REGDOC-2.4.2, Probabilistic Safety Assessment (PSA) for Reactor Facilities Version 2 / Études probabilistes de sûreté (EPS) pour les centrales nucléaires, version 2 / March 31, 2021 – July 15, 2021

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

Comments received:

- during first round (March 31 to June 29, 2021): 49 comments from six (6) reviewers
- during feedback period (June 30 to July 15, 2021): no comments were received

Commentaires reçus:

- lors de la première période (du 31 mars au 29 juin 2021) : 49 commentaires reçus de six (6) examinateurs
- lors de la période des observations (du 30 juin au 15 juillet 2021) : aucun commentaire reçu

Table A: Comments on the "Request for Information" that was included for comment with the draft document:

	Reviewer	Section or Para. #	Reviewer's Comment and Proposed Change	Response	
I	No comments specific to the Request for Information statement were received. All comments received during public consultation are listed in Table B, below. Feedback on comments is listed in Table C.				

Table B: Comments received on the draft document

	Reviewer	Section or Para. #	Reviewer's Comment and Proposed Change	
1	1 AG Lee Consulting Comment on the potential impacts of this document		By replacing the term "nuclear power plant" or "NPP" in the current version of REGDOC-2.4.2 with the term "reactor facility", version 2 of REGDOC-2.4.2 will be applicable to nuclear facilities that are either fission or fusion reactors, and that are used for more applications than just generating electricity on a commercial scale. This is a welcome change because it enables version 2 of REGDOC-2.4.2 to be relevant and applicable to the emerging small modular reactor and advanced reactor designs.	
		potential impacts of this	As written, the draft REGDOC does not set out what a non-NPP licensee needs to do to meet the expectations in this safety control area. As drafted, this REGDOC would make a safety analysis far more complicated and use more resources than is necessary for the risks at facilities such as research reactors.	
3	SNC-Lavalin	Comment on the potential impacts of this document	Section 1.1: Suggest: "In addition, this document provides guidance for conducting PSA for new reactor facilities." Section 3.1: Please provide a clear definition of the "year average and instantaneous risk" so this can be used consistently by all utilities. Section 3.5: Suggest: "The licensee shall inform the CNSC on the impacts of the updated models on the Level 1 and Level 2 PSA results. Section 3.9: Reference to IAEA Safety Standard SSG-3; IAEA Safety Standard SSG-4 and CSA N290.17-17 is already made in section 1.4 of the guidance document. No need to repeat them again in this section. It is clear from section 1.4 that these are the main guides to be followed.	
4	McMaster University	Comment on document as a whole	Version 2 of this REGDOC has a significant change in scope. Instead of applying only to NPP facilities, all reactor facilities are now required to follow the REGDOC, including small modular reactors (SMRs) and research reactors. No rationale or explanation is given for this change. Additionally, newly added "in scope" facilities have the following disadvantages in reviewing or meeting the requirements in this draft document: • All of the supplied reference documents only apply to NPP facilities. • The CNSC, for current users of version 1 of the REGDOC, has highlighted the changes in the version 1 draft. This provides useful information for NPP facilities. No similar action is taken for licensees that are now in scope for the document for the first time, to identify what is different for those users. Facilities for whom the document now applies should be given aid equivalent or greater to current users on how to assess the draft. • Licensees of facilities like the McMaster Nuclear Reactor are deeply concerned with the application of the	

