

REGDOC-2.11.1, Volume III: Comments received in advance of the workshop with industry

REGDOC-2.11.1, tome III: Commentaires reçus en vue de l’atelier avec l’industrie

Note: Comments submitted, including names and affiliations are intended to be made public, in the official language in which they are received.

Remarque : Les commentaires reçus, y compris les noms et les affiliations, seront rendus publics, dans la langue officielle dans laquelle ils auront été reçus.

	Organization / Organisation	Section	Comment / Commentaire	CNSC Response / Réponse la CCSN
1.	Bruce Power, BWXT, Cameco, CNA, CNL, CANDU Owners Group, Hydro-Québec, Kinetrics, NB Power, NWMO, OPG, Orano	1.1	<p>MAJOR While it has been clarified that the REGDOC applies to all types of radioactive waste, and therefore licensees, it should be acknowledged that not all licensees will host to their own disposal facility.</p> <p>Suggested change: Add a sentence such as, “This includes waste generated by another licensee and transferred to a waste owner for disposal under a commercial agreement.”</p> <p>Impact on industry: As issues related to waste management draw increased political and public scrutiny, it’s imperative that all readers of this REGDOC understand the relationship between waste producers and owners and their commercial agreements. Plain language helps reduce misunderstandings.</p>	<p>No change made. The requirements of this REGDOC are for the licensee or applicant.</p> <p>The potential transfer of ownership from one licensee to another is outside of the scope of the REGDOC.</p>
2.	Bruce Power, BWXT, Cameco, CNA, CNL, CANDU Owners Group,	1.2	<p>MAJOR Licensees believe the Scope requires further refinements. Specifically: 1) The 2nd sentence of the 1st paragraph adds more confusion than clarity. Are the “long-term radioactive waste management facilities where there is no intention to retrieve the waste” not disposal facilities? What period is considered “long-term?” Clarification is required for times when this REGDOC sets requirements above those in REGDOC 2.11.1 Volume I. 2) CNSC changed the wording in this version. What the difference is between the “type” of waste and “class” of waste?</p>	<p>1) The paragraph was changed to: “This regulatory document addresses the development of a safety case and supporting safety assessment for the post-closure phase of disposal systems facilities, which includes locations or sites, for all classes of radioactive waste. This document also applies to long-term radioactive waste management facilities, locations or sites where there is no intention to retrieve the waste. Note: In this regulatory document, the term ‘disposal facilities’ also refers to disposal locations or sites, which are not classified as ‘nuclear facilities’ under the NSCA.”</p>

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	Hydro-Québec, Kinetrics, NB Power, NWMO, OPG, Orano		<p>3) Earlier comments on the need for a glossary of waste management classifications appear to have been disregarded. Even if all waste types are captured, it is still necessary to include a clear definition of disposal.</p> <p>4) The 2nd paragraph is unclear when it says, “The post-closure safety case considers information from the preclosure phase (site preparation, construction, operation, decommissioning) insofar as this information impacts post-closure safety.”</p> <p>Suggested change: For clarity:</p> <p>1) Amend the 1st paragraph to read, “This regulatory document addresses the development of a safety case and supporting safety assessment for the post-closure phase of disposal systems (facilities, locations or sites) for all classes of radioactive waste. This document also applies to longterm radioactive waste management facilities where there is no intention to retrieve the waste”</p> <p>2) If ‘type’ and ‘class’ are intended to mean the same thing, make the wording consistent in all sections.</p> <p>3) Provide a clear definition of disposal. Waste management and disposal-related definitions should also be consistent (e.g., captured in REGDOC-3.6, Glossary of CNSC Terminology, or simply the same in each of the interdependent REGDOCs).</p> <p>4) Is there a specific safety case? Is this post-closure only? The comment does not align with the safety case definition and “all aspects” not just post-closure. Is there a pre-closure safety case? The use of the terms ‘safety case’ vs ‘safety assessment’ needs to be reviewed.</p> <p>Impact on industry:</p> <p>A failure to differentiate long-term waste management and disposal could lead to misunderstandings by licence holders and members of the public. Also, the requirements listed in this document are different than those for an operating waste management facility as defined in REGDOC 2.11.1 Volume I. This may result in expectations that are unclear for both Licensees and interveners. Without more clarity, this REGDOC could result in additional safety cases</p>	<p>2) When referring to licensees or wastes, the term “type” was replaced with “class” throughout the document.</p> <p>3) The definition of disposal is in the CNSC glossary</p> <p>4) The first paragraph of the section states that “This regulatory document addresses the development of a safety case and supporting safety assessment for the post-closure phase of disposal...” Pre-closure or the operational phase is discussed in other regulatory documents and CSA standards on the operation of waste facilities.</p>

