

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

**Comments:** August 28 to December 5 (extended from November 27), 2020

**Feedback on comments:** December 6 to January 12 (extended from January 6), 2021

The CNSC received 70 distinct comments from 14 stakeholders.

**Table A:** Comments on Request for Information

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change
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 and "feedback on comments" are combined)

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change
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 offers unique and exclusive nuances that may not be easily accounted for in a 'one size fits all' type of REGDOC such as this.
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.

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3.	Cameco Corporation	General	<p>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.</p> <p>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.</p>
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.

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5.	Canadian Nuclear Association (CNA)	General	<p>The Canadian Nuclear Association (CNA) and its members would like to thank the CNSC for the opportunity to comment on REGDOC 2.4.4. ...</p> <p>However, the CNA feels it is necessary to highlight several over-arching concerns with the draft document:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> </ul> <p>In concluding, the CNA believes that further work needs to be done before this document should proceed.</p>
6.	Bruce Power	General	<p>Most of the concepts in this draft document rely heavily on Class 1A-style requirements.</p> <p>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.</p>
7.	Ontario Power Generation (OPG)	General	<p>OPG's primary comments on the proposed document as currently written can be broadly summarized as follows:</p> <ul style="list-style-type: none"> <li>• The draft REGDOC as written is too reactor-specific at this time; and</li> <li>• This draft REGDOC uses terms that do not align with those in other regulatory documents, such as REGDOC-3.6, <i>Glossary of CNSC Terminology</i> and REGDOC-2.2.5, <i>Minimum Staff Complement</i>; we also request specific terminology to be made consistent throughout the document.</li> </ul>

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change
8.	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	<p>1) This draft REGDOC is too reactor-specific.</p> <p>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.</p> <p>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."</p>

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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	<p>2) This draft REGDOC uses terms that do not align with those in other regulatory documents, such as REGDOC-3.6, <i>Glossary of CNSC Terminology</i> and REGDOC-2.2.5, <i>Minimum Staff Complement</i>. For example:</p> <p>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.</p> <p>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. Imprecise use of terminology has the potential to generate confusion and compliance challenges.</p> <p>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.</p> <p>Please see [other comments] for other examples.</p>

	<b>Reviewer</b>	<b>Section or Para.</b>	<b>Reviewer's Comment and Proposed Change</b>
10.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Ontario Power Generation (OPG)	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.
	Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO)		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.
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.

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12.	Brian Beaton, Coalition for Responsible Energy Development in New Brunswick	General	<p>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 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.</p> <p>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.</p>
13.	Brian Beaton, Coalition for Responsible Energy Development in New Brunswick	General	<p>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.</p> <p>Thank you for considering the issues I am attempting to raise with this intervention. I hope my intervention is helpful to the Commission.</p>
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	<p>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."</p>

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15.	Brian Beaton, Coalition for Responsible Energy Development in New Brunswick	Sections 1.0, Introduction and 1.1, Purpose	<p>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 systematic evaluation of the potential hazards) safety analysis documents, records and reporting".</p> <p>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.</p> <p>"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?</p> <p>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.</p> <p>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 unable to find any reference to these actions by the nuclear industry contained in the proposed "program".</p>



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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	<p>The Scope requires additional clarity. Specifically:</p> <ol style="list-style-type: none"> <li>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.</li> <li>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.</li> </ol> <p>For clarity, the CNSC is urged to:</p> <ol style="list-style-type: none"> <li>1) Use the definition of a Class 1B facility from the Class 1 facility regulations or from REGDOC 3.6</li> <li>2) Amend the 2nd paragraph to be general to all disposal facilities.</li> </ol> <p>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.</p>
17.	Brian Beaton, Coalition for Responsible Energy Development in New Brunswick	Section 1.2, Scope	<p>The document is meant to "provide requirements and guidance for safety analysis of the following Class IB nuclear facilities:</p> <ul style="list-style-type: none"> <li>• a plant for the processing, reprocessing or separation of an isotope of uranium, thorium or plutonium</li> <li>• a plant for the manufacture of a product from uranium, thorium or plutonium</li> <li>• 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, thorium or plutonium</li> <li>• a facility prescribed by paragraph 19(a) or (b) of the General Nuclear Safety and Control Regulations: <ul style="list-style-type: none"> <li>• 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</li> </ul> <p>note: for the scope of this regulatory document, some examples of these facilities include:</p> <ul style="list-style-type: none"> <li>• any facility for the storage of fissionable material before and after irradiation</li> <li>• any facility for associated waste conditioning, effluent treatment and facilities for storage of waste that allow for retrieval of the waste for later disposal</li> <li>• a plant for the production of deuterium or deuterium compounds using hydrogen sulphide</li> </ul> </li> </ul> <p>"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:</p>

