

REGDOC-1.2.2, Licence Application Guide: Class IB Processing Facilities/Guide de présentation d'une demande de permis : Installations de traitement de catégorie IB

Comments received from public consultation / Commentaires reçus dans le cadre du processus de consultation

Comments received:

- during first round (October 12, 2021 to February 14, 2022): 67 comments from five (5) reviewers
- during feedback period (February 15 to March 2, 2022): no comments were received

Commentaires reçus :

- lors de la première période du 12 octobre, 2021 au 14 février, 2022) : 657 commentaires reçus de cinq (5) examinateurs
- lors de la période des observations (15 février au 2 mars, 2022) : aucun commentaire reçu

Comments received during first round / Commentaires reçus lors de la première période:

	Section	Organization	Comment	CNSC Response
1.	Several	Canadian Nuclear Laboratories (CNL), New Brunswick Power (NB Power), Nordion, NWMO, Ontario Power Generation (OPG)	<p>Issue</p> <p>The draft REGDOC says it "... sets out requirements and guidance on submitting a formal application to the CNSC to obtain a licence to prepare a site for, construct, operate and/or decommission a Class IB processing facility in Canada, and identifies the information that should be included in the application."</p> <p>While the REGDOC is intended to be a Licence Application Guide (LAG) for various licensing stages, its focus appears to be on the licence to operate. For example, Section 4.7 on radiation protection does not address what requirements are relevant to a licence to prepare a site. This comment also applies to all other SCAs and the applicability of REGDOCs, codes and standards from one licensing step to another.</p> <p>Suggested Change</p> <p>The REGDOC should address the incremental</p>	

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			<p>requirements that are relevant from one licensing step to another throughout the document or be clear that the LAG is for a licence to operate.</p> <p>If the scope for a new facility remains, the REGDOC should be clear on what is needed for a new/initial licence application. As it stands, the process for pre-licensing arrangements, the integration with IA/EA (and <i>REGDOC-2.9.1</i>), and the applicable content for an initial licence/new facility is unclear.</p> <p>MAJOR</p> <p>Increased clarity for the various licensing stages would provide regulatory certainty, e.g., for newer facilities.</p>	
2.	General	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>The document should cover the possibility it will be used offline and as a printed, hard copy. In this initial draft, the use of hyperlinks to external documents appears somewhat random and doesn't consider offline/hard copy use.</p> <p>Suggested Change</p> <p>For ease of use in all formats, future drafts should:</p> <ul style="list-style-type: none"> • Show hyperlinked internet addresses as text rather than being hidden by hyperlink names (ex. CNCS's website). • Ensure references include all mentioned external documents, including the NSCA and associated regulations. These are hyperlinked to laws and not listed under References. 	

	Section	Organization	Comment	CNSC Response
			<i>Clarification</i>	
3.	General	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>The draft contains numerous mentions of “regulatory requirements” without proper context.</p> <p>Suggested Change</p> <p>The document must make clear that every mention of “regulatory requirements” is, in fact, “regulatory requirements set under the NSCA” and that any other “regulatory requirements” are clarified on a case-by-case basis.</p> <p><i>Clarification</i></p>	
4.	General	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>There is some inconsistency between the body of the REGDOC and Appendix C. For example:</p> <ul style="list-style-type: none"> •<i>REGDOC-2.7.1</i> is a guidance document but it is listed in Table C.1 as a REGDOC that has to be met. Would it be more appropriate to list it in Table C.3 as a REGDOC to be considered? <i>REGDOC-2.13.1</i> is not a guidance document but it is listed in both Table C.1 and C.3. Should it be removed from Table C.3? <p>Suggested Change</p> <p>The REGDOC should ensure reference REGDOCs are provided consistently.</p> <p>MAJOR</p> <p>As written, this promotes regulatory uncertainty and inconsistency with “shall” requirements.</p>	

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5.	1.1	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>As written, the draft leads to confusion around applicable facilities.</p> <p>Suggested Change</p> <p>The description of type 1B facilities should align with similar applicable documentation, such as <i>REGDOC-2.4.4</i>.</p> <p>The REGDOC should also make it clear which facilities are covered. For example, Section 1.1 refers to a "Class IB nuclear facility for..." and Section 1.2 refers to a "Class IB processing facility." Class IB processing facility should be defined and this REGDOC should be clear that it applies to this sub-type of a Class IB facility and not all Class IB facilities.</p> <p><i>Clarification</i></p>	
6.	2.2	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Licensees have the following concerns with this subsection:</p> <p>1)The 3rd paragraph says, "The licensing process is initiated when the applicant submits a licence application." This conflicts with later language which suggests consultation with CNSC staff prior to the licence application to ensure the application contains all required information. For example, the opening sentence in the 2nd paragraph of sub-section 2.4 says, "Early in the licensing process, the CNSC may provide guidance ..." If the licensing process begins with the licence application, then the CNSC is</p>	