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			being developed for the different project lifecycle phases when what is required is a safety assessment and updates to the facility's existing safety case.	
3.	Bruce Power, BWXT, Cameco, CNA, CNL, CANDU Owners Group, Hydro-Québec, Kinetrics, NB Power, NWMO, OPG, Orano	2	<p>MAJOR As per licensees' general comment, the waste management REGDOCs (2.11.1 Vols I, III and 2.11.2) are clearly interdependent as cited in the 1st list of bullets. However, their review and publication seem independent, or phased.</p> <p>Suggested change: Present the complete package of interdependent REGDOCs to the Commission at the same time so that the final, published versions reference only the published REGDOCs.</p> <p>Impact on industry: Draft guidance is subject to change. There are references to both draft and published REGDOCs in this version. Together with the LCH effective dates, these versions make the path (e.g., timing of) to compliance unclear.</p>	<p>The following draft REGDOCs will be presented to the Commission as a package to complete the CNSC's regulatory framework related to waste management:</p> <ul style="list-style-type: none"> ● 1.2.1, <i>Guidance on Deep Geological Repository Site Characterization</i> ● 2.11.1, <i>Waste Management, Volume I: Management of Radioactive Waste</i> ● 2.11.1, <i>Waste Management, Volume III: Safety Case for the Disposal of Radioactive Waste, Version 2</i> ● 2.11.2, <i>Decommissioning</i> ● 3.3.1, <i>Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities</i>
4.	Bruce Power, BWXT, Cameco, CNA, CNL, CANDU Owners Group, Hydro-Québec, Kinetrics, NB Power, NWMO, OPG, Orano	4	<p>MAJOR The 2nd sentence in the 1st paragraph needs to be amended since a safety case will always include some form of safety assessment.</p> <p>Suggested change: Amend to read, "A safety case normally includes a safety assessment, but could also typically include information (such as supporting evidence and reasoning) on the robustness and reliability of the disposal system safety assessment and the assumptions made therein."</p> <p>Impact on industry: If the intention is the reliability and robustness of the safety assessment then this is a major comment. It is unclear how this requirement can be adequately demonstrated.</p>	<p>The definition aligns with REGDOC 3.6, therefore no change was made.</p> <p>REGDOC 2.11.1, Volume III sections on General Requirements and Components of a Safety Case stipulate that the requirement for a disposal facility safety case include a safety assessment and the safety case strategy include key elements such as robustness.</p>
5.	Bruce Power, BWXT,	7.2	MAJOR	The change was made as suggested.

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	Cameco, CNA, CNL, CANDU Owners Group, Hydro- Québec, Kinetrics, NB Power, NWMO, OPG, Orano		<p>The description of containment and isolation should make it clear that it is the overall barrier system that will provide protection over the timeframe of the safety case.</p> <p>Suggested change: Amend the 1st sentence under the Containment and Isolation section to read, "...by presenting evidence that the overall barriers system retains its their safety functions during the safety case timeframe."</p> <p>Impact on industry: As written, the sentence can be interpreted to apply to each individual barrier.</p>	
6.	Bruce Power, BWXT, Cameco, CNA, CNL, CANDU Owners Group, Hydro- Québec, Kinetrics, NB Power, NWMO, OPG, Orano	7.2 and 7.4.1.1	<p>MAJOR Section 7.2 says the strategy shall identify elements to provide confidence in safety and includes passive safety features among the bullets. In section 7.4.1.1., under Passive Safety, it says "...should take passive safety means into account in the design of the facility to minimize the dependence of safety on active means, as much as possible."</p> <p>Suggested change: Revise section 7.2 to be consistent with 7.4.1.1.</p> <p>Impact on industry: Should vs. Shall agreement. Wording needs to be consistent between sections so it's clear how to comply.</p>	The "should" statement in section 7.4.1.1 was changed to a "shall".
7.	Bruce Power, BWXT, Cameco, CNA, CNL, CANDU Owners Group,	7.4.1.1	<p>MAJOR Site selection is a separate process that is normally carried out in support of the impact assessment. Site selection findings could contribute to the Safety Case, but there is no need to duplicate the site selection process here.</p> <p>Suggested change:</p>	<p>The sentence was changed to: "The licensee or applicant shall ensure that the safety assessment describes and/or references the approach and criteria used in site selection and demonstrate that the site selected is in accordance with the safety strategy and any criteria that have been established."</p>