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			<ul style="list-style-type: none"> <li>• any facility for the handling and packaging of fuel associated with a DGR</li> <li>• the operational activities at a DGR associated with the handling, packaging and placement of radioactive material in the DGR</li> <li>• safety analysis documents, records and reporting</li> </ul> <p>"This document is the first version of REGDOC 2.4.4, Safety Analysis for Class IB Nuclear Facilities."</p> <p>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."</p>
18.	H. Ragheb, Safety Probe International	Section 2.0, Safety Objectives	<p>The last paragraph lists the areas where the SAR is used. It appears that the last sentence that starts with "develop and maintain ..." is intended to be a third bullet but the bullet is missing.</p> <p>Additionally, we recommend that a fourth use (fourth bullet) should say:</p> <ul style="list-style-type: none"> <li>• confirm that the design of the facility meets design and safety requirements</li> </ul>

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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	<p>The Safety Objectives could be further clarified. Specifically:</p> <ol style="list-style-type: none"> <li>1) In the 2nd paragraph, is “potential hazards” limited to radiological hazards?</li> <li>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:”</li> <li>3) The SAR is also used to demonstrate safety.</li> </ol> <p>CNSC staff is urged to:</p> <ol style="list-style-type: none"> <li>1) Clarify if “potential hazards” is limited to radiological hazards</li> <li>2) Specifically state what “it” is. Otherwise, avoid using “it”</li> <li>3) Add “demonstrate safety” to the use of the SAR.</li> </ol>
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”
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.

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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	<p>Applying to sections 2.1 , 4.3.1, 4.7 and 5.2:</p> <p>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.</p> <p>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.</p> <p>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."</p>
	Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO)		<p>Applying to sections 2.1 , 4.3.1, 4.7 and 5.2:</p> <p>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.</p> <p>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.</p> <p>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 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."</p>

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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	<p>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</p> <p>More specifically, licensees believe additional clarity can be added in the following areas:</p> <ol style="list-style-type: none"> <li>1) In the 1st sentence of the 2nd paragraph, what does “normally defined” mean in this context?</li> <li>2) The definition of AOO in Level 2 needs to be updated</li> <li>3) A minor wording update is required in Level 4.</li> <li>4) What is meant by the phrase “releases of radioactive material and associated hazardous material” in Level 3?</li> </ol> <p>Before finalizing this REGDOC, CNSC staff is encouraged to consider:</p> <ul style="list-style-type: none"> <li>• If this section is consistent with the licensing and design basis of the Operating IB facilities for all accidents.</li> <li>• If the levels are consistent with the consequences so a graded process in design can be used depending on the accident.</li> <li>• Whether this is a practicable back-fit if the design was not completed following this practice.</li> <li>• Whether the importance of integration of designers and operators to defence-in-depth is stated clearly.</li> </ul> <p>Also, CNSC staff is urged to:</p> <ol style="list-style-type: none"> <li>1) Clarify what is meant by “normally defined” in this context.</li> <li>2) Amend Level 2 to read, “The aim of the second level of defence is to detect, intercept and control</li> </ol>

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			<p>deviations from normal operation in order to prevent anticipated operational occurrences (AOOs) ...”</p> <p>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.”</p> <p>4) Clarify if this means only hazardous material with radioactive properties is to be looked at.</p>
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”
25.	J. MacDonald, SRB Technologies (Canada) Inc.	Section 2.2, Safety analysis objectives	<p>The requirement for the licensee to maintain ‘adequate capability’ to perform or procure safety analysis is vague.</p> <p>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.</p> <p>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?</p> <p>Suggested change: Add guidance on what is meant by ‘adequate capability’ and which branch of the regulatory body ultimately makes that determination.</p>
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	<p>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.</p> <p>Additional clarity is also sought in the following:</p> <p>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?</p>

