR-4 de l'AIEA, *Sûreté des installations du cycle du combustible nucléaire* [3].

Pour chaque séquence d'événements, le titulaire de permis doit déterminer les fonctions de sûreté, les SSC correspondants importants pour la sûreté [4] et les exigences administratives en matière de sûreté qui sont utilisées pour mettre en œuvre le concept de défense en profondeur.

Afin d'être cohérent avec les résultats de l'analyse de la sûreté, le titulaire de permis doit s'assurer que [3] :

- les SSC importants pour la sûreté sont conçus pour résister aux effets des charges et des conditions environnementales extrêmes (p. ex., la température, l'humidité, la pression et les niveaux de rayonnement extrêmes) qui peuvent survenir dans les états de fonctionnement et dans les conditions d'accident
- les intervalles requis pour les essais et inspections périodiques des SSC importants pour la sûreté sont définis
- les codes et normes applicables aux SSC importants pour la sûreté sont déterminés et leur utilisation est justifiée
- les niveaux nécessaires de disponibilité et de fiabilité des SSC importants pour la sûreté, tels qu'ils ont été établis dans l'analyse de la sûreté, sont atteints

Afin d'assurer une protection contre les dangers potentiels, le titulaire de permis doit veiller à ce que la hiérarchie suivante des mesures de conception et des mesures administratives soit utilisée dans la mesure du possible [3] :

1. la sélection du processus (pour éliminer le danger)
2. les caractéristiques de conception passives
3. les caractéristiques de conception actives
4. les contrôles administratifs

4.6 Limites et conditions d'exploitation

Exigences

Le titulaire de permis doit déterminer les LCE à partir de l'analyse de la sûreté. Il doit documenter les LCE avant d'entamer l'exploitation de l'installation.

Orientation

Les LCE comprennent les conditions limites pour une exploitation sûre (valeurs, conditions), les systèmes de surveillance et les réglages d'alarme connexes, ainsi que les exigences de surveillance et les exigences administratives. Les LCE devraient fixer des exigences minimales pour la disponibilité du personnel et de l'équipement. Pour obtenir de plus amples renseignements sur la disponibilité du personnel, veuillez consulter le REGDOC-2.2.5, *Effectif minimal* [13].

Lorsqu'il n'est pas possible de définir avec précision les limites de sûreté de tous les paramètres pertinents, les LCE devraient être fixées de manière à définir les limites de l'évaluation, afin d'empêcher l'exploitation dans des conditions non analysées ou non analysables.

L'annexe B présente des exemples de paramètres qui peuvent être gérés par l'intermédiaire des LCE pour une large plage d'installations.

4.7 Critères d'acceptation

Exigences

Le titulaire de permis doit établir des critères explicites concernant le niveau de sûreté à atteindre pour démontrer qu'il prend des dispositions adéquates afin de protéger l'environnement ainsi que la santé, la sûreté et la sécurité des personnes [3].

Le titulaire de permis doit fixer des limites pour ce qui est des conséquences radiologiques et des conséquences chimiques connexes pour les travailleurs et le public en cas d'exposition directe aux rayonnements ou de rejets de radionucléides dans l'environnement. Ces limites doivent :

- être fixées à un niveau égal ou inférieur aux :
  - dispositions du *Règlement sur la radioprotection*, lorsqu'elles s'appliquent et dans la mesure du possible, sinon
  - aux critères établis dans les normes nationales ou internationales comme déclencheurs des mesures de protection en cas d'urgence radiologique ou chimique (p. ex., pour la mise à l'abri ou pour la distribution de comprimés d'iode)
- s'appliquer aux conséquences des états de fonctionnement et aux conséquences possibles des IFP et des AD à l'installation
- s'appliquer aux limites du site de l'installation autorisée lorsque des conséquences hors site touchant le public sont prises en considération

Pour les nouvelles conceptions, le titulaire de permis doit envisager des objectifs qui sont inférieurs à ces limites.

Le titulaire de permis doit établir des critères d'acceptation dérivés pour démontrer que les barrières permettant de retenir les substances nucléaires ou les substances dangereuses connexes sont efficaces, c'est-à-dire que les barrières :

- préviennent le risque de défaillances indirectes à la suite d'un événement initiateur
- maintiennent les SSC importants pour la sûreté dans une configuration qui empêche les rejets de substances nucléaires ou de substances dangereuses connexes dans l'environnement ou dans l'installation
- empêchent les conséquences qui s'étendent au-delà des limites du site de l'installation autorisée
- sont compatibles avec les exigences de conception des SSC de l'installation

Pour connaître les critères d'acceptation de la sûreté-criticité nucléaire, veuillez consulter le document REGDOC-2.4.3, *Sûreté-criticité nucléaire* [14].

4.8 Objectifs de sûreté

Exigences

Le titulaire de permis doit démontrer que les conséquences hors site, conformément à ce qui est calculé aux limites du site de l'installation autorisée, d'un AHD inclus dans les CAD ne dépassent pas les critères établis comme déclencheurs d'une évacuation temporaire, d'une réinstallation à long terme de la population locale, ou à la fois d'une évacuation temporaire et d'une réinstallation à long terme selon les documents suivants :

- Santé Canada, *Lignes directrices canadiennes sur les interventions en situation d'urgence* [15]
- AIEA GSR Part 7, *Préparation et conduite des interventions en cas de situation d'urgence nucléaire ou radiologique* [16]

Lorsqu'il aborde le concept de la défense en profondeur, le titulaire de permis doit inclure les événements de l'AHD dans les CAD. Au minimum, il doit inclure les événements suivants dans les CAD [7] :

- une perte prolongée d'alimentation en courant alternatif (PPACA)
- les EIH et les séquences d'événements, y compris ceux qui sont propres ou uniques à l'installation, qui appartiennent à une catégorie d'événements anormaux crédibles [7]

Dans le cas des EIH d'origine naturelle (p. ex., les séismes, les inondations et les phénomènes météorologiques violents), lorsque la sélection d'événements anormaux crédibles n'est pas pratique, le titulaire de permis doit inclure dans les CAD les événements plus graves que ceux qui sont pris en compte dans les analyses des AD, conformément aux orientations des normes nationales ou internationales (voir l'annexe C).

La classification doit être fondée sur la probabilité, comme il est indiqué à la section 4.4.2.

5. Documents et dossiers d'analyse de la sûreté

Les documents relatifs à l'analyse de la sûreté décrivent les méthodes utilisées pour effectuer ces analyses et consignent les résultats de chaque analyse. Ils corroborent le choix du site, la conception, la mise en service, l’exploitation et le déclassement d’une installation nucléaire. Ils démontrent que les risques pour la santé, la sûreté et la sécurité des personnes sont gérés et atténués, et ces documents contribuent également à démontrer que la défense en profondeur a été établie.

5.1 Objectif et portée des documents et dossiers d’analyse de la sûreté

Orientation

Les documents et dossiers relatifs à l’analyse de la sûreté fournissent des informations sur l’analyse de la sûreté, à savoir :

- ils démontrent que les buts, objectifs et critères d’acceptation de la sûreté sont atteints
- ils permettent de déterminer ou de confirmer les LCE qui sont conformes aux exigences de conception et de sûreté de l’installation
- ils aident à établir et à valider des procédures et des lignes directrices d’exploitation et d’urgence

Le champ d’application des documents et dossiers d’analyse de la sûreté couvre les événements internes et externes qui pourraient mener à un rejet de substances nucléaires ou de substances dangereuses connexes, à un accident de criticité ou à une exposition accidentelle à des champs de rayonnement élevés.

5.2 Contenu des documents et dossiers d’analyse de la sûreté

Exigences

Le titulaire de permis doit communiquer les résultats de l’analyse de la sûreté de manière suffisamment détaillée pour permettre au personnel de la CCSN de les examiner.

Le titulaire de permis doit veiller à ce que le contenu des documents et dossiers d’analyse de la sûreté d’une installation comprenne au minimum le RAS et les LCE (ou l’équivalent) [3].

Le RAS doit contenir un résumé représentatif des documents et dossiers d’analyse de la sûreté. Il doit :

- décrire les caractéristiques du site
- indiquer les substances nucléaires et les substances dangereuses connexes et leur emplacement
- déterminer les critères d’acceptation applicables aux conséquences hors site pour le public des accidents pertinents (des exemples d’accidents pertinents sont les accidents radiologiques, chimiques et de criticité nucléaire et les incendies, y compris les explosions)
- indiquer les SSC qui empêchent ou atténuent le rejet de substances nucléaires ou de substances dangereuses connexes, ou qui préviennent l’exposition accidentelle à des champs de rayonnement élevés (dans la mesure où cela est approprié pour l’installation, selon une approche graduelle)
- classer les SSC en fonction de leur importance pour la sûreté
- indiquer les procédures d’exploitation et d’urgence ainsi que les actions qui permettent de prévenir ou d’atténuer le rejet de substances nucléaires ou de substances dangereuses connexes
- indiquer les hypothèses incluses dans l’analyse de la sûreté (p. ex., les conditions limitatives, la configuration de l’installation et les délais d’intervention de l’opérateur); nombre de ces hypothèses peuvent être documentées dans les LCE

- indiquer les événements initiateurs crédibles qui peuvent avoir un impact sur le contrôle des substances nucléaires ou des substances dangereuses connexes par le titulaire de permis, y compris :
  - les événements internes (p. ex., les défaillances de composant, les erreurs humaines, les incendies ou les inondations)
  - les événements externes (p. ex., un séisme, un incendie, une inondation ou des conditions météorologiques extrêmes)
- regrouper tous les événements initiateurs qui présentent des caractéristiques similaires et déterminer les événements limitatifs afin de les analyser
- fournir les résultats de l'analyse des conséquences des événements analysés
- inclure, le cas échéant, les résultats des analyses des incertitudes et de sensibilité
- comparer les résultats aux critères d'acceptation
- fournir les résultats et les conclusions
- faire l'objet d'un examen indépendant selon le système de gestion du demandeur ou du titulaire de permis
- fournir des références aux analyses détaillées qui appuient les résultats de l'analyse de la sûreté

Orientation

Le titulaire de permis peut incorporer des informations par renvoi. Par exemple, de nombreuses hypothèses de l'analyse de la sûreté peuvent être documentées dans les LCE du demandeur ou du titulaire de permis et peuvent être incorporées dans le RAS par renvoi.

Le titulaire de permis devrait s'assurer que des employés de diverses perspectives (p. ex., des représentant des employés) ont la possibilité d'examiner le RAS et de formuler des commentaires indépendants.

Les risques pour l'environnement découlant des rejets habituels (qui font partie de l'exploitation normale) sont pris en compte dans l'évaluation des risques environnementaux (ERE) du demandeur ou du titulaire de permis pour l'installation, et par conséquent ne sont pas pris en compte dans le RAS.

Pour de plus amples renseignements sur :
- la validation et la vérification des outils servant à l'analyse de la sûreté, veuillez consulter la section 6
- un exemple de structure et de contenu d'un RAS, voir l'annexe A

5.3 Documentation et consignation des événements initiateurs hypothétiques et des accidents de dimensionnement

Exigences

Le titulaire de permis doit décrire le comportement de l'installation à la suite d'un EIH et le comparer aux critères d'acceptation de l'analyse.

Orientation

Dans le cas des AD, le titulaire de permis devrait décrire chaque événement dans le RAS comme suit :

- le moment d'occurrence des principaux événements, y compris :
  - l'événement initial et toute défaillance ultérieure
  - les moments où l'équipement d'atténuation est activé
  - les moments où l'opérateur intervient
  - le moment où un état stable à long terme et sûr est atteint
- la présentation graphique des principaux paramètres en fonction du temps pendant l'événement (les paramètres devraient être sélectionnés de manière à ce que l'on puisse comprendre pleinement le déroulement de l'événement dans le contexte du critère d'acceptation envisagé)
- la comparaison avec les critères d'acceptation
- la conclusion de l'événement

5.4 Tenue des documents et des dossiers d'analyse de la sûreté

Le RAS et les autres documents et dossiers d'analyse de la sûreté sont mis à jour périodiquement tout au long du cycle de vie de l'installation. La période de mise à jour du RAS est indiquée dans le manuel des conditions de permis (MCP) de chaque installation. La période recommandée est de cinq ans, mais d'autres périodes peuvent être fixées, p. ex., en fonction de l'impact global de l'installation sur la sûreté ou de changements importants apportés à l'installation.

Exigences

Le titulaire de permis doit procéder à une évaluation continue du site. Si cette évaluation permet de relever de nouvelles informations sur les caractéristiques du site (en d'autres mots, les résultats de la détermination et de la classification des EIH ont changé), les mesures de sûreté (p. ex., des contrôles techniques et des dispositions d'urgence) pourraient alors devoir être examinées et révisées.

Orientation

Le processus de mise à jour devrait répondre aux exigences du programme d'analyse de la sûreté et devrait comprendre ce qui suit :

- la détermination des sections à réviser pour les raisons suivantes :
  - changements apportés aux événements initiateurs
  - changements apportés aux procédures ou à l'équipement de l'installation
  - prolongation de la durée d'exploitation de l'installation
  - changements apportés aux exigences réglementaires
  - nouvelles connaissances découlant de la recherche ou de l'expérience en exploitation
  - vieillissement des SSC
- le rendement de l'analyse
- un examen indépendant
- les documents et dossiers dans le RAS

Les éléments de l'analyse de la sûreté peuvent être réalisés à différents moments, pour diverses raisons. Normalement, toute analyse actualisée de la sûreté effectuée au milieu d'un cycle est incluse dans la mise à jour prévue subséquente du RAS.

6. Validation et vérification des outils d'analyse de la sûreté

Orientation

Les outils d'analyse de la sûreté devraient être validés et vérifiés. Pour obtenir de plus amples renseignements, veuillez consulter les documents suivants :

- REGDOC-3.5.3, *Principes fondamentaux de réglementation* [2]
- Groupe CSA, norme N286, *Exigences relatives au système de gestion des installations nucléaires* [5]
- Groupe CSA, norme N292.0, *Principes généraux pour la gestion des déchets radioactifs et du combustible irradié* [17]
- Groupe CSA, norme N292.1, *Entreposage humide du combustible irradié et d'autres matières radioactives* [7]
- Groupe CSA, norme N292.2, *Entreposage à sec provisoire du combustible irradié* [18]

7. Approche graduelle

Orientation

Pour obtenir plus d'information sur l'approche graduelle tenant compte du risque de la CCSN, veuillez consulter le REGDOC-3.5.3, *Principes fondamentaux de réglementation* [2].

Les installations nucléaires de catégorie IB ont des profils de risque qui varient considérablement en fonction des caractéristiques particulières de l'activité ou de l'installation. Le titulaire de permis peut proposer des mesures de conception particulières, des analyses ou d'autres mesures qui sont proportionnelles au niveau de risque posé, s'il fournit une justification adéquate.

Voici quelques exemples d'éléments de l'analyse de la sûreté qui peuvent être pris en compte dans une approche graduelle :

- les limites de fréquence pour les divers états de l'installation (IFP, AD et CAD)
- la rigueur de la validation et de la vérification des outils d'analyse de la sûreté
- la rigueur de l'évaluation des incertitudes
- l'étendue des études de sensibilité
- la quantité et la qualité des preuves à l'appui de l'analyse

Annexe A : Exemple de structure et de contenu d'un rapport d'analyse de la sûreté

Voici un exemple de structure d'un RAS. Le titulaire de permis n'est pas obligé de suivre ce format. Toutefois, tel qu'il est décrit aux sections 2 à 5 du présent document d'application de la réglementation, le rapport doit comprendre tous les renseignements qui s'appliquent.

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Annexe B : Exemple de paramètres à utiliser pour les limites et conditions d’exploitation

Cette annexe présente quelques exemples de conditions limitatives pour l’exploitation sûre de l’installation, en tenant compte des exigences pour les aspects suivants :

- les substances nucléaires (type, forme chimique et physique, capacité maximale de l’installation, composition isotopique)
- les substances dangereuses connexes (par exemple, les produits chimiques) à l’intérieur de l’installation et de ses équipements
- les exigences minimales de disponibilité pour :
  - les SSC importants pour la sûreté
  - les exigences relatives aux valeurs d’essai des SSC

  Remarque : Dans certains cas, les limites et conditions d’exploitation (LCE) concernant la disponibilité des SSC peuvent inclure des exigences pour leur essai, notamment :
    - les essais initiaux et périodiques
    - les types d’essais
    - la vérification
    - l’étalonnage ou l’inspection
    - la fréquence requise des inspections
    - la période entre deux essais successifs

- les moyens de confinement :
  - les flux d’air (et, le cas échéant, la température et l’humidité) à l’intérieur de l’installation et dans ses procédés
  - les chutes de pression cible dans les filtres
  - les pressions à l’intérieur des bâtiments de l’installation (pièces, cellules ou boîtes selon le cas) par rapport à l’atmosphère (dans des conditions normales et d’urgence)
  - l’isolement des moyens de confinement et l’activation de la ventilation d’urgence
  - les opérations nécessitant un confinement
  - la configuration et l’équipement minimal du système de ventilation
  - le taux de fuite des moyens de confinement
  - l’efficacité des filtres

- la radioprotection et la gestion des déchets radioactifs :
  - le réglage des systèmes d’alarme-criticité, de détection des rayonnements et de l’équipement et de l’instrumentation de surveillance
  - les limites de concentration des substances nucléaires dans l’air
  - les niveaux de contrôle de l’exposition aux rayonnements pour l’exploitation, y compris les seuils d’intervention pour les doses de rayonnement
  - les limites de la contamination de surface
  - la capacité de stockage des déchets nucléaires liquides et solides

- la manutention des matériaux, y compris les exigences concernant :
  - les mouvements de substances nucléaires et de substances dangereuses connexes, y compris le transfert sur le site et le transport hors site
  - les outils et équipements de manutention, y compris les grues (charges maximales admissibles et exigences en matière d'essais)
  - les conteneurs de stockage
- les systèmes électriques, y compris les exigences concernant :
  - l'alimentation électrique de secours
  - la fréquence des essais
  - la disponibilité et la fiabilité de l'alimentation électrique ininterrompue et des groupes électrogènes au diesel
- les autres systèmes, par exemple :
  - les systèmes de protection-incendie
  - les systèmes auxiliaires de procédés
  - les systèmes de communication
  - les systèmes d'éclairage d'urgence
- les systèmes de surveillance et les réglages des systèmes d'alarme connexes :
  - les valeurs de réglage de l'instrumentation de l'installation
  - les valeurs de réglage de l'équipement de procédé nécessaire à la sûreté
- les exigences administratives :
  - les effectifs (p. ex., l'effectif minimal et les heures de travail)
  - les conditions préalables aux activités importantes pour la sûreté (p. ex., le transport de matières radioactives ou fissiles, sur le site ou hors site)

Annexe C : Événements initiateurs hypothétiques

Voici les types d'événements initiateurs hypothétiques (EIH) et les plages de conditions applicables aux installations nucléaires de catégorie IB.

C.1 Événements initiateurs hypothétiques sélectionnés

Voici quelques exemples d'EIH :

1. spécification incorrecte des matières entrantes et transférées
2. perte de services
   - perte d'alimentation électrique
   - perte d'air comprimé
   - perte d'atmosphère inerte
   - perte de réfrigérant
   - perte de source froide ultime
3. perte de contrôle de la sûreté-criticité
   - chute de combustible pendant la manutention
   - perte de géométrie
   - inondation
   - perte de poison neutronique
   - réflexion ou modération excessive
   - changement de phase accidentel
   - défaillance ou effondrement de composants structurels
   - erreur d'entretien
   - erreur du système de contrôle
   - surdosage (double dosage)
4. erreurs de traitement
   - configuration incorrecte de l'installation
   - réactif ou liquide de refroidissement insuffisant, ajouté trop rapidement ou trop tôt
   - pression ou débit de gaz incorrect, rupture
   - température incorrecte ou extrême
   - changements de phase imprévus menant à la criticité ou à la perte de confinement
   - fonction requise pour la sûreté non appliquée
   - fonction de sûreté appliquée trop tard
5. défaillances de l'installation et des équipements
   - défaut de confinement ou fuite
   - isolation inadéquate des fluides de procédé
   - blocage ou contournement d'un filtre ou d'une colonne
   - actionnement intempestif d'un SSC important pour la sûreté
   - défaillances structurelles
6. erreurs de manipulation
   - chute d'une charge dangereuse
   - lourde charge déposée sur un ou plusieurs SSC importants pour la sûreté
   - défaillance des mécanismes de verrouillage de sécurité lorsqu'on active le mécanisme
   - protection inadéquate pour ce qui est des freins, de la survitesse ou de la surcharge

- voie obstruée menant à une collision
- défaillance d’un élément de levage (p. ex., crochet, poutre ou câble)
- charge fixée au sol

7. événements spéciaux internes
    - incendies ou explosions internes
    - inondations internes (p. ex., due aux systèmes d’extincteur ou à d’autres conduites d’eau)
    - défaillance dans le cadre d’une expérimentation
    - accès inapproprié de personnes aux zones d’accès restreint
    - événement de criticité
    - jets de fluide, effet de fouet de tuyau, missiles internes
    - réaction chimique exothermique
    - inflammation de gaz combustibles accumulés (p. ex., hydrogène)
    - défaillance due à la corrosion
    - perte d’absorption des neutrons
    - accidents sur les voies de transport internes (y compris les collisions à l’intérieur du bâtiment de l’installation)
8. événements externes
    - incendies ou explosions externes
    - séismes (y compris la formation de failles ou les glissements de terrain induits par des séismes)
    - inondations (y compris la rupture d’un barrage en amont ou en aval, blocage d’une rivière, ou dommages causés par des ondes de tempête ou de fortes vagues)
    - tornades et missiles projetés par les tornades
    - phénomènes météorologiques extrêmes (y compris les précipitations, les tempêtes de sable, les ouragans, les tempêtes et la foudre)
    - écrasements d’aéronefs
    - déversements de substances toxiques
    - effets des installations adjacentes (p. ex., installations nucléaires, installations chimiques et installations de gestion des déchets)
    - risques biologiques, notamment la corrosion microbienne, les dommages structurels ou les dommages causés à l’équipement par les rongeurs ou les insectes
    - sautes de puissance ou surtensions sur la ligne d’alimentation externe
9. erreurs humaines
    - erreurs ou omissions des travailleurs
    - erreurs ou omissions dans l’entretien

C.2 Éventail des événements sélectionnés à prendre en considération quant à leur applicabilité

Il faut prendre en considération la classification et les plages ci-dessous pour les événements internes afin d’en déterminer l’applicabilité :

- **incident de fonctionnement prévu (IFP) :** un événement dont la probabilité d’occurrence est supérieure à 10^{-2} par année
- **accident de dimensionnement (AD) :** un événement dont la probabilité d’occurrence est inférieure à 10^{-2} par année mais supérieure à 10^{-5} par année
- **conditions additionnelles de dimensionnement (CAD) :** un événement dont la probabilité d’occurrence est inférieure à 10^{-5} par année mais supérieure à 10^{-6} par année

Les plages suivantes des événements externes sélectionnés doivent être prises en compte pour déterminer leur applicabilité.