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	Hydro-Québec, Kinetrics, NB Power, NWMO, OPG, Orano		Amend the 1st sentence on page 10 to read, "...ensure that the safety assessment describes references the approach and criteria used in site selection..." Impact on industry: Introduction of the site selection process duplicates what is an exhaustive process that has already been carried out.	
8.	Bruce Power, BWXT, Cameco, CNA, CNL, CANDU Owners Group, Hydro-Québec, Kinetrics, NB Power, NWMO, OPG, Orano	7.4.1.2	MAJOR Licensees believes this passage is too general should be amended for clarity and to better align with IAEA SSR 23 Operational Aspects relevant for longterm safety. Suggested change: Amend to read, "While operational safety aspects are outside the scope of this document, the impacts of preclosure activities on the post-closure safety shall be minimized. While operational safety aspects are outside the scope of this document, the licensee shall ensure that post-closure safety will not be impacted by preclosure activities." Impact on industry: The phrasing "not be impacted by pre-closure activities" is too general. For example, the basic pre-closure activity of excavation impacts the post-closure safety, in that the excavation and excavation damaged zone (EDZ) must be accounted for post-closure. The suggested change clarifies that the post-closure safety assessment has considered the operational activities that took place pre-closure.	The paragraph was changed to: "While operational safety aspects are outside the scope of this document, the licensee shall ensure that the impacts of pre-closure activities on post-closure safety are assessed and minimized."
9.	Bruce Power, BWXT, Cameco, CNA, CNL, CANDU Owners Group,	7.10	MAJOR Licensees have the following concerns and suggestions for this section: 1) The 2nd bullet says the licensee should compare end points to acceptance criteria" but 7.10.1 says the licensee or applicant shall compare endpoints to acceptance criteria. 2) The word "any" in the 3rd bullet of the 2nd bullet list is too broad. It should be based on significance.	1) The second bullet was removed. Bullets in section 10 were revised to incorporate IAEA recommendation. 2) Bullet was changed to: "provide findings that contradict the arguments made in the safety case" 3) The sentence was changed to: "In addition, the licensee or applicant should[...]"

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	Hydro-Québec, Kinetrics, NB Power, NWMO, OPG, Orano		<p>3) There is no need to divide the list of bullets. Align bullets 3 to 5 of second paragraph with IAEA SSG-23 Paragraph 4.77.</p> <p>Suggested change: For clarity, the CNSC is urged to: 1) Remove 2nd bullet (7.10). It is not necessary. 2) Amend the 3rd bullet in the 2nd bullet list to read, “provide significant any findings that...” 3) Deleted the 2nd use of “The licensee or applicant should” and continue the bullets from the previous paragraph. 4) Align with IAEA-SSG-23 Paragraph 4.77, which says, “The bullets listed are sub bullets in the case where there is a contradiction as indicated below: Findings that are in contradiction to arguments made in the safety case and uncertainties should also be discussed and analysed. This necessitates a detailed discussion of the following: — The treatment of uncertainty in the safety case and supporting assessment; — The quality and reliability of the science and the design work that form the basis for the safety case; — The quality and reliability of the safety assessment, including the development of each scenario, the adequacy of the range of scenarios considered, assessments of their likelihood, and the adequacy of the methods, models, computer codes and databases used;</p> <p>Impact on industry: Should vs. Shall agreement. Wording needs to be consistent between sections so it’s clear how to comply.</p>	4) No change as this aligns with the CSA standard.
10.	Bruce Power, BWXT, Cameco, CNA, CNL, CANDU Owners Group,	8.1.1.1	<p>MAJOR Licensees have the following concerns with this section: 1) This section refers to “benchmarks” enabling the licensee to identify likely sources of data, however there is no guidance provided how this data is to be used to derive appropriate requirements and acceptance criteria. 2) Bullets (a) and (b) are essentially duplicates of (c) and (d) 3) The CNSC changed the wording to “if the expected annual dose of less than 1 mSv...”</p>	The proposed changes have been incorporated as suggested.

