canadian nuclear association cna anc association nucléaire canadienne

Sept 16, 2019

Mr. B. Torrie
Director General, Regulatory Policy Directorate
Canadian Nuclear Safety Commission
P.O. Box 1046
280 Slater Street
Ottawa, Ontario K1P 5S9

Canadian Nuclear Association Comments on REGDOC 2.11.1, Waste Management, Volume 111: Safety Case for Long-Term Radioactive Waste Management.

Dear Mr. Torrie:

The Canadian Nuclear Association (CNA) and its members would like to thank the CNSC for the opportunity to comment on REGDOC 2.11.1. The CNA has collaborated with its members to review the proposed regulatory document in detail. Our detailed comments are contained in the attached document; however, the CNA would like to highlight the following issues:

- The CNA appreciates the CNSC's desire to provide early drafts to industry, but our members felt that perhaps more time could have been spent improving the editorial quality of the document. Our members felt that it would have been much easier to provide constructive feedback with more consistent wording, better definition of terms and less repetition of themes. Members also noted several redundant sections. CNA notes that this has not been a significant issue in the past and that it is rare to have a significant number of editorial concerns in a document.

- The CNA feels that the document does not clearly define the lifecycle phases of a facility or the requirements that apply to each phase. In our view the document also fails to make it clear which waste storage facilities are included in this document. This lack of clarity is likely to result in challenges to compliance. Safety compliance is best served through clarity.

- A graded approach to the application of this document is clearly required but there are only a couple of references to it and no meaningful discussion in this draft. The guidance provided represents a significant and perhaps unnecessary undertaking for some of the lower-risk licensees, who appear to be captured in the scope.

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- CNA members are of the view that this REGDOC should not apply to radioactive waste management at uranium mines and mills. It is our view that the nature of the wastes created and appropriate facilities for the long-term storage of wastes at uranium mines and mills require specific assessments which are covered in REGDOC 2.11.1. Waste Management, Volume II: management of Uranium Mine Waste Rock and Mills Tailings.

- There are detailed design requirements in various sections of the document. CNA members believe these are unnecessary for this document and risk creating confusion. CNA has noted a number design requirements that we believe should be removed from the document.

Once again, thank you for the opportunity to comment on the REGDOC. If you have any questions or concerns, please contact me at [personal information redacted].

.Sincerely,

Steve Coupland
Director, Regulatory and Environmental Affairs
Canadian Nuclear Association

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Industry comments on draft *REGDOC-2.11.1, Waste Management, Volume III: Safety Case for Long-Term Radioactive Waste Management, Version 2*

#	Document / Excerpt of Section	Industry Issue	Suggested Change (*if applicable*)	Major Comment/ *Request for Clarification*[1]	Impact on Industry, *if major comment*
1.	**General**	Licensees found the editorial quality of this document below the CNSC's usual standards for drafts issued for industry or public review. While industry appreciates this is an early version and subject to further editing, reviewers were challenged to provide concise, meaningful feedback due to the volume of inconsistent wording, undefined terms, repetitive themes and redundant sections. There are also several references to draft REGDOCs that have not yet been published, which means requirements may not be fully understood and informed comments difficult to provide. To ensure a better understanding of the REGDOC and its requirements, industry requests the CNSC circulate a revised version for further review by subject matter experts prior to publication.	Please see specific examples in the table below where licensees have suggested wording changes to improve the document. Generally, licensees believe future drafts could make better use of Appendix A to align the document's sections and titles to areas being discussed. As currently laid out, reviewers found it is easy to get lost in the sections.	**MAJOR**	REGDOCs that are clearly written in an easy-to-read, logical format promote better understanding for all stakeholders. In turn, this leads to better compliance and improved nuclear safety.
2.	**General**	The document does not clearly define the lifecycle phases of a facility or the requirements that apply to each phase. Specifically, licensees found operational concepts for assessing a typical nuclear facility have been added to this draft. However, a disposal facility generally has the following lifecycle phases: siting; construction; operation; pre-closure monitoring; closure; decommissioning of ancillary facilities; post-closure. While some concepts can be applied to the operational phase of a waste management or disposal facility, they cannot be directly applied to the unique aspects or post-closure timeframe of a repository.	Applicability of requirements for specific timeframes need to clear and should not inadvertently create other safety issues. For example, Section 3 should clarify if lifecycle incudes closure and post-closure.	**MAJOR**	Unclear expectations could challenge compliance verification. Stakeholders are best served if there is a clear and common understanding as to which radioactive waste management facilities this guidance applies to.
3.	**Preface, 1.2**	A graded approach to the application of this REGDOC is clearly required, but there are only a couple of references to it and no discussion. The guidance	Describe how a scaled or graded approach to this guidance should be applied based on the radioactive waste and licensee types. Clarify	**MAJOR**	Without more clarity on the application of a graded approach, there is the potential for licensees to be out of compliance