Charges dues aux vents et aux tornades

Pour l'évaluation des accidents de dimensionnement (AD) :
Le risque d'occurrence de tornades dans la région concernée est évalué sur la base de données historiques détaillées et de données enregistrées au moyen d'instruments pour la région. Par exemple, les charges éoliennes dans la conception d'une installation existante, si elles sont prescrites par un code de construction applicable, auraient une probabilité annuelle de dépassement supérieure ou égale à 2×10^{-2}. Pour obtenir de plus amples renseignements, veuillez consulter le document *Standard Review Plan for Fuel Cycle Facilities Licence Applications, NUREG-1520* [19].

Pour l'évaluation des conditions additionnelles de dimensionnement (CAD) :
Selon la situation géographique de l'installation, il pourrait être nécessaire de prendre en compte les effets d'une tornade ayant une probabilité de dépassement annuelle de 10^{-5} ou plus s'il est possible que les CAD de l'installation puissent avoir des conséquences hors site menant à des mesures d'atténuation d'urgence hors site.

Dangers d'inondation

Pour l'évaluation des AD :
Les installations existantes doivent généralement être situées au-dessus de la plaine inondable correspondant à la crue centenaire.

Pour l'évaluation des CAD :
La plaine inondable probable maximale devrait être utilisée si les CAD de l'installation peuvent avoir des conséquences hors site menant à des mesures d'atténuation d'urgence hors site.

Dangers sismiques

Les études régionales proches devraient porter sur une zone géographique dans un rayon d'au moins 25 km en général. Les études des environs du site devraient couvrir une zone géographique dans un rayon d'au moins 5 km. Les études de zones de site devraient porter sur l'ensemble de la zone couverte par l'installation. Pour obtenir de plus amples renseignements, veuillez consulter le document SSG-9 de l'AIEA, *Seismic Hazards in Site Evaluation for Nuclear Installations* [20].

On devrait recueillir et documenter des données sur les séismes préhistoriques, historiques et enregistrés par des instruments dans la région. Pour obtenir de plus amples renseignements, veuillez consulter le document NS-R-3 (Rév. 1) de l'AIEA, *Évaluation des sites d'installation nucléaire* [21].

Pour l'évaluation des AD :
Les structures des installations existantes faisant partie du cycle du combustible nucléaire sont construites conformément aux codes de construction. On devrait utiliser l'orientation présentée dans la norme CSA N289.5, *Exigences relatives à l'instrumentation sismique des centrales et des installations nucléaires* [22] si l'installation présente un potentiel de conséquences hors site d'un AD qui pourraient mener à des mesures d'atténuation d'urgence hors site.

Pour l'évaluation des CAD :
La norme CSA N289.5, *Exigences relatives à l'instrumentation sismique des centrales et des installations nucléaires* [22] fournit une orientation en ce qui concerne le respect des critères relatifs à un séisme de référence ayant une probabilité de dépassement annuelle entre 10^{-3} et 10^{-4}. On devrait utiliser la norme CSA N289.5 [22] si l'installation présente un potentiel de conséquences hors site des CAD qui pourraient mener à des mesures d'atténuation d'urgence hors site.

Écrasements d'aéronefs

Il convient de tenir compte des risques d'écrasement d'aéronef, y compris les impacts, les incendies et les explosions sur le site, notamment les aspects suivants :

- les caractéristiques prévisibles du trafic aérien, de l'emplacement et des types d'aéroports
- les caractéristiques des aéronefs, y compris ceux qui ont une autorisation spéciale de survoler l'installation ou de s'en approcher, notamment les avions de lutte contre les incendies et les hélicoptères

Pour obtenir de plus amples renseignements, veuillez consulter le document NS-R-3 (Rév. 1) de l'AIEA, *Évaluation des sites d'installation nucléaire* [21].

Pour l'évaluation des AD et des CAD :
Les dangers potentiels résultant d'écrasements d'aéronefs doivent être pris en compte si :

- les voies aériennes ou les approches d'aéroport passent à moins de 4 km du site
- les aéroports sont situés dans un rayon de 10 km du site pour tous les aéroports, sauf les plus grands
- dans le cas des grands aéroports, si la distance (d) en kilomètres entre l'aéroport et le site proposé est inférieure à 16 km et si le nombre de vols annuels prévus est supérieur à 500 d^2

Lorsque la distance (d) est supérieure à 16 km, le danger doit être pris en compte si le nombre de vols annuels prévus est supérieur à 1 000 d^2.

Dans le cas des installations militaires ou de l'utilisation de l'espace aérien à des fins spéciales (p. ex., pour les exercices de bombardement ou les champs de tir) qui pourraient présenter un danger pour le site, le danger doit être pris en compte si ces installations se trouvent dans un rayon de 30 km du site proposé.

Pour obtenir de plus amples renseignements, veuillez consulter le document NS-G-3.1 de l'AIEA, *Les événements externes d'origine humaine dans l'évaluation des sites de centrales nucléaires* [23].

Glossaire

Les définitions des termes utilisés dans le présent document figurent dans le REGDOC-3.6, *Glossaire de la CCSN*, qui comprend des termes et des définitions tirés de la *Loi sur la sûreté et la réglementation nucléaires*, de ses règlements d'application ainsi que des documents d'application de la réglementation et d'autres publications de la CCSN. Le REGDOC-3.6 est fourni à titre de référence et pour information.

Les termes suivants sont soit nouveaux, soit modifiés. À la suite de la consultation publique, la version définitive des termes et des définitions sera ajoutée à la prochaine version du REGDOC-3.6, *Glossaire de la CCSN*.

événement anormal crédible *(credible abnormal event)*
Comme il est défini dans la norme N292.1 du Groupe CSA, *Stockage en piscine du combustible irradié et autres matières radioactives* [7], il s'agit d'un événement ou d'une séquence d'événements naturels ou d'origine humaine dont la fréquence est égale ou supérieure à 10^{-6} par an.

lieu de commande *(control location)*
Lieu doté d'un personnel permanent pendant la période où l'événement en question peut se produire, p. ex., une salle de commande.

programme d'analyse de la sûreté *(safety analysis program)*
Activités visant à planifier, réaliser, vérifier et documenter les analyses de la sûreté, à déterminer les travaux de recherche et l'expérience et prendre les mesures qui s'imposent, à former des analystes et à préserver les connaissances. Le programme d'analyse de la sûreté comprend les interfaces avec d'autres programmes afin de garantir que l'analyse de la sûreté est entreprise lorsque cela est nécessaire et que ses résultats sont utilisés de manière appropriée.

Ajouter à l'« annexe A : Sigles et abréviations » dans le REGDOC-3.6 :

PPACA *(ELAP)*	Perte prolongée de l'alimentation en courant alternatif
FINAS *(FINAS)*	Systèmes de notification et d'analyse des incidents relatifs au cycle du combustible
RAS *(SAR)*	Rapport d'analyse de la sûreté

Références

La CCSN pourrait inclure des références à des documents sur les pratiques exemplaires et les normes, comme celles publiées par le Groupe CSA. Avec la permission du Groupe CSA, qui en est l'éditeur, toutes les normes de la CSA associées au nucléaire peuvent être consultées gratuitement sur la page Web de la CCSN « Comment obtenir un accès gratuit à l'ensemble des normes de la CSA associées au nucléaire ».

1. Commission canadienne de sûreté nucléaire (CCSN). REGDOC-2.11.1, *Gestion des déchets, tome III : Dossier de sûreté pour la gestion à long terme des déchets radioactifs*, Ottawa, Canada.
2. CCSN. REGDOC-3.5.3, *Principes fondamentaux de réglementation*, Ottawa, Canada.
3. Agence internationale de l'énergie atomique (AIEA). SSR-4, *Sûreté des installations du cycle du combustible nucléaire*, Vienne, Autriche, 2017.
4. CCSN. REGDOC-3.6, *Glossaire de la CCSN*, Ottawa, Canada.
5. Groupe CSA. CSA N286-12, *Exigences relatives au système de gestion des installations nucléaires*, confirmée en 2017.
6. AIEA. Guide de sûreté nº GS-G-3.5, *The Management System for Nuclear Installations*, Vienne, Autriche, 2009
7. Groupe CSA. CSA N292.1, *Entreposage humide du combustible irradié et d'autres matières radioactives*, 2016.
8. CCSN. REGDOC-2.5.2, *Conception d'installations dotées de réacteur*, Ottawa, Canada.
9. Groupe CSA. CSA N286.7-16, *Assurance de la qualité des programmes informatiques scientifiques, d'analyse et de conception*, 2016 (revisée 2021)
10. AIEA. Guide de sûreté, SSG-5, *Safety of Conversion Facilities and Uranium Enrichment Facilities*, Vienne, Autriche, 2010.
11. AIEA. Guide de sûreté, SSG-6, *Safety of Uranium Fuel Fabrication Facilities*, Vienne, Autriche, 2010.
12. AIEA. TECDOC n° 1267, *Procedures for Conducting Probabilistic Safety Assessment for Non-Reactor Nuclear Facilities*, Vienne, Autriche, 2002.
13. CCSN. REGDOC-2.2.5, *Effectif minimal*, Ottawa, Canada.
14. CCSN. REGDOC-2.4.3, *Sûreté-criticité nucléaire*, Ottawa, Canada.
15. Santé Canada. H46-2/03-326F, *Lignes directrices canadiennes sur les interventions en situation d'urgence*, Ottawa, Canada, 2003.
16. AIEA. Prescriptions générales de sûreté, n° GSR Part 7, *Préparation et conduite des interventions en cas de situation d'urgence nucléaire ou radiologique*, Vienne, Autriche, 2015.

17. Groupe CSA. CSA N292.0, *Principes généraux pour la gestion des déchets radioactifs et du combustible irradié,* 2019.

18. Groupe CSA. CSA N292.2, *Entreposage à sec provisoire du combustible irradié*, 2013 (confirmée en 2018).

19. United States Nuclear Regulatory Commission (NUREG). *Standard Review Plan for Fuel Cycle Facilities License Applications (NUREG-1520)*, Révision 2, 2015.

20. AIEA. Guide de sûreté particulier, n° SSG-9, *Seismic Hazards in Site Evaluation for Nuclear Installations*, Vienne, Autriche, 2010.

21. AIEA. Prescriptions générales de sûreté, n° NS-R-3 (Rev. 1), *Évaluation des sites d'installation nucléaire*, Vienne, Autriche, 2016.

22. Groupe CSA. CSA N289.5, *Exigences relatives à l'instrumentation sismique des centrales et des installations nucléaires*, confirmée en 2017.

23. AIEA. Guide de sûreté, n° NS-G-3.1, *Les événements externes d'origine humaine dans l'évaluation des sites de centrales nucléaires*, Vienne, Autriche, 2002.

Renseignements supplémentaires

La CCSN pourrait recommander d'autres documents sur les pratiques exemplaires et les normes, comme ceux publiés par le Groupe CSA. Avec la permission du Groupe CSA, qui en est l'éditeur, toutes les normes de la CSA associées au nucléaire peuvent être consultées gratuitement à partir de la page Web de la CCSN « Comment obtenir un accès gratuit à l'ensemble des normes de la CSA associées au nucléaire ».

Les documents suivants fournissent des renseignements supplémentaires qui pourraient être pertinents et faciliter la compréhension des exigences et de l'orientation fournis dans le présent document d'application de la réglementation :

- Groupe CSA. CSA N291, *Exigences relatives aux enceintes reliées à la sûreté des centrales nucléaires*, 2019.
- Agence internationale de l'énergie atomique (AIEA). Prescriptions générales de sûreté, *GSR Part 4 (Rev. 1), Évaluation de la sûreté des installations et activités*, Vienne, Autriche, 2016.
- AIEA. Guide de sûreté, GS-G-4.1, *Format and Content of the Safety Analysis Report for Nuclear Power Plants*, Vienne, Autriche, 2004.
- Nuclear Regulatory Commission (NRC) des États-Unis. *Integrated Safety Analysis Orientation Document (NUREG-1513)*, 2001.

Séries de documents d’application de la réglementation de la CCSN

Les installations et activités du secteur nucléaire du Canada sont réglementées par la CCSN. En plus de la *Loi sur la sûreté et la réglementation nucléaires* et de ses règlements d’application, il pourrait y avoir des exigences en matière de conformité à d’autres outils de réglementation, comme les documents d’application de la réglementation ou les normes.

Les documents d’application de la réglementation préparés par la CCSN sont classés en fonction des catégories et des séries suivantes :

1.0 Installations et activités réglementées

Séries	1.1	Installations dotées de réacteurs
	1.2	Installations de catégorie IB
	1.3	Mines et usines de concentration d’uranium
	1.4	Installations de catégorie II
	1.5	Homologation d’équipement réglementé
	1.6	Substances nucléaires et appareils à rayonnement

2.0 Domaines de sûreté et de réglementation

Séries	2.1	Système de gestion
	2.2	Gestion de la performance humaine
	2.3	Conduite de l’exploitation
	2.4	Analyse de la sûreté
	2.5	Conception matérielle
	2.6	Aptitude fonctionnelle
	2.7	Radioprotection
	2.8	Santé et sécurité classiques
	2.9	Protection de l’environnement
	2.10	Gestion des urgences et protection-incendie
	2.11	Gestion des déchets
	2.12	Sécurité
	2.13	Garanties et non-prolifération
	2.14	Emballage et transport

3.0 Autres domaines de réglementation

Séries	3.1	Exigences relatives à la production de rapports
	3.2	Mobilisation du public et des Autochtones
	3.3	Garanties financières
	3.4	Séances de la Commission
	3.5	Processus et pratiques de la CCSN
	3.6	Glossaire de la CCSN

Remarque : Les séries de documents d’application de la réglementation pourraient être modifiées périodiquement par la CCSN. Chaque série susmentionnée peut comprendre plusieurs documents d’application de la réglementation. Pour obtenir la plus récente liste de documents d’application de la réglementation, veuillez consulter le site Web de la CCSN.

Consultation Report: REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities*
Rapport de consultation: REGDOC-2.4.4, *Analyse de la sûreté pour les installations de catégorie IB*

Introduction

REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities*, clarifies requirements and provides guidance for applicants and licensees to demonstrate the safety of a Class IB nuclear facility, including:

- a safety analysis program (the managed process that governs conduct of a safety analysis)
- conduct of a safety analysis (a systematic evaluation of the potential hazards)
- safety analysis documents, records and reporting

This document provides requirements and guidance for safety analysis of many (but not all) Class IB nuclear facilities. The full list is provided in section 1.2, Scope, of the regulatory document.

Introduction

Le document d'application de la réglementation REGDOC-2.4.4, *Analyse de la sûreté pour les installations de catégorie IB*, clarifie les exigences et fournit l'orientation que doivent suivre les demandeurs et les titulaires de permis pour démontrer la sûreté d'une installation nucléaire de catégorie IB, notamment :

- un programme d'analyse de la sûreté (le processus géré qui régit la conduite d'une analyse de la sûreté)
- la réalisation d'une analyse de la sûreté (une évaluation systématique des dangers potentiels)
- les documents, dossiers et rapports d'analyse de la sûreté

Ce document décrit les exigences et l'orientation relatives à l'analyse de la sûreté pour de nombreuses (mais pas toutes) installations nucléaires de catégorie IB. La liste exhaustive est fournie à la section 1.2, Portée, du document d'application de la réglementation.

Consultation process

On August 28, 2020, a draft version of REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities*, was issued for public consultation until December 5, 2020.

During the consultation period, the CNSC received 69 comments from 14 respondents:

- Brian Beaton, Coalition for Responsible Energy Development in New Brunswick
- Bruce Power
- Cameco Corporation

Processus de consultation

Du 28 août au 5 décembre 2020, une ébauche du REGDOC-2.4.4, *Analyse de la sûreté pour les installations de catégorie IB* a été diffusée aux fins de consultation publique.

Au cours de la période de consultation, la CCSN a reçu 69 commentaires de 14 répondants :

- Brian Beaton, Coalition for Responsible Energy Development in New Brunswick
- Bruce Power

- Canadian Nuclear Association (CNA)
- Canadian Nuclear Laboratories (CNL)
- Canadian Nuclear Workers Council
- Énergie New Brunswick Power (NB Power)
- P. Hader, consultant
- Nordion
- Nuclear Waste Management Organization (NWMO)
- Ontario Power Generation (OPG)
- Safety Probe International
- SRB Technologies
- M. Stephens, AECL (retired)

Consultation submissions were posted for feedback on comments from December 6, 2020 to January 12, 2021. No additional feedback was received.

A follow-up review by email was held with all respondents from November 5 to 18, 2021, to discuss any remaining requests for additional clarity on the CNSC's responses to the comments received during public consultation. Following the review, the CNSC hosted a workshop with those who commented in the follow-up review. The workshop was attended by:

- Bruce Power
- BWXT
- CANDU Owner's Group
- Cameco Corporation
- CNA
- CNL
- NB Power
- NWMO
- OPG
- SRB Technologies

The full responses to stakeholder feedback on draft REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities*, can be found in the comment disposition table included as part of the Commission Member Document package.

- Cameco Corporation
- Association nucléaire canadienne (ANC)
- Laboratoires Nucléaires Canadiens (LNC)
- Conseil canadien des travailleurs du nucléaire
- Énergie Nouveau-Brunswick (Énergie NB)
- P. Hader, consultant
- Nordion
- Société de gestion des déchets nucléaires (SGDN)
- Ontario Power Generation (OPG)
- Safety Probe International
- SRB Technologies
- M. Stephens, EACL (retraité)

Les mémoires relatifs à la consultation ont été affichés du 6 décembre 2020 au 12 janvier 2021 aux fins de rétroaction sur les commentaires. Aucun commentaire supplémentaire n'a été reçu.

Un examen de suivi par courriel a été réalisé avec tous les répondants du 5 au 18 novembre 2021 afin de discuter des demandes de clarification restantes concernant les réponses de la CCSN aux commentaires reçus pendant la consultation publique. Après cet examen, la CCSN a organisé un atelier avec les personnes qui ont fourni des commentaires lors de l'examen de suivi. Les participants à l'atelier étaient les suivants :

- Bruce Power
- BWXT
- Groupe des propriétaires de CANDU
- Cameco Corporation
- ANC
- LNC
- Énergie NB
- SGDN
- OPG
- SRB Technologies

Les réponses complètes aux observations des parties intéressées relatives au projet de REGDOC-2.4.4, *Analyse de la sûreté pour les installations de catégorie IB*, figurent dans le tableau de réponse aux commentaires faisant partie de la trousse de documents à l'intention des commissaires.

Key comments

The following summarizes the key comments received during the consultation period and provides the CNSC's responses:

Comment 1:

Representatives of some Class IB nuclear facility licence holders expressed a concern that REGDOC-2.4.4 is overly prescriptive with respect to the concepts of environmental qualification, minimum staff complement, credited operator action times, and to a lesser degree, the now-mandatory methodology in the application of defense-in-depth, particularly where nuclear substance processing facilities may intersect with the requirements.

Not all Class IB facilities are "nuclear fuel cycle" facilities per se; they do not play any role in the manufacture or processing of fuel for nuclear reactors. Despite this, the International Atomic Energy Agency (IAEA)'s SSR-4, *Safety of Nuclear Fuel Cycle Facilities* is referenced as the fundamental guiding document for this regulatory document, and the requirements therein applied to all Class IB nuclear facilities on the basis of being Class IB.