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			<p>providing guidance after the application is submitted.</p> <p>2)The inclusion of links and explanations of the environmental review process, although the document does not require the submission of an environmental review. An environmental review can as one of the steps in the licencing process and better explained in detail under a dedicated heading.</p> <p>Suggested Change</p> <p>For future drafts, licensees urge CNSC staff to:</p> <p>1)Amend the 1st sentence of the 3rd paragraph to read, “The licensing process is initiated when the applicant <u>advises CNSC staff of their intent to submit a licence application on a specified date submits a licence application.</u>”</p> <p>2)More clearly outline the licensing process, including steps and the anticipated decision terms for each step of the licencing process. Perhaps include a flowchart.</p> <p>For further clarity, staff is urged to:</p> <ul style="list-style-type: none"> •Remove the 4th paragraph. The information is redundant here as it is does not clarify the licencing process. •Cross-reference this draft for use with <i>REGDOC-2.9.1, Environmental Protection</i> and provide better guidance on early engagement with respect to the environmental assessment process Specifically: What is the preferred format to pursue 	

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			<p>engagement -written, in-person, other? What level or type of information is required for this to be meaningful? How does this other conversation interconnect with the licensing application process?</p> <ul style="list-style-type: none"> •For new applications, explain how funding/payment for this type of work is assessed. <p>Include guidance on how to handle situations where a particular SCA does not apply.</p> <p>MAJOR</p> <p>As written, an applicant could submit a complete licence application without consultation and then be required to resubmit an entire application if it does not meet the requirements of CSNC staff. There needs to be a trigger for CNSC staff to provide expectations.</p> <p>Without more clarity, it would be difficult to plan new licence applications and understand the timing/duration of the required effort.</p>	
7.	2.4	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Similar to comments #1 and #6, licensees have concerns with the 6th paragraph, which reads, "For new licence applications, the applicant should consult with CNSC staff to confirm which editions of the codes and standards applicable to the facility are acceptable. This should be done prior to developing proposed safety policies, programs, processes, procedures and other safety and control measures." This appears to be discussing pre-licensing application work.</p>	

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			<p>Suggested Change</p> <p>Please see the previous suggestions under comments #1 and #6.</p> <p>MAJOR</p> <p>Without more clarity, it would be difficult to plan new licence applications and understand the timing/duration of the required effort.</p>	
8.	2.4	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>The 3rd paragraph is misplaced in this section and unclear when it says, “The applicant may provide references to any documents included in a previous licence application.”</p> <p>Suggested Change</p> <p>The statement should either be moved under the heading “Licence renewals” where similar text exists, or be changed to read, “The applicant may provide references to any documents included in <u>another</u> licence application” if this was meant to say any other licence application.</p> <p><i>Clarification</i></p>	
9.	3.1.6	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>More clarity is sought for this subsection.</p> <p>Suggested Change</p> <p>Would evidence of ownership be required from the owner where the owner and the applicant are not the same person? The statement “has authority</p>	

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			<p>from the owner of the site” does not cover a verification of the ownership, which should be covered as well.</p> <p><i>Clarification</i></p>	
10.	3.2.5	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>In the 1st bullet, is "maximum quantity" of a nuclear substance at one time? Per annum? Other?</p> <p>Suggested Change</p> <p>Clarify the intent of “maximum” quantity. Potentially break into sub-items, if helpful, to reduce misunderstanding between CNSC staff and applicants.</p> <p><i>Clarification</i></p>	
11.	3.2.5	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>The definition of “hazardous substance” needs to be abundantly clear. The one cited in <i>REGDOC-3.6</i> is too broad and the “hazardous substance” references are ambiguous in the 2nd bullet and the sentence that follows it, which reads, “The applicant should provide the scientific name of each nuclear and hazardous substance.”</p> <p>Suggested Change</p> <p>For clarity in future drafts, CNSC staff is urged to:</p> <ul style="list-style-type: none"> •Link the term “hazardous substance” with the definition outlined in 122 (1) of Part II of the <i>Canada Labour Code</i>. This should be a change that is also integrated with CNSC <i>REGDOC-3.6</i>. <p>Clarify the meaning of “any hazardous substances”</p>	