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	Reviewer	Section or Para. #	Reviewer's Comment and Proposed Change
			graded approach as it applies to this document. The "shall" statements are inconsistent with a licensee's ability to apply a graded approach, which is not remedied by "the graded approach may be proposed by the applicant or licensee in accordance with the REGDOC-3.5.3, Regulatory Fundamentals" in the Scope section. This is a meaningless statement in a REGDOC that is entirely prescriptive. In addition, REGDOC-3.5.3 offers no assistance because it merely defines a graded approach and states that the CNSC applies it without providing any guidance for licensees. Further, it is unclear in what context a licensee would make a graded approach proposal. Industry strongly recommends the draft REGDOC be revised to clarify the expectations for this safety control area in a manner that is specifically applicable to and commensurate with the risks at non-NPP facilities in consideration of a graded approach.
5	Canadian Nuclear	Comment on document	Industry Issue: Major
	Association (CNA)	as a whole	Version 2 of this REGDOC has a significant change in scope. Instead of applying only to NPP facilities, all reactor facilities are now required to follow the REGDOC, including small modular reactors (SMRs) and research reactors. No rationale or explanation is given for this change. Additionally, newly added "in scope" facilities have the following disadvantages in reviewing or meeting the requirements in this draft document: • All of the supplied reference documents only apply to NPP facilities. • The CNSC, for current users of version 1 of the REGDOC, has highlighted the changes in the version 1 draft. This provides useful information for NPP facilities. No similar action is taken for licensees that are now in scope for the document for the first time, to identify what is different for those users. Facilities for whom the document now applies should be given aid equivalent or greater to current users on how to assess the draft. • Licensees of facilities like the McMaster Nuclear Reactor are deeply concerned with the application of the graded approach as it applies to this document. The "shall" statements are inconsistent with a licensee's ability to apply a graded approach, which is not remedied by "the graded approach may be proposed by the applicant or licensee in accordance with the REGDOC-3.5.3, Regulatory Fundamentals" in the Scope section. This is a meaningless statement in a REGDOC that is entirely prescriptive. In addition, REGDOC-3.5.3 offers no assistance because it merely defines a graded approach and states that the CNSC applies it without providing any guidance for licensees. Further, it is unclear in what context a licensee would make a graded approach proposal. Suggested Change: Industry strongly recommends the draft REGDOC be revised to clarify the expectations for this safety control area in a manner that is specifically applicable to — and commensurate with — the risks at non-NPP facilities in consideration of a graded approach. Impact on Industry: As written, the draft REGDOC does not se
6	CNA, Bruce Power and NB Power	Comment on document as a whole	Industry Issue: Clarification The definitions included in REGDOC6, Glossary of CNSC Terminology should be reviewed, in light of the expanded scope of this and other REGDOCs, to
			include all reactor facilities. Definitions such as level 1 PSA and core damage frequency may not apply as stated to all reactor facility designs. Suggested Change: Review the definitions within REGDOC-3.6 to ensure they are applicable to all reactor facilities.
7	CNA	Comment on document as a whole	This comment has been reposted under glossary.

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	Reviewer	Section or Para. #	Reviewer's Comment and Proposed Change
8	McMaster University	Comment on the Preface	Version 1 of REGDOC-2.4.2 contains the following statement, "An applicant or licensee may put forward a case to demonstrate that the intent of a requirement is addressed by other means and demonstrated with supportable evidence."
	The		The expansion of the scope of this REGDOC to include all reactor facilities means that flexibility should be maintained on how the intent of a requirement
			is met. Some designs and safety analysis are being done using codes and standards from other jurisdictions.
			Alternative analysis should not be limited to non-reactor sources (e.g. new hazards not covered by current methodologies). Accordingly, amend section
			3.2 in Version, to read, "An applicant or licensee may put forward a case to demonstrate that the intent of a requirement is addressed by other means
			and demonstrated with supportable evidence." If industry cannot use an alternate approach or show equivalency for has been done, then it represents a
			potentially significant effort to redo the PSA and will impact the feasibility of a project and acceptance of the analysis.
9	CNA, Bruce Power and NB Power	Comment on the Preface	Industry Issue: Major
			Version 1 of REGDOC-2.4.2 contains the following statement, "An applicant or licensee may put forward a case to demonstrate that the intent of a
			requirement is addressed by other means and demonstrated with supportable evidence. "
			The expansion of the scope of this REGDOC to include all reactor facilities means that flexibility should be maintained on how the intent of a requirement
			is met. Some designs and safety analysis are being done using codes and standards from other jurisdictions.
			Suggested Change:
			Alternative analysis should not be limited to non-reactor sources (e.g. new hazards not covered by current methodologies). Accordingly, amend section 3.2 in Version, to read, "An applicant or licensee may put forward a case to demonstrate that the intent of a requirement is addressed by other means and demonstrated with supportable evidence."
			Impact on Industry:
			If industry cannot use an alternate approach or show equivalency for has been done, then it represents a potentially significant effort to redo the PSA and will impact the feasibility of a project and acceptance of the analysis.
10	AG Lee Consulting	Comment on section 1 and 1.1	I suggest that a footnote be added for the definition of "reactor facility" in REGDOC-3.6 in the same manner that has been done for the definition of Level 1 and Level 2 PSA.
	AG Lee Consulting	Comment on section 2	Please clarify whether "REGDOC-2.5.2, Design of Reactor Facilities [5]" is intended to be "REGDOC-2.5.2, Design of Reactor Facilities, Version 2 [5]".
12	McMaster University	Comment on section 2	Since REGDOC-2.5.2 is applicable only for new water-cooled reactor facilities, recommends bullet "d" be amended to add rigor to the statement. Amend
			bullet "d" to read, "as defined for new reactor facilities in REGDOC-2.5.2, Design of Reactor Facilities [5], or as already established in licensing basis for the facility current facilities"
13	CNA, Bruce Power and	Comment on section 2	Industry Issue: Clarification
	NB Power		Since REGDOC-2.5.2 is applicable only for new water-cooled reactor facilities, recommends bullet "d" be amended to add rigor to the statement.