Other reviewers noted that other referenced documents, including the CSA N292.x series, are not currently requirements for all Class IB licensees and are provided as guidance documents in some Licence Conditions Handbooks (a document that provides licensing conditions that are specific to the licensee's activity or facility).

Principaux commentaires

Les principaux commentaires reçus lors de la période de consultation sont résumés ci-après, accompagnés des réponses de la CCSN.

Commentaire 1

Les représentants de certains titulaires de permis d'installations nucléaires de catégorie IB sont préoccupés par la nature trop normative du REGDOC-2.4.4 en ce qui concerne la qualification environnementale, l'effectif minimal, les interventions créditées de l'opérateur et, dans une moindre mesure, la méthodologie devenue obligatoire pour l'application de la défense en profondeur, particulièrement dans les cas où les exigences ont une incidence sur les installations de traitement de substances nucléaires.

Les installations de catégorie IB ne sont pas toutes des installations du cycle du combustible nucléaire à proprement parler, car elles ne jouent pas toutes un rôle dans la fabrication ou le traitement du combustible pour les réacteurs nucléaires. Malgré cela, le document SSR-4, *Sûreté des installations du cycle du combustible nucléaire* de l'Agence internationale de l'énergie (AIEA) est cité en référence à titre de document d'orientation fondamental pour ce document d'application de la réglementation, et les exigences qu'il contient s'appliquent à toutes les installations nucléaires de catégorie IB par le fait même que celles-ci font partie de cette catégorie.

D'autres examinateurs ont noté que certains documents en référence, y compris la série de normes CSA N292.x, ne sont pas actuellement des exigences pour tous les titulaires de permis d'installations de catégorie IB mais qu'ils sont fournis à titre de référence dans certains manuels de conditions de permis (un document qui énonce les conditions du permis s'appliquant à l'activité ou l'installation d'un titulaire de permis).

CNSC staff response:

CNSC agrees that not all Class IB nuclear facilities are nuclear fuel cycle facilities, and CNSC staff took that into account in the development of REGDOC-2.4.4 and, also, in reviewing the existing safety analyses from these facilities.

IAEA SSR-4 is listed as a source of more information on a variety of topics (for example, defence in depth, establishing internal safety committees, and on interfaces with other facilities and installations that may affect the facility's safety). There is no statement in REGDOC-2.4.4 that says requirements in IAEA SSR-4 would be applied to facilities that are not nuclear fuel cycle facilities. To add clarity, the text in sections 3 and 4.3 has been revised to explicitly place the references to IAEA SSR-4 in the guidance subsections.

The CSA N292.x series is mentioned in a guidance section as a source of more information on the validation and verification of safety analysis tools, and CSA N292.1 also provides a definition of a credible abnormal event. The overall content of CSA N292.1 explicitly takes into account Class IB facilities that are not nuclear fuel cycle facilities.

The requirements in this regulatory document, which is consistent with other documents in the 2.4 series of regulatory documents, set the foundation on performing a safety analysis on a Class IB nuclear facility and promote consistency across the industry. CNSC staff expect that many licensees will apply a graded approach, which is consistent with how CNSC staff is currently assessing safety analysis for these facilities.

Réponse du personnel de la CCSN

La CCSN convient que ce ne sont pas toutes les installations de catégorie IB qui sont aussi des installations du cycle du combustible nucléaire, et le personnel de la CCSN en a tenu compte dans l'élaboration du REGDOC-2.4.4 et dans son examen des analyses de la sûreté actuelles pour ces installations.

Le document SSR-4 de l'AIEA est cité comme source d'information supplémentaire sur divers sujets (comme la défense en profondeur, l'établissement de comités de sécurité internes et l'interface avec d'autres installations qui pourraient avoir une incidence sur l'état d'une installation donnée). Le REGDOC-2.4.4 ne contient aucun passage stipulant que les exigences du document SSR-4 de l'AIEA seraient appliquées aux installations ne faisant pas partie du cycle du combustible nucléaire. Par souci de clarté, le texte des sections 3 et 4.3 a été modifié pour que les références au document SSR-4 se trouvent explicitement dans les sous-sections Orientation.

La série de normes CSA N292.x est mentionnée à la section Orientation comme source d'information supplémentaire sur la validation et la vérification des outils d'analyse de la sûreté, et la norme CSA N292.1 fournit aussi une définition d'un événement anormal crédible. Le contenu général de cette norme tient expressément compte des installations de catégorie IB qui ne font pas partie du cycle du combustible nucléaire.

Les exigences dans ce document d'application de la réglementation, lequel est conforme aux autres documents de la série 2.4, servent de fondement à l'analyse de la sûreté d'une installation nucléaire de catégorie IB et assurent la cohérence au sein du secteur. Le personnel de la CCSN s'attend à ce que plusieurs titulaires de permis appliquent une approche graduelle, ce qui correspond à la méthode d'évaluation qu'emploie actuellement le personnel pour évaluer les analyses de la sûreté de ces installations.

Comment 2:

A number of reviewers requested more clarity on their application of a risk-informed graded approach to safety analysis at their nuclear facility.

The reviewers commented that the requirements ("shall" statements) included in REGDOC-2.4.4 are inconsistent with a licensee's ability to apply a risk-informed graded approach. In their opinion, REGDOC-2.4.4 is entirely prescriptive. While the risk-informed graded approach is described in REGDOC-3.5.3, *Regulatory Fundamentals*, they expressed that the information is of limited assistance because it merely defines a graded approach and states that the CNSC applies it but does not provide any further guidance for licensees. Further, it is unclear in what context a licensee would make a graded approach proposal.

Commentaire 2

Certains examinateurs ont demandé d'autres clarifications sur l'application d'une approche graduelle fondée sur le risque pour la réalisation d'analyses de la sûreté à leur installation nucléaire.

Les examinateurs ont commenté que les exigences (les énoncés contenant le terme « doit ») dans le REGDOC-2.4.4 sont incompatibles avec la capacité d'un titulaire de permis à appliquer une approche graduelle fondée sur le risque. Selon eux, le REGDOC-2.4.4 est entièrement normatif. Même si l'approche graduelle fondée sur le risque est décrite dans le REGDOC-3.5.3, *Principes fondamentaux de réglementation*, l'information les aide peu, puisqu'elle ne fait que définir ce qu'est une approche graduelle et indique que la CCSN l'applique, mais ne fournit aucune autre orientation aux titulaires de permis. De plus, il n'est pas clair dans quel contexte un titulaire de permis proposerait une approche graduelle.

CNSC staff response:

Text in REGDOC-2.4.4 has been revised for clarity and to confirm the CNSC's risk-informed graded approach. A risk-informed graded approach can be applied to any requirement ("shall statements) if the licensee provides adequate justification.

REGDOC-2.4.4 is clear on the licensee's option to propose specific design measures, analyses or other measures that are

Réponse du personnel de la CCSN

Le texte du REGDOC-2.4.4 a été revu pour le rendre plus clair et confirmer ce qu'est l'approche graduelle fondée sur le risque de la CCSN. Cette approche peut être appliquée à n'importe quelle exigence (les énoncés contenant le terme « doit ») si le titulaire de permis donne une justification adéquate.

Le REGDOC-2.4.4 indique clairement qu'un titulaire de permis peut proposer des mesures commensurate with the level of risks posed, if they provide adequate justification. Text supporting this option is provided in the Preface, section 1.2 (Note 2) and in section 7.

REGDOC-3.5.3, *Regulatory Fundamentals* is being revised to add information on the CNSC's risk-informed graded approach. Specifically, the CNSC is adding a new appendix on graded approach to REGDOC-3.5.3. Comments on the graded approach have been passed to the regulatory team working on that regulatory document. This document is expected to be provided to the Commission for approval shortly.

Comment 3:

Reviewers expressed concern that REGDOC-2.4.4 uses terms that are defined for power reactors which may not apply directly to Class IB nuclear facilities.

Reviewers are concerned that the use of nuclear reactor terminology and incident classification suggests that there is a change in the expectation for well-established and accepted safety analyses for Class IB nuclear facilities thereby creating regulatory uncertainty.

CNSC staff response:

Each requirement in this regulatory document has a link to the IAEA's SSR-4, *Safety of Nuclear Fuel Cycle Facilities* or CSA Group's CSA N292.x series of standards, which apply to Class IB facilities. All of the terms that are included in REGDOC-2.4.4 are consistent with the terminology used in IAEA SSR-4 and the

de conception précises, des analyses ou d'autres mesures proportionnelles aux niveaux de risque, si une justification adéquate est fournie. Le texte à l'appui de cette option est fourni dans la Préface, la section 1.2 (remarque 2) et la section 7.

Le REGDOC-3.5.3, *Principes fondamentaux de réglementation* est en cours de révision pour y ajouter de l'information sur l'approche graduelle fondée sur le risque de la CCSN. Plus précisément, la CCSN ajoutera une nouvelle annexe sur l'approche graduelle au REGDOC-3.5.3. Les commentaires sur l'approche graduelle ont été transmis à l'équipe chargée de ce document, et celui-ci devrait devrait être fourni à la Commission pour approbation sous peu.

Commentaire 3

Des examinateurs ont dit qu'ils sont préoccupés du fait que le REGDOC-2.4.4 utilise des termes s'appliquant aux réacteurs de puissance, qui pourraient ne pas s'appliquer directement aux installations nucléaires de catégorie IB.

Ils s'inquiètent aussi du fait que l'utilisation d'une terminologie propre aux réacteurs nucléaires et à la classification des incidents suggère que les attentes ont changé relativement aux analyses de la sûreté bien établies et acceptées pour les installations nucléaires de catégorie IB, créant ainsi de l'incertitude sur le plan de la réglementation.

Réponse du personnel de la CCSN

Chaque exigence de ce document d'application de la réglementation est liée au document SSR-4, *Sûreté des installations du cycle du combustible nucléaire* de l'AIEA ou à la série de normes N292.x du Groupe CSA, les deux s'appliquant aux installations de catégorie IB. Tous les termes dans le REGDOC-2.4.4 sont

CSA Group’s N292.x series.

To address this concern, the CNSC will update REGDOC-3.6, *Glossary of CNSC Terminology*, in the near future to add clarity to the definitions that were identified as requiring additional clarity.

conformes à la terminologie du document SSR-4 de l’AIEA et de la série de normes N292.x du Groupe CSA.

Pour donner suite à cette préoccupation, la CCSN mettra à jour le REGDOC-3.6, *Glossaire de la CCSN* prochainement pour clarifier les définitions posant problème.

Comment 4:

Reviewers expressed concern about the treatment of external hazards and postulated initiating events (PIEs). They believe that external hazards/events should not be referred to as PIEs, similar to the approach in REGDOC-2.4.1, *Deterministic Safety Analysis* where they need to be considered, but they do not necessarily result in a PIE.

Commentaire 4

Les examinateurs sont préoccupés par le traitement des dangers externes et des événements initiateurs hypothétiques (EIH). Selon eux, les dangers et événements externes ne devraient pas être appelés des EIH, comformément à l’approche dans le REGDOC-2.4.1, *Analyse déterministe de la sûreté* selon laquelle ils doivent être considérés, mais ne mènent pas forcément à un EIH.

CNSC staff response:

The requirement is that “The applicant or licensee shall identify PIEs (both internally and externally initiated) that could lead to:

- radiation exposure to workers or to the public
- a release of significant amounts of nuclear substances
- a release of hazardous substances (such as hazardous chemicals) associated with the nuclear substances”

External events are identified at the beginning of the process and identified by the licensee as “credible” or “not credible” for that facility. The licensee starts with a wider range and then decreases to the range to “credible”. It is the licensee’s responsibility to identify the events that do not necessarily lead to a failure. This identification (of the event as “credible” or “not credible”) is the 2nd step of the licensee’s 3-step analysis.

Réponse du personnel de la CCSN

L’exigence stipule ce qui suit : « Le demandeur ou le titulaire de permis doit déterminer les EIH (autant internes qu’externes) qui pourraient mener aux conditions suivantes :

- une exposition aux rayonnements des travailleurs ou du public
- un rejet de quantités importantes de substances nucléaires
- un rejet de substances dangereuses (p. ex. des produits chimiques dangereux) associées aux substances nucléaires »

Les événements externes sont identifiés au début du processus et désignés par le titulaire de permis comme crédibles ou non crédibles pour l’installation. Le titulaire de permis commence par une portée plus grande, puis la réduit jusqu’à « crédible ». Il est responsable d’identifier les événements qui n’entraînent pas forcément une défaillance. L’identification de l’événement comme crédible ou non crédible est la deuxième étape de l'analyse en 3 étapes du titulaire de permis.

It is the responsibility of the applicant or licensee to assess all potential hazards and select all appropriate ones for further safety analysis. However, the CNSC is not asking licensees to run safety analysis on events that, for that facility, would not lead to an accident.

Le demandeur ou le titulaire de permis est responsable d'évaluer tous les dangers potentiels et de choisir tous ceux qui sont appropriés pour une analyse approfondie de la sûreté. Cependant, la CCSN ne demande pas aux titulaires de permis de mener des analyses de la sûreté pour les événements qui n'entraîneraient pas un accident à l'installation donnée.

Concluding remarks

This project has undergone extensive stakeholder consultations. CNSC staff have listened to concerns and the document has been modified, as appropriate.

Mot de la fin

Ce projet a fait l'objet de vastes consultations auprès des parties intéressées. Le personnel de la CCSN a entendu les préoccupations et a modifié le document, au besoin.

Public Consultation / Consultation publique
Draft REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities*
Projet de REGDOC-2.4.4, *Analyse de la sûreté les installations nucléaires de catégorie IB*

Comments: August 28 to December 5 (extended from November 27), 2020
Feedback on comments: December 6 to January 12 (extended from January 6), 2021
Feedback on responses to comments: received November 18, 2021

The CNSC received 69 distinct comments from 14 stakeholders during public consultation ("comments" and "feedback on comments"); and during "feedback on responses to comments", received 2 additional comments and further feedback on 4 distinct topics (comments 2, 39, 62 and 63 in table B; feedback on other comments supported those distinct topics). The 2 new comments are included in table C, below.

Commentaires : Du 28 août au 5 décembre (prolongé du 27 novembre), 2020
Réactions aux commentaires : Du 6 décembre au 12 janvier (prolongé du 6 janvier), 2021
Commentaires sur les réponses aux commentaires : reçus le 18 novembre 2021

La CCSN a reçu 69 commentaires distincts de 14 parties intéressées au cours de la consultation publique (" commentaires " et " rétroaction sur les commentaires ") ; et au cours de la " rétroaction sur les réponses aux commentaires ", elle a reçu 2 commentaires supplémentaires et d'autres rétroactions sur 4 sujets distincts (commentaires 2, 39, 62 et 63 dans le tableau B ; la rétroaction sur les autres commentaires a appuyé ces sujets distincts). Les 2 nouveaux commentaires sont inclus dans le tableau C, ci-dessous.

Table A: Comments on Request for Information

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change	Response
I.	No comments specific to the Request for Information were received.			

Table B: Comments on draft REGDOC-2.4.4, *Safety Analysis for Class IB Nuclear Facilities* (original comments, "feedback on comments" and "feedback on responses to comments" are combined)

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change	Response
1.	J. MacDonald, SRB Technologies (Canada) Inc.	General	Most of the concepts and requirements listed here rely heavily on the Class 1A-style requirements, and if there is a step-wise gap between the rigour demanded here and the Class IA-level of analysis, it is not clearly shown in this draft REGDOC. The expectation going into this exercise is that if a separate Class IB REGDOC is to be published on safety analysis, it would arguably contain significant differences when compared to Class IA / reactor facility safety analysis, simply by definition. The current safety analysis on file for the SRBT facility has been accepted and in place for years, and adequately captures the bounding PIEs and outcomes. The intent of these comments is not to imply that the level of investment of resources are not achievable by SRBT, and whatever is needed to ensure a compliant safety analysis will obviously be put forward; however, each Class IB facility	Text has been revised for clarity. Text has been added to the Preface and to section 1.2 (Note 2) to describe that "Class IB nuclear facilities have risk profiles that vary significantly, depending on the particular characteristics of the activity or facility" and that, therefore, "the applicant or licensee may propose a graded approach in accordance with REGDOC-3.5.3". Each requirement in this regulatory document has a link to the International Atomic Energy Agency (IAEA)'s SSR-4, *Safety of Nuclear Fuel Cycle Facilities* or CSA Group's CSA N292.x

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change	Response
			offers unique and exclusive nuances that may not be easily accounted for in a 'one size fits all' type of REGDOC such as this.	series of standards, which apply to Class IB facilities. The CNSC will revise the definitions of some terms included in REGDOC-3.6, *Glossary of CNSC Terminology*, to address the key terminology. See also response to comment #4, below. Based on CNSC staff's reviews of Safety Analysis Reports (SARs), which were updated during the most-recent licensing cycle, CNSC staff's observation is that the SARs of most licensees are already consistent with this regulatory document (REGDOC-2.4.4). For new licences, site- or facility-specific adjustments are accounted for by the applicant providing a justification in the licence application, which is reviewed by the CNSC.
2.	Cameco Corporation	General	Cameco's main concern with this REGDOC is the application of the graded approach. The "shall" statements are inconsistent with a licensee's ability to apply a graded approach, which is not remedied by "the graded approach may be proposed by the applicant or licensee in accordance with the REGDOC-3.5.3, Regulatory Fundamentals" in the Scope section. In our view, this is a meaningless statement in a REGDOC that is entirely prescriptive. We also note that REGDOC-3.5.3 offers no assistance because it merely defines a graded approach and states that the CNSC applies it without providing any guidance for licensees. Further, it is unclear in what context a licensee would make a graded approach proposal.	Text has been revised for clarity and to confirm the CNSC's risk-informed graded approach. REGDOC-2.4.4 is clear on the licensee's option to propose specific design measures, analyses or other measures that are commensurate with the level of risks posed, if they provide adequate justification. Text supporting this option is provided in the Preface, section 1.2 (Note 2) and in section 7. A risk-informed graded approach can be applied to any requirement ("shall" statements) if the licensee provides adequate justification. REGDOC-3.5.3, *Regulatory Fundamentals* is being revised to add information on the CNSC's risk-informed graded approach.
			Further feedback based on the CNSC's response: In its proposed update to REGDOC-3.5.3, CNSC staff is encouraged to review IAEA-TECDOC-1980, "Application of a Graded Approach in Regulating Nuclear Installations" to incorporate relevant elements and reference as appropriate. Please note that a graded approach may be "risk-informed," but not necessarily	The CNSC is adding a new appendix on graded approach to REGDOC-3.5.3, *Regulatory Fundamentals*. Comments on the graded approach will be passed to the regulatory team working on that appendix. Note that TECDOC-1980 is generic. It can be used for additional

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change	Response
			quantitatively if it is rooted in safety factors that can be ranked. IAEA-TECDOC-1980 is clear that when assessing risk, consideration of likelihood may be done quantitatively, qualitatively, or deterministically (see end of 2nd paragraph, page 88)	information on applying a graded approach.
3.	Cameco Corporation	General	Cameco's other main concern is the use of nuclear reactor terminology and incident classification, which suggests that there is a change in the expectation for well-established and accepted safety analyses for Class IB facilities thereby creating regulatory uncertainty. In our view, the REGDOC does not set out what a licensee needs to do to meet the expectation in this safety control area and, as drafted, this REGDOC would make a safety analysis far more complicated and use more resources than is necessary for the risks at Cameco's facilities. Cameco strongly recommends that the REGDOC be revised and clarify the expectations for this safety control area in a manner that is specifically applicable to and commensurate with the risks at Class IB facilities in consideration of a graded approach.	No change to the document because the document already allows usage of alternative terminology provided the terminology and classification meet the same risk-based intent. Based on CNSC staff's reviews of SARs, which were updated during the most-recent licensing cycle, CNSC staff's observation is that Cameco SARs are already aligned with this regulatory document. For example, section 5.1.1 of "Safety Analysis Report for the Blind River Refinery" (Cameco, BRR EP 200, January 2021) is titled "Defence in Depth" and provides detailed description of all five levels as implemented by Cameco"; section 9.1 is titled "Beyond Design Basis" and describes safety analyses of credible release scenarios. For new licences, current text of the regulatory document is important due to the following reasons. As described in the response to comment #1, each requirement in this regulatory document has a link to the International Atomic Energy Agency (IAEA)'s SSR-4, *Safety of Nuclear Fuel Cycle Facilities* or CSA Group's CSA N292.x series of standards, which apply to Class IB facilities. See also response to comment #4, below.
4.	Nuclear Waste Management Organization (NWMO)	General	NWMO's main comment is the document uses terms that are defined for power reactors which may not apply directly to Class IB facilities.	No change to REGDOC-2.4.4 because the document already allows usage of alternative terminology provided the terminology and classification meet the same risk-based intent. Based on CNSC staff's reviews of SARs, which were updated during the most-recent licensing cycle, CNSC staff's observation is that SARs of most licensees are already aligned with terms of this regulatory document. For NWMO, terms used in this document are consistent with those in the CSA N292.7 *Disposal of Radioactive Waste and Irradiated Fuel* that was developed on