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		provided represents a significant and perhaps unnecessary undertaking for some of the lower-risk licensees, who appear to be captured in the scope. Similar to comment #2, and as indicated in industry's previous feedback on *REGDOC 2.11.1 Vol I*, it is not clear which licensees this REGDOC applies to, or what type of radioactive waste (low, intermediate, or high level) management. For instance, in Section 5 it is not clear what is captured by the phrase, "a long-term radioactive waste management facility or site." Is Chalk River Laboratories an example of a long-term radioactive waste management site? Is the existing Western Waste Management Facility a short-term storage facility? Or, if operation is to be continued for 30 to 50 years, would it be re-classified as a "long term" interim storage facility, pending transfer of stored waste into a future permanent waste disposal facility?	what type of radioactive waste and waste management facility is being referenced and those that would be excluded (i.e., milling waste). Clarify when a facility transitions from short-term to long-term and ensure all terms are defined and cross-referenced in *REGDOC-3.6, Glossary of CNSC Terminology* as appropriate.		because of a lack of understanding as to which radioactive waste management facilities this guidance applies to.
4.	**Preface**	This draft introduces the term "must" to express requirements in some passages and uses the traditional term "shall" in others. It also uses "should," "may" and "can" to describe various levels of guidance. Licensees appreciate this may be part of a wider move to use plain, everyday language in legal and regulatory documents. However, mixing terms for requirements or guidance inadvertently generates more confusion than clarity. Further, this revision of the REGDOC introduces numerous "shall" statements that merely describe the normal process used in a safety analysis. For example, section 6.4.2 says, "The licensee or applicant *shall* use data obtained from the	Industry urges the CNSC to choose just one word to signify a requirement and one for guidance and apply them exclusively in this and all other REGDOCs. While "must" is more commonly used in everyday language, "shall" is used in most other REGDOCs and nuclear standards and may be more easily applied across the CNSC's regulatory framework. Also, licensees urge the CNSC to use "will" statements for normal process descriptions such as the one in 6.4.2, which more properly should	**MAJOR**	On its surface, the use of different words to express requirements or guidance appears inconsequential. It is not. Readers of this and other recent draft REGDOCs have found it increasingly difficult to determine what is truly obligatory and what is optional. Simple language used consistently – like "shall" for requirements and "may" for guidance – will reduce confusion and inaccurate interpretations.

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		waste management system description as inputs to the safety analysis, and provide boundary conditions for the quantitative models." The arbitrary use of "shall" statements leads to confusion with respect to what CNSC expectations a licensee/applicant will be required to meet.	read, "The licensee or applicant will ~~shall~~ use data …"		
5.	**1.1**	As per comment #2, the Purpose section does not make it clear which waste storage facilities are included in this draft REGDOC. For long-term radioactive waste management facilities that have been operating, decommissioned or closed before 2020, this document is to be considered guidance. No exemption is provided for interim or short-term radioactive waste management facilities. Lack of clarity generates questions. For instance: Does future storage in the Point Lepreau Nuclear Generating Station (PLNGS) Solid Radioactive Waste Management Facility (SRWMF) fall within the scope of this document? Does storage and disposal include 'in-situ' disposal? Does facility also mean site or contaminated site?	Add an exemption for interim or short-term radioactive waste management facilities. These facilities should only have to implement *REGDOC-2.4.4, Safety Analysis for Class 1B Nuclear Facilities*. Clearly define "long-term waste management" and "facility" and apply them consistently.	**MAJOR**	An unclear purpose could lead to incorrect assumptions regarding requirements for facility type – long term storage vs short-term storage.
6.	**1.2**	Licensees strongly disagree that the scope of this REGDOC should apply to radioactive waste management at uranium mines and mills. As recognized in *CSA N292.0-14, General Principles for the Management of Radioactive Waste and Irradiated Fuel* Section 1.4 and A.8, the nature of the wastes generated and the facilities appropriate for the long-term storage of wastes at uranium mines and mills requires specific safety assessments for which sufficient guidance is provided in *REGDOC-2.11.1,*	Remove radioactive waste management at uranium mines and mills from this REGDOC.	**MAJOR**	For mines and mill licensees to apply this REGDOC "as applicable" in this case would essentially require mines and mill licensees to translate and re-write a complex and detailed REGDOC creating both uncertainty and a significant administrative burden without any benefit. Should there be any specific guidance regarding the safety case applicable to mines and mill wastes that is not Volume III, it would be more efficient

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		Waste Management, Volume II: Management of Uranium Mine Waste Rock and Mill Tailings (Volume II).			and simpler for that limited information to be added to Volume II.
7.	**1.2**	As per comment #1, the Scope of this REGDOC is unclear and: 1. Introduces of the term "closure" without defining its context in the Scope, Glossary or within *REGDOC-3.6, Glossary of CNSC Terminology*. 2. Does not recognize that Regulatory and Guidance Documents are no longer differentiated, which effectively makes this REGDOC guidance for all the facilities, locations and sites to which it applies. Regarding the last sentence in the 1st paragraph, not all radioactive waste management facilities require a safety analysis. Nor are they all Class IB licensees. This is related to industry's concerns cited in comment #2.	For clarity, licensees suggest exclusions should be noted and the Scope amended to read, "The Monitoring and Surveillance component of the safety case and Operational Safety Analysis component of the Safety Assessment are excluded since they are covered in other regulatory documents." Additionally: 1. A definition of when a nuclear power plant is considered closed should be included in this REGDOC and *REGDOC-3.6.* 2. The 2nd paragraph should be deleted. Licensees further urge the CNSC to clarify where the guidance on safety analysis for radioactive waste management facilities can be found for each of the respective types of licensees and which types of radioactive waste and waste management facilities are excluded from this guidance.	**MAJOR**	Compliance is challenged when there is a lack of clarity regarding which guidance applies to which radioactive waste management facilities.
8.	**1.2, 1.3, 2, 5.0, 6.4.2, 6.4.3, 6.9, 6.10, 7.1.3.1,**	As per comment #1, draft REGDOCs are mentioned in all of these sections. As a matter of principle, draft REGDOCs should only reference other REGDOCs that are currently published and not out for review. Otherwise, approved requirements may not be fully understood and informed comments cannot be provided. For example, since *REGDOC-2.11.2* will supersede *G-219*, is the reference to *G-219* being "under revision" correct? Should *G-219* be	Cite only currently published versions of REGDOCs.	Clarification	