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			<p>in the 2nd bullet since the 1st bullet talks about “any nuclear substance.” For the 2nd bullet, would those be only “non-nuclear” or any “nuclear and non-nuclear”?</p> <p><i>Clarification</i></p>	
12.	3.2.5 4.11	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Is waste included in these sections?</p> <p>Suggested Change</p> <p>Similar waste information is required under Section 3 of the <i>General Nuclear and Control Regulations</i>. It should be added to this list to ensure completeness. This has recently been pointed out by intervenors during licence applications and requirements should be clearly articulated.</p> <p><i>Clarification</i></p>	
13.	3.3.2 3.3.3	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>The “foreign regulatory body” references in these sections are unclear.</p> <p>Suggested Change</p> <p>Are the references to “any foreign regulatory body” to be read as “a regulatory body of an IAEA member nation?” (If so, please include the clarification in future drafts.) Or, is it really meant as “any foreign” body?</p> <p><i>Clarification</i></p>	
14.	4	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p>	

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			<p>The current title of the section -- “Safety Policies, Programs, Processes, Procedures and Other Safety and Control Measures” -- does not reflect the content.</p> <p>Suggested Change</p> <p>Industry suggests the section be renamed to something like, “Regulatory Requirements and Guidance Applicable to Safety and Control Areas” since it lists the applicable regulatory requirements under the NSCA and provides guidance for each SCA. This will support the requirement to provide this information with an application, regardless if a “by-SCA” format is used or not.</p> <p><i>Clarification</i></p>	
15.	4.1.1	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>It’s unclear what specific details applicants are to include about the role of external safety assessment organizations.</p> <p>Suggested Change</p> <p>Please clarify.</p> <p><i>Clarification</i></p>	
16.	4.1.2	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>The title duplicates that of subsection 4.1</p> <p>Suggested Change</p> <p>Licensees urge CNSC staff to rename subsection 4.1.2 to “Management system program.” The title “Management system” is already given to</p>	

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			<p>subsection 4.1. Similarly, include “program” in the text of subsection 4.1.2 as well.</p> <p><i>Clarification</i></p>	
17.	4.1.8	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>It’s unclear why this is defined in this subsection. This topic is covered under physical design.</p> <p>Suggested Change</p> <p>Please provide clarity, expectations and the source of requirements.</p> <p><i>Clarification</i></p>	
18.	4.1.10	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Licensees seek added clarity for the 3rd bullet, which currently reads, “Sabotage, including cyberattacks and hacker activity.”</p> <p>Suggested Change</p> <p>For clarity and accuracy, CNSC staff is urged to list sabotage and cyberattacks as separate bullets. Cyberattacks do not necessarily result in sabotage and some cyberattacks may go unnoticed altogether. Also, “hacker activity” would normally qualify as a cyberattack and can be deleted from the statement.</p> <p><i>Clarification</i></p>	
19.	4.1.10	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>This is a new requirement and some of the requested information may not be suitable for the public domain. Should these requirements</p>	

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			<p>for the plan be placed into the LCH before they are required in an application?</p> <p>Suggested Change</p> <p>For consistency with other programs/plans, licensees suggest the 1st sentence be changed to read, “The application should <u>describe</u> include a business continuity plan.”</p> <p><i>Clarification</i></p>	
20.	4.2	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Even though the text indicates the regulatory focus is personnel training, the subsection on training is the second component of 4.2. As written, it implies that a human performance program is also required.</p> <p>Suggested Change</p> <p>Licensees suggest future drafts should move subsection 4.2.3 “Personnel training” ahead in the regulatory framework as it is the consistent requirement for all Class 1Bs.</p> <p>Placing the “shall” sections ahead of “should” sections emphasizes the significance of the sections. This section could easily be misread by an intervenor.</p> <p><i>Clarification</i></p>	
21.	4.2.4	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>There is a lack of clarity in the 1st sentence, which currently reads, “The application should describe the minimum number of workers with specific qualifications required for normal operations and unusual conditions (minimum staff complement).”</p>	