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			<p>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.</p> <p>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.</p> <p>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.</p> <p>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”</p> <p>CNSC staff is urged to:</p> <ol style="list-style-type: none"> <li>1) Add guidance on what is meant by “adequate capability” and which branch of the regulatory body ultimately makes that determination.</li> <li>2) Add “as appropriate or applicable” to the introductory clause.</li> <li>3) Change “data” to “results” or “outputs”</li> <li>4) Amend to read, “...safety analysis basis to:”</li> <li>5) Change “human performance” to “human errors” and define what is deemed “credible estimates” of human performance</li> </ol> <p>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.</p> <p>It’s important to ensure public perception of what is presented in the SAR is clear to all potential readers.</p>

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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.
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.
29.	Cameco Corporation	Section 3, Safety Analysis Program	<p>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.</p> <p>The REGDOC should set out the expectations for an acceptable safety analysis report in accordance with the facility management system. This redundancy would require licensees to reallocate resources to maintaining a program without any corresponding safety benefit.</p> <p>Cameco recommends that this section of the REGDOC be deleted in its entirety.</p>



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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	<p>Licensees have a significant concern with the Safety Analysis Program section. Specifically:</p> <p>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.</p> <p>2) The 2nd paragraph on internal committees refers to “safety issues” and “safety matters.” What is the difference?</p> <p>CNSC staff is urged to:</p> <p>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.</p> <p>2) Explain the difference between “safety issues” and “safety matters.”</p> <p>MAJOR -- Introducing this new requirement could force licensees to reallocate limited resources to comply without providing any corresponding benefit to nuclear safety.</p>
31.	H. Ragheb, Safety Probe International	Section 3.1, Elements of a safety analysis program	<p>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”</p> <p>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.</p>

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change
32.	P. Hader, Consultant	Section 3.1, Elements of a safety analysis program	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.
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.
	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."

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change
34.	Cameco Corporation	Section 4, Safety Analysis	<p>The facility classes used in this section were developed for reactors when the nature of the 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."</p>
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	<p>Licensees have a series of concerns and clarifications regarding the Classification of events into facility states. Specifically:</p> <ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>3) The term "conditions" in the 3rd bullet is not necessary and may impede clarity.</li> <li>4) As per comment #1, some terminology used for NPPs (such as "shutdown") may not 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."</li> <li>5) The requirement is to classify events into AOOs, DBAs or BDBAs, "or equivalent." As per comment</li> </ol>

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change
			<p>#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.</p> <p>CNSC staff is urged to:</p> <ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>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?</li> <li>4) Consider replacing terminology or providing alternate definitions for all terms that could be applied to Class 1B facilities.</li> <li>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.”</li> </ol> <p>MAJOR -- As written, this draft creates regulatory uncertainty; licensee cannot comply with inapplicable requirements.</p> <p>Class 1B facilities can be complex facilities with varying operations. What is the expectation for Normal Operations?</p> <p>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</p>

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			<p>methodologies to be used to assess the design against DEC values?</p> <p>Please see related remarks regarding Section 4.8, Safety Goals.</p>
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”
37.	J. MacDonald, SRB Technologies (Canada) Inc.	Section 4.2, Safety analysis assumptions	<p>The depth of the requirements for qualified systems and operator actions may be disproportionate to the risk profile of said facility.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>
38.	J. MacDonald, SRB Technologies (Canada) Inc.	Section 4.2, Safety analysis assumptions	<p>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.</p> <p>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.</p> <p>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.</p>
	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian		<p>Licensees have a series of concerns with the safety analysis assumptions section. Specifically:</p> <p>1) As per comment #1, the depth of the requirements for qualified systems and operator actions may be</p>