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		alternatively replaced by draft *REGDOC-2.11.2* in Section 2?			
9.	**1.3**	As per comment #1: • The bullet list is incomplete • The acronym "NSCA" not spelled out in 1st use • The Class II Nuclear Facilities Regulations title not fully cited	• Add references to the *Nuclear Substances and Radiation Devices Regulations* and the *Nuclear Fuel Waste Act.* • Spell out all acronyms for 1st use • Amend to read, "Class II Nuclear Facilities and Prescribed Equipment Regulations"	Clarification	
10.	**2**	As per comment #1, section 2 duplicates information provided in Appendix A.	For ease of reading, remove repetitive passages.	Clarification	
11.	**3, 6.4**	As per comment #1, the definitions of safety case, safety assessment and safety analysis do not clearly distinguish these activities, in particular between assessment and analysis. The previous version of this REGDOC was organized essentially on Safety Case and Safety Assessment and did not try to distinguish Safety Analysis. This version is organized into Safety Case and Safety Analysis. The addition of a third layer in this version is not particularly clear. Analysis should be used to refer to the (various) specific quantitative models or calculations that support a safety assessment. Related to this, in section 6.4, the scope of what is regarded as a safety assessment vs a safety analysis report (SAR) vs a post-closure assessment vs a safety case is unclear. Reviewers found it difficult to determine if safety assessments are considered any analysis and the SAR and safety case are collections of these analyses. This leads to confusion as to expectations of where the different types of analysis should be presented.	Industry urges the CNSC to: • Retain the structure of the previous version of this REGDOC • Refer to items in Section 7 as part of the Safety Assessment rather than Safety Analysis • Keep the REGDOC focused on the long-term aspects	**MAJOR**	This REGDOC was previously focused on assessing long-term safety and applied to waste management concepts that required a long-term safety case (e.g., DGRs). The scope appears to have broadened without clarity on what types of facilities this REGDOC applies to and at which part of the lifecycle. It also mixes safety assessment/analysis concepts without clarity on when a safety case, safety assessment or safety analysis are required. Unclear expectations could lead to different approaches, misalignment of expectations and inconsistent submissions to the CNSC from various licensees.
12.	**3.**	Further to the comment above, Section 3 does not:	Industry urges the CNSC to:	**MAJOR**	Unclear expectations could challenge compliance verification and inadvertently

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		1. Align well with the relevant acts and regulations. For example, a safety assessment does not assess the safety of a facility, its design, siting etc. It assesses the activities carried out for each of the listed aspects. This is important. According to the Nuclear Safety and Control Act, it is the activity that is licenced. It is difficult to show compliance with the Act if the safety assessment doesn't align with the requirements. Also, since *REGDOC-2.11.1, Volume I* seems to align with the IAEA, industry suggests the IAEA definitions should be used, especially since they align better with the Act. 2. Provide consistency with Section 6 regarding the requirement for a safety assessment being included in a safety case. 3. List the applicable regulatory requirements cited in the 1st paragraph. 4. The term "global" is not clearly expressed in the 4th paragraph. 5. Clarify what is meant by lifetime in the phrase "over the lifetime of the facility" in the 3rd paragraph. 6. Clarify between guidance and requirements in the final paragraph, which says Appendix A outlines the components of a safety case, safety assessment and safety analysis. It's unclear if the outline is guidance or requirements since it's under the definitions section of the document	1. Use the definitions given in the IAEA Radioactive Waste Management Glossary. Where CNSC REGDOC glossary definitions are not aligned with the IAEA, provide additional information for clarity 2. Amend the 2nd sentence to read, "A safety case ~~normally~~ includes a safety assessment supported by additional lines of evidence and the assumptions made therein. (See Section 3, paragraph 3, sentence 1 ("A safety assessment forms the core of") and Section 6, bullet 4 ("safety case shall include a safety assessment") 3. List the applicable regulatory requirements in the 1st paragraph to ensure licensees understand which ones are applicable. 4. Amend the 3rd sentence of the 4th paragraph to read, "…or some other relevant ~~global~~ measure of the overall impact on safety." 5. Define "lifetime of the facility" since it is ambiguous whether the lifetime includes the post-closure stage. Paragraph 4 in Section 4.2 seems to indicate that lifetime excludes post-closure for disposal facilities. (See similar comment on Section 4.2) 6. Delete the last paragraph since it's duplicated in other sections where there is no ambiguity of requirement.		result in confusion for members of the public as to expected requirements for facilities.

Industry comments on draft *REGDOC-2.11.1, Waste Management, Volume III: Safety Case for Long-Term Radioactive Waste Management, Version 2*

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13.	**4.1**	As per comment #1, Section 3 defines a Safety Case but Section 4.1 describes it differently. Additional clarity is sought in a number of areas: • The need to identify that a safety case relates to all hazards. • As per the CNSC's definition in Section 3, the safety case would "demonstrate the safety of a facility and the meeting of all applicable regulatory requirements." While a safety case would support the selection of a site, it would not be used to select and characterize the site. • The monitoring program is not used to determine if the safety case is appropriate. The data only shows that the system is performing as expected or there is an issue. • New terminology such as "limits, controls, and conditions" is being used without being defined. • In the 2nd paragraph, the term "closure" should be clarified with respect to "post closure" activities (if applicable).	Define the new terminology included in this section and clarify the difference between "closure" and "post-closure" activities. Amend the following passages: • 1st paragraph, "The safety case relates to all hazards and is the main tool to document and demonstrate …" • 2nd paragraph, "support the selection of a ~~and characterize the~~ site" • 3rd paragraph, "The safety case is also a tool to design the monitoring program and the data obtained from the monitoring program is used to confirm that the assumptions made by the safety case are appropriate ~~or to develop an updated safety case~~. • 4th paragraph, "The safety case supports decision making and is also a means of communication and consultation with interested parties at specific decision points throughout the facility's lifecycle."	Clarification	
14.	**4.2**	Reference to the "lifetime" of the facility in the 4th paragraph is unclear. It infers the release from CNSC licensing after decommissioning, but doesn't clearly state abandonment. If the facility has to be removed because it is at the end of life, then a safety case meeting this requirement is not needed as it will no longer exist. If the facility is abandoned then where will the safety case be kept? Also, licensees cannot know what information future generations will want.	The approach to the release from CNSC licensing after decommissioning needs to be addressed in this REGDOC. A definition of "lifetime of the facility" is needed since it is ambiguous whether the lifetime includes the post-closure stage. The 4th paragraph seems to indicate that lifetime excludes post-closure for disposal facilities. The paragraph should be amended to say the safety case "will contain ~~all the~~ information ~~that~~ future generations may ~~should~~ require …"	**MAJOR**	Release from CNSC licensing after decommissioning is allowed under the Regulations, but a lack of clarity on how this is obtained could result in major uncertainty in the design, operation, closure and lifetime of the facility. It is not feasible, credible or sensible to manage a facility in perpetuity especially if, at some point, the hazards associated with facilities become negligible.
15.	**5**	Section 5 incorrectly infers that a safety case is a standalone document that contains all necessary	Clarify that a safety case is a high-level document that summarizes the detailed analysis	**MAJOR**	Unclear expectations as to what constitutes a safety case can lead to regulatory