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change	Response
				a consensus basis with active participation of NWMO. For example, para 9.3.2.1 of CSA N292.7 states: "The design and operating requirements for the disposal facility system shall address credible abnormal events that might lead to AOO, DBA, or DEC"; para 7.3.1.2 states "Defence-in-depth shall be provided in multiple levels…", etc. Further technical justification: all of the terms that are included in the regulatory document are consistent with the terminology used in IAEA SSR-4 and the CSA Group's N292.x series. REGDOC-3.6, *Glossary of CNSC Terminology* is an evergreen document, which is frequently updated to take into account relevant terms based on new and existing regulatory documents. Consequently, REGDOC-3.6, *Glossary of CNSC Terminology* will be revised to add clarity to the following definitions: - anticipated operational occurrence (AOO) - design basis accident (DBA) - design extension conditions (DEC) - facility state - operator (especially as regarding "operator actions") - shutdown - SSCs important to safety - systems important to safety The definitions for "beyond design basis accident" and "severe accident" will not be revised, because they already align with the CSA definitions related to safety analysis. The following definitions will be added to REGDOC-3.6: - "authority having jurisdiction" and "intelligent customer" have both been posted for consultation (in REGDOC-1.1.2, *Licence Application Guide: Licence to Construct a Reactor Facility*, Version 2) and will be added to REGDOC-3.6 in a near-future update - "containment" as it relates to waste management has recently been published (in REGDOC-1.2.1, *Guidance on*

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change	Response
				Deep Geological Repository Site Characterization) and will be added to the pending update of REGDOC-3.6
5.	Canadian Nuclear Association (CNA)	General	The Canadian Nuclear Association (CNA) and its members would like to thank the CNSC for the opportunity to comment on REGDOC 2.4.4. ... However, the CNA feels it is necessary to highlight several over-arching concerns with the draft document: • The purpose of REGDOC 2.4.4 is to provide specific guidance and requirements for non-reactor facilities and in our view this draft does not do that. The CNA believes that this REGDOC relies too much on Class 1A style requirements and in some cases applies Class 1A requirements on Class 1B facilities without considering the lower risk profiles of Class 1B facilities. In addition, this draft uses reactor specific terminology for non-reactor applications. There is little point in having a separate REGDOC for non-reactor facilities if the basis of the document is the Safety Analysis required for Class 1A facilities. • There are several occasions where the draft REGDOC uses terms that do not align with their use in other REGDOCs. This has the potential to create uncertainty and confusion. This challenge occurs periodically with other REGDOCs and CNA would ask CNSC staff to doublecheck definitions prior to release of draft REGDOCs. • Further to the above comments and as outlined in greater detail in the attached industry comments, the CNA believes that the REGDOC as drafted creates regulatory uncertainty and by failing to use language that is graded to the lower risk profiles of Class 1B facilities could compel licensees to reallocate scarce resources to comply with its requirements without and corresponding benefit to nuclear safety. In concluding, the CNA believes that further work needs to be done before this document should proceed.	Thank you for your investment of time and knowledge in providing your comments. • No change to the document. As described in the response to comment #1, each requirement in this regulatory document has a link to the International Atomic Energy Agency (IAEA)'s SSR-4, *Safety of Nuclear Fuel Cycle Facilities* or CSA Group's CSA N292.x series of standards, which apply to Class IB facilities. See also response to comment #4, above. • No change to REGDOC-2.4.4; however, as described in the response to comment #4, REGDOC-3.6, *Glossary of CNSC Terminology* will be revised to add clarity to certain definitions. • No change based on this specific comment. As described in the response to comment #2, REGDOC-2.4.4 is clear on the licensee's option to apply a risk-informed graded approach, with adequate justification. The CNSC has a robust procedure for developing and revising regulatory documents such as REGDOC-2.4.4. All comments received during public consultation are addressed to improve the draft document, and to add clarity.
6.	Bruce Power	General	Most of the concepts in this draft document rely heavily on Class 1A-style requirements.	Text has been revised for clarity. Text has been added to the Preface and to section 1.2 (Note 2) to describe that "Class IB

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change	Response
			If there is a step-wise gap between the rigour demanded by this draft and the Class IA level of analysis, it is not clearly shown. Please see [Bruce Power's other comments] for specific examples of this concern, along with several requests for clarification.	nuclear facilities have risk profiles that vary, significantly, depending on the particular characteristics of the activity or facility" and that, therefore, "the applicant or licensee may propose specific design measures, analyses or other measures that are commensurate with the level of risks posed, based on the CNSC's risk-informed graded approach, if they provide adequate justification". As described in the response to comment #1, each requirement in this regulatory document is consistent with existing standards that apply to Class IB facilities.
7.	Ontario Power Generation (OPG)	General	OPG's primary comments on the proposed document as currently written can be broadly summarized as follows: • The draft REGDOC as written is too reactor-specific at this time; and • This draft REGDOC uses terms that do not align with those in other regulatory documents, such as REGDOC-3.6, *Glossary of CNSC Terminology* and REGDOC-2.2.5, *Minimum Staff Complement*; we also request specific terminology to be made consistent throughout the document.	Text has been revised to clarify the application of a graded approach (see comment 6) and REGDOC-3.6, *Glossary of CNSC Terminology*, will be revised soon. • As described in the response to comment #1, each requirement in this regulatory document is consistent with existing standards that apply to Class IB facilities. • As described in the response to comment #4, REGDOC-3.6, *Glossary of CNSC Terminology* will be revised to include safety analysis terminology related to Class IB facilities. • The terminology has been reviewed and is consistent throughout the document. Terminology in other regulatory documents (such as REGDOC-2.2.5, *Minimum Staff Complement*) will be reviewed and revised as necessary in the next periodic update to each regulatory document. For more detail, see the responses to comments 1, 4, 8 and 9.
			Further feedback based on the CNSC's response: Please see industry's response to comment #2.	See response above to comment 2.
8.	Bruce Power, Cameco	General	1) This draft REGDOC is too reactor-specific.	No change to the document because the document already allows

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change	Response
	Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)		a) Most of the concepts and requirements in this draft rely heavily on the Class 1A-style requirements. If there is a step-wise gap between the rigour demanded here and the Class IA-level of analysis, it is not clearly shown in this draft. By definition, if a separate Class IB REGDOC is to be published on safety analysis it should contain significant differences when compared to a Class IA/reactor facility safety analysis. Class IB facilities have safety analyses that have been accepted by CNSC and in place for several years. They adequately capture the bounding events and outcomes for their facilities. Each Class IB facility offers unique and exclusive nuances that may not be easily accounted for in a 'one size fits all' type of REGDOC such as this. b) Similarly, as currently written, this draft uses reactor-specific terminology for non-reactor applications. This is contrary to the stated intent of REGDOC-2.4.4, which is to provide specific guidance and requirements for non-reactor facilities. For instance, the reactor-specific term "postulated initiating event" is used throughout this draft. Licensees urge CNSC staff to use plain-language terminology, such as "fault" or "fault sequence" for this example, which also has the advantage of being more broadly understood internationally. Using reactor-specific terms in a document which explicitly does not scope reactor facilities creates the potential for confusion with other available, reactor-specific literature and its applicability to Class IB facilities. Please see [other comments] for examples."	usage of alternative terminology provided the terminology and classification meet the same risk-based intent. Based on CNSC staff's reviews of SARs, which were updated during the most-recent licensing cycle, CNSC staff's observation is that SARs of most licensees are already aligned with terminology and concepts of this regulatory document. For new licences, current text of the regulatory document is important due to the following reasons. a) As described in the response to comm ent #1, each requirement in this regulatory document links to standards that apply to Class IB facilities. b) The term "postulated initiating event" is used throughout the draft in accordance with Requirement 19 of IAEA SSR-4, *Safety of Nuclear Fuel Cycle Facilities*. Furthermore, this term is used in dozens of Safety Analysis Reports for Class IB facilities, submitted by OPG and CNL during the last ~20 years. The proposed alternative terms, such as "fault" or "fault sequence", are not consistent with either international standards or Canadian nuclear industry practices.
9.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)	General	2) This draft REGDOC uses terms that do not align with those in other regulatory documents, such as REGDOC-3.6, *Glossary of CNSC Terminology* and REGDOC-2.2.5, *Minimum Staff Complement*. For example: a) Under REGDOC-3.6, the objective of "safety goal" is to protect facility staff, the public and the environment from releases of radioactive material. However, this document suggests the goal is to protect against radioactive material and hazardous materials. b) Similarly, the term "chemical hazards" is used throughout this draft even though chemical hazards are already covered within the broader category of radiological and hazardous substances.	No change to the terminology. Based on CNSC staff's reviews of SARs, which were updated during the most-recent licensing cycle, CNSC staff's observation is that SARs of most licensees are already aligned with terminology of this regulatory document. For new licences, current terminology of the regulatory document is important due to the following reasons. All of the terms that are included in REGDOC-2.4.4 are consistent with the terminology used in IAEA SSR-4 and the CSA Group's N292.x series. However, REGDOC-3.6, *Glossary of CNSC Terminology* will be revised to add clarity to specific definitions. See response to comment #4.

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			Imprecise use of terminology has the potential to generate confusion and compliance challenges. c) The term "operator" has a very specific meaning in REGDOC-3.6, which may be misconstrued as used in this draft. CNSC staff is encouraged to change "operator"' to "worker" since the definition of worker in REGDOC-3.6 better aligns with the usage in the document. Please see [other comments] for other examples.	a) No change. Based on CNSC staff's reviews of SARs updated during the most-recent licensing cycle, CNSC staff's observation is that SARs of all existing licensees already include information on protection against radioactive material and hazardous materials. Further technical justification: REGDOC-2.4.4 includes protection against • radiation exposure to workers or to the public • a release of significant amounts of nuclear substances • a release of hazardous substances (such as hazardous chemicals) associated with the nuclear substances which is consistent with paras 1.4, 1.8, 2.4, 2.13, 3.11, 6.1, 6.29, 6.43, 6.45, etc. of IAEA SSR-4 b) Text has been revised to use the terminology "nuclear and associated hazardous substances" and where necessary, including the phrase "such as hazardous chemicals". See also response to comment #22. c) In some cases, the term "operator" has been changed to "worker" as this term is more inclusive. However, the phrase "operator action" has been retained for information related to crediting operator action (in section 4.2, Safety analysis assumptions, and also a few other sections where the text refers to operator actions). Both terms are used in IAEA SSR-4; therefore, the terminology remains consistent. REGDOC-3.6, *Glossary of CNSC Terminology*, will be revised to add clarity to the terms "operator" and "operator action" as they relate to Class IB nuclear facilities.

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10.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Ontario Power Generation (OPG) Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO)	General	It is unclear how the use of containers for handling of materials during transport is covered in this draft. If there is an interfacing link to another licensed operation, it should be documented somewhere in the SAR or a reference be provided for the approved container used in transportation. It is unclear how the handling of transport packages is covered in this draft. If there is an interfacing link to another licensed operation, it should be documented somewhere in the SAR or a reference provided for transport packages.	Text in Appendix B has been revised for terminology, as described below. Appendix B provides examples of material handling, including requirements for onsite transfer and offsite transportation as a limiting condition for safe operation of the facility. IAEA SSR-4, *Safety of Nuclear Fuel Cycle Facilities* refers to 'onsite transfer' and "offsite transportation". The terminology in appendix B has been revised as follows: o movements of nuclear and associated hazardous substances, including onsite transfer and offsite transportation
11.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)	General	As written, the references to SCAs require prior understanding to comprehend. Provide a cross-reference to a suitable background document.	Text has been revised as follows: The first paragraph in section 2 has been deleted. To provide some general background information about the safety and control areas (SCAs): • The CNSC's regulatory requirements and expectations for the safety performance of programs are grouped into three functional areas and 14 safety and control areas (SCAs). The CNSC uses SCAs as the technical topics to assess, review, verify and report on regulatory requirements and performance across all regulated facilities and activities. The SCAs are further divided into specific areas that define the key components of each SCA. • A table of the SCAs is provided in many licence application guides, and the SCAs have been listed on the back cover of every regulatory document since 2013. • As explained in many licence application guides, the applicant or licensee may choose to organize their information in any structure.
12.	Brian Beaton, Coalition for Responsible Energy	General	As I move through this document I am struck by its complete complacent and compromised approach to addressing the nuclear industry and its poor safety efforts	No change to REGDOC-2.4.4. Thank you for submitting this comment. The issues raised go beyond the scope and immediate

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	Development in New Brunswick		especially when it comes to addressing their deadly waste materials. Instead of accepting responsibility for their creations, they are now wanting to make it a problem for others. And they are willing to spend billions to do this. Instead this document must offer other options such as the proponents must have a detailed local waste handling solution that involves long term storage and management options within the facility being proposed. This addition to the document would force proponents to directly address the issue of the production of the deadly high-level waste materials they are creating. It also avoids the need for involving other communities and regions in the introduction and handling of these deadly poisons this industry is creating. We need a fresh new look at how the safety analysis for nuclear facilities is conducted and managed. Canadians deserve a fair and informed process where our input is valued and respected. This effort would replace the current nuclear industry narrative and marketing efforts that is evident in this current document. Canadians deserve to feel well informed about these proposed developments without having to wade through a mountain of documents that then reference other documents while hiding important information. This current document is full of examples of this type of mind-boggling distractions and diversions to the real issues and work that is attempting to be presented here.	content of this draft regulatory document. The CNSC's mandate is to ensure that the operation of nuclear facilities and activities is done safely. The CNSC does not set government policy. Comments on nuclear waste policy might be better submitted to the current initiative by Natural Resources Canada (NRCan). For more information on government policy, see the NRCan website: - www.nrcan.gc.ca - https://www.nrcan.gc.ca/our-natural-resources/energy-sources-distribution/nuclear-energy-uranium/radioactive-waste/7719 and, to register to participate in NRCan's current initiative on modernizing Canada's radioactive waste policy: -https://www.rncanengagenrcan.ca/en/collections/modernizing-canadas-radioactive-waste-policy Some of these issues may be addressed by other regulatory documents, especially the waste management and decommissioning documents published in January 2021: • REGDOC-1.2.1, *Guidance on Deep Geological Repository Site Characterization* • REGDOC-2.11.1, *Waste Management, Volume I: Management of Radioactive Waste* • REGDOC-2.11.1, *Waste Management, Volume III: Safety Case for the Disposal of Radioactive Waste, Version 2* • REGDOC-2.11.2, *Decommissioning* • REGDOC-3.3.1, *Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities* The particular comments that go beyond the immediate content of this draft regulatory document will be sent to CNSC management and other staff for consideration in projects specifically related to these concerns. With respect to a "fair and informed process where our input is

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				valued and respected", the CNSC strives to provide all stakeholders with access to the information and a forum to submit their comments and feedback. The comments and feedback are taken into consideration in the next update of each appropriate document.
13.	Brian Beaton, Coalition for Responsible Energy Development in New Brunswick	General	One last recommendation is that this important document continues to be revised to address the concerns I raise. This recommendation requires that there be continuing public consultation to ensure all the required revisions and concerns are addressed. Thank you for considering the issues I am attempting to raise with this intervention. I hope my intervention is helpful to the Commission.	The CNSC has a robust procedure for developing and revising regulatory documents such as REGDOC-2.4.4. All comments received during public consultation are addressed to improve the draft document, and to add clarity. Anyone who submits a comment during public consultation receives information about how the draft document has been revised and how the comments have been addressed in advance of the Commission's consideration of the final document. All published regulatory documents are subject to periodic reviews and revision. The CNSC welcomes feedback on any regulatory document at any time. Thank you for taking the time to comment. All comments are appreciated, and are taken into consideration when developing regulatory documents.
14.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)	Sections 1.0, Introduction and 1.1, Purpose	Additional clarity could be added to the 1st paragraph of the Purpose. Add a statement or footnote after the first use of the term "nuclear facility" to make it clear that "nuclear facility" only means a "Class IB nuclear facility" throughout the balance of this REGDOC."	Text has been revised as requested. The title, purpose and scope provide additional clarity that the information in this regulatory document refers to Class IB nuclear facilities.
15.	Brian Beaton, Coalition for Responsible Energy	Sections 1.0, Introduction	My intervention consists of my concerns about the "safety analysis program (the managed process that governs conduct of a safety analysis) conduct of a safety analysis (a	No changes to REGDOC-2.4.4. Thank you for submitting this comment. The issues raised go beyond the scope and immediate

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	Development in New Brunswick	and 1.1, Purpose	systematic evaluation of the potential hazards) safety analysis documents, records and reporting". I believe Canada requires a safety analysis program that emphasizes and clearly demonstrates its complete independence of the CNSC and the actual safety process from the nuclear industry and its subsidiary "developments" and "proposals". As it appears today, there seems to be so many conflicts of interest with the staffing of CNSC being hired or appointed to be doing this work after having been directly involved by employment or association with the nuclear industry itself. I am unable to find any mention of these conflicts-of-interests and how they will be addressed in this document. How can any one feel safe with the deadly poisons being created by any nuclear reactor when members of the nuclear industry are directly determining what is "safe". How can anyone feel safe when members of the nuclear industry now employed by CNSC are examining the data and the reports received from the same industry where they once worked? I am also concerned about the safety analysis program and its relationship to the systemic and environmental racism that is inherent in these types of efforts to create another "program" or "process" or "solution" that maybe helps the commission staff but makes no reference to the recommendations from the Truth and Reconciliation Commission or to UNDRIP. This effort demonstrates both the disrespect of the original people of this land along with the negligence this highlights for meaningful engagement and informed consent that includes those who offer a different and often opposing perspective and set of research countering the application. As it stands today, the nuclear industry is able to purchase their desired results that include access to the lands they want to build facilities to develop their Deep Geological Repository without any meaningful or support for opposing perspectives. Supportive communities, individuals and groups are receiving millions of dollars IF they sign their acceptance of a set of conditions that only supports the industry and its proponent's desired results. Opposing positions being delivered by organizations and individuals are both ignored and undermined as organizations and their staff such as the Nuclear Waste Management Organization (NWMO) label these people and groups as "security risks". How do these efforts by opposition groups to create meaningful and informed information consent figure into this "safety analysis program"? Maybe I missed something but I am	content of this draft regulatory document. This comment will be sent to CNSC management and other staff for consideration in projects specifically related to these concerns. Please see the full response to comment #12. That response is summarized here: - The CNSC's mandate is to ensure that the operation of nuclear facilities and activities is done safely. The CNSC does not set government policy. - To register to participate in NRCan's current initiative on modernizing Canada's radioactive waste policy: https://www.rncanengagenrcan.ca/en/collections/modernizing-canadas-radioactive-waste-policy - Some of these issues may be addressed by other regulatory documents that were published in January 2021. The CNSC apologizes if providing a list of "regulatory documents related to waste management" is construed as supporting your comment that "Canadians deserve to feel well informed about these proposed developments without having to wade through a mountain of documents that then reference other documents while hiding important information" (comment 12, above); that is not the intent. However, both of the topics that are mentioned (nuclear safety, and federal engagement with Indigenous communities) are wide-ranging and require a definitive level of detailed information; hence, the information cannot be provided in a single regulatory document. The CNSC has a well established policy and processes with regards to Indigenous consultation and engagement that aims to meaningfully consult and engage Indigenous peoples throughout the lifecycle of CNSC regulated facilities and activities. The CNSC engages Indigenous peoples on a wide variety of its regulatory processes and initiatives and its processes and approach are consistent with the principles outlined in the United Nations Declaration on the Rights of Indigenous Peoples

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			unable to find any reference to these actions by the nuclear industry contained in the proposed "program".	(UNDRIP). To learn more about the CNSC's approach to consultation, engagement and reconciliation please see: [Indigenous consultation, engagement and reconciliation - Canadian Nuclear Safety Commission] The CNSC strives to provide all stakeholders with access to the information and a forum to submit their comments and feedback.
16.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)	Section 1.2, Scope	The Scope requires additional clarity. Specifically: 1) The description of a Class 1B facility in the 1st paragraph is confusing. For instance, the difference between a plant and a facility is unclear. These should be consistent throughout the document. 2) The 2nd paragraph says, "For a deep geological repository (DGR), this regulatory document applies for the operational phase…" Why just a DGR? Shouldn't this be for all disposal facilities? This could lead to uncertainty as to how to address other types of disposal facilities. For clarity, the CNSC is urged to: 1) Use the definition of a Class 1B facility from the Class 1 facility regulations or from REGDOC 3.6 2) Amend the 2nd paragraph to be general to all disposal facilities. MAJOR -- The Scope of this document needs to clearly define a Class IB facility and be applicable to all disposal facilities, not just a DGR.	The text has been revised to provide additional clarity. Specifically: - The text quotes the regulations, with attribution. - The text has been separated into separate quotes for separate regulations, with cross-references where needed. - Where text from the regulations has been added, but does not apply to the scope of this regulatory document, an explanatory note has been added for clarity (for example, even though the regulations mention particle accelerators, this regulatory document does not apply to particle accelerators) - The phrase "deep geological repository (DGR)" has been replaced by "disposal facility"
17.	Brian Beaton, Coalition for Responsible Energy Development in New Brunswick	Section 1.2, Scope	The document is meant to "provide requirements and guidance for safety analysis of the following Class IB nuclear facilities: • a plant for the processing, reprocessing or separation of an isotope of uranium, thorium or plutonium • a plant for the manufacture of a product from uranium, thorium or plutonium • a plant, other than a Class II nuclear facility as defined in section 1 of the Class II Nuclear Facilities and Prescribed Equipment Regulations, for the processing or use, in a quantity greater than 1015 Bq per calendar year, of nuclear substances other than uranium,	The text being quoted in the comment has been revised for added clarity in response to comment 16. Overall, the issues raised go beyond the scope and immediate content of this draft regulatory document. The comments regarding the vendor designs and the DGR facilities will be shared with management and staff in the licensing and compliance divisions of the CNSC.