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			<p>Minimum staff complement is required for operations, not for “conditions.” Also, the terms “abnormal” or “upset” conditions may be more appropriate than “unusual.”</p> <p>Suggested Change</p> <p>Amend the 1st sentence to read, “The application should describe the minimum number of workers with specific qualifications required for <u>safe operations in normal and upset conditions</u> (minimum staff complement).”</p> <p><i>Clarification</i></p>	
22.	4.3.1	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Licensees seek additional clarity for the use of “or other” in the 2nd bullet, which currently reads, “- adhere to any applicable provincial legislation or other applicable codes and standards.” This should be “and” since legislation and applicable codes/standards are not mutually exclusive. Also, “other” should be deleted since “codes and standards” are not legislation.</p> <p>Suggested Change</p> <p>Amend to read, “- adhere to any applicable provincial legislation <u>and</u> or other applicable codes and standards.”</p> <p><i>Clarification</i></p>	
23.	4.3.2	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Licensees believe the inclusion of “load and transport nuclear and hazardous substances” is misplaced in the 2nd bullet.</p>	

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			<p>Suggested Change</p> <p>Delete the text “load and transport nuclear and hazardous substances” in future drafts. The topic is discussed under P&T.</p> <p><i>Clarification</i></p>	
24.	4.3.4	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Licensees believe this section is ambiguous as currently written: “The application shall include the analysis of operating performance including the causes of events, accidents, injuries, unplanned shut downs and reportable events. For more information, refer to <i>REGDOC-3.1.2....</i>”</p> <p>Suggested Change</p> <p>With regard to analysis of historic data, this can only be applicable to licence renewal applications. Instead of vague statements, the section should set a requirement for the licence application to explain how an applicant’s facility intends to comply with the requirements of <i>REGDOC- 3.1.2</i> with regard to periodic and unplanned-events’ reporting.</p> <p><i>Clarification</i></p>	
25.	4.3.5	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Why would the act of stating the safe operating limits and conditions be a “should” statement? One would think this is absolutely necessary for any application for a Class IB nuclear facility.</p> <p>Suggested Change</p>	

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			<p>Review the use of the term “should” in this case.</p> <p><i>Clarification</i></p>	
26.	4.3.5	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Rather than state limits and conditions, an application should clearly describe the actions to be taken if limits and conditions are not met.</p> <p>Suggested Change</p> <p>Amend the 1st sentence to read: “The application should state <u>describe the actions to be taken if the safe operating limits or conditions are not met.</u>”</p> <p><i>Clarification</i></p>	
27.	4.3.5	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>This text, and recent conversations with CNSC staff, indicate “operational limits and conditions” is not limited to production limits, environmental release limits and derived release limits.</p> <p>Operating outside of limits in a licence is a “stop, report and investigate” situation. It’s not clear why this should be spelled out in an application. Exceedance of a limit triggers additional regulatory requirements specific to the situation and this request is confusing.</p> <p>Suggested Change</p> <p>Guidance or expectations on the scope of information for operational limits and conditions should be provided.</p>	

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28.	4.4.2 4.4.3 4.4.4	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>If section 4.4.1 is met by the application, these additional clauses will also have been met by definition. As a result, repeating the requirements on PIEs and deterministic safety analysis is redundant and unnecessary.</p> <p>Suggested Change</p> <p>Remove these clauses as they are not needed.</p> <p>MAJOR</p> <p>Repeating requirements is an unnecessary administrative task.</p>	
29.	4.4.2	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>The terminology is “common-cause failure event” as opposed to “common cause event.”</p> <p>Suggested Change</p> <p>Amend the 2nd paragraph to read, “The application should describe how the design and safety analyses have taken into account the potential for specific hazards from common-cause failure events on the site.”</p> <p><i>Clarification</i></p>	
30.	4.4.2	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>As written, this draft REGDOC does not consider its impact on existing facilities when renewing a licence.</p>	

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			<p>Suggested Change</p> <p>For future drafts, CNSC staff is asked to address the impacts this REGDOC may have on existing licensees seeking to renew a licence.</p> <p>The current license basis for a class IB waste facility, for example, is based around <i>CSA N292.0</i>, which gives screening cut-off criteria for credible events as 1E-06. <i>REGDOC 2.4.4</i> gives cut-off criteria for AOO, DBA, DEC at different values, which impacts the hazards assessment for future renewals. Furthermore, AOO/DBA in the context of REGDOC 2.4.1 have dose limits of 0.5 mSv and 20 mSv effective dose, whereas some current waste facilities are licensed for accident worker dose limits of 50 mSv and public worker dose limits of 1 mSv following postulated accidents. In renewing a licence, there may be a significant amount of safety analysis work required to meet the new REGDOC.</p> <p>MAJOR</p> <p>The draft REGDOC creates a significant potential burden on existing licensees when renewing a license.</p>	
31.	4.4.2	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>As per comment #28, this subsection is redundant if the requirement in subsection 4.4.1 is met.</p> <p>If subsection 4.4.2 is not removed from future drafts, it requires clarification on several fronts.</p> <p>Suggested Change</p>	