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		information. It is not. A safety case is a top-level document that refers out to the technical input. It summarizes the arguments and evidence presented in supporting documents to demonstrate safety. To licence an activity, the safety case points to the evidence given in supporting documents, which is the information relied upon for informing decisions.	that has been undertaken by a licensee to demonstrate an activity is safe. Ensure the REGDOC does not suggest that it needs to be a standalone document, but may be a collection of documents.		challenges and increased resource demands.
16.	**5**	As per comment #1, licensees believe the bullets in Section 5 require several clarifications. These include: 1. 1st bullet - only an activity can be licenced as per governing legislation. 2. 2nd bullet – a safety case cannot *prevent* unreasonable risk. It documents the processes, design, and controls etc. in place to demonstrate the activities undertaken do not present unreasonable risks. In addition, "persons" is not defined and "unreasonable" is vague and open to interpretation. 3. 3rd bullet, what is required by the phrase "ensure that the safety case is sufficiently detailed and comprehensive" 4. 4th bullet – the phrase "information that is traceable..." does not give any guidance on the quality or veracity of the information required, merely that it can be found. 5. 7th bullet - what is meant by "periodically review?"	Amend: 1. 1st bullet to ensure it's clear that only an activity can be licensed. 2. 2nd bullet, amend to read, "demonstrate through the safety case that the proposed site and facility will be safe. Clarify: 3. What "sufficiently detailed and comprehensive" entails. 4. Expectations for information by providing examples of what is acceptable. 5. How review periods will be established.	**MAJOR**	Without clarifying the 1st bullet, stakeholders may be confused over whether it is the activity or the facility that requires a licence. Similarly, without clarifying the 2nd bullet, stakeholders could easily misunderstand that the safety case demonstrates that risk is being effectively managed, *not* prevented. Additional resources would be required to explain the true nature of the safety case. Poorly defined expectations and review periods can result in an excessive burden.
17.	**5, 6.2 and 6.11**	Further to comment #1 and the list above, the term "safety requirements" is not well defined in this document, leading to potential confusion with respect to CNSC expectations. For example, Section 6.2 says, "Overall system robustness can be demonstrated by	Define "safety requirements."	Clarification	

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		showing that despite the failure of one or more barriers or safety functions, none of the safety requirements would be jeopardized." Also, Section 6.11, 3rd bullet, says, "… it should be noted that meeting specific criteria… is not sufficient to meet all requirements." *REGDOC-3.6* does not define this term.			
18.	**6**	As per comment #1: • What is meant by "as applicable" in the 1st sentence when, in this instance, the components have already been identified as requirement by the use of "shall"? • All bullets are not aligned with Appendix A	Clarify the section by: • Amending the 1st sentence to read, "…appendix A ~~(as applicable)~~" • Ensure consistency by aligning bullets with Appendix A. Break out the components that are further sub-categorized either here or in Appendix A for ease of use/clarity. Provide a numbering system that can be easily followed.	Clarification	
19.	**6.1**	The 2nd sentence appears to be a general statement that should apply to the whole safety case as opposed to just the safety case context. The term "the graded approach" indicates there is a *single* graded approach. If so, this should be provided. As per comment #2, clarity is needed for the final sentence of the 3rd paragraph, which reads, "The scope, extent and level of detail are commensurate with the risk posed by the facility or site and the stage of the facility's development."	Licensees suggest moving the 2nd sentence to the main discussion of Section 6. What is *the* graded approach? If there is a single approach, it should be described. Otherwise, amend to read, "The licensee or applicant should ensure that the safety case applies a ~~the~~ graded approach in its development." Once again, the document needs to clearly define the lifecycle phases of a facility or the requirements that apply to each phase.	Clarification	
20.	**6.2**	As per comment #2, it's unclear which lifecycle phase and associated terms are being discussed throughout this section. Nor are "Time frames" listed among the key elements, which licensees believe is an oversight.	Industry encourages the CNSC to amend this section to make it clear which life cycle phase is being discussed under each sub-section. "Time frames" should be added to the list of key elements, the section titled renamed to 'Safety	**MAJOR**	Imprecise language could lead to confusion and compliance issues. Language that is typically applied to different phases needs to be clearly articulated in this document.

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		Also, the section titles do not align naturally with Appendix A, which makes it confusing for the reader.	Case Strategy' and Appendix A adjusted to align with the sub sections.		
21.	**6.2, 6.3, 6.4**	There are detailed ***design requirements*** in various sections of this draft REGDOC. For example: • The final sentence under 6.2 Robustness, which says, "Therefore, the longer the hazardous lifetime of the waste, the more robust the natural and engineered barriers must be." • The last sentence under 6.2 Time frames, which says, "The design of the facility should be based on design-basis events (such as earthquakes, glaciation, climate change, etc.) that are consistent with the time frame of the normal evolution scenario." • The final paragraph of 6.3, which says, "The safety case and its supporting safety assessment should explain and justify the safety functions of each barrier. For example, the container or package could have multiple safety functions to prevent the release of radioactive material. If seals and/or welds are used to contain the waste they must be maintained during long-term storage and disposal for as long as practicable. The container may be designed so that the seal can be monitored and repaired or replaced during the operational period." • Section 6.4, which says, "The licensee or applicant should take into account, in the design of the facility, passive safety measures to minimize the dependence of safety on active systems during operation and after closure, as applicable." It may not be possible or appropriate to ensure safety	The cited passages are all design requirements that licensees believe should be removed from this document. Alternatively, a specific chapter for design requirements could be created, which is preferable than having them scattered throughout the document. If they are kept, licensees urge the CNSC to promote clarity by: • Amending the final sentence of section 6.2 to read, "Therefore, the effect of the long time frames on robustness should be considered" • Revising the final paragraph of 6.3 to remove the references to monitor and repair and focus on the requirement to define the safety functions. • Clarifying the scope of application for Section 6.4. Again, as per comment #2, it is not clear which licensees and radioactive waste types this applies to.	**MAJOR**	Having design requirements in this document generates confusion for readers, especially when they are spread across numerous sections.