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			thorium or plutonium • a facility prescribed by paragraph 19(a) or (b) of the General Nuclear Safety and Control Regulations: • a facility for the management, storage or disposal of waste containing radioactive nuclear substances at which the resident inventory of radioactive nuclear substances contained in the waste is 1015 Bq or more note: for the scope of this regulatory document, some examples of these facilities include: • any facility for the storage of fissionable material before and after irradiation • any facility for associated waste conditioning, effluent treatment and facilities for storage of waste that allow for retrieval of the waste for later disposal • a plant for the production of deuterium or deuterium compounds using hydrogen sulphide "For a deep geological repository (DGR), this regulatory document applies for the operational phase, which includes the licensed activities conducted up to the closure of the repository. Some examples of licensed activities in the operational phase include: • any facility for the handling and packaging of fuel associated with a DGR • the operational activities at a DGR associated with the handling, packaging and placement of radioactive material in the DGR • safety analysis documents, records and reporting "This document is the first version of REGDOC 2.4.4, Safety Analysis for Class IB Nuclear Facilities." The DGR facilities remain hypothetical and consist of a lot of powerpoint and marketing presentations. These "vendor designs" are just marketing concepts that the nuclear industry is using to create the impression they are effectively dealing with the deadly poisons they created through the creation of these dump sites in far-away places that have nothing to do with the nuclear facilities that created these deadly radioactive waste materials in the first. Where are these facts highlighted in this so-called "safety analysis program"? "The DGR is just one possible solution for dealing with these facilities' waste material. And yet this proposed document makes the proposed DGR as the solution. There are way too many proposed solutions contained in this document that reflect a nuclear industry bias from the CNSC staff. This again highlights the conflict-of-interest between the nuclear industry and CNSC staff who produce and approve these types of documents."	The purpose of this regulatory document is to clarify requirements and provide guidance for applicants and licensees to demonstrate the safety of a Class IB nuclear facility, including disposal facilities (such as DGRs). While regulatory documents provide important information, the CNSC's process of verifying that licensees are in compliance with their licensing basis and are conducting their licensed activities in a safe manner is much more stringent; it also involves site inspections and the detailed licence renewal process. Some of these concerns may be addressed by other regulatory documents, especially the waste management and decommissioning documents published in January 2021: • REGDOC-1.2.1, *Guidance on Deep Geological Repository Site Characterization* • REGDOC-2.11.1, *Waste Management, Volume I: Management of Radioactive Waste* • REGDOC-2.11.1, *Waste Management, Volume III: Safety Case for the Disposal of Radioactive Waste, Version 2* • REGDOC-2.11.2, *Decommissioning* • REGDOC-3.3.1, *Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities*
18.	H. Ragheb, Safety Probe	Section 2.0,	The last paragraph lists the areas where the SAR is used. It appears that the last sentence	The formatting has been corrected. Our apologies; this was a

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	International	Safety Objectives	that starts with "develop and maintain …" is intended to be a third bullet but the bullet is missing. Additionally, we recommend that a fourth use (fourth bullet) should say: • confirm that the design of the facility meets design and safety requirements	formatting error in the HTML version provided for review, while the formatting in the PDF file was correct. You are correct, this is meant to be a third bullet and the CNSC will verify that it appears in the correct formatting in the final HTML version. Text has been revised as suggested; the fourth bullet has been added.
19.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)	Section 2.0, Safety Objectives	The Safety Objectives could be further clarified. Specifically: 1) In the 2nd paragraph, is "potential hazards" limited to radiological hazards? 2) The use of the word "it" is unclear in the 2nd sentence of the 3rd paragraph, which reads, "It is documented in a safety analysis report (SAR)." Similarly, it is unclear in the 5th paragraph, which reads, "A facility's SAR forms an important part of the licensing basis for the facility. It is used to:" 3) The SAR is also used to demonstrate safety. CNSC staff is urged to: 1) Clarify if "potential hazards" is limited to radiological hazards 2) Specifically state what "it" is. Otherwise, avoid using "it" 3) Add "demonstrate safety" to the use of the SAR.	Text has been revised for clarity, as follows: 1) "Potential hazards" are never limited to radiological hazards. Depending on the situation, "potential hazards" relating to nuclear activities and facilities include, but are not limited to, radiological hazards, hazardous chemicals, conventional hazards to health and safety, and the entire range of hazards mentioned in Appendix C (such as equipment failures, fires, tornados, flooding, and seismic events), to name just a few of the potential hazards mentioned throughout this draft regulatory document. This specific text has not been revised, because adding a sufficient range of examples would create a wordy, obtuse paragraph while bringing little additional value. 2) No change to text. The paragraphs follow standard rules of grammar; that is, unless otherwise specified, "it" is interpreted as referring to the noun in the sentence immediately preceding the sentence starting with "it". Hence: - "it" in the 2nd sentence of the (now 2nd) paragraph refers to the noun in the 1st sentence, and can be fully understood to mean "A safety analysis program is documented in a safety analysis report (SAR)" without burdening the reader with dense, repetitive text - "it" in the 5th paragraph (now 4th) can, likewise, be fully understood to mean "A facility's SAR is used to:" 3) No change to text. The phrase "The SAR is used to demonstrate safety" is a overall summary of the 4 (was 3; added one) specific points in the bulleted list.

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20.	H. Ragheb, Safety Probe International	Section 2.1, Defence in depth	Suggest adding the following to Level 1 definition for clarification: "The aim of the first level …. Relied upon for safety. This is achieved by good design and proven engineering practices"	Text has been revised to address the intent of the comment. The following text has been added: For more information on defence in depth, **including means of achieving its aims (such as good design and proven engineering practices),** see: • REGDOC-3.5.3, *Regulatory Fundamentals* [2] • IAEA SSR-4, *Safety of Nuclear Fuel Cycle Facilities* [3]
21.	P. Hader, Consultant	Section 2.1, Defence in depth	Defense in depth is a critical safety management approach for nuclear facilities. The requirement to demonstrate defense in depth needs to be a mandatory requirement.	Text has been revised to address the intent of the comment. The first paragraph of section 2.1 has been changed from "should" to "shall". This requirement is consistent with IAEA SSR-4: • Requirement 10: "The design of a nuclear fuel cycle facility shall apply the concept of defence in depth. The levels of defence in depth shall be independent as far as is practicable.") • para 6.24: "The safety analysis for a nuclear fuel cycle facility shall extend to the fourth and fifth levels of defence in depth." and with the second paragraph of section 4.5 of this regulatory document (REGDOC-2.4.4).

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22.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Ontario Power Generation (OPG)	Section 2.1, Defence in depth	Applying to sections 2.1 , 4.3.1, 4.7 and 5.2: The term "chemical hazards" is used throughout the document in the cited sections. Clearer scope and requirements are required for licensees to understand the CNSC's expectations when addressing hazardous materials, and chemical hazards in specific. Propose rewording "chemical consequences" and "chemical hazards" to the more generic "associated consequences" and "hazardous substances." This keeps the description general (maintaining chemical considerations) while not minimizing other potential consequences. In addition, CNSC staff is urged to provide clearer guidance as to expectations on chemical hazards. The release of hazardous substances may not lead to a criticality or radiological accident. CNSC needs to define the requirement for analyzing hazardous substances or chemical consequences. The introduction of chemical hazards has a potential impact across all regulatory documents concerning safety analysis. Chemical hazards are already covered within the broader category of radiological and hazardous substances. Licensees should have the option to either include chemical hazards inside in the safety analysis report or through a stand-alone mechanism."	Text has been revised throughout the document to use "nuclear and associated hazardous substances". This phrase is consistent with IAEA SSR 4, *Safety of Nuclear Fuel Cycle Facilities*.
	Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO)		Applying to sections 2.1 , 4.3.1, 4.7 and 5.2: The term "chemical hazards" is used throughout the document in the cited sections. Clearer scope and requirements are required for licensees to understand the CNSC's expectations when addressing hazardous materials, and chemical hazards specifically. Propose rewording "chemical consequences" and "chemical hazards" to the more generic "associated consequences" from "radiological and hazardous substances." This keeps the description general (and can incorporate chemical considerations) while not minimizing other potential consequences. In addition, CNSC staff is urged to provide clearer guidance as to expectations on chemical hazards. The release of radiological and hazardous substances may not lead to a criticality or radiological accident. CNSC needs to define the requirement for analyzing substances with chemical consequences. The introduction of chemical hazards has a potential impact across all regulatory documents concerning safety analysis. Chemical hazards are already	

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			covered within the broader category of radiological and hazardous substances. Licensees should have the option to either assess chemical hazards in the safety analysis report or through a stand-alone mechanism."	
23.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)	Section 2.1, Defence in depth	Additional clarity is required in this section. In addition to safety analysis, there is still a major role for the designers and operators -- including maintainers, trainers and management -- to play in defence-in-depth. As written, this guidance appears to have Safety Analysts assess the five levels as they perform their SA. But this is only possible if: the design was set up following this same process; knowledge of process-system or safety-related defences are clearly documented in the historical information; the records are readily available to future personnel More specifically, licensees believe additional clarity can be added in the following areas: 1) In the 1st sentence of the 2nd paragraph, what does "normally defined'" mean in this context? 2) The definition of AOO in Level 2 needs to be updated 3) A minor wording update is required in Level 4. 4) What is meant by the phrase "releases of radioactive material and associated hazardous material" in Level 3? Before finalizing this REGDOC, CNSC staff is encouraged to consider: • If this section is consistent with the licensing and design basis of the Operating IB facilities for all accidents. • If the levels are consistent with the consequences so a graded process in design can be used depending on the accident. • Whether this is a practicable back-fit if the design was not completed following this practice. • Whether the importance of integration of designers and operators to defence-in-depth in stated clearly. Also, CNSC staff is urged to: 1) Clarify what is meant by "normally defined" in this context. 2) Amend Level 2 to read, "The aim of the second level of defence is to detect, intercept and control deviations from normal operation in order to prevent anticipated operational	For each specific comment: 1) Text has been revised for clarity, to add "in accordance with the guidance provided in REGDOC-3.5.3, *Regulatory Fundamentals* [2]." 2) Text has been revised as suggested. Thank you for spotting that. 3) Text has been revised as suggested. Thank you for spotting that. 4) As discussed in comment 19, above, "hazards" are never limited to radiological hazards.

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			occurrences (AOOs) …" 3) Amend the 2nd sentence of Level 4 to read, "The most important objective for this level is to ensure that the containment function is maintained." 4) Clarify if this means only hazardous material with radioactive properties is to be looked at.	
24.	H. Ragheb, Safety Probe International	Section 2.2, Safety analysis objectives	Fifth bullet under "Requirements". I suggest the following addition: "operating experience, including experience from similar facilities and any applicable experience from other nuclear or industrial facilities"	Text has been revised as suggested, to add "and any applicable experience from other nuclear or industrial facilities"
25.	J. MacDonald, SRB Technologies (Canada) Inc.	Section 2.2, Safety analysis objectives	The requirement for the licensee to maintain 'adequate capability' to perform or procure safety analysis is vague. Without guidance on what is meant by 'adequate capability', and the process by which how this regulatory judgment is rendered, the document could introduce considerable uncertainty, and affect licensee resource distribution. Is it the Commission that renders the decision on whether a prospective licensee has 'adequate capability' when a licence is issued? Or is it a judgment of CNSC staff during compliance verification activities? Suggested change: Add guidance on what is meant by 'adequate capability' and which branch of the regulatory body ultimately makes that determination.	Text has been revised to add guidance on how an applicant or licensee may demonstrate 'adequate capability' and to add references where applicants and licensees can find additional information, as follows: **Guidance** Whether a licensee performs the safety analysis or procures a service that provides it, the licensee still holds the responsibility for that analysis. Supplier qualification requirements help to ensure adequate selection for the provision of a service, such as a safety analysis. Therefore, it is necessary for the licensee to possess the: • ability to qualify the supplier • ability to assess the sufficiency of the service provided For more information on demonstrating the capability of a licensee's staff to perform safety analysis, or on procuring safety analysis as a service, see: • CSA N286-12, *Management system requirements for nuclear facilities* [5] • IAEA Safety Guide No. GS-G-3.5, *The Management System for Nuclear Installations* [6] The two referenced documents provide the information as to who makes the assessment and how the assessment is verified.

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26.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)	Section 2.2, Safety analysis objectives	REGDOC-3.6's says the objective of "safety goals" is protecting workers, the public and the environment from releases of radioactive material. However, the safety analysis objectives in this draft suggest the goal is to protect against radioactive material and hazardous materials. Additional clarity is also sought in the following: 1) The requirement for the licensee to maintain "adequate capability" to perform or procure safety analysis is vague in the 1st paragraph under Requirements. Without guidance on what is meant by "adequate capability" - and the process by which this regulatory judgment is rendered - this document could introduce considerable uncertainty and affect licensee resource distribution. Is it the Commission that renders the decision on whether a prospective licensee has "adequate capability" when a licence is issued? Or, is it a judgment of CNSC staff during compliance verification activities? 2) The "shall" statement in the 2nd paragraph under Requirements implies all bullets are required when the last two bullets do not apply, or do not apply significantly, to all Class 1B facilities. 3) In the final bullet of the 1st paragraph, "data" is not the correct terminology since it means "facts and statistics collected together for reference or analysis." The SAR would provide outputs or estimates in most instances to support planning. 4) Under Requirements, the 1st paragraph should say "safety analysis basis", not "safety analysis", since the updates may not specifically require an update to the SAR every time. This should be clear or else this may result in significant work for every change. 5) The final bullet in the 2nd paragraph of the Requirements section is unclear. It currently reads, "Human factors considerations to ensure that credible estimates of human performance are used in the analysis" CNSC staff is urged to: 1) Add guidance on what is meant by "adequate capability" and which branch of the regulatory body ultimately makes that determination. 2) Add "as appropriate or applicable" to the introductory clause. 3) Change "data" to "results" or "outputs"	No change to text on safety goals, see changes to parts of other text below. "Safety analysis objectives" are compatible with "safety goals". As stated in section 4.3.1, *Identification of postulated initiating events*, the application of REGDOC-2.4.4 includes protection against • radiation exposure to workers or to the public • a release of significant amounts of nuclear substances • a release of hazardous substances (such as hazardous chemicals) associated with the nuclear substances which is consistent with IAEA SSR-4 (for example, paras 1.4, 1.8, 2.4, 2.13, 3.11, 6.1, 6.29, 6.43, 6.45, etc.). To provide additional clarity: 1) See response to comment #25. 2) Text has been revised to add "if applicable to the specific Class IB nuclear facility" to each of the last two bullets, to clarify that the last two bullets may apply, or may not apply, or do not apply significantly, to a particular Class IB facility (given the wide range of Class IB facilities). 3) Text has been revised to state "results" instead of "data". 4) No change in section 2.2. For additional context, this requirement ensures compliance with the *General Nuclear Safety and Control Regulations*. The intent of this comment is addressed in section 5.4, *Maintaining safety analysis documents and records*, which describes updates to the SAR. Section 5.4 has been revised to include the following text: "The updates may not specifically require an update to the SAR every time". 5) Text has been revised to improve the clarity; it now states "if applicable, **considerations of human factors** to ensure…"

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			4) Amend to read, "…safety analysis basis to:" 5) Change "human performance" to "human errors" and define what is deemed "credible estimates" of human performance Without these suggested amendments, licensees are concerned the draft is not aligned with other REGDOCs, specifically REGDOC-3.6. It could also create regulatory uncertainty - licensee cannot comply with inapplicable requirements. It's important to ensure public perception of what is presented in the SAR is clear to all potential readers.	As stated in the response to comments #4 and #9, REGDOC-3.6, *Glossary of CNSC Terminology*, will be revised to address these concerns.
27.	B. Walker, Canadian Nuclear Workers' Council	Section 3, Safety Analysis Program	The CNWC suggests adding a requirement to engage Employee Representatives in the Safety Analysis Program.	Text has been revised to incorporate the intent of the comment. This cannot be a "requirement", as requirements are set by the NSCA, the regulations and, in exceptional situations (such as responding to events like Fukushima), by the Commission. The following text has been added to the guidance: "In establishing the internal safety committees, the applicant or licensee should involve staff with a variety of perspectives; for example, employee representatives." See also response to comment #59.
28.	J. MacDonald, SRB Technologies (Canada) Inc.	Section 3, Safety Analysis Program	For smaller Class IB facilities, the concept of training a designated 'analyst' may not fit within the organizational structure / management system. Suggested change: Add 'if applicable' to the inclusion of training of analysts.	The text has been revised to remove Section 3.1, *Elements of a safety analysis program*, which includes removing the text referring to the concept of training an analyst. The topic of training is adequately addressed in REGDOC-2.2.2, *Personnel Training*.
29.	Cameco Corporation	Section 3, Safety Analysis Program	It is not clear whether the expectation is that licensees would include the safety analysis program in the safety analysis report or as a stand-alone document. Cameco does not believe that licensees should be required to develop specific program when other risk assessments required under the licensing basis (e.g. environmental risk assessments, fire hazard analysis) do not have a program that sets out the requirements. The REGDOC should set out the expectations for an acceptable safety analysis report in	The text has been revised to remove some prescriptive text (see comment 28). The remaining text describes the requirements at a high level and provides guidance. The text has been revised as follows: - The section cannot be deleted, because the first paragraph is a quote from every licence. The requirements and

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			accordance with the facility management system. This redundancy would require licensees to reallocate resources to maintaining a program without any corresponding safety benefit. Cameco recommends that this section of the REGDOC be deleted in its entirety.	guidance provide the context and further detail on what constitutes a safety analysis program. - The following text has been added to the Guidance: "The applicant or licensee is not required to create a separate document for the safety analysis program – neither a standalone document nor within the SAR.
30.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)	Section 3, Safety Analysis Program	Licensees have a significant concern with the Safety Analysis Program section. Specifically: 1) The REGDOC should be limited to the safety analysis required to ensure that risks are assessed and hazards controlled. No other "risk assessment" required under the licensing basis (ERA, DRL, FHA) requires a program for developing and maintaining the assessment. To introduce this requirement into this REGDOC is confusing and minimizes the significance of the analysis. 2) The 2nd paragraph on internal committees refers to "safety issues" and "safety matters." What is the difference? CNSC staff is urged to: 1) Revise the document to set out what a licensee needs to do to produce a safety analysis that meets the expectations under this SCA and remove the Safety Analysis Program section. 2) Explain the difference between "safety issues" and "safety matters." MAJOR -- Introducing this new requirement could force licensees to reallocate limited resources to comply without providing any corresponding benefit to nuclear safety.	Text has been revised for clarity and to provide additional guidance, as follows: 1) The section cannot be deleted, because the first paragraph is a quote from every licence. The requirements and guidance provide the context and further detail on what constitutes a safety analysis program. The text has been revised to remove Section 3.1, *Elements of a safety analysis program*. The following text has been added to the Guidance: "The applicant or licensee is not required to create a separate document for the safety analysis program – neither a standalone document nor within the SAR. 2) "Safety matter" has been changed to "safety issue". See also responses to comments 28 and 29.
31.	H. Ragheb, Safety Probe International	Section 3.1, Elements of a safety analysis program	1- I suggest adding another bullet to include program activities that may be conducted by third party, particularly offsite, such as computer codes owned and operated by contractors. The licensee usually ensures that these software are subject to acceptable quality assurance standards. The new bullet may read: "interfaces with third parties involved in safety analysis activities to ensure their compliance with applicable regulatory requirements and standards"	This comment no longer applies, because the text has been revised to remove Section 3.1, *Elements of a safety analysis program*. The requirements and guidance remain, but are now simply part of the overall Section 3.0, *Safety Analysis Program*.

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			2- I suggest removing the paragraph under "Requirement". It introduces "Essential elements" and defines them as policy "statements" which causes confusion with the program elements already defined in previous bullets in the same section as activities. Furthermore, the organization's public commitment to implement policies does not appear to be relevant.	
32.	P. Hader, Consultant	Section 3.1,	The guidance regarding the elements of the safety analysis program require some clarification. It should be completely clear which elements are mandatory "shall" requirements and which elements are useful but not mandatory.	The text has been revised for clarity and to provide guidance, as follows: • section 3.1, *Elements of a safety analysis program* has been removed • the requirements and guidance remain, but are now simply part of the overall Section 3.0, *Safety Analysis Program*
33.	J. MacDonald, SRB Technologies (Canada) Inc.	Section 3.1, Elements of a safety analysis program	For smaller Class IB facilities, the concept of training a designated 'analyst' may not fit within the organizational structure / management system. Suggested change: Add 'if applicable' to the inclusion of training of analysts.	The text has been revised to remove Section 3.1, *Elements of a safety analysis program*, which includes removing the text referring to the concept of training an analyst. The topic of training is adequately addressed in REGDOC-2.2.2, *Personnel Training*.
	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)		The information under Requirements is part of the licensing basis for Class 1B facilities and is found in other documents referenced in the facility Licence Conditions Handbook. Repeating these requirements is unnecessary. Also, for smaller Class IB facilities, the concept of training a designated "analyst" may not fit within their organizational structure / management system. Delete this section. The information is covered in the facility management system – which covers all licensed activities. If retained, add "if applicable" to the inclusion of training of analysts. MAJOR -- This section, as currently written, could force licensees to reallocate limited resources to comply without providing any corresponding benefit to nuclear safety."	
34.	Cameco Corporation	Section 4,	The facility classes used in this section were developed for reactors when the nature of the	See response to comment 35, below.