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	<p>Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO), Ontario Power Generation (OPG)</p>		<p>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.</p> <p>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.</p> <p>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.</p> <p>4) The word “shall” is inappropriately included twice in the Guidance portion of this section.</p> <p>CNSC staff is urged to:</p> <p>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.</p> <p>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.</p> <p>3) The ambiguous category of “operator action” should be divided into meaningful categories, such as:</p> <ul style="list-style-type: none"> <li>• Performance of complex emergency procedures (more than one discrete action, system feedback required)</li> <li>• Activation of an alarm</li> <li>• Actuation of equipment emergency stop</li> <li>• Initiation of a manual fire suppression system</li> <li>• Evacuation</li> </ul> <p>4) Change the two “shall” references in the Guidance section to “should.” Otherwise, move the statements to the requirements area.</p>

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change
			<p>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.</p> <p>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.</p>
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.
40.	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	<p>Given the broad range of tools which may be used, it is unclear what analysis details the licensee is expected to provide.</p> <p>Provide guidance that corresponds to the 'Requirements'.</p>
41.	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"

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change
42.	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.
43.	J. MacDonald, SRB Technologies (Canada) Inc.	Section 4.3.1, Identification of postulated initiating events Section 4.3.1, Identification of postulated initiating events	<p>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.</p> <p>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?</p>
	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)		<p>Additional clarity is sought for the following:</p> <ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>3) The 2nd bullet under Requirements, which reads, "A release of significant amounts of nuclear substances" is unclear.</li> <li>4) The use of "all" in the sub-bullets on page 7 cannot be verified or audited.</li> <li>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) ..."</li> </ol> <p>CNSC staff is urged to:</p>



	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change
			<p>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.</p> <p>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.</p> <p>3) Clarify what is meant by “significant amounts” in the 2nd bullet.</p> <p>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”</p> <p>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.</p> <p>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."</p>
44.	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	<p>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.</p> <p>This REGDOC should remain focused on the “Safety Analysis” required for a Class IB facility per the Regulations. "</p>
45.	M. Stephens, AECL (retired)	Section 4.4, Safety assessment	<p>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.</p>

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change
46.	J. MacDonald, SRB Technologies (Canada) Inc.	Section 4.4.1, Assessment of consequences	<p>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.</p> <p>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.</p> <p>Suggested change: Ensure that the level and rigour of validation of computational tools is commensurate with the level of risk.</p>
	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)		<p>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.</p> <p>Why does the applicant or licensee have to validate computational tools?</p> <p>CNSC staff is urged to:</p> <ol style="list-style-type: none"> <li>1) Ensure the level and rigour of validation of computational tools is commensurate with the level of risk.</li> <li>2) Amend the 2nd sentence of the 2nd paragraph to read, "The applicant or licensee shall use validated computational tools to calculate consequences."</li> </ol> <p>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.</p>
47.	P. Hader, Consultant	Section 4.4.3, Examples of acceptable methods	<p>The CNSC might want to improve the clarity about which methods besides the 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.</p>

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48.	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”.
49.	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.
50.	Cameco Corporation	Section 4.5, Identification of structures, systems and components important to safety	In section 4.5, the information for the requirements in the bulleted list is included in 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.
51.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Canadian Nuclear Laboratories (CNL), Énergie New Brunswick Power (NBPower), Nordion, Nuclear Waste Management Organization (NWMO),	Section 4.5, Identification of structures, systems and components important to safety	Licenses 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.

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	Ontario Power Generation (OPG)		<p>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."</p> <p>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.</p> <p>5) It is unclear whether the details required by the bulleted list are to be included in the SAR when this information is included in maintenance programs or design control.</p> <p>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.</p> <p>CNSC staff is urged to:</p> <ol style="list-style-type: none"> <li>1) Address the should/shall discrepancy</li> <li>2) Environmental qualifications should be permitted to be reasonable and justifiably aligned with the risk profile of said facility</li> <li>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.</li> <li>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.</li> </ol>

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change
			<p>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.</p> <p>6) Change to “Where applicable...”To ensure compliance, licensees need firm direction on SHALL versus SHOULD language.</p> <p>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.</p> <p>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.</p>
52.	P. Hader, Consultant	Section 4.6, Operational limits and conditions	Staff availability and competency are a critical component of the operational 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.
53.	J. MacDonald, SRB Technologies (Canada) Inc.	Section 4.6, Operational limits and conditions	<p>The concept of minimum requirements for the availability of staff should not be automatically referenced.</p> <p>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.</p> <p>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.</p> <p>Suggested change: Add language such as ‘if warranted’ to account for smaller, less complex facilities of a lower risk profile.</p>