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		through passive means for every type of radioactive waste management facility. • All of subsection 6.6			
22.	**6.2, containment and isolation**	The document uses the terms “acceptance criteria” throughout without specifying the purpose of the criteria. For example, acceptance criteria can be used when receiving material into a facility or when judging the acceptability of safety assessment results. See comment #47 for additional, related points.	The REGDOC should be clear on what acceptance criteria are to be established and for which point in the lifecycle phase as these are being discussed in different sections of the REGDOC.	**MAJOR**	Unclear expectations could challenge compliance verification. This could also inadvertently result in confusion for members of the public as to expected requirements for facilities.
23.	**6.2, Multiple safety functions and defence in depth**	As per comment #2, it is not clear whether the REGDOC is referring to establishing “safety functions” for long-term safety or for an operating waste facility.	The REGDOC should clarify the lifecycle phase for which the guidance is being provided. For example, international guidance illustrates how safety functions could be assigned for a disposal facility which is different given that the wastes are isolated. E.g., SSG-23 clause 4.29 "if waste packaging is assigned a containment function and degrades more quickly than anticipated, the surrounding backfill material can provide a further element of physical containment to retard the migration of radionuclides by adsorption; or …"; and clause 6.32 "Safety functions are fulfilled by elements of a disposal facility, such as a physical or chemical property of part of the disposal system, or a process or combination of processes, that contribute to containment and isolation of the waste (e.g. low hydraulic conductivity, slow corrosion rates, slow dissolution of the waste matrix, low radionuclide leaching rates, low radionuclide solubility, high sorption)."	**MAJOR**	Unclear expectations could challenge compliance verification. Stakeholders are best served if there is a clear and common understanding of the lifecycle phases specific guidance applies to.

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24.	**6.2 Multiple safety functions and defence in depth**	As per comment #1, subjective words such as "redundancy" and "additional" promote confusion, not clarity. Additional clarity is also sought as to how defence in depth is achieved and maintained and what is meant by passive barriers and controls.	Amend the 1st sentence to read, "The principle of defence in depth shall be applied in order to provide ~~redundancy and additional~~ a margin of safety." Provide additional guidance on achieving defence in depth and passive barriers and controls. The document should discuss common mode failure rather than the barrier function since diversity in achieving the function is the key to defence in depth.	**MAJOR**	Additional clarity can generate opportunities to improve defence in depth. A lack of clarity regarding barriers and controls can result in misalignment of testing and maintenance requirements for SSCs. With clarity, safety features may not meet CNSC's expectations with respect to use of active and passive controls.
25.	**6.2 Robustness**	Clarity is sought for the 1st sentence of the 2nd paragraph, which says, "For disposal facilities with longer time frames …"	Clarify what constitutes a "longer time frame." Longer than what?	Clarification	
26.	**6.2 Time frames**	Editorially, the 1st sentence in the final paragraph is duplicated and clarity is sought for the 3rd bullet, which reads, "type and severity of events considered in the safety analysis." More importantly: 1. This section does not discuss the application of a graded approach (as per comment #3) or how hazards can change over long time frames and so should the consideration of events. 2. The scenarios associated with the DGR's post-closure time frames should be classified as "normal evolution" and "disruptive scenarios" similar to the current REGDOC. 3. The statement, "The design of the facility should be based on design-basis events (such as earthquakes, glaciation, climate change, etc.) that are consistent with the time frame of the normal	Future drafts should remove the duplicate sentence, clarify the CNSC's expectations regarding the 3rd bullet and: 1. Include a meaningful discussion on a graded approach and what is required to enable a licence to be obtained. Application of standards should be commensurate with the hazard to be managed. For instance, hazards for a Low Level Waste facility will be lower than those for a power reactor. The REGDOC should also inform readers how hazard levels change with time, i.e. the hazard assessment should consider hazard reductions that take place due to decay. 2. Remove the term "design basis events" from the section or clarify that it only applies to certain time frames (i.e., in the pre-closure period).	**MAJOR**	More clarity would better inform the public, licensees and the regulator so all stakeholders better understand the concept of multiple time frames and how design basis events vary and facility robustness changes over time.

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		evolution scenario" should not apply to some facility types. For example, a surface disposal facility is not designed to withstand glaciation.	3. Remove the reference to glaciation.		
27.	**6.3**	As per comment #1, licensees feel this section requires clarification and editing in the following areas: 1. The title of section 6.3 is the same as 7.1.3 2. The bulleted list does not include the typical documents that the safety case would reference to demonstrate the requirements 3. In the 1st bullet, recognize FEPS as a commonly used phrase 4. In the 3rd bullet, the description of biosphere should include surfaces features (such as lakes, rivers) and fields, in additional to human and non-human biota. 5. In the 6th main bullet, explicitly stating "waste package" assumes that all materials are in packages. Waste may not be required to be placed into a waste package, e.g. a LLW waste facility may have design features to allow safe emplacement of bulk waste. 6. What is the difference, if any, between "container" and "package" in terms of this document? Package" is defined in *REGDOC-3.6*, but "container" is not. Where is "container" defined? 7. The term "structure, systems, and components" is first referenced in the 8th bullet, but the acronym SSC not cited until the final paragraph of the section.	Licensees suggest the section be amended for clarity in the following ways: 1. Retitle section 6.3 to avoid duplication 2. Update the list to include the typical information that the safety case would reference. 3. Amend 1st bullet to read, "a specific understanding of features, events and processes (FEPs) …" 4. Amend the 3rd bullet to read: "a description of the biosphere including human and non-human biota and surface features" 5. Amend the 6th bullet to read, "which includes the waste form ~~package~~ …" 6. State the difference between "container" and "package" 7. Include the acronym SSC after in the 8th bullet and simplify the 2nd sentence of the final paragraph to read, "The licensee or applicant shall ~~also~~ identify individual structures, systems and components (SSCs) important to safety. ~~and assess the performance of the waste management system and the SSCs in terms of their ability to fulfil the safety functions"~~	Clarification	

