

OPG Proprietary

N-CORR-00531-19390

Dear Mr. Torrie,

The purpose of this e-mail is to provide OPG's comments on the final draft of REGDOC-2.1.1 *Management System*.

OPG appreciates the opportunity to comment on the informative draft Regulatory Document, which we reviewed in conjunction with other licensees.

The following are some key highlights from the detailed comments table:

Industry appreciates the CNSC drafting an information-only REGDOC that refers to an existing suite of well-developed standards and does not introduce new requirements.

To promote even further clarity, the CNSC is encouraged to strengthen the REGDOC by ensuring identical language from codes and standards is referenced rather than paraphrasing passages. This will help avoid unintended administrative effort to develop opinions or justifications on how to apply the information in the REGDOC for regulatory compliance purposes.

If you require any additional information or have any questions regarding this submission, please contact Ms. Leslie Mitchell, Manager, Regulatory Programs Strategy & Support, at (905)839-6746 x 5198, or by e-mail at leslie.j.mitchell@opg.com.

Regards,

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VP, Nuclear Regulatory Affairs and Stakeholder Relations
OPG

Comments on draft REGDOC-2.1.1, Management System

#	Document/ Excerpt of Section	Industry Issue	Suggested Change (if applicable)	Major Comment/ Request for Clarification ¹	Impact on Industry, if major comment
1.	Preface	<p>Industry appreciates the CNSC drafting an information-only REGDOC that refers to an existing suite of well-developed standards and does not introduce new requirements that can lead to regulatory uncertainty.</p> <p>Slight wording changes to the Preface would reinforce this intent and make it clear that emerging issues related to management systems are best captured by revisions to <i>N286, Management system requirements for nuclear facilities</i> through the CSA Group’s standard process.</p>	<p>For enhanced clarity, industry recommends amending:</p> <ul style="list-style-type: none"> • The last sentence in the 2nd paragraph to read, “... along with supplemental information on various and emerging issues related to management systems.” • The final sentence of the 3rd paragraph to read, “However, it provides <u>additional clarifications</u> more specific direction for those requirements.” • The 4th paragraph to read, “Guidance contained in this document exists to inform the applicant, elaborate further on requirements or provide <u>information</u> direction to licensees and applicants on how to meet requirements.” 	MAJOR	<p>As an information-only document, consistent use of language is especially important to avoid misinterpretations.</p> <p>Words like ‘direction’ can generate uncertainty for both licensees and the regulator if CNSC personnel interpret the document as setting additional requirements. This leads to unintended administrative effort to develop opinions or justifications on how to apply the information in the REGDOC for regulatory compliance purposes.</p>
2.	General	<p>Section 3.5 on Software Quality Assurance is a particularly clear, concise and well written passage. It properly refers to the relevant standards without attempting to state the material in new or slightly-revised words.</p>	<p>None.</p> <p>Industry believes this section is very clear in its language and intent. This is a good practice that should be emulated throughout the document.</p>	MAJOR	<p>Section 3.5 directly references the relevant standards, which avoids potential confusion and future configuration management issues. If applied to all other sections, this approach would further improve clarity and precision.</p>
3.	1.1 Purpose	<p>To some readers, the 3rd bullet might mistakenly infer that REGDOC-2.1.1 will be frequently updated based on emergent issues. As per comment #1, emerging issues related to management systems are best captured by revisions to <i>N286-12</i> through the CSA Group’s standard process.</p>	<p>Industry recommends removing the 3rd bullet.</p>	Clarification	

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		Industry recognizes the CNSC’s efforts to consider recent developments in management system standards when drafting this REGDOC. However, most readers will assume that to be the case and this bullet may unintentionally create more confusion than value.			
4.	2. Management system Information	The use of the term “core management processes” is ambiguous and used differently by various licensees.	For clarity, industry recommends simplifying the 1 st sentence to read, “The CNSC expects licensees to adhere to all CSA N286-12 [1] principles as the basis of their management system and the corresponding core management processes. ”	MAJOR	This slight edit would help preserve the flexibility of licensees to develop the elements and processes of their management systems that best meet their business needs.
5.	2. Management System Information	The CNSC expects licensees to adhere to all <i>N286-12</i> principles as the basis of their management system. Supplemental guidance material should be graded as well.	The CNSC is urged to include a statement that, as with <i>N286-12</i> , a graded approach may be applied to management system elements in the REGDOC depending on the safety significance and complexity of the work being performed.	Clarification	
6.	2. Management System Information (and 3.1 Leadership)	<i>CAN/CSA-ISO 9001:15</i> is the proper reference for the document recognized as a national standard of Canada. It ensures the international document (if not already available) is also published in both official languages. When referencing it as a certification standard, it should be listed as <i>ISO 9001:2015</i>	For precision, change all references to <i>CAN/CSA-ISO 9001:16</i> to <i>ISO 9001:2015</i>	Clarification	
7.	2. CSA N286-12 Structure and Principles	This section extensively references <i>N286-12</i> , but either paraphrases or does not quote the referenced passages verbatim. This increases the likelihood for confusion or misinterpretation. For instance, the 2 nd sentence of the 2 nd paragraph says “... licensees are expected	This section is an excellent opportunity to enhance the document’s clarity by following the good practice used in Section 3.5. For example, this section would be clearer if it simply referenced <i>N286-12 Section 4.1.2</i> for the list of 12 principles and the Commentary	MAJOR	Rephrasing or summarizing passages from referenced standards can lead to uncertainty for both licensees and the regulator. Unclear or imprecise language may lead CNSC personnel to interpret the document as setting additional requirements. In turn, this can unintentionally result in significant effort to justify how to apply the information in the REGDOC for regulatory compliance purposes.

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		to design, plan and control their activities in order to meet all requirements ..." The corresponding item from N286-12 says, "The business is defined, planned and controlled." The words 'defined' and 'design' do not carry the same meaning.	document for N286-12 for further guidance. Should the CNSC opt to retain bulleted lists in future drafts, it is urged to align the words precisely with those in N286-12. For example, the 2 nd sentence of the 2 nd paragraph should read, "... licensees are expected to <u>define</u> design, plan and control their activities in order to meet all requirements ..."		
8.	3.1 Leadership	<p>This section also references a series of standards, but either paraphrases or does not quote the referenced passages verbatim. For instance, the bulleted list is similar, but not identical to, the IAEA's <i>GSR Part 2, Leadership and Management for Safety: General Safety Requirements</i>.</p> <p>These differences, however slight, increase the likelihood for confusion, misinterpretation and the potential introduction of additional requirements from those in N286-12.</p>	<p>Once again, this section would benefit from following the example set in Section 3.5 and simply refer to the relevant standards without attempting to state the material in new or slightly-revised words.</p> <p>To enhance the clarity of Section 3.1, industry recommends the CNSC remove the bullet points, keep the opening paragraph and:</p> <ul style="list-style-type: none"> Amend the final sentence in the 2nd paragraph to replicate the words in section 4.13.b of N286-12 by saying, "Expectations ofTop management <u>is expected to continually improve (by) periodically critically assessing the effectiveness of the management system to achieve the planned results.</u>" include making use of effectiveness reviews to continuously assess and improve its management system, as well as utilizing the latter 	MAJOR	<p>Rephrasing or summarizing passages from referenced standards can