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			<p>CNSC staff is urged to remove 4.4.2. Otherwise, it's asked to clarify:</p> <ul style="list-style-type: none"> • If existing license holders looking to renew will need to comply with this REGDOC. • If common cause includes the impact of nearby facilities in cases where a 1B facility to be licenced is in close proximity to a different facility (class 1). <p>What the qualifiers "serious" with respect to consequences or "significant" with respect to frequencies mean? Should they be defined? If the subsection is kept, the last sentence in the 1st paragraph should be amended to read, "The information provided should demonstrate that all credible events <u>are anticipated and considered.</u>"</p> <p><i>Clarification</i></p> <p><i>If comment #33 is needed, please clarify</i></p>	
32.	4.4.4	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>The requirement is ambiguous.</p> <p>Suggested Change</p> <p>Would there be any limiting likelihood for analysis of simultaneous events?</p> <p><i>Clarification</i></p>	
33.	4.4.5	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Licensees seek clarity on the sentence, "The few criticality accidents that have occurred show frequency and severity rates far below those typical of non-nuclear accidents." The information is irrelevant to application guidance and it's unclear</p>	

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			<p>why it was included in this draft.</p> <p>Suggested Change</p> <p>CNSC staff is urged to delete the sentence.</p> <p><i>Clarification</i></p>	
34.	4.5.1	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>The 1st sentence is unclear as currently written.</p> <p>Suggested Change</p> <p>Amend the 1st sentence to read, “The application shall also describe <u>the general approach to the design</u> and performance of the SSCs.”</p> <p><i>Clarification</i></p>	
35.	4.5.3	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Site characterization being captured under Physical Design seems out of place. Characterization of the site belongs in either Safety Analysis or Environmental Protection, especially considering the document refers to CSA N288.6 in this clause.</p> <p>Suggested Change</p> <p>Remove 4.5.3 or move it to a more appropriate section of the document.</p> <p><i>Clarification</i></p>	
36.	4.5.4	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>This approach reflects a typical/historical “waterfall” design approach, where a design is mature prior to any construction activities. Can</p>	

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			<p>proposals be made for alternative approaches, and how should this information be conveyed? Otherwise, licensees face a lack of ability to take advantage of new and potentially improved planning and development methodologies.</p> <p>Suggested Change</p> <p>Future drafts would benefit from an explanation of needs and requirements for design schemes with parallel design development alongside field works.</p> <p><i>Clarification</i></p>	
37.	4.5.4	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>The terminology is “common-cause failure event” as opposed to “common cause event”</p> <p>Suggested Change</p> <p>Amend the 3rd bullet to read, “- is resistant to the effects of common-cause failure events and, to the extent practicable, to severe accidents.”</p> <p><i>Clarification</i></p>	
38.	4.5.4	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>The language used in this subsection is appropriate for a new facility, but may not make sense for a facility constructed 30-50 years ago (e.g. the original design documentation may no longer exist).</p> <p>For instance:</p> <ul style="list-style-type: none"> •The text in the 1st paragraph and its bullets is appropriate for a new facility. However, an older facility will have to demonstrate that an equivalent level of safety is maintained 	

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			<p>– typically through the safety analysis or fitness for service programs.</p> <ul style="list-style-type: none"> •The statements in paragraphs 2 and 3 would be applicable to a construction licence or a request to increase the production limits. In a standard licence renewal of an operating facility, this would be addressed through the safety analysis and isn't appropriate for an application <p>Suggested Change</p> <p>CNSC staff is urged to:</p> <ul style="list-style-type: none"> •Amend the 1st paragraph to read, "The applicant shall ensure that new builds or changes to the design of an existing facility ..." •Delete paragraphs 2 and 3 for operating facilities. Consideration for equivalency should be incorporated. <p>MAJOR</p> <p>Some facilities may not be able to comply with literal interpretations of this subsection. This would create regulatory uncertainty.</p>	
39.	4.5.5	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>The final sentence in this subsection is ambiguous</p> <p>Suggested Change</p> <p>For clarity, amend the final sentence to read, "<u>For areas where emergency ventilation may be required for personnel safety, the appropriate requirements should be clearly identified and listed.</u>"</p>	