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28.	**6.3**	As per comment #3, a graded approach needs to be discussed in more detail in this section and throughout the document. Editorially, the 2nd paragraph repeats the term "*the* graded approach," which suggests an identified graded approach system, If one has been identified, it should be described. Otherwise, it should be changed to "*a* graded approach"	For low-risk, low-hazard facilities, the level of geological investigations should be commensurate with the risk and clearly stated throughout the document. Amend the 2nd paragraph to read, "a ~~the~~ graded approach"	**MAJOR**	Without a true graded approach, additional data and/or investigations could be requested by the CNSC or members of the public that will not impact the design or safety functions and are not commensurate with the level of risk associated with the facility. This can result in an excessive burden with no corresponding improvement to nuclear safety.
29.	**6.4**	As per comment #1, licensees believe section 6.4 requires clarification in a number of areas, such as: 1. As per the 2nd paragraph, it is not possible to address "all risks". Typically, low risk events are screened out of safety assessments as either low hazard or extremely unlikely to occur. 2. The 2nd paragraph suggests there is a FEPs analysis, but does not explain what that is. Also, recognize that FEPS was defined in Section 6.3.	For clarity, amend the second in the following ways: 1. Remove reference to "all risks" 2. Explain what a FEPs analysis is and amend the last sentence of the 2nd paragraph to read, "… evolution of the site and the occurrence of any potential disruptive events identified in the ~~features, events, and processes~~ (FEPs) analysis.	**MAJOR**	A lack of clarity can result in public perception that there are no risks compared to an understanding that the risks are acceptable
30.	**6.4.2**	As per comment #1, where is "site descriptive model" defined?	Define "site descriptive model"	Request for Clarification	
31.	**6.4.4**	The 2nd paragraph should be focused on assessment of consequences (i.e., consistent with the idea of developing normal evolution and disruptive scenarios in the long-term safety assessment).	Change focus of statement to look at potential consequences taking into account the condition of both the barriers and the hazard as opposed to generally using the term "risks."	**MAJOR**	Hazard reduction needs to be considered with the long time frames and with barrier design. Otherwise, it could result in an excessive burden to demonstrate design adequacy and determine compliance.
32.	**6.7**	As per comment #1, clarification is sought on the determination of limits, controls and conditions.	Is this meant for a specific lifecycle phase i.e. operations or for all phases? Would these limits ultimately be determined by *REGDOC-2.4.4 Safety Analysis for Class IB Nuclear Facilities*?	Clarification	
33.	**6.8**	As per comment #1, section 6.8 would benefit from additional clarity. Specifically, it:	Provide additional clarity for readers by: 1. Defining and include all terms in the Glossary of this REGDOC and *REGDOC-3.6*	Clarification	

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		1. Introduces the "complementary safety arguments," which seem to be based on the "complementary indicators of safety" used in the previous version. However, "complementary indicators" continue to be used in this document as well. The lack of clarity could lead to potential for confusion with respect to the terms used. 2. It is unclear why the 1st sentence of the 4th paragraph emphasizes that a monitoring program would be a requirement of the licence. 3. It is unclear to what is meant by "trigger criteria" in the final sentence of the 4th paragraph	2. Amend the 1st sentence of the 4th paragraph to read, "Complementary indicators as identified from the safety assessment can also be used to derive the monitoring program~~, which would be a requirement of the licence~~." 3. Delete the final sentence in the 4th paragraph~~, "In such cases, trigger criteria should be determined for the parameters, and courses of action and decisions should be developed in case of deviations from the criteria."~~		
34.	**6.10**	Regarding the 3rd paragraph, institutional controls will be relied on to ensure future land use is managed appropriately and that long-term safety is documented and verified. The document does not recognize that institutional controls are a way to ensure long-term monitoring. The 5th paragraph assumes a complete failure of a system specifically designed to prevent this from happening. An assessment of inadvertent human intrusion is realistic and should be considered in safety assessments but it shouldn't be based on the failure of institutional controls.	The 2nd paragraph cautions against reliance on institutional controls (not be used to justify a reduction in the level of design performance), but the 3rd paragraph undermines the entire premise of institutional controls and should be removed. Amend the 1st sentence of the 5th paragraph to read, "~~With the end of institutional control,~~ There is a risk of future inadvertent human intrusion into the facility, particularly with near-surface facilities."	**MAJOR**	This document undermines the process of institutional controls.
35.	**6.11**	As per comment #1, the structure of this section is not clear. The list of items the licensee / applicant should do to integrate the safety arguments is shown immediately after the paragraph referring to limitations on the understanding. These are the kinds of arguments that address the limitations, but this is not clearly drawn out in current wording.	Revise this section as follows: • Combine the 2nd paragraph with the 2nd bullet point on page 12 and move this new paragraph to the send of the section. • Replace the last bullet on page 13 identifying things the licensee/applicant should do as part of the integration to read,	**MAJOR**	Unclear expectations could challenge compliance verification. Stakeholders are best served if there is a clear and common understanding of the lifecycle phases specific guidance applies to.