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Reviewer	Section or Para. #	Reviewer's Comment and Proposed Change
		Suggested Change: Amend bullet "d" to read, "as defined for new reactor facilities in REGDOC-2.5.2, Design of Reactor Facilities [5], or as already established in licensing basis for the facility current facilities"
14 AG Lee Consulting	Comment on section 3 and 3.1	In section 3.1, I suggest that a line with "Guidance" be included to separate the first and second paragraphs. The first paragraph clearly states a regulatory requirement. The second paragraph and the bullet points under the sentence "The PSA program may include the following elements" clearly state guidance on a best practice expectation for fulfilling the regulatory requirement.
15 McMaster University	Comment on section 3 and 3.1	This section is identical to a licence condition for an NPP, only specific to PSA. Each NPP licensee will have a licence condition to have and follow a safety analysis program, which includes PSA. This new text duplicates the LC in the REGDOC.
16 McMaster University	Comment on section 3 and 3.1	The final bullet says, "management of Incremental Risk from Abnormal Plant Configurations, and risk input to decision-making" but does not define what is meant by Abnormal Plant Configurations. Without context, It can be interpreted to be either: • A configuration that is not accounted for in the PSA. Or • When unplanned events or conditions place the plant in a configuration of elevated risk due to: (a) equipment failures or (b), discovery issues related to a change in design bases, analysis results, experimental findings or knowledge interpretation where the baseline risk as calculated by PSA may be higher than previously believed. Include a definition for Abnormal Plant Configurations in REGDOC-3.6 so licensees of all facility types are clear on the CNSC's expectations.
17 CNA	Comment on section 3 and 3.1	'Industry Issue: ClarificationThis section is identical to a licence condition for an NPP, only specific to PSA. Each licensee will have a licence condition to have and follow a safety analysis program, which includes PSA. This new text duplicates the LC in the REGDOC. Suggested Change:Suggest the 1st sentence of this section be removed so it reads, "The licensee shall establish a program for the development and use of PSA as a means to manage radiological risks and to contribute to safe design and operation of reactor facilities. "The PSA program may include the following elements: —preparation, maintenance and application of the PSA —safety goals and numerical criteria, both the year average and instantaneous risk, against which the PSA results are compared, as well as the actions to be taken when these numerical criteria are exceeded. —management of Incremental Risk from Abnormal Plant Configurations, and risk input to decision-making"
18 CNA, Bruce Power and NB Power	Comment on section 3 and 3.1	Industry Issue: Clarification The final bullet says, "management of Incremental Risk from Abnormal Plant Configurations, and risk input to decision-making" but does not define what is meant by Abnormal Plant Configurations. Without context, It can be interpreted to be either: • A configuration that is not accounted for in the PSA. Or • When unplanned events or conditions place the plant in a configuration of elevated risk due to: (a) equipment failures or (b), discovery issues related to a change in design bases, analysis results, experimental findings or knowledge interpretation where the baseline risk as calculated by PSA may be higher than previously believed. Suggested Change: Include a definition for Abnormal Plant Configurations in REGDOC-3.6 so licensees of all facility types are clear on the CNSC's expectations.
19 AG Lee Consulting	Comment on section 3.2	In section 3.2, I suggest that a line with "Guidance" be included to separate the first and second paragraphs from the third paragraph. The first and second paragraphs clearly state regulatory requirements. The third paragraph clearly states guidance on a best practice expectation that can be used to fulfill the regulatory requirement in the second