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40.	4.5.6	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>The two items in this subsection seem out of place. The 1st paragraph belongs in the Waste Management SCA and the 2nd belongs in the Environmental Protection SCA.</p> <p>Suggested Change</p> <p>Remove 4.5.6 or move its content to a more appropriate section of document.</p> <p><i>Clarification</i></p>	
41.	4.5.7, 4.5.8 4.6.2, 4.6.3 4.6.4	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>The phrases, “The applicant shall identify” and “The application shall include” imply that the details must be in the application. Given the level of detail that is associated with these subjects, as well as the potential for confidential information to be part of those requirements, it would be more appropriate to require a description of the program(s) which include the requested information. It is likely these programs will be notification documents in the LCH anyway.</p> <p>Suggested Change</p> <p>Suggest changing the phrases to “The applicant shall describe the program” and “The application shall describe the program and/or relevant information.”</p> <p>MAJOR</p>	

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			<p>The use of descriptions following a “shall” are critically important to balance the information that is publicly available, the interpretation of requirements by intervenors and the licensee’s various requirements for confidentiality or non-disclosure. As written, this draft will increase the administrative burden and costs to respond to intervenors.</p>	
42.	4.6.1	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Incorrect use of terminology.</p> <p>Suggested Change</p> <p>Delete “Mean Time Failure” from the example - Mean Time Failure is not a methodology. “Mean Time To Failure” and “Mean Time To Repair” (MTTF/MTTR) are only parameters used by methodologies to determine the appropriate maintenance frequencies.</p> <p><i>Clarification</i></p>	
43.	4.6.3	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>The wording here suggests that Aging Management strategies are expected for production equipment. Should this not be limited to Items Important to Safety, and/or failure modes with potential for safety consequences? This may potentially emphasize business needs as a primary topic of the licence application instead of radiological safety.</p> <p>Suggested Change</p> <p>Clarify which types of SSC are intended to be addressed by this topic</p>	

	Section	Organization	Comment	CNSC Response
			<i>Clarification</i>	
44.	4.6.3	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Certain Class IB facilities may not require Aging Management to be a formal component of their Fitness for Service-related programs in order to provide adequate, continuous nuclear safety assurance.</p> <p>Suggested Change</p> <p>Change “shall” to “should” or note “if applicable” in the clause.</p> <p><i>Clarification</i></p>	
45.	4.6.4	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>The 3rd paragraph includes a “shall” statement requiring a maintenance program for pressure boundary components. Some licensees will not have any pressure boundary elements in SSCs pertaining to safety.</p> <p>Suggested Change</p> <p>Add “if applicable” to the beginning of the statement.</p> <p><i>Clarification</i></p>	
46.	4.6.4	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>This subsection should ensure a more systematic approach to the requirement.</p> <p>Suggested Change</p>	

	Section	Organization	Comment	CNSC Response
			<p>This subsection should be combined with 4.6.2 “Maintenance program” to sync requirements and avoid repetition of information. “Inspection and testing” essentially fall under preventive maintenance.</p> <p><i>Clarification</i></p>	
47.	4.7.1	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>The <i>General Nuclear Safety and Control Regulations</i> are worded more strongly with respect to action levels needing to be included in an application. 3 (1)(f) is a “shall” statement where an applicant must include any proposed action level.</p> <p>Suggested Change</p> <p>Align the need for proposed action levels with the regulation.</p> <p><i>Clarification</i></p>	
48.	4.8.2	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>This should refer to the specific regulation in the <i>Canada Occupational Health and Safety Regulations</i> instead of the <i>ACGIH</i>, in order to eliminate problems if the regulation changes its requirement away from the listed values from that organization.</p> <p>Suggested Change</p> <p>Refer to the relevant section of the <i>COHSR</i> instead.</p> <p><i>Clarification</i></p>	
49.	4.9	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Licensees have concerns with the 2nd bullet in the</p>	