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change
	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)		<p>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.</p> <p>Add language such as ‘if warranted’ to account for smaller, less complex facilities of a lower risk profile.</p> <p>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.</p>
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 4.7, Acceptance criteria	<p>Licensees have a series of clarifications related to acceptance criteria. Specially:</p> <ol style="list-style-type: none"> <li>1) The term ‘associated chemical consequences’ is written here, when associated hazardous materials has been used previously.</li> <li>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.</li> <li>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.</li> <li>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?</li> </ol>

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change
			<p>CNSC staff is urged to:</p> <ol style="list-style-type: none"> <li>1) Amend the 2nd paragraph to read, "...shall set limits on consequences from releases of radioactive and associated hazardous materials" for consistency.</li> <li>2) Clarify the intent of this reference</li> <li>3) Clarify why the phrase "or hazardous material" is used.</li> <li>4) Clarify if 'in the reactor core or wet storage bay' applies to class 1B facilities.</li> </ol>
55.	<p>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)</p>	<p>Section 4.8, Safety goals</p>	<p>As written, this section is unclear in some areas. Specifically:</p> <ol style="list-style-type: none"> <li>1) The use of BDBA in the first two paragraphs is unnecessary.</li> <li>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.</li> <li>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.</li> </ol> <p>CNSC staff is urged to:</p> <ol style="list-style-type: none"> <li>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.</li> <li>2) Provide clear guidance on safety goals, with consideration of the range in both scale and nature of Class 1B activities.</li> <li>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</li> </ol>

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			<p>standards disagree, or indicate that selection of appropriate standard itself may be part of a licensee's proposed graded approach.</p> <p>Licenses are challenged to demonstrate compliance when the criteria are ambiguous.</p> <p>As written, the draft requires licenses 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.</p> <p>This needs better clarity to align public understanding of goals and how they are applied in a SAR.</p>
56.	Bruce Power, Cameco Corporation, Canadian Nuclear Association (CNA), Ontario Power Generation (OPG)	Section 5, Safety Analysis Documents and Records	<p>Why do licenses have to demonstrate if defence in depth has been achieved, when defense in depth "should be addressed" as per section 2.1?</p> <p>Amend the last sentence of the 1st paragraph to read, "...demonstrate if defence in depth has been considered achieved."</p>
	Canadian Nuclear Laboratories (CNL), Nordion, Nuclear Waste Management Organization (NWMO)		<p>Licenses should demonstrate that defence in depth "should be addressed" as per section 2.1.</p> <p>Amend the last sentence of the 1st paragraph to read, "...demonstrate if defence in depth has been addressed."</p>
	Énergie New Brunswick Power (NB Power)		<p>Licenses should demonstrate that defense in depth "should be addressed" as per section 2.1 as opposed to achieved.</p> <p>Amend the last sentence of the 1st paragraph to read, "...demonstrate if defence in depth has been addressed."</p>



	<b>Reviewer</b>	<b>Section or Para.</b>	<b>Reviewer's Comment and Proposed Change</b>
57.	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" "
58.	P. Hader, Consultant	Section 5.2, Content of safety analysis documents and records	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 conclusions of the SAR.
59.	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"
60.	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.

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change
61.	J. MacDonald, SRB Technologies (Canada) Inc.	Section 5.2, Content of safety analysis documents and records	<p>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.</p> <p>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.</p>
	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)		<p>Licensees have a series of concerns and clarifications related to this section. Specifically:</p> <ol style="list-style-type: none"> <li>1) The requirements for the content of the SAR are overly prescriptive and may be disproportionate to the risk profile of said facility.</li> <li>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.</li> <li>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.</li> <li>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?”</li> <li>5) In the 3rd paragraph, 5th bullet, existing facilities have historically applied a binary: SSC are either important to safety, or not.</li> <li>6) For the 11th bullet in the 3rd paragraph, no requirement or guidance is provided as to when uncertainty or sensitivity analysis is expected.</li> </ol> <p>CNSC staff is urged to:</p>