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		Regarding the 1st bullet on page 13, it is unclear what the CNSC staff would consider "sufficient" to meet "all requirements" if meeting regulatory criteria is "not sufficient." Similarly, it is unclear what "fully document" would be considered as acceptable by the CNSC staff as per the 4th bullet on page 13.	"Acknowledge their limitations on the understanding of waste management system, its evolution, and its potential impact on people and the environment." • Delete "~~it should be noted that meeting specific criteria such as for dose or risk alone is not sufficient to meet all requirements"~~ from the 1st bullet on page 13 and the word ~~"fully"~~ from the 4th bullet.		
36.	**7**	As per earlier comments, it is not clear what constitutes "long-term."	Define or cross-reference in *REGDOC-3.6, Glossary of CNSC Terminology* as appropriate.	Clarification	
37.	**7.1.1**	As per comment #1, Section 7.1.1 is similar to section 6.1 but worded differently.	For consistency, this section should be laid out similarly to 6.1 as they are similar in content.	Clarification	
38.	**7.1.1.1**	Paragraphs 1 and 2 appear to be a repeat of summarized information from Section 6 and not need here. However, if kept, licensees cite the following concerns with this section: 1. As per our earlier comments, a safety margin is not an acceptance criterion. The acceptance criteria should be the limit of what is deemed acceptable to ensure the required level of safety/risk. 2. The 3rd paragraph introduces a new definition of "design dose target" from the previous version of this REGDOC and suggests it "should be challenging" without defining what challenging might be. 3. The REGDOC does not suggest alternative methods for determining benchmarks for the protection of person from hazardous substances.	Remove paragraphs 1 and 2 to avoid duplication. If not, 1. Amend the 1st sentence of the 2nd paragraph to read, "The licensee or applicant may choose to apply an additional margin of safety in deriving ~~acceptance criteria, such as~~ a dose target or a safety factor." 2. Remove the subjective word ~~"challenging"~~ from the 3rd paragraph. 3. Add the following paragraph on substances without guidelines to the 'Protection of persons from hazardous substances' section: "If none are available, benchmarks can be derived from the toxicity literature or other regulatory agencies, or from CCME protocols for the derivation of criteria." 4. Add ICRP Publication 108 as a reference, which discusses Derived Consideration	Clarification	

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		4. Under the 'Radiological protection of the environment' subsection, licensees suggest referring to the ICRP documentation. 5. Under 'Radiological protection of persons,' there is no mention of extreme scenarios being excluded from the public exposure limit. In the case of a human intrusion scenario, the 1mSv/yr is unlikely to be achievable with ILW and HLW where it is expected that institutional controls will be in place. Also, the 1st sentence of the 2nd paragraph contradicts the above paragraph. As the dose target should be a fraction "to account for the possibility of exposure to multiple sources", it is specifically being used to account for uncertainties. 6. Regarding the final sentence on page 14, licensees anticipate this analysis will be in accordance with *REGDOC-2.4.4* or *REGDOC-2.4.1.* 7. The 2nd paragraph under 'Protection of the environment from hazardous substances' does not specify a boundary for where the benchmarks can end. Without this being defined, analyses may be subject to a moving yardstick, resulting in potential rework each time that a new potential contaminant is identified.	Reference Levels and the concept of Reference Animals and Plants. 5. Add "… for natural evolution scenarios" to the 1st paragraph of the 'Radiological protection of persons' subsection, Clarification needs to be provided as to how uncertainties should be accounted for in the determination of dose targets 6. Clarify that this analysis requirement will be presented in *REGDOC-2.4.4 Safety Analysis for Class IB Nuclear Facilities* 7. The CCME and provincial guides (or equivalents) are used as benchmarks. Other literature may be used as supplemental		
39.	**7.1.1.2**	Licensees seek clarification for the line, "A licensee or applicant should use multiple risk-informed approaches to estimate the release" Are they saying using the correct model for the scenario? Or asking for multiple methods to model the same thing?	Please clarify in the revised REGDOC.	Clarification	

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40.	**7.1.1.3**	Industry has a major concern with the 1st paragraph under "Identification of human and environmental receptors"	The process for receptor selection and characterization has been detailed in CSA documents which include CNSC input and acceptance. Where applicable, human and environmental receptor selection should be consistent with receptors identified following CSA N288.6-12 Environmental Risk Assessments at Class1 nuclear facilities and uranium mines and mills.	**MAJOR**	Uncertainty created by inconsistent requirements.
41.	**7.1.1.3**	Other licensee concerns with this section include: 1. The additional parameters listed as "end points" of the safety analysis are in fact complementary indicators of safety. 2. Hazardous material protection" is discussed prior to this section but there is no mention of "environmental protection" until this sentence. 3. Same section title as section 6.3 4. Section 6.3 does not identify criticality safety. 5. Lack of clarity on the definition of "waste management system." The definition in the Glossary seems to allude to the system encompassing the entire phase of the facility (design, operations, post-closure). The 2nd paragraph, 2nd sentence, requires NCS analysis on only post-closure phase. The first sentence does not discriminate. What is the intention here?	Clarify the section by: 1. Moving the list of "additional parameters" to Section 6.8 and combining it with the existing list of complementary indicators of safety. 2. Change ~~"environmental protection"~~ to "hazardous material protection" 3. Change one title for clarity 4. Update section 6.3 to include criticality 5. Clarify the intention	Clarification	
42.	**7.1.3**	Licensees see a lack of clarity in requirements versus suggestions regarding the need for criticality safety analysis in appropriate waste management systems.	Change the first sentence in the second paragraph to "The waste management system shall ~~also consider~~ demonstrate that criticality safety has been considered as applicable."	**MAJOR**	This wording will help to ensure that criticality safety is considered when fissionable material is present in the facility. If no fissionable material is present, it should be a requirement to at least state