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		Safety Analysis	materials and the potential release mechanisms at a Class IB facility do not create the same potential for a wide-scale nuclear incident. The section goes on to require licensees to categorize and analyze based on these classes when the classes may have little or no practical application (e.g. facilities with low risk activities may have little to assess for the design-basis accident or design extension condition classes) and when the "shall" statements prohibit the application of a graded approach as discussed above. This creates regulatory uncertainty because a licensee cannot comply with an inapplicable requirement."	
35.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)	Section 4.1, Classification of events into facility states	Licensees have a series of concerns and clarifications regarding the Classification of events into facility states. Specifically: 1) As per comment #1, these categories were developed for Power Reactors and are not necessarily directly applicable for all class 1B facilities; they may just be an example of a model to be used. Additional information is required because Class 1B nuclear facilities are typically more reliant on worker operations and can consist of a variety of normal operations that may change based on the work requested. DEC is introduced as a new categorization and REGDOC-3.6 defines DEC as, "A subset of beyond-design-basis accidents that are considered in the design process of the facility in accordance with best-estimate methodology to keep releases of radioactive material within acceptable limits. Design extension conditions could include severe accident conditions. DEC is a plant state." This draft REDGOC requires licensees to perform assessments to ensure doses fall within emergency response guidelines. However, it is not clear if this is intended as a limited-scope adoption of DEC concepts for non-reactors. 2) The potential for a wide-scale nuclear incident is different in non-reactor facilities due to the nature of the materials in the process(es) and the potential release mechanisms – classification in this manner will make the analysis more complicated than is required to ensure safety of the facility, particularly for facilities with low risk activities that may have little to assess in DBA and DEC conditions. 3) The term "conditions" in the 3rd bullet is not necessary and may impede clarity. 4) As per comment #1, some terminology used for NPPs (such as "shutdown") may not	Text has been revised as follows: 1) No change to text: - Facility states are consistent with those defined and used in IAEA SSR-4, *Safety of Nuclear Fuel Cycle Facilities*; see the definition on page 134. - The definition and use of DEC in the draft REGDOC 2.4.4 is fully consistent with such national and international standards for Nuclear Fuel Cycle Facilities as IAEA SSR-4, CSA N292.0, .1, .3. - The definitions in REGDOC 3.6 will be reviewed and updated as appropriate, as part of that document's "evergreen" cycle. 2) No change to text. Based on CNSC staff's reviews of SARs, which were updated during the most-recent licensing cycle, CNSC staff's observation is that SARs of most licensees are already aligned with concepts of DBA and DEC conditions in this regulatory document. For new licences, current text of the regulatory document on concepts of DBA and DEC is important due to the following reasons. The potential may be different; however, an assessment of the potential must be performed in accordance with the defence in depth concept (Fundamental Safety Principles, IAEA Safety Standards Series No. SF-1, Principle 8; IAEA SSR-4, paras 2.10-2.14, 6.19-6.27) for all five levels of defence

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			have the same definitions for Class IB nuclear facilities. For example, "shutdown state" is defined in REGDOC-3.6 as "A subcritical reactor state with a defined margin to prevent a return to criticality without external actions. See also guaranteed shutdown state; safe shutdown state." 5) The requirement is to classify events into AOOs, DBAs or BDBAs, "or equivalent." As per comment #1, it is likely multiple Class 1B facilities have not constructed their safety analysis based on this classification, typically used in nuclear power plants. The requirement should be more explicit for alternative, equivalent classifications so that it is interpreted accurately by regulator and licensee. CNSC staff is urged to: 1) Provide additional guidance for normal operations assessments. If DEC is intended to be in scope as presented: recommend the adoption of separate terminology to avoid conflation with reactor-space specific requirements. In addition, delineation on adoption requirements needs to be made for existing versus new facilities. If the selection of previously-BDBA frequency occurrences is also now required to have design provisions: requirements for what level of design and operational features are required should be defined in this regulatory document. In addition, delineation on adoption requirements needs to be made for existing versus new facilities. 2) Replace "shall" with "may" in the second paragraph or add "as applicable" to the end of the sentence or require safety analysis for credible scenarios. 3) Amend the 3rd bullet to read, "DBA." It's unclear why "conditions" is beside only DBA, since each of the states will result in conditions that are different in nature. Should the document first say it wants the states classified into these states? 4) Consider replacing terminology or providing alternate definitions for all terms that could be applied to Class IB facilities. 5) Amend the 1st paragraph to read, "…within BDBA referred to as design extension conditions (DEC). Alternative classification schemes may be used as long as they meet the same probability-based intent." MAJOR -- As written, this draft creates regulatory uncertainty; licensee cannot comply	including DBA and DEC. Note that this section does not prescribe the level of complexity. As per sections 4.7 and 4.8, the complexity of the analysis is the responsibility of the applicant or licensee who needs to demonstrate compliance with acceptance criteria and safety goals. As per section 4.1, the list of DBA and DEC conditions is determined by the licensee based on the identification and classification of postulated initiating events (PIE). 3) The term "conditions" has been removed. 4) REGDOC-3.6, *Glossary of CNSC Terminology* will be revised to add clarity to the definition of shutdown for non-reactor facilities. 5) These terms are used in national and international standards for Nuclear Fuel Cycle Facilities. The requirement already provides flexibility and allows "equivalent" terminology. Text has been added as guidance to provide additional clarity. 1) No change. Detailed guidance is provided in the following appendices: -Appendix B: Sample Parameters for Operational Limits and Conditions -Appendix C: Postulated Initiating Events 2) No change. Based on CNSC staff's reviews of SARs, which were updated during the most-recent licensing cycle, CNSC staff's observation is that SARs of most licensees are already aligned with these concepts in this regulatory document. For new licences, current text of the regulatory document on credible scenarios is important because safety analysis is to include the mandatory applicability of IAEA principles and concepts to the safety of nuclear fuel cycle facilities. 3) Text about "DBA conditions" has been revised to just "DBA".

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			with inapplicable requirements. Class 1B facilities can be complex facilities with varying operations. What is the expectation for Normal Operations? As presented, the inclusion of DEC represents a significant and immediate escalation in the requirements for safety analysis of existing nuclear facilities. What should be used to define DEC values and analysis methodologies to be used to assess the design against DEC values? Please see related remarks regarding Section 4.8, Safety Goals.	4) REGDOC-3.6, *Glossary of CNSC Terminology* will be revised to add clarity to the definition of shutdown for non-reactor facilities. 5) The following text has been added as guidance to provide additional clarity: **Guidance** As indicated by the phrase “or equivalent”, above, the applicant or licensee may use an alternative classification scheme, provided the classifications meet the same risk-based intent.
36.	H. Ragheb, Safety Probe International	Section 4.2, Safety analysis assumptions	I suggest adding, under “Requirements” the following bullet to ensure accessibility of the operator to location where action is to be taken: “Credible, protected and accessible path for the operator to carry out safely the actions required in the procedures”	Text has been revised as suggested.
37.	J. MacDonald, SRB Technologies (Canada) Inc.	Section 4.2, Safety analysis assumptions	The depth of the requirements for qualified systems and operator actions may be disproportionate to the risk profile of said facility. Linking the requirements of this document with requirements in the NPP realm (REGDOC 2.5.2) does not consider the differentiation between risk profiles of Class 1A and 1B facilities. The depth of analysis on these fronts should be commensurate with the risks posed by the facility, and mandating ‘qualification’ on safety systems is a significant leap from current practice. If the concept of NPP-style qualification of safety systems is imposed on smaller Class IB licensees such as SRBT, the effect on risk would likely be marginal, while a significant amount of resources may need to be diverted to this initiative and allocated to ensure compliance. Suggested change: Remove the requirements pertaining to the ‘qualification’ of systems, and instead use terminology / language that is graded to the lower risk profiles of Class IB facilities in Canada.	Text has been added to provide clarity that the reference is provided for information only. The cross-reference to REGDOC-2.5.2, *Design of Reactor Facilities* is provided in the Guidance subsection simply as a source of additional information on crediting systems important to safety. The applicant or licensee is not required to apply the requirements of REGDOC-2.5.2 to a Class IB facility. Text now states: For more information on crediting SSCs important to safety, see REGDOC-2.5.2, *Design of Reactor Facilities* [7]. Note: This reference is provided only as a source of information; the applicant or licensee does not need to apply the requirements or other guidance in REGDOC-2.5.2 to their safety analysis for a Class IB nuclear facility.

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38.	J. MacDonald, SRB Technologies (Canada) Inc.	Section 4.2, Safety analysis assumptions	The technical justification for imposing a temporal delay in operator actions is not clear. If these are standard times for NPP safety management, this requirement does not consider the differentiation between risk profiles of Class 1A and 1B facilities. Mandating NPP-level delay times may in turn require Class IB licensees to significantly change facility process and safety system designs in order to meet safety objectives, where operator actions previously were credited without this magnitude of delay based on operating experience and in-force safety analyses. Suggested change: Allow licensees to assess reasonable temporal delays in operator actions that are in line with realistic scenarios, instead of defaulting to these values, when analysing chains of events.	No change. The temporal delays are listed as guidance. Further, this draft regulatory document states that operator action time credited in the safety analysis report (SAR) shall be justified by the applicant or licensee. Thus, applicants and licensees are already allowed to assess reasonable temporal delays in operator action that are in line with realistic scenarios. Operator action times are important for every Class IB facility that is within the scope of this regdoc. This is important for such possible PIEs as a tornado warning.
	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)		Licensees have a series of concerns with the safety analysis assumptions section. Specifically: 1) As per comment #1, the depth of the requirements for qualified systems and operator actions may be disproportionate to the risk profile of said facility. Linking the requirements of this document with requirements in the NPP realm (REGDOC 2.5.2) does not consider the differentiation between risk profiles of Class 1A and 1B facilities. The depth of analysis on these fronts should be commensurate with the risks posed by the facility, and mandating 'qualification' on safety systems is a significant leap from current practice. 2) The technical justification for imposing a temporary delay in operator actions is not clear. As per comment #1, if these are standard times for NPP safety management, this requirement does not consider the differentiation between risk profiles of Class 1A and 1B facilities. 3) Similarly, with respect to an action to be performed by an appropriately qualified individual at the control location or response location, the guidance as written requires grouping potentially different responses into a single, overly pessimistic model. 4) The word "shall" is inappropriately included twice in the Guidance portion of this section.	1) No change. See response to comment #37. 2) No change. As described above, the temporal delays are listed as guidance. 3) No change. The guidance is provided as guidance; applicants and licensees have the option to group potentially different responses as best suits their activity or facility; however, the applicant or licensee must justify the option. 4) Text has been revised for clarity. The implicit requirement of "The applicant or licensee shall set operator action times." has

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			CNSC staff is urged to: 1) Remove the requirements pertaining to the 'qualification' of systems, and instead use terminology / language that is graded to the lower risk profiles of Class IB facilities in Canada. 2) Allow licensees to assess reasonable delays in operator actions that are in line with realistic scenarios, instead of defaulting to these values, when analysing chains of events. 3) The ambiguous category of "operator action" should be divided into meaningful categories, such as: • Performance of complex emergency procedures (more than one discrete action, system feedback required) • Activation of an alarm • Actuation of equipment emergency stop • Initiation of a manual fire suppression system • Evacuation 4) Change the two "shall" references in the Guidance section to "should." Otherwise, move the statements to the requirements area. MAJOR -- If the concept of NPP-style qualification of safety systems is imposed on smaller Class IB licensees, the effect on risk would likely be marginal, while a significant amount of resources may need to be diverted to this initiative and allocated to ensure compliance. Mandating NPP-level delay times may in turn require Class IB licensees to significantly change facility process and safety system designs to meet safety objectives, where operator actions previously were credited without this magnitude of delay based on operating experience and in-force safety analyses. The proposed delay is long, and exceeds the expected duration to both respond to a simple event and evacuate an associated, potentially high-radiation exposure area. This would require the introduction of additional, substantial pessimism into conservative safety cases for existing and new facilities.	been specifically added, and the two "shall" statements that were in the guidance have been moved to align with that text. This revision is consistent with the provisions of IAEA SSR-4, paragraphs 6.14, 6.21d and 6.84. The delay times are provided in the guidance; they are not mandatory. These delay times are examples of what is used at some Class IB nuclear facilities. Applicants and licensees have flexibility to use other delay times; however, the applicant or licensee must justify their delay times.
			Further feedback based on the CNSC's response: Please see industry's response to comment #39 below.	See response to comment 39.

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39.	Cameco Corporation	Section 4.3, Postulated initiating events	Regarding 4.3 Postulated initiating events, given the broad range of tools a licensee may use, it is unclear what analysis details the licensee is expected to provide. Cameco recommends that each requirement provide corresponding guidance to clarify expectations.	No change. The requested detailed guidance is already provided in appendix C, *Postulated Initiating Events*. In section 4.3, a reference is provided to this appendix.
	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)	Section 4.3, Postulated initiating events	Given the broad range of tools which may be used, it is unclear what analysis details the licensee is expected to provide. Provide guidance that corresponds to the 'Requirements'.	
			Further feedback based on the CNSC's response: External hazards such as earthquakes, high winds, etc., to which a site is susceptible are assessed for their magnitudes versus a range of annual frequency of exceedances (=1/(return period)). As guidance, paragraph 3.14 in IAEA SSG-2 states that "postulated initiating events should be defined in such a way that it covers all credible ***failures***." ***[emphasis added]***. This is consistent with CNSC staff's response to comment #41 below. However, IAEA SSR-4 appears to apply a disparate process where PIE's have been defined more broadly to include external hazards as well, which is likely to cause regulatory and licensee confusion in the future on how to apply external hazards in the safety assessment of facilities. IAEA guidance is typically adopted in Canada (where applicable) through the REGDOC process, which includes adapting the guidance for the Canadian context. For example, the approach in REGDOC-2.4.1 for treating external hazards would meet the overall intent of SSR-4 and would remain consistent with the approach used in the safety analysis for other facilities in Canada. That being said, external hazards, including those listed in Appendix C item 8, *do not necessarily lead to a failure* (PIE) in the sense of a traditional safety analysis approach or an accident condition or a release. Failures depend on the design robustness of facilities and any exposed equipment. If the facilities' structures can protect what is inside up to a defined DEC review level condition beyond the design basis, then the external hazard	IAEA SSG-2 is for nuclear power plants. IAEA SSR-4 is similar but broader. However, the requirement in section 4.3 states: The applicant or licensee shall identify PIEs (both internally and externally initiated) that could lead to: • radiation exposure to workers or to the public • a release of significant amounts of nuclear substances a release of hazardous substances (such as hazardous chemicals) associated with the nuclear substances Thus, there is no potential for confusion and there is no difference between the intent of IAEA SSR-2 and SSR-4. External events are identified at the beginning of the process and identified by the licensee as "credible" or "not credible" for that facility. The licensee starts with a wider range and then decreases to the range to "credible". It is the licensee's responsibility to identify the events that do not necessarily lead to a failure.

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			could be screened from further consideration. To ensure consistency with past practice in verifying the plant is safe from potentially changing external hazard magnitudes and annual frequencies of exceedance (AFE), the approach adopted in the closure criteria for Fukushima Action Item 2.1.2 (see e-Doc 4079868) should be applied. In this way, adequate design protection is evaluated and assured for both design basis and beyond design basis hazards magnitudes (AFE of 1E-04/yr for beyond design basis hazards), which can be of probabilistic or deterministic nature, or a combination of both. Regardless, external hazards/events should not be referred to as Postulated Initiating Events, similar to the approach in REGDOC-2.4.1. They need to be considered, but they do not necessarily result in a PIE by definition.	This identification (credible or not credible) is the 2nd step of the licensee's 3-step analysis. The CNSC is not asking licensees to run safety analysis on events that, for that facility, would not lead to an accident. Regarding the reviewer's text "That being said, external hazards, including those listed in Appendix C item 8, *do not necessarily lead to a failure* (PIE) in the sense of a traditional safety analysis approach or an accident condition or a release"… … Appendix C is an information reference that the applicant or licensee may use to meet the requirements of section 4.3. As follows from section 4.3, it is the responsibility of the applicant or licensee to assess all potential hazards and select all appropriate ones for further safety analysis. Regarding the reviewer's text "Regardless, external hazards/events should not be referred to as Postulated Initiating Events"… … CNSC staff cannot identify any issues in the existing wording. The requirement in section 4.3 states that "the applicant or licensee shall identify PIEs (both internally and externally initiated) that could lead to…"
40.	H. Ragheb, Safety Probe International	Section 4.3.1, Identification of postulated initiating events	In the second bullet under "Requirement" I recommend changing the word "significant" with the corresponding licensed limits for releases from the facility. The requirement may read: "A release of amounts of nuclear substances exceeding the allowable limits for the facility"	No change to section 4.3.1. The intent of the comment is already included in section 4.3.2, *Classification of postulated initiating events*, where identified PIEs are analysed and the consequences compared to the acceptance criteria. The primary purpose of section 4.3.1 is to identify the broadest range of PIEs (that is, all "PIEs that could lead to"). This requirement for identification ensures that no "PIEs that have a potential to lead to a violation of the acceptance criteria" are excluded from further analyses.

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				"Significant" is contextual; that is, "as compared to the licensed release limits for the specific activity or facility". Therefore, "significant" is activity- or site-specific.
	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)		Further feedback based on the CNSC's response: Please see industry's response to comment #39.	See response to comment 39.
41.	Cameco Corporation	Section 4.3.1, Identification of postulated initiating events	Cameco also strongly recommends that the sub-bullets in second bulleted list in section 4.3.1 at the top of page 7 be replaced with "This list should be developed through a comprehensive assessment of credible failures of the facility's structures, systems, and components (SSCs) and documentation of credible human errors that could occur in any of the operating conditions of the facility." It is impossible to audit or verify the requirements as drafted.	The suggested text has been added as guidance. However, no change to the requirements, because it is aligned with, and addresses, the provisions of clause 6.50 of IAEA SSR-4.
			Further feedback based on the CNSC's response: Please see industry's response to comment #39. PIE's are traditionally defined in safety analysis in the context of credible failures. External hazards do not necessarily lead to a PIE and should be treated separately from other credible failures.	See response to comment 39.