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			<p>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.</p> <p>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</p> <p>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.</p> <p>4) Add a description of the facility to this section. Confirm that “pertinent” should be accidents that are quantitatively assessed.</p> <p>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.</p> <p>6) Confirm licensees understanding of “as appropriate” to mean - for high consequence events, where safety analysis results are close to acceptance criteria</p> <p>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.</p> <p>For #5. Requirement to develop and apply new rules to existing SSC without evident benefit to safety.</p>

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62.	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	<p>Licensees seek the following clarifications in this section:</p> <ol style="list-style-type: none"> <li>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.</li> <li>2) Under Guidance, 1st paragraph, 2nd bullet, a description of the progression of the fault sequence should be sufficient</li> </ol> <p>CNSC staff is urged to:</p> <ol style="list-style-type: none"> <li>1) Adopt inclusive language such as “event conclusion.”</li> <li>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.</li> </ol> <p>Development of visual aids for physically less complex scenarios represents a significant increase in modelling effort, without corresponding safety benefit.</p>
63.	<p>P. Hader, Consultant</p> <hr/> <p>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)</p>	Section 5.4, Maintaining safety analysis documents and records	<p>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.</p> <hr/> <p>Licensees seek clarification regarding the 1st paragraph under Requirements, which reads, “The applicant or licensee shall perform an ongoing site evaluation.”</p> <p>Why just the site? What about the plant / facility? CNSC should define "Site evaluation."</p> <p>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.</p>

	<b>Reviewer</b>	<b>Section or Para.</b>	<b>Reviewer's Comment and Proposed Change</b>
64.	J. MacDonald, SRB Technologies (Canada) Inc.	Section 7, Graded Approach	<p>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.</p> <p>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?</p> <p>Suggested change: Add less prescriptive language to all pertinent sections of the document allowing for judgment and the application of a graded approach.</p>
	<p>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)</p>		<p>Guidance on how to best present the graded approach to meeting the intent of the requirements of the REGDOC are not clear.</p> <p>Add less prescriptive language to all pertinent sections of the document allowing for judgment and the application of a graded approach.</p>
65.	M. Stephens, AECL (retired)	Appendix A, Sample Structure and Content	<p>The first sentence of Appendix A contains a typo. "This appendix provides a sample structure for an SAR." "an" should be "a".</p>
66.	B. Walker, Canadian Nuclear Workers' Council	Appendix A, Sample Structure and Content	<p>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.</p>

	Reviewer	Section or Para.	Reviewer's Comment and Proposed Change
67.	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."
	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)		<p>Licensees seek clarity on the following elements of Appendix A:</p> <ol style="list-style-type: none"> <li>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.</li> <li>2) What does 'safety relevant' mean under Chapter 6?</li> <li>3) Presumably Chapter 13 is referring to non-radiological effects from radiological releases? For example, effects from associated hazardous materials?</li> <li>4) Chapter 16, Public information program, is misplaced in this document and should be separate from the Safety Analysis.</li> </ol> <p>CNSC staff is urged to:</p> <ol style="list-style-type: none"> <li>1) Replace these chapters with one chapter which references the site programs requirements for an operating licence.</li> <li>2) Clarify what is meant by "safety relevant"</li> <li>3) Clarify the reference</li> <li>4) Remove Chapter 16. Public information is a requirement captured in REGDOC-3.2.1, Public Information and Disclosure</li> </ol>

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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 B, Sample Parameters for Operational Limits and Conditions	<p>As per earlier comments about hazard materials, the 2nd and 6th bullets references “hazardous materials.” Only those associated with nuclear materials?</p> <p>Clarify if this is only those substances associated with nuclear materials.”</p>
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)	Appendix C, Postulated Initiating Events	<p>Licensees have concerns with the following elements of Appendix C.2:</p> <p>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.</p> <p>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 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.</p> <p>CNSC staff is urged to:</p> <p>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”</p> <p>2) Adding the following to the updated version of this REGDOC, “Licensees should propose an evaluation method graded commensurate with facility risk.”</p> <p>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</p>

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			<p>which use undefined terminology.</p> <p>Severe escalation to the seismic design basis for all existing and future Class 1B facilities.</p>
70.	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	<p>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.</p> <p>Revise the definition for “SSCs important to safety” in REGDOC-3.6 so it is applicable to non-reactor facilities.</p>