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	Reviewer	Section or Para. #	Reviewer's Comment and Proposed Change	
			paragraph.	
20	McMaster University	Comment on section 3.2	As referenced in the 3rd paragraph, section 3.8 does not seem relevant in the context of the sentence. Rather, it should refer to a graded approach.	
2:	McMaster University	Comment on section 3.2	Amend the 3rd paragraph to read, "For radioactive sources outside the reactor core, the licensee may, subject to a graded approach, choose an alternate analysis method to conduct the assessment."	
22	CNA, Bruce Power and NB Power	Comment on section 3.2	Industry Issue: Clarification The "1" following PSA should be superscript in the 1st sentence. Suggested Changes: Amend the 1st sentence to read, "The licensee shall perform a level 1 and level 2 PSA11 for each reactor facility."	
23	CNA, Bruce Power and NB Power	Comment on section 3.2	Industry Issue: Clarification As referenced in the 3rd paragraph, section 3.8 does not seem relevant in the context of the sentence. Rather, it should refer to a graded approach. Suggested Change: Amend the 3rd paragraph to read, "For radioactive sources outside the reactor core, the licensee may, subject to Section 3.8 a graded approach, choose an alternate analysis method to conduct the assessment."	
24	AG Lee Consulting	Comment on section 3.3	In section 3.3, I suggest adding a line with "Guidance" between the first and second paragraphs to distinguish the regulatory requirement in the first paragraph and guidance on best practices for fulfilling the requirement.	
25	AG Lee Consulting	Comment on section 3.5	The first sentence in section 3.5 states "The licensee shall update the PSA models every five years". This requirement essentially duplicates the requirement in section 4.2 of REGDOC-3.1.1, which states "The licensee shall file an updated probabilistic safety assessment for the site within five years of the date of the previous submission or when requested to do so by the CNSC". I suggest replacing the first sentence in section 3.5 with "The licensee shall update the PSA models in accordance with the schedule requirements in REGDOC-3.1.1." This suggestion would eliminate the potential for conflicting requirements for PSA updates if the schedule requirements in section 4.2 of REGDOC-3.1.1 were to be changed in the future, such as to align with the frequency for periodic safety reviews.	
26	CNA, Bruce Power and NB Power	Comment on section 3.5	Industry Issue: Major Is the intent of the 2nd paragraph to be a qualitative or quantitative assessment of the impact? What is the medium and the frequency under which the licensee shall provide the impact to the CNSC of each update of the PSA model? As an example, New Brunswick Power performed 23 packages of changes to its PSA model in 2019, 16 packages of changes in 2020 and so far in 2021, 8 packages of changes have already been processed. It is impossible to re-quantify the PSA in order to assess the impact on each modification package. At this time, these modification packages are summarized in its ARR and a qualitative impact statement is provided. These modification packages are available to the CNSC upon request. Suggested Change: Amend the final sentence to read, "The licensee shall inform the CNSC of the impacts of on the update in models on the results of the level 1 and level 2	