	Section	Organization	Comment	CNSC Response
			<p>3rd paragraph, which says, “- account for uncertainty by keeping all releases to the environment as low as reasonably achievable and apply the best available technology and techniques economically available.”</p> <p>This needs to be considered in the implementation of the environmental program, but to call it out in a licence application provides a higher level of emphasis that may not be appropriate. Just because another technology is available doesn’t mean that it should be discussed in licensing – it should be reviewed through the licensee’s continual improvement program. Only demonstrated non-compliances with a regulatory requirement in the environment SCA should be discussed in front of the Commission.</p> <p>Suggested Change</p> <p>Amend the 2nd bullet to read, “- account for uncertainty by keeping all releases to the environment as low as reasonably achievable and apply the best available technology and techniques economically available.”</p> <p>MAJOR</p> <p>As written, this draft has the significant potential to force licensees into a capital expenditure that is not warranted due to the public influence on the Commission process.</p>	
50.	4.9.2	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>The concept of effluent and emission control is described here, but monitoring should also be specifically included as an “if applicable”</p>	

	Section	Organization	Comment	CNSC Response
			<p>requirement.</p> <p>Suggested Change</p> <p>Include effluent monitoring as a “should” or “if applicable” requirement.</p> <p><i>Clarification</i></p>	
51.	4.9.2	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>This section refers to the development of licenced release limits and action levels per <i>REGDOC 2.9.2</i>, which has not been issued yet.</p> <p>Suggested Change</p> <p>Remove the reference to <i>REGDOC 2.9.2</i> until it has been issued.</p> <p>MAJOR</p> <p>Industry cannot be expected to implement a REGDOC that is not yet issued.</p>	
52.	4.10.1	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>The 2nd paragraph and bulleted list are not necessary, as this is already described in <i>REGDOC-2.10.1</i> and thus, if paragraph 1 is met, this will have been achieved. This draft should not repeat information that is already captured in a referenced REGDOC that is already a requirement.</p> <p>Suggested Change</p> <p>Remove this unneeded paragraph.</p> <p><i>Clarification</i></p>	

	Section	Organization	Comment	CNSC Response
53.	4.10.1	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Licensees seek clarity on the last paragraph, which reads, “The application should reference population studies and emergency planning considerations related to the site.”</p> <p>Suggested Change</p> <p>Clarify the meaning of “population studies.”</p> <p><i>Clarification</i></p>	
54.	4.10.4	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Why would CSA N393 not be referenced here as a requirement for this category of nuclear facility? Are there Class IB facilities where it is expected that CSA N393 will not form a key element of the nuclear safety requirements for licensing?</p> <p>Suggested Change</p> <p>Add N393 as a required document for licence application for any Class IB nuclear facility, unless there are expected exceptions to this.</p> <p><i>Clarification</i></p>	
55.	4.11.1	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Licensees have concerns with the phrase, “The application should contain a waste management program that meets the requirements of REGDOC-2.11.1.” The word “contain” implies a detailed program which really should be “described” at the licensing level as the program would be in the licensing basis and LCH.</p>	

	Section	Organization	Comment	CNSC Response
			<p>Suggested Change</p> <p>Amend to read, “the application should contain <u>describe</u> a waste management program ...”</p> <p><i>Clarification</i></p>	
56.	4.11.2 4.11.3 4.11.4	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>How can these clauses be “shall” statements if the previous clause is a “should” statement?</p> <p>Suggested Change</p> <p>For future drafts, change 4.11.2, 4.11.3 and 4.11.4 to “should” statements to align with 4.11.1.</p> <p><i>Clarification</i></p>	
57.	4.11.4	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Licensees have concerns with the 1st bullet, which reads, “- be responsible for the safe management of its radioactive waste, taking into consideration the health and safety of persons, the environment and national security.” Licensees are responsible for safeguarding and management of nuclear materials, health and safety, but not directly for national security.</p> <p>Suggested Change</p> <p>Amend the 1st bullet to read, “- be responsible for the safe management of its radioactive waste, taking into consideration the health and safety of persons <u>and</u> the environment and—national security.”</p>	

	Section	Organization	Comment	CNSC Response
			<i>Clarification</i>	
58.	4.11.4	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Inventory of waste is not included here.</p> <p>Suggested Change</p> <p>Further to the previous comment regarding subsection 3.2.5, waste inventory is required in an application, according to the regulations, so should be required in this document somewhere. This has come up in recent licensing activity due to intervenor comments.</p> <p>MAJOR</p> <p>Intervenor submissions impose administrative and cost implications for licensees and documents.</p>	
59.	4.11.5 5.3.2	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Text should be added to say the PDP is for developing the financial guarantee and does not constitute a decision on the future decommissioning activity. This needs to be communicated as much as possible to the public because it is poorly understood and requires repeated clarification during Commission meetings and hearings.</p> <p>Suggested Change</p> <p>The financial guarantees section should also provide linkage to the PDP section.</p> <p><i>Clarification</i></p>	