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42.	J. MacDonald, SRB Technologies (Canada) Inc.	Section 4.3.1, Identification of postulated initiating events Section 4.3.1, Identification of postulated initiating events	The depth of the requirements for establishment and review of Class IB PIEs may be disproportionate to the risk profile of said facility. There is little difference between what is required of Class IA and 1B. If there is a mandated level of technical expertise required for all Class IB facilities, the effect on risk would likely be marginal, while a significant amount of resources may need to be diverted to this initiative and allocated to ensure compliance. Suggested change: Use terminology / language that is graded to the lower risk profiles of Class IB facilities in Canada - for example, mandating the use of experts in safety analysis may be excessively prescriptive. What is an 'expert' in this context – someone with experience doing safety analyses in power plants? Someone with an expert-level of understanding of the unique facility processes and systems?	Guidance in this section has been enhanced, using the text suggested by the commenters. No change to requirements, as the requirements are consistent with national and international standards for Class IB nuclear facilities; for example, IAEA SSR-4; IAEA Safety Standards Series No. SF-1; and CSA N292.0, .1, and .3). The terminology is fully consistent with such national and international standards for Nuclear Fuel Cycle Facilities as IAEA SSR-4, CSA N292.0, .1, .3. REGDOC-3.6, *Glossary of CNSC Terminology* will be revised to add the definitions as they apply to Class IB nuclear facilities.
	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)		Additional clarity is sought for the following: 1) As per comment #1, the depth of the requirements for establishment and review of Class IB PIEs may be disproportionate to the risk profile of said facility. There is little difference between what is required of Class IA and 1B. 2) Under Requirements, "List of PIE" on the 1st line of page 7 is a specific description and could take on many forms. Recommend rewording. 3) The 2nd bullet under Requirements, which reads, "A release of significant amounts of nuclear substances" is unclear. 4) The use of "all" in the sub-bullets on page 7 cannot be verified or audited. 5) Additional clarity could be added to Appendix C as per the 1st sentence in section 4.3.1 which reads, "The applicant or licensee shall identify PIEs (both internally and externally initiated) …" CNSC staff is urged to: 1) Use terminology/language that is graded to the lower risk profiles of Class IB facilities in Canada. This list shall be created using a structured and documented process as opposed to focusing on the expertise of technical staff.	1) See response to comment 41, above. 2) Guidance has been added to incorporate the intent of the comment. 3) No change to this document. "Significant" is contextual; that is, "as compared to the acceptance criteria for the specific activity or facility". Therefore, "significant" is activity- or site-specific. For comparison to acceptance criteria, see section 4.7. 4) No change to the subbullet points. The complete phrase, "all credible", provides context. Guidance has been added to state that the list can be revised whenever the applicant or licensee identifies a credible failure or credible human error that has not yet been included in their list. 5) For additional clarity on transport: - in appendix C, item 7, "special internal events", the last bullet has been revised to add the word "internal" to "transport routes" - appendix B provides examples of material handling, including requirements for onsite transfer and offsite

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			2) Make "list of PIE" more generic, or provide clarification on this, since it should be able to take on many forms depending on the complexity of the facility. This can be captured in SAR and subsequent reviews. 3) Clarify what is meant by "significant amounts" in the 2nd bullet. 4) Revise to read, "This list should be developed through a comprehensive assessment of credible failures of the facility's structures, systems, and components (SSCs) and documentation of credible human errors that could occur in any of the operating conditions of the facility" 5) Clarify Appendix C to separate transport and handling to-and-from the facility from transport within the facility since the hazards along the routes and steps are different. Both should be included in Chapter 7 of the SAR. MAJOR -- This section, as currently written, could compel licensees to reallocate limited resources to comply with its requirements without any corresponding benefit to nuclear safety."	transportation as a limiting condition for safe operation of the facility.
			Further feedback based on the CNSC's response: Please see industry's response to comment #39.	See response to comment 39.
43.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)	Section 4.3.2, Classification of postulated initiating events	This section precedes the section on Safety Assessments, yet starts with "During the Safety Assessment." It is used before being introduced or explained. According to the CNSC glossary, a safety assessment is "an assessment of all aspects relevant to safety of the siting, design, construction, commissioning, operation or decommissioning of a nuclear facility." Therefore, the scope of the safety assessment seems to be broader than the scope of the safety analysis, yet the safety assessment is contained within the scope of the safety analysis. This REGDOC should remain focused on the "Safety Analysis" required for a Class IB facility per the Regulations. "	No change. Section 4.3 provides information on preparation for a safety assessment. The applicant or licensee must consider the identification and classification of PIEs before commencing the safety assessment, where the applicant or licensee shall classify them. Section 4.3 is a proactive step in preparation for section 4.4. The applicant or licensee must demonstrate that they have met the requirements and considered the guidance in this regulatory document; however, the applicant or licensee can achieve the requirements in any order before submitting their safety analysis to the CNSC.

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44.	M. Stephens, AECL (retired)	Section 4.4, Safety assessment	Safety analysis is defined in Clause 2.0. Safety assessment is defined (I think) in Clause 4.4. The relationship between them is not clear. Does one include the other; do they just overlap a bit? A Figure showing how they fit together would be helpful.	No change to this regulatory document. The terms are used in this draft in accordance with their definitions in REGDOC-3.6, *Glossary of CNSC Terminology*. CNSC staff will review the terms in REGDOC-3.6 and, if more clarity can be provided, the definitions will be adjusted in the next update of REGDOC-3.6.
45.	J. MacDonald, SRB Technologies (Canada) Inc.	Section 4.4.1, Assessment of consequences	Mandating the validation of computational tools for smaller Class IB facilities may be disproportionate to the risk profile of said facility. Smaller licensees may rely on commonly available commercial modeling / data analysis software. Depending on the degree and rigour of the validation process mandated, the effect on risk would likely be marginal, while a significant amount of resources may need to be diverted to this initiative and allocated to ensure compliance. Suggested change: Ensure that the level and rigour of validation of computational tools is commensurate with the level of risk.	Text has been revised to add guidance for this section, using the informational points provided by the commenters. No change to the requirements. For more information on demonstrating validation of software tools, see section 6 of this regulatory document (REGDOC-2.4.4) and CSA N286.7-16, *Quality assurance of analytical, scientific and design computer programs*.
	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)		Mandating the validation of computational tools for smaller Class IB facilities may be disproportionate to the risk profile of said facility. Smaller licensees may rely on commonly available commercial modeling/data analysis software. Why does the applicant or licensee have to validate computational tools? CNSC staff is urged to: 1) Ensure the level and rigour of validation of computational tools is commensurate with the level of risk. 2) Amend the 2nd sentence of the 2nd paragraph to read, "The applicant or licensee shall use validated computational tools to calculate consequences." MAJOR -- Depending on the degree and rigour of the validation process mandated, the effect on risk would likely be marginal, while a significant amount of resources may need to be diverted to this initiative and allocated to ensure compliance.	
46.	P. Hader, Consultant	Section 4.4.3,	The CNSC might want to improve the clarity about which methods besides the methods	Text has been revised to clarify the intent of the list of examples

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		Examples of acceptable methods	described by the IAEA are acceptable. For instance there are a variety of analyses methods that are labelled as HAZOP and FMEA but not all of these would provide an effective assessment.	of acceptable methods; that is, that "typically for Class IB nuclear facilities", the applicant or licensee uses one of the methods provided as examples. As mentioned in the comment, not all options for analysis methods would be acceptable to the CNSC for a safety analysis for a Class IB nuclear facility.
47.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)	Section 4.4.3, Examples of acceptable methods	The title of this section is unclear. The word "acceptable" implies other options may not be acceptable. Reword to read, "Examples of Safety Analysis Methods".	Some other options may, indeed, not be acceptable to the CNSC. However, this section is intended as guidance towards methods that will be accepted for a safety analysis for a Class IB nuclear facility. Text has been revised such that the list of examples of acceptable methods is now guidance within section 4.4.2.
48.	J. MacDonald, SRB Technologies (Canada) Inc.	Section 4.5, Identification of structures, systems and components important to safety	Mandating the described level of environmental qualification of SSCs does not consider the risk profile of the facility. Depending on the degree and rigour of the qualification of SSCs for environmental extremes mandated, the effect on risk would likely be marginal, while a significant amount of resources may need to be diverted to this initiative and allocated to ensure compliance. Suggested change: Environmental qualifications should be permitted to be reasonable and justifiably aligned with the risk profile of said facility.	No change, since the described level of environmental qualification of SSCs does consider the risk profile of the facility as explained below. - The existing text for the environmental qualification of SSCs does consider the risk profile of the facility: - The text includes the explicit qualifier: "To be consistent with the safety analysis results". - In the safety analysis, the applicant or licensee should have determined the risk profile of the facility. The qualification of SSCs for environmental extremes is mandated to be consistent with the risk profile. For further guidance, see section 7, Graded approach. - REGDOC-2.4.4 is consistent with Requirement 13 of IAEA SSR-4, *Safety of Nuclear Fuel Cycle Facilities*.
49.	Cameco Corporation	Section 4.5,	In section 4.5, the information for the requirements in the bulleted list is included in	No change. This concern is already addressed in section 5.2,

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		Identification of structures, systems and components important to safety	maintenance programs or design control and it is unclear whether this information must be included in a safety analysis report. Cameco recommends that the REGDOC include a statement that the requirements would be met by providing links or references to the document in which the information is stored to avoid unnecessary administrative burden.	"Content of safety analysis documents and records", as follows: - The SAR shall contain a representative summary of the safety analysis documents and records. **- Guidance** The applicant or licensee may incorporate information by reference.
50.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)	Section 4.5, Identification of structures, systems and components important to safety	Licensees have a series of concerns and clarifications related to this section. Specifically: 1) The 2nd paragraph says, "For each event sequence applicant or licensee SHALL identify the administrative safety requirements that are used to implement the defense in depth concept. Section 2.1 says that defence in depth SHOULD be addressed. 2) As per comment #1, mandating the described level of environmental qualification of SSCs does not consider the risk profile of the facility. 3) What is 'important to safety' and how is the importance to safety threshold determined? Without this definition, the system will be artificially driven to be 'important to safety' when not required resulting in excess costs and effort. REGDOC-3.6 defines SSC important to safety as: "Systems of a reactor facility associated with the initiation, prevention, detection or mitigation of any failure sequence and that have an impact in reducing the possibility of damage to fuel, associated release of radionuclides or both. OR "With respect to reliability programs for a reactor facility, those structures, systems and components of the facility that are associated with the initiation, prevention, detection or mitigation of any failure sequence and that have the most significant impact in reducing the possibility of damage to fuel, associated release of radionuclides or both." 4) The section title includes "structures, systems and components important to safety." Prior to this section, this is termed "systems important to safety." The appendices refer to "items important to safety." REGDOC-3.6 defines "systems important to safety." The terminology must be consistent. 5) It is unclear whether the details required by the bulleted list are to be included in the	Some text has been revised for clarity, as follows: 1) In response to an earlier comment, section 2.1 has been revised to state the applicant or licensee <u>shall</u> address the concept of defence in depth. 2) No change. The existing text for the environmental qualification of SSCs does consider the risk profile of the facility. See also response to comment #48. 3) As described in responses to earlier comments, the terminology is fully consistent with such national and international standards for Nuclear Fuel Cycle Facilities as IAEA SSR-4, CSA N292.0, .1, .3; and REGDOC-3.6, *Glossary of CNSC Terminology*, will be revised to add the definitions as they apply to Class IB nuclear facilities. 4) Text has been revised for clarity. Thank you for noting this discrepancy. Throughout this regulatory document, the terms "systems important to safety" and "items important to safety" have been revised to "SSCs important to safety". REGDOC-3.6, *Glossary of CNSC Terminology*, will be revised to add the definition for "SSCs important to safety" as it applies to Class IB nuclear facilities. 5) No change. See response to comment #49.

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			SAR when this information is included in maintenance programs or design control. 6) Under Requirements, 3rd paragraph final bullet - given that availability and reliability targets are required, this suggests that some kind of quantitate analysis is required for SSC important to safety. Require clarification for the level of targets required. CNSC staff is urged to: 1) Address the should/shall discrepancy 2) Environmental qualifications should be permitted to be reasonable and justifiably aligned with the risk profile of said facility 3) Consider that the definition of an SSC important to safety does not align with operations in a Class 1B facility, especially for a facility which doesn't handle fuel. Additional consideration is required in defining SSC important to safety for a Class 1B nuclear facility. 4) Replace with "structures, systems and components important to safety (SSCs important to safety)" throughout. Note this would need to be incorporated in REGDOC-3.6. 5) This section should specify that the requirements are met by providing links or references to the document in which the required information is stored. 6) Change to "Where applicable…"To ensure compliance, licensees need firm direction on SHALL versus SHOULD language. Depending on the degree and rigour of the qualification of SSCs for environmental extremes mandated, the effect on risk would likely be marginal, while a significant amount of resources may need to be diverted to this initiative and allocated to ensure compliance. Also, licensees need clear guidance on what is "significant." Otherwise, this will result in inconsistencies as to how risk is handled across the industry and increased public scrutiny/questions.	6) No change. The text includes the explicit qualifier "as established in the safety analysis". The safety analysis is to use likelihood categories and corresponding acceptance criteria for each category, and therefore the availability and reliability targets are to be consistent with these.
51.	P. Hader, Consultant	Section 4.6,	Staff availability and competency are a critical component of the operational conditions	Text has been revised for clarity by incorporating some of the

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		Operational limits and conditions	and therefore the minimum requirements for availability of competent staff must be part of the OLCs. The wording needs to be revised to clarify this.	suggested wording. However, the information about minimum requirements for the availability of staff is guidance for safety analysis and remains as "should". Further information on the applicability of this component of the operational conditions to various activities and facilities is available in the referenced document (REGDOC-2.2.5). See also response to comment #52.
52.	J. MacDonald, SRB Technologies (Canada) Inc.	Section 4.6, Operational limits and conditions	The concept of minimum requirements for the availability of staff should not be automatically referenced. REGDOC 2.2.5 states that "expectations for use of this document will vary with the complexity of facility operations and the consequences of potential events on the environment, health and safety of persons, and maintenance of national security and measures required to implement international obligations". This allows for a level of judgment commensurate with risk, which may be lost with the current text of the draft REGDOC 2.4.4. Depending on the application of REGDOC 2.2.5 against the requirements of this draft REGDOC, the effect on risk would likely be marginal, while a significant amount of resources may need to be diverted to this initiative and allocated to ensure compliance. Suggested change: Add language such as 'if warranted' to account for smaller, less complex facilities of a lower risk profile.	No change to text. The information about minimum requirements for the availability of staff is clearly identified as guidance (subheading and "should"). Further information on the applicability of this component of the operational conditions to various activities and facilities is available in the referenced document (REGDOC-2.2.5). Adding any text such as "if warranted" to this regulatory document (REGDOC-2.4.4) creates a risk of unintended changes to the application of REGDOC-2.2.5. See also response to comment #51.
	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)		The concept of minimum requirements for the availability of staff should not be automatically referenced. REGDOC 2.2.5 says, "expectations for use of this document will vary with the complexity of facility operations and the consequences of potential events on the environment, health and safety of persons, and maintenance of national security and measures required to implement international obligations." This allows for a level of judgment commensurate with risk, which may be lost with the current text of the draft REGDOC 2.4.4. Add language such as 'if warranted' to account for smaller, less complex facilities of a lower risk profile.	

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			Depending on the application of REGDOC-2.2.5 against the requirements of this draft REGDOC, the effect on risk would likely be marginal, while a significant amount of resources may need to be diverted to this initiative and allocated to ensure compliance.	

53.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)	Section 4.7, Acceptance criteria	Licensees have a series of clarifications related to acceptance criteria. Specially:
			
			1) The term 'associated chemical consequences' is written here, when associated hazardous materials has been used previously.
			
			2) The way this is written it sounds like the chemical emergencies are separate from the radiological emergencies, when, based on how the document has been written to this point, the hazardous materials are associated with the radiological material.
			
			3) Why is 'or hazardous material' here? Isn't the intent to prevent releases of nuclear material and associated hazardous materials? So, if you prevent the radiological release, there will by definition, be no associated hazardous material released. The way this is written it sounds like the radiological and hazardous materials are to be treated separately, when, based on the document up to this point, they are linked.
			
			4) REGDOC-3.6 defines severe accident as, "An accident more severe than a design-basis accident and involving severe fuel degradation in the reactor core or wet storage bay." Does 'in the reactor core or wet storage bay' apply to class 1B facilities?
			
			CNSC staff is urged to:
			
			1) Amend the 2nd paragraph to read, "…shall set limits on consequences from releases of radioactive and associated hazardous materials" for consistency.
			
			2) Clarify the intent of this reference
			
			3) Clarify why the phrase "or hazardous material" is used.
			
			4) Clarify if 'in the reactor core or wet storage bay' applies to class 1B facilities.
				Text in this section has been revised due to an issue identified outside of consultation on this document. In response to these specific comments from consultation:
				1) No change to text. The terminology is consistent. Hazardous materials may lead to 'associated chemical consequences'.
				
				2) Throughout the document, the phrase has been standardized to "nuclear and associated hazardous substances".
				
				3) Text has been revised slightly to state "or associated hazardous substances". As described above, the hazardous materials are associated with the radiological materials, but may lead to chemical consequences. CNSC staff consider that the text "The applicant or licensee shall establish derived acceptance criteria to demonstrate that the barriers to prevent the release of nuclear or associated hazardous substances are effective; that is, the barriers:…" is accurate.
				
				4) Text has been revised for clarity, as follows:
				These limits shall:
				• be set equal to, or below:
				  • …
				  • criteria established by national or international standards as triggers for protective measures during radiological or chemical emergencies (for example, for sheltering~~, evacuation, temporary relocation and permanent resettlement,~~ or **for** distribution of iodine pills)
				• apply to the consequences of operational states and

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				the possible consequences of AOO and DBA at the facility and (to avoid confusion with the term 'severe accident'): The applicant or licensee shall establish derived acceptance criteria to demonstrate that the barriers to prevent the release of nuclear or hazardous substances are effective; that is, the barriers: • avoid the potential for consequential failures resulting from an initiating event • maintain SSCs important to safety in a configuration that prevents releases of nuclear or associated hazardous substances to the environment or in the facility • prevent ~~development of a severe accident (that is, with effects~~ consequences that extend~~ing~~ beyond the site boundaries of the licensed facility 1) No change; the suggested modification excludes off-site radiological consequences from ionizing radiation emitted by sources within the licensed site. 2) No change. The reference to REGDOC-2.4.3, *Nuclear Criticality Safety* provides additional information that, if the reader wishes to establish acceptance criteria for, specifically, nuclear criticality safety, then REGDOC-2.4.3 is the best source for that information. 3) Text has been revised to use the term "associated hazardous substances". 4) Text has been revised for clarity, as described above (replaced "prevent development of a severe accident" with "prevent consequences that…". REGDOC-3.6, *Glossary of CNSC Terminology* will be revised to add clarity on the definition of a severe accident.

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54.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)	Section 4.8, Safety goals	As written, this section is unclear in some areas. Specifically: 1) The use of BDBA in the first two paragraphs in unnecessary. 2) In the 1st paragraph, the safety goals are referenced to a suite of position papers which do not reach a fixed conclusion and do not fully align in their limited conclusions. In addition, the section of safety goals is incomplete and missing the overall safety goal of protection of the workers, public and the environment. 3) In the 3rd paragraph, the noted standards are for reactors; this change implicitly requires non-reactor facilities to meet standards created for reactors, and in many cases, power reactors. The requirement does not address the cases where national and international standards are not in agreement. CNSC staff is urged to: 1) Amend the 1st sentence of the 1st paragraph to read, "… consequences in the DEC …" and the 1st sentence of the 2nd paragraph to read, "… shall include events from the DEC." A DEC is a subset of a BDBA. As currently written, it appears to be backwards or, at least, unclear. 2) Provide clear guidance on safety goals, with consideration of the range in both scale and nature of Class 1B activities. 3) Establish the noted standards as guidelines, and clarify which elements of a graded approach are suitable for non-reactor facilities. Identify the approach to be taken where international and national standards disagree, or indicate that selection of appropriate standard itself may be part of a licensee's proposed graded approach. Licensees are challenged to demonstrate compliance when the criteria are ambiguous. As written, the draft requires licensees to apply reactor-level design goals for certain external events, without due consideration to the real hazard. Lack of guidance indicates that conflict in interpretation and understanding will occur, given differences between national and international guidelines and requirements.	Text has been revised to add a link to explain how this requirement is part of addressing the fundamental principles of defence in depth: As part of addressing the concept of defence in depth, the applicant or licensee shall… The treatment of DEC in this regulatory document is consistent with a Class IB specific approach, as originally documented in CSA N292.1, *Wet storage of irradiated fuel and other radioactive materials*. 1) The complete term 'a BDBA included in the DEC' is used to avoid potential misinterpretations and concerns. 2) The safety goals are referenced to a suite of the national or international standards, not position papers. The referenced standards are complete because they include all protection measures; these also include overall statements concerned. 3) All references noted in this section are for any radiological situation, not just for reactors. The CSA standard, CSA N292.1, *Wet storage of irradiated fuel and other radioactive materials* (reference number [6]) is not exclusive to reactors, it also applies to Class IB facilities such as Nordion and all wet storage waste management facilities. 1) No change; see above. 2) The same safety goals (that is, the same level of protection of the public) apply to any range in both scale and nature of Class IB activities. 3) The standards are set as requirements to avoid ambiguous interpretations and to maintain consistency with the requirements of IAEA SSR-4, *Safety of Nuclear Fuel Cycle Facilities*, CSA Group's CSA N292.x series of standards, and REGDOC 2.4.3,

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			This needs better clarity to align public understanding of goals and how they are applied in a SAR.	*Nuclear Criticality Safety*.
55.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Ontario Power Generation (OPG)	Section 5, Safety Analysis Documents and Records	Why do licensees have to demonstrate if defence in depth has been achieved, when defense in depth "should be addressed" as per section 2.1? Amend the last sentence of the 1st paragraph to read, "…demonstrate if defence in depth has been considered achieved."	Text has been revised such that this comment no longer applies. In response to comment #21, the first paragraph of section 2.1 has been changed from "should" to "shall".
	Canadian Nuclear Laboratories (CNL), Nordion, Nuclear Waste Management Organization (NWMO)		Licensees should demonstrate that defence in depth "should be addressed" as per section 2.1. Amend the last sentence of the 1st paragraph to read, "…demonstrate if defence in depth has been addressed."	
	Énergie New Brunswick Power (NB Power)		Licensees should demonstrate that defense in depth "should be addressed" as per section 2.1 as opposed to achieved. Amend the last sentence of the 1st paragraph to read, "…demonstrate if defence in depth has been addressed."	
56.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)	Section 5.1, Purpose and scope of safety analysis documents and records	Wording here is inconsistent with earlier sections. Amend the 2nd paragraph to read, "… events that could lead to a release of nuclear material and associated hazardous materials" "	Text has been revised to address the intent of the comment. Throughout the document (except for a few items where "nuclear material" or "radioactive material" is intentionally used), the text has been standardized as "nuclear and associated hazardous substances".
57.	P. Hader, Consultant	Section 5.2, Content of safety	The words "as appropriate" need to be removed from the SAR requirements regarding uncertainty and sensitivity analysis results. The SAR needs to include uncertainty and sensitivity analysis results to demonstrate the reliability and credibility of the results and	Text has been revised to state "when applicable". If such analysis has been done, it shall be included. However, small facilities may not have quantitative analysis.