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	Reviewer	Section or Para. #	Reviewer's Comment and Proposed Change
			PSA. Impact on Industry: As written, the statement could be interpreted as the licensee shall re-quantify the full PSA on each modification package and report the impact to the CNSC upon performing the change (via letter). As per the industry issue, New Brunswick Power performed 23 packages of changes to the PSA model in 2019, 16 packages of changes in 2020 and so far in 2021, 8 packages of changes have already been processed. It is impossible to re-quantify the PSA to assess the impact on each modification package.
27	AG Lee Consulting	Comment on section 3.6	In section 3.6, I suggest adding a line with "Guidance" after the paragraph "The screening criteria of hazards shall be acceptable to the CNSC." The text in the last three paragraphs in section 3.6 are clearly guidance and examples of best practices.
28	McMaster University	Comment on section 3.6	This section should include potential combinations of the external hazards. There is no basis to exclude combinations of internal hazards or combinations of an internal hazard with an external hazard. Deleting "external" would make REGDOC-2.4.2 consistent with N290.17-17 clause 6.3.
29	McMaster University	Comment on section 3.6	Similar to section 3.2, the 4th paragraph of this draft says, "The licensee may, subject to Section 3.8, choose an alternate analysis method to conduct the assessment of internal and external hazards." Section 3.8 does not seem relevant in the context of the sentence. It should rather refer to a graded approach.
30	CNA, Bruce Power and NB Power	Comment on section 3.6	Industry Issue: Clarification Similar to comment #8, the 4th paragraph of this draft says, "The licensee may, subject to Section 3.8, choose an alternate analysis method to conduct the assessment of internal and external hazards." Section 3.8 does not seem relevant in the context of the sentence. It should rather refer to a graded approach. Suggested Change: Amend the 4th paragraph to read, "The licensee may, subject to Section 3.8 a graded approach, choose an alternate analysis method to conduct the assessment of internal and external hazards."
31	CNA, Bruce Power and NB Power	Comment on section 3.6	Industry Issue: Clarification This section should include potential combinations of the external hazards. There is no basis to exclude combinations of internal hazards or combinations of an internal hazard with an external hazard. Deleting "external" would make REGDOC-2.4.2 consistent with N290.17-17 clause 6.3. Suggested Change: Delete the word "external" from the sentence.
32	AG Lee Consulting	Comment on section 3.9	In section 3.9, I suggest adding a line with "Guidance" after the first paragraph to distinguish the regulatory requirement from the suggested guidance for meeting the requirement.
33	McMaster University	Comment on section 3.9	Additional clarity is sought around the proposed change in language on methodology acceptance from "seeking acceptance for the purposes of this document" to "seeking acceptancefor meeting the requirements of this document."
34	CNA, Bruce Power and NB Power	Comment on section 3.9	Industry Issue: Clarification Additional clarity is sought around the proposed change in language on methodology acceptance from "seeking acceptance for the purposes of this document" to "seeking acceptancefor meeting the requirements of this document." Suggested Change: CNSC staff is urged to clarify the purpose for this change. Does this new wording alter staff's expectations for licensees?

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	Reviewer	Section or Para. #	Reviewer's Comment and Proposed Change
35	Bruce Power and NB Power	Comment on section 3.9	It is noted that the following standards provide general guidance for conducting high-quality PSA: IAEA SSG3, IAEA SSG4 and CSA N290.17-17. While these standards will be used for general guidance, there should not be an expectation that industry will comply with them, clause by clause. Amend this section so it is clear these standards will be used for general guidance only and there is no expectation for industry to comply with them clause by clause."
36	McMaster University, CNA, Bruce Power and NB Power	Comment on section 3.10	Industry Issue: Clarification The licensee should be allowed to disposition other operational states in accordance with CSA N290.17 which states: "potential POS may be screened out of the PSA if it can be shown that the time averaged risk attributable to the potential POS is very low." Suggested Change: Amend the 2nd paragraph to read, "The licensee shall perform a PSA for other states which have not been dispositioned as screened out where the reactor is expected to operate for extended periods of time and that are not covered by the at-power and shutdown PSAs.
37	McMaster University	Comment on Glossary	The definitions included in REGDOC-3.6, Glossary of CNSC Terminology should be reviewed, in light of the expanded scope of this and other REGDOCs, to include all reactor facilities. Definitions such as level 1 PSA and core damage frequency may not apply as stated to all reactor facility designs.
38	CNA, Bruce Power and NB Power	Comment on Glossary	Industry Issue: Clarification The definitions included in REGDOC6, Glossary of CNSC Terminology should be reviewed, in light of the expanded scope of this and other REGDOCs, to include all reactor facilities. Definitions such as level 1 PSA and core damage frequency may not apply as stated to all reactor facility designs. Suggested Change: Review the definitions within REGDOC-3.6 to ensure they are applicable to all reactor facilities.
39	McMaster University	Comment on References	N286.7-99 is used as a reference but has been superseded by N286.7-16.
40	CNA, Bruce Power and NB Power	Comment on References	Industry Issue: Clarification N286.7-99 is used as a reference but has been superseded by N286.7-16. Suggested Change: Refer to N286.7-16 "Quality Assurance of Analytical, Scientific, and Design Computer Programs instead as it supersedes N286.7-99 "Quality Assurance of Analytical, Scientific and Design Computer Programs for Nuclear Power Plants"

Table C: "Feedback on comments" (opportunity to provide feedback on the comments received):

	Reviewer	Section or Para. #	Reviewer's Comment and Proposed Change	Response
a)	No comments received.			