	Section	Organization	Comment	CNSC Response
60.	4.12.2 4.12.3 4.12.4	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>There appears to be a conflict between requirements in these subsections. Also, the information associated with security is typically prescribed, which makes it impossible to include in a document going into the public domain.</p> <p>Suggested Change</p> <p>The draft should be changed to include affirmation that the security plan for the facility includes the requirements. Some of the requested information (i.e. duties of security officers) is prescribed information and should be treated as such</p> <p>MAJOR</p> <p>As written, this creates regulatory uncertainty and the risk of prescribed information being released to the public.</p>	
61.	4.12.5	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>The final bullet: “- lifecycle approach to cyber assets” – in unclear.</p> <p>Suggested Change</p> <p>Amend to read, “lifecycle approach to cyber essential assets” (ex. as per CSA N290.7)</p> <p><i>Clarification</i></p>	
62.	4.13	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Many “shall” statements in this section seem to assume that safeguard-covered materials are used at all Class IB facilities. This is not necessarily the</p>	

	Section	Organization	Comment	CNSC Response
			<p>case.</p> <p>Suggested Change</p> <p>Add “if applicable” statements in this section.</p> <p><i>Clarification</i></p>	
63.	4.13.1	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Licensees seek clarity for the sentence, "The CNSC encourages applicants to submit the completed questionnaire early, particularly for novel technologies where safeguards measures have not yet been developed." Can “early” be defined? How should this be performed? Is a partially completed questionnaire appropriate? What type of records should be shared or submitted, and in what format?</p> <p>Suggested Change</p> <p>Please clarify these questions for future drafts.</p> <p><i>Clarification</i></p>	
64.	4.14.1	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>What is meant by “all shipping packages?”</p> <p>Suggested Change</p> <p>CNSC staff is asked to clarify if this intended to apply to devices/containers used for moving material within the same building or nuclear facility? As written, this creates the potential to misapply expectations and requirements.</p>	

	Section	Organization	Comment	CNSC Response
			<i>Clarification</i>	
65.	Appendix A	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>This draft uses incorrect terminology (Appendix title, Table A1 title, and Table A1 second column)</p> <p>Suggested Change</p> <p>For future drafts, replace the word “Clause” with “Provision.”</p> <p>“Provision” is used for legislation, and “clause” is used in contracts and treaties.</p> <p><i>Clarification</i></p>	
66.	Appendix C.1	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>Appendix C is defined as regulatory documents and industry standards to be applied as requirements for all applicants. However, some of these documents (for example <i>REGDOC-2.2.4</i>) only apply to a subset of Class 1B licensees. Some of the listed documents have never been discussed in the context of the licensing basis for some Class 1B facilities. They can’t be requirements if not included in the LCH of the facility.</p> <p>Suggested Change</p> <p>Amend the title to read, “C.1 Regulatory documents and industry standards to be applied as required <u>and as appropriate</u> for applicants.”</p> <p>Amend the 1st line to read, “Licensees are required to meet these requirements, codes and standards <u>as applicable to their facility type</u>.”</p>	

	Section	Organization	Comment	CNSC Response
			<p>MAJOR</p> <p>As currently written, the draft document would require some licensees to meet the requirements of documents/standards at significant cost even though such documents/standards do not apply to their facilities.</p>	
67.	Appendix C.3	CNL, NB Power, Nordion, NWMO, OPG	<p>Issue</p> <p>In this section, the CNSC is requesting (should, not shall) that licensees demonstrate the guidance documents have been considered. However, it is not clear what this means in practice. Do licensees need to provide a statement in licence applications/renewals that explicitly state which parts of the guidance documents have been implemented in their cross-references? Guidance documents are available to assist licensees in developing programs that would meet CNSC standards but should not be confused with requirements.</p> <p>Suggested Change</p> <p>Amend the 1st sentence to read, "<u>For all facilities, the application should consider the guidance in the following regulatory documents and industry standards and should make reference where such guidance has been incorporated into the application.</u>"</p> <p>MAJOR</p> <p>The role of guidance documents is not clear and seems to be blurred with requirements documents.</p>	