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					this is the reason for a lack of criticality safety analysis in the safety case**.**
43.	**7.1.3.1**	As per comment #1, site characterization is covered in 6.4.2. The section is redundant.	Delete	Clarification	
44.	**7.1.4**	Additional clarity is sought on the safety assessment scenarios and time frames. Also, the 2nd last paragraph is incomplete as written and the 1st sentence of the last paragraph on Page 20 does not read correctly.	Licensees suggest splitting this into two sections since they are discussed separately. For example: 7.1.4 Safety Assessment Scenarios 7.1.5 Safety Assessment Time Frames	Clarification	
45.	**7.1.4.1**	Industry has major concerns with this section as written. As currently written, this section could be interpreted that all analyses, including scoping and bounding analyses, will have to include the period of time during which the maximum impact is expected to occur. Bounding analyses could estimate the maximum impact without the need to include the time dependence. A graded approach is not recognized with respect to the safety analysis. The intent of the last paragraph of this section is particularly unclear. The discussion on design-basis events should be removed since the safety assessment for the long term considers normal evolution and disruptive event scenarios. For some facility types, events may be considered in relation to the lifetime of the barriers and not necessarily the assessment timeframe.	Industry suggests the following change, based on wording from the previous REGDOC: "Assessments of the future impact that may arise from the radioactive waste would be expected to include the period of time during which the maximum impact is predicted to occur. In some cases, only the magnitude of the maximum impact, independent of time, may be sufficient for the assessment (e.g., in bounding assessments using calculations based on solubility constraints)." Overall, the REGDOC should reflect that the longer post-closure time frame may necessitate examination of the robustness of the waste management facility for disruptive scenarios based on external hazard assessments. Robustness could be demonstrated through fragility assessment of the structure or by other accepted means. The discussion on design-basis events should be removed since the subsections that follow rightfully focus on normal evolution	**MAJOR**	This approach provides unnecessarily high design requirements and does not take into account the changing requirements due to normal evolution of the facility over longer timescales. The new requirement could restrict the flexibility of the industry to perform scoping and bounding safety analyses.

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		The final paragraph also adds numerical details that lead to misinterpretation. Specifically, licensees have two issues with this final paragraph: 1. "The longer the time frame, the more severe the design-basis events become" is not necessarily true. For example, the magnitude of the earthquake associated with the design basis return period is fixed. It does not change with time. Nor does it change for any other external hazard. Rather, the "likelihood" of the event occurring increases, not the severity. 2. The existing Canadian fleet is designed, for the most part, to a design basis earthquake magnitude equivalent to a 1,000 year return period. The example should be removed or changed to reflect 1,000 years and not 10,000 years to avoid providing a misconception that 10,000 years as a "design" return period is required (recognizing that 10,000 years is required per REGDOC-2.5.2 for new builds).	and disruptive scenarios for the long-term safety assessment.		
46.	**7.1.4.3**	The sentence in the 3rd paragraph that reads, "Acceptance criteria for human intrusion should be defined" is new compared with the prior version. If there is an expectation on criteria definition, this should be identified in Section 7.1.1.1 Acceptance Criteria. Regarding the 4th paragraph, if a facility is under institutional control, then inadvertent human intrusion should not be a scenario during this period since this would require deliberate attempts to access this	Delete the sentence in the 3rd paragraph, ~~"Acceptance criteria for human intrusion should be defined"~~ Clarify that the 4th paragraph applies to post institutional control.	Clarification	

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		waste. Controls and mitigation events are already in place to prevent human intrusion during institutional control. Additional work to prevent this would not be necessary.			
47.	**7.1.5**	As per comment #1, developing and using safety analysis models is discussed earlier in the document and provides no added value here.	Delete	Clarification	
48.	**7.1.5.1**	The 1st sentence implies that commercially available software packages, developed for a variety of non-specific uses, are not allowed to be used in the safety analysis.	Amend the 1st sentence to what was in the previous version of this REGDOC, i.e., "The computing tools used to solve the equations in the assessment model can range from commercially available software packages to computer programs that are developed specifically for the given assessment."	**MAJOR**	Not recognizing commercially available software packages could lead to significant limitations to the development of computer models used in safety analysis by the licensee or applicant.
49.	**7.1.5.2**	This information in the 3rd paragraph is too specific and offers little value.	Delete the 3rd paragraph	Clarification	
50.	**7.1.6.1**	Licensees found several aspects of this section unclear. Specifically: 1. The emphasis on the concept that the criteria are not met in this section is confusing. 2. The last paragraph about levels of protection, etc. is out of place here, as this is the safety analysis discussion, referring to numerical results. 3. The entire "acceptance" discussion needs to fold in likelihoods and safety margins and complementary arguments, which is a safety case discussion, not a safety analysis one. 4. The last paragraph says that simply being below dose limits is not enough as "protection is required to be optimized and demonstrated by multiple lines of evidence." This section is about acceptance criteria though, not dose limits.	Clarify the section by: 1. Emphasizing that safety analysis must meet the criteria, and not get into what-if it does not. 2. Remove or move the last paragraph to a more appropriate section. 3. If the CNSC expects the licensee or applicant to do more than meet the current regulatory criteria, then that should be in a single well-marked and discussed section as part of the Safety Case (i.e. Section 5). 4. Remove the last paragraph to address the inconsistencies.	**MAJOR**	Unclear expectations could challenge compliance verification. This could also inadvertently result in confusion for members of the public as to expected requirements for facilities.

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		Section 7.1.1.1 says that a "licensee or applicant may choose to apply an additional margin of safety in deriving acceptance criteria" and "A dose SHOULD be reduced below a target if this can be done at a justifiable cost, taking into consideration social and economic factors." Yet 7.1.6.1 says protection is REQUIRED to be optimized below dose limits. This is inconsistent.			
51.	**7.1.6.2**	This information in the 2nd and 4th paragraphs was discussed earlier in the document and provides no additional value here.	Delete	Clarification	
52.	**Glossary**	Glossary is incomplete	Add the relevant definitions and/or cross-reference *REGDOC-3.6, Glossary of CNSC Terminology,* where appropriate.	Clarification	
53.	**References**	ICRP Publication 108, Environmental Protection - the Concept and Use of Reference Animals and Plants" is not included in the list of references.	Add ICRP Publication 108 to the list of references.	Clarification	