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	Hydro-Québec, Kinetrics, NB Power, NWMO, OPG, Orano		<p>Suggested change: For clarity, the CNSC is urged to:</p> <ol style="list-style-type: none"> 1) Add clarity that the benchmark data does not become the requirement by default. Rather, it is an input to the process that is being used to determine the requirements. Reference RD-2.9.1. 2) Delete (a) and (b) since (c) to (e) are consistent with IAEA SSR-5 3) Change “dose of less than” to “dose is less than”. <p>Impact on industry: With no guidance, benchmark data may result in overly conservative requirements.</p>	
11.	Bruce Power, BWXT, Cameco, CNA, CNL, CANDU Owners Group, Hydro-Québec, Kinetrics, NB Power, NWMO, OPG, Orano	8.1.4.2	<p>MAJOR This section now says, "The licensee should verify and validate all computer software used for the safety assessment." But if this is commercial software being used in accordance with its manual etc., the licensee or applicant should be able to refer to existing validation. Also, 'or applicant' is missing from this line.</p> <p>Suggested change: Remove the licensee performed validation from commercial software. Reference to existing validation should be sufficient. Add “or applicant” after “Licensee”</p> <p>Impact on industry: Licensee or applicant shouldn’t have to validate commercial software that is being used appropriately. References to existing validation should be sufficient.</p>	The change was made as suggested.
12.	Bruce Power, BWXT, Cameco, CNA, CNL,	Figure 1 and 5.2	<p>Confirm that the illustration of a postclosure safety case in Figure 1 and the description in Section 5.2 are aligned with the application requirements in the regulations (e.g., GNSCR and Class I).</p> <p>Suggested change: This REGDOC should align with the requirements for submitting safety analysis reports in the Class I Regulations (i.e., preliminary safety analysis</p>	The <i>Class I Nuclear Facilities Regulations</i> and this REGDOC are aligned. This regdoc provides greater detail and clarity about how to implement the Class I requirements for the submission of a safety analysis for the post-closure period.

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	CANDU Owners Group, Hydro-Québec, Kinetrics, NB Power, NWMO, OPG, Orano		with the construction licence application and final safety analysis for operations).	
13.	Bruce Power, BWXT, Cameco, CNA, CNL, CANDU Owners Group, Hydro-Québec, Kinetrics, NB Power, NWMO, OPG, Orano	4	The labels in the Figure 1 headings should be consistent with sections within the REGDOC. Suggested change: Please confirm for consistency	The figure was updated accordingly.
14.	Bruce Power, BWXT, Cameco, CNA, CNL, CANDU Owners Group, Hydro-Québec,	7	Additional context should be added to the 1st paragraph, which says, “The safety case shall include the following components, as illustrated in figure 1:” Suggested change: Add a comment that this information can be combined, e.g. disposal system description could include safety features. This would provide flexibility for licensees to present the required information.	A sentence was added at the end of the section as follows: “Note that there are many possible ways of structuring and documenting the safety case.”

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	Kinetrics, NB Power, NWMO, OPG, Orano			
15.	Bruce Power, BWXT, Cameco, CNA, CNL, CANDU Owners Group, Hydro-Québec, Kinetrics, NB Power, NWMO, OPG, Orano	7.9	<p>This section title could better reflect its content.</p> <p>Suggested change: The focus of this section is on requirements for institutional control vs safety features. Licensees suggest the title be amended to reflect the focus of section.</p>	The title was changed to “Institutional control”.
16.	Bruce Power, BWXT, Cameco, CNA, CNL, CANDU Owners Group, Hydro-Québec, Kinetrics, NB Power, NWMO, OPG, Orano	8.1.1.3	<p>Under the ‘Identification of human and environmental receptors’ section, the 2nd sentence requires a slight edit since there may not always be a different pathway.</p> <p>Suggested change: Amend to read, “The exposures of persons and the various receptor organisms can will occur by different pathways and will be judged by different acceptance criteria even when all receptors are present in the same environment at the same time.”</p>	The change was made as suggested.