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		analysis documents and records	conclusions of the SAR.	The guidance has been revised to add a cross-reference to section 6, which provides information on the validation and verification of safety analysis tools.
58.	H. Ragheb, Safety Probe International	Section 5.2, Content of safety analysis documents and records	I suggest adding an additional bullet under "Requirements" to read: "Provide references to detailed analyses that support the analyses results"	Text has been revised to add the suggested bullet point.
59.	B. Walker, Canadian Nuclear Workers' Council	Section 5.2, Content of safety analysis documents and records	The CNWC suggests including a requirement to ensure Employee Representatives have been engaged in the Safety Analysis Program including the Safety Analysis and Safety Analysis Report (SAR). This should include confirmation that Employee Representatives have had an opportunity to review the SAR and provide an option to include independent comments.	Text has been revised to incorporate the intent of the comment. This cannot be a "requirement", as requirements are set by the NSCA, the regulations and, in exceptional situations (such as responding to events like Fukushima), by the Commission. The following text has been added to the guidance: "The applicant or licensee should ensure that staff with a variety of perspectives (for example, employee representatives) have an opportunity to review the SAR and to provide independent comments." See also response to comment #27.
60.	J. MacDonald, SRB Technologies (Canada) Inc.	Section 5.2, Content of safety analysis documents and records	The requirements for the content of the SAR are overly prescriptive, and may be disproportionate to the risk profile of said facility. A significant amount of resources may need to be diverted to ensuring the report structure aligns with these requirements, with an unknown effect on the magnitude of safety and risk reduction for smaller, less complex Class IB facilities. Suggested change: Add language that allows for a level of regulatory judgment in considering the adequacy of the format of a given Class IB facility SAR.	No change. The information requirements are consistent with the list of the information prescribed by the *General Nuclear Safety and Control Regulations* and the *Class I Nuclear Facilities Regulations* and with Requirement 1 of IAEA SSR-4, *Safety of Nuclear Fuel Cycle Facilities*. The text of the requirement already includes language that allows for a level of regulatory judgment in considering the adequacy; that is: - The SAR shall contain a representative summary of the safety analysis documents and records.
	Bruce Power, Cameco Corporation, Canadian Nuclear		Licensees have a series of concerns and clarifications related to this section. Specifically:	

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	Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)		1) The requirements for the content of the SAR are overly prescriptive and may be disproportionate to the risk profile of said facility. 2) In the guidance to this section, the risks to the environment are to be excluded from the scope of the safety analysis report. However, in Appendix A, a sample TOC is given for the SAR, and the effects to the environment are included. The extent of the discussion on environmental aspects is unclear. 3) The 3rd paragraph should also state that addendums, or additional safety assessment may be included, outside the SAR to account for changes to the facility. And that these updates would then be incorporated into the SAR as part of periodic updated. This allows for small, but significant changes to be made to a facility without opening up the SAR as a whole. This saves time and effort. Also this allows for a more focused review by CNSC on the change itself. 4) The 1st and 3rd bullets in the 3rd paragraph should be revised to include a facility description and operations description as well. What is "pertinent?" 5) In the 3rd paragraph, 5th bullet, existing facilities have historically applied a binary: SSC are either important to safety, or not. 6) For the 11th bullet in the 3rd paragraph, no requirement or guidance is provided as to when uncertainty or sensitivity analysis is expected. CNSC staff is urged to: 1) Add language that allows for a level of regulatory judgment in considering the adequacy of the format of a given Class IB facility SAR. 2) Consider including the exclusion related to the environment in the scope section of the REGDOC and to reflect it accordingly in the entire document 3) Add a statement regarding additional safety assessments to compliment an existing SAR. This allows for a timely, more structured approach to updating facility configuration.	- The applicant or licensee may <u>incorporate information by reference</u> 1) No change. See response above. 2) Text in section 5.2 and in appendix A has been revised for clarity. Appendix A is not a requirement; it provides guidance in the form of a sample structure that is based on existing practices that some CNSC licensees already follow. 3) No change. The proposed text could be interpreted as contradicting the *Class I Nuclear Facilities Regulations*. See response to comment 62, which provides more information about how an "updated safety analysis performed in mid-cycle is included with the next scheduled update of the SAR". 4) No change to text for facility and operations descriptions. For "pertinent", text has been revised for clarity to state "some examples of pertinent accidents are…". The appendices also provide some additional information. 5) Text has been revised for clarity; the terms "systems important to safety" and "items important to safety" have been revised to "SSCs important to safety". See response to comment 50 for additional information. 6) Text has been revised to state "when applicable". If such analysis has been done, it shall be included. However, small facilities may not have quantitative analysis. The guidance has been revised to add a cross-reference to section 6, which provides information on the validation and verification of safety analysis tools.

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			4) Add a description of the facility to this section. Confirm that "pertinent" should be accidents that are quantitatively assessed. 5) Classification of existing SSC has been applied conservatively, calling out strict rules for design, procurement and maintenance, among other requirements. Additional grading should be an option the licensee may pursue at its option. As per comment #1, this document should separate and clarify requirements for existing versus new facilities and SSC. 6) Confirm licensees understanding of "as appropriate" to mean - for high consequence events, where safety analysis results are close to acceptance criteria MAJOR -- A significant amount of resources may need to be diverted to ensuring the report structure aligns with these requirements, with an unknown effect on the magnitude of safety and risk reduction for smaller, less complex Class IB facilities. For #5. Requirement to develop and apply new rules to existing SSC without evident benefit to safety.	
61.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)	Section 5.3, Documenting and recording postulated initiating events and design-basis accidents	Licensees seek the following clarifications in this section: 1) Regarding the 1st paragraph, 4th bullet, under Guidance -- many DBA in non-reactors do not involve long-term conditions. As an example, there may be limited radioactive material to release, in which case a simplified conservative model may be used in the safety analysis. 2) Under Guidance, 1st paragraph, 2nd bullet, a description of the progression of the fault sequence should be sufficient CNSC staff is urged to: 1) Adopt inclusive language such as "event conclusion." 2) Consider that outside of the unique scenario of fuel, which requires ongoing forced cooling, a description of the progression of the fault sequence should be sufficient.	No change. This text provides guidance. To confirm that these stakeholders' understanding of the issue is correct: 1) Yes, the CNSC agrees that, in this case, a simplified conservative model may be used in the safety analysis. 2) Yes, the CNSC agrees that, in certain circumstances, a description of the progression of the fault sequence would be sufficient, and visual aids may not be necessary. The last bullet point has been revised to state "the conclusion of the event".

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			Development of visual aids for physically less complex scenarios represents a significant increase in modelling effort, without corresponding safety benefit.	
62.	P. Hader, Consultant	Section 5.4, Maintaining safety analysis documents and records	The CNSC may want to provide additional clarification regarding the wording of the requirement "applicant or licensee shall perform an ongoing site evaluation". This requirement may not be realistically practical considering that the day-to-day operations would be executed under the licensee's accepted SAR. Suggest that wording be modified to require periodic site evaluation as defined within the OLCs derived from the SAR.	No change. Clarification is already included as part of the guidance: "Items of safety analysis may be performed at various times, for a variety of reasons. Normal practice is that any updated safety analysis performed in mid-cycle is included with the next scheduled update of the SAR." For the specific suggested wording change, the licence conditions handbook (LCH) for each licensee establishes a 5-year (that is, periodic) update of SAR. However, in addition to the 'periodic' trigger for SAR update, as per SSR-4, a second trigger is required -- an 'on-going' one, which is a trigger for immediate update when a new aspect appears. The CNSC's definition for site evaluation is included in REGDOC-3.6, *Glossary of CNSC Terminology*, as follows: site evaluation *(évaluation de l'emplacement)* The processes and methodologies used to determine whether the characteristics of a site and the surrounding region are appropriate for the construction, operation and future decommissioning and abandonment of a nuclear facility regulated under the *Nuclear Safety and Control Act*. This terminology is fully consistent with the title and the contents of sections 5.13 and 5.14 of IAEA SSR-4, *Safety of Nuclear Fuel Cycle Facilities*. As follows from the text of both the requirement and guidance in draft REGDOC-2.4.4 section 5.4, all of the aspects mentioned in the comment are already included in the scope of REGDOC-2.4.4. This definition also appears to CNSC staff to be fully consistent with the concept that "site evaluation is a process that continues throughout the lifecycle of the proposed facility…".
	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)		Licensees seek clarification regarding the 1st paragraph under Requirements, which reads, "The applicant or licensee shall perform an ongoing site evaluation." Why just the site? What about the plant / facility? CNSC should define "Site evaluation." Clarify the intent of this passage. Site evaluation is a process that continues throughout the lifecycle of the proposed facility to ensure the facility's design basis and safety case remains current with changing environmental conditions or modifications to the facility itself. Site evaluation information is also a key input into facility design and subsequent lifecycle phases.	

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	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)		Industry has no comment on the specific disposition, but suggests the authors of REGDOC-2.4.4 confer with their CNSC colleagues regarding proposed changes to LCH's to ensure consistency in safety analysis compliance. As a specific example, CNSC staff is encouraged to discuss proposed changes to Section 4.1 of the draft LCH for Point Lepreau Nuclear Generating Station. This will help REGDOC-2.4.4 dovetail as much as possible with existing requirements and guidance.	The draft LCH for Point Lepreau Nuclear Generating Station is for a Class 1A facility. As suggested, CNSC staff did review section 4.1 of the draft LCH. The draft LCH is consistent with the response provided by CNSC staff, in that the draft LCH has an expectation for updating some of the safety analysis models every 5 years. As explained in more detail in the CNSC's response to comment #2, in case of differences, the LCH takes precedence over a regulatory document. Also note that the LCH for any nuclear facility may include site-specific details that require some differences in the requirements from other nuclear facilities.
63.	J. MacDonald, SRB Technologies (Canada) Inc.	Section 7, Graded Approach	Inclusion of this section in the draft REGDOC may address most of our previous comments; however, the guidance on how to best present the graded approach to meeting the intent of the requirements of the REGDOC are not clear. What is acceptable? How can we achieve an acceptable graded approach without investing more resources into pursuing that goal vs. investing resources into full compliance to the letter of the REGDOC? Suggested change: Add less prescriptive language to all pertinent sections of the document allowing for judgment and the application of a graded approach.	Text in section 7 has been revised to add clarity that the applicant or licensee may propose specific design measures, analyses or other measures that are commensurate with the level of risks posed, if they provide adequate justification. The intent of this comment has also been addressed by some changes to text in other sections. CNSC staff are pleased to inform stakeholders that REGDOC-3.5.3, *Regulatory Fundamentals* is being revised to add more information on applying the graded approach and on risk-informed approaches. This revision of REGDOC-3.5.3 will address the intent of this comment more suitably than expanding the text in this section of REGDOC-2.4.4.
	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)		Guidance on how to best present the graded approach to meeting the intent of the requirements of the REGDOC are not clear. Add less prescriptive language to all pertinent sections of the document allowing for judgment and the application of a graded approach.	

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	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)		Further feedback based on the CNSC's response: As per comment #2, when revising REGDOC-3.5.3, CNSC staff is encouraged to refer to IAEA-TECDOC-1980, which provides specific considerations for graded approach applications in nuclear facility regulation.	CNSC staff agree. We will pass this comment on to the regulatory team working on the new appendix for REGDOC-3.5.3, *Regulatory Fundamentals*.
64.	M. Stephens, AECL (retired)	Appendix A, Sample Structure and Content	The first sentence of Appendix A contains a typo. "This appendix provides a sample structure for an SAR." "an" should be "a".	No change. If reading "SAR" as an acronym, this would indeed be a typo; however, general usage within the CNSC indicates that "SAR" is more generally read as an initialism ("an es-eh-ar").
65.	B. Walker, Canadian Nuclear Workers' Council	Appendix A, Sample Structure and Content	The CNWC suggests Appendix A include a confirmation that Employee Representatives have had an opportunity to review the SAR and provide an option to include independent comments.	No change to appendix A. The intent of this comment was accepted and the text in section 5.2 was revised to include this information (see comment #59).
66.	Cameco Corporation	Appendix A, Sample Structure and Content	Chapters 11-16 duplicate information in site licensing basis documentation; Chapters 3, 8 and 9 includes information that is better documented in other site programs. Cameco recommends that these chapters all be replaced with one chapter which references the site program requirements for an operating licence."	No change to text. See responses below for additional information. 1) No change to text. Appendix A is not a requirement. It provides guidance in the form of a sample structure that is based on existing practices that some CNSC licensees already follow. 2) Text has been revised for clarity and consistency. The phrase "safety relevant systems" has been replaced with "SSCs important to safety". 3) No change to text; other than the change throughout the document to "nuclear and associated hazardous substances". Yes, that chapter refers to the non-radiological effects from radiological releases.
	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)		Licensees seek clarity on the following elements of Appendix A: 1) Chapters 11-16 duplicate information detailed in site licensing basis documentation. Chapters 3, 8 and 9 include information that is better documented in other programs. 2) What does 'safety relevant' mean under Chapter 6? 3) Presumably Chapter 13 is referring to non-radiological effects from radiological releases? For example, effects from associated hazardous materials?	

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change	Response
			4) Chapter 16, Public information program, is misplaced in this document and should be separate from the Safety Analysis. CNSC staff is urged to: 1) Replace these chapters with one chapter which references the site programs requirements for an operating licence. 2) Clarify what is meant by "safety relevant" 3) Clarify the reference 4) Remove Chapter 16. Public information is a requirement captured in REGDOC-3.2.1, Public Information and Disclosure	4) See response to 1) above.
67.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)	Appendix B, Sample Parameters for Operational Limits and Conditions	As per earlier comments about hazard materials, the 2nd and 6th bullets references "hazardous materials." Only those associated with nuclear materials? Clarify if this is only those substances associated with nuclear materials."	Text has been revised to state "associated hazardous substances".
68.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)	Appendix C, Postulated Initiating Events	Licensees have concerns with the following elements of Appendix C.2: 1) The provided, expected assessment method for DBA flooding is just an assumption. It does not provide information for cases of existing facilities which may be below the 100-year flood plain. It does not speak to new facilities at all. DEC assessment methodology uses the term "maximum probable flood plain," which is not defined. 2) Regarding seismic hazards, the stated DBA assessment method is an assumption, and applies only to a subset of existing fuel cycle facilities. This does not appropriately encompass the Class 1B facility archetype. The proposed DEC methodology requires all	No change based on this comment. 1) As stated at the beginning of the subsection, "This appendix describes the types of PIEs and the ranges of conditions to be considered for applicability at Class IB nuclear facilities. The term "probable flood plain" is provided by the CNSC's staff specialists. It is based on consistency with national and international standards (such as documents from the CSA Group).

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			Class 1B facilities to meet the level of robustness of a nuclear reactor, with no consideration of the relative complexity or importance of the safety functions systems may need to perform following a rare event. The DEC and DBA guidance use the same reference level. CNSC staff is urged to: 1) Provide an expected methodology which can be used for both existing and new facilities. Provide a technical definition for the terminology "maximum probable flood plain" 2) Adding the following to the updated version of this REGDOC, "Licensees should propose an evaluation method graded commensurate with facility risk." MAJOR -- As written, the text is predicated on assumptions that cannot be assumed to be valid for all existing and future Class 1B facilities. Licensees are not likely to be successful fulfilling requirements which use undefined terminology. Severe escalation to the seismic design basis for all existing and future Class 1B facilities.	The information requested in the comment (assessment methodology for external events for both existing and new facilities, definition of term "maximum probable flood plain", etc.) is out of scope for appendix C. However, it can be found by searching for it in the referenced standards and documents. 2) The proposed DEC methodology for seismic hazards does not require all Class IB facilities to meet the level of robustness of a nuclear reactor. It does provide the information to be considered for applicability at Class IB nuclear facilities. Note that the treatment of DEC is not based on Class IA, it is based on Class IB-specific approach, as originally documented in CSA N292.1, *Wet storage of irradiated fuel and other radioactive materials*.
			Further feedback based on the CNSC's response: Please see industry's response to comment #39. External hazards should be treated separately from PIE's to maintain consistency with the traditional safety analysis approach and the approach documented in the closure criteria for Fukushima Action 2.1.2 (see e-Doc 4079868).	The CNSC is not asking licensees to run safety analysis on events that, for that facility, would not lead to an accident.
69.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)	Glossary	The definition for Systems Important to Safety in REGDOC-3.6 only relates to reactor facilities. If the concept is to be extended to Class 1B facilities, the definition must be extended. Revise the definition for "SSCs important to safety" in REGDOC-3.6 so it is applicable to non-reactor facilities.	No change to this regulatory document (REGDOC-2.4.4). REGDOC-3.6, *Glossary of CNSC Terminology*, will be revised in a near-future update to address this definition (among a few others). In the meantime, the terminology used in REGDOC-2.4.4 is consistent with IAEA terminology for safety analysis for Class IB nuclear facilities.

Table C: Additional comments received as part of "feedback on responses to comments"

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change	Response
a)	J. MacDonald, SRB Technologies (Canada) Inc.	General	After going through the disposition table, SRBT does not have any additional specific comments that warrant documenting, considering the explanation for where changes were (or were not) made. CNSC staff's dispositions were clear and concise, which is always appreciated. Thematically, we remain of the opinion that the REGDOC is perhaps overly prescriptive with respect to the concepts of environmental qualification, minimum staff complement, credited operator action times, and to a lesser degree, the now-mandatory methodology in the application of defense-in-depth, particularly where nuclear substance processing facilities may intersect with the requirements. Of course we wholeheartedly believe that these are all very important components in nuclear safety management, but I don't think sufficiently clear allowance for a more rational approach for facilities like SRBT are included in the document. SRBT is a Class IB facility; however, we are not a 'nuclear fuel cycle' facility per se, as we do not play any role in the manufacture or processing of fuel for nuclear reactors. Despite this, IAEA SSR-4, *Safety of Nuclear Fuel Cycle Facilities* is referenced as the fundamental guiding document for this REGDOC, and the requirements therein applied to our facility type on the basis of being Class IB. It is repeatedly mentioned that a graded approach can always be advocated for, but in practice this can be challenging when dealing with CNSC staff, who may tend to be more inflexible when assessing the validity of such an approach, given that the REGDOC could be viewed prescriptively. That being said, SRBT confirms that we are prepared and able to conduct and document our facility SAR in line with these requirements. We understand that no REGDOC can perfectly accommodate every facility type, especially facilities that are so unique (such as our own).	CNSC agrees that SRBT is not a nuclear fuel cycle facility, and CNSC staff took that into account in development of REGDOC-2.4.4 and, also, in reviewing SRBT's safety analysis. IAEA SSR-4 is listed as a source of more information on a variety of topics (for example, defence in depth, establishing internal safety committees, and on interfaces with other facilities and installations that may affect the facility's safety). In addition, the overall content of CSA N292.1 explicitly takes into account facilities such as SRBT. There is no statement in REGDOC-2.4.4 that says requirements in SSR-4 would be applied to SRBT's facility type. The following text has been revised to add clarity that SSR-4 is provided as a source of more information and not as requirements: -In section 3, the text "For more information, see IAEA SSR-4…" has been moved into the Guidance section. -In section 4.3, Postulated initiating events, the subheading "Guidance" has been added before the introductory paragraphs describing PIEs. The CNSC is adding a new appendix on graded approach to REGDOC-3.5.3, *Regulatory Fundamentals*. Comments on the graded approach will be passed to the regulatory team working on that appendix.

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change	Response
b)	Nordion	General	Overall, Nordion has the concern that the proposed REGDOC 2.4.4, based on CNSC's responses to the comments, still links to the NS-R-5 and CSA N292.x series of documents. The CNSC notes that these documents apply to Class 1B facilities. However, these documents are not currently requirements for all Class 1B licensees and are provided as guidance documents in Nordion's Licence Condition Handbook. The NS-R-5 document is specific to nuclear fuel cycle facilities and should not apply to all Class 1B licensees. Although the CNSC notes that licencees may take a graded, risk-based approach, this requires that licensee must submit, for CNSC review and approval, a justification for the graded approach. We believe that further work is required on REGDOC 2.4.4 to create a safety analysis framework that accurately reflects the different facilities and risk profiles among Class 1B licensees.	There is no link to NS-R-5 in this regulatory document. If the reviewer meant NS-R-3, that document is mentioned in an appendix as a source for more information. If the reviewer meant SSR-4, please see the response to the preceding comment. The CSA N292.x series is mentioned in a guidance section as a source of more information on the validation and verification of safety analysis tools, and CSA N292.1 also provides a definition of a credible abnormal event. In addition, the overall content of CSA N292.1 explicitly takes into account facilities such as Nordion. The requirements in the licensee's Licence Conditions Handbook take precedence over any information in any regulatory document. That is, if there is a difference between the LCH and a regulatory document, the licensee must adhere to the licensing basis in their LCH. On the other hand, if the licensee's LCH simply adds a specific regulatory document to the licensing basis without specifically identifying any differences, then the licensee must adhere to the requirements in the regulatory document. In this case, Nordion should adhere to their Licence Conditions Handbook which forms part of their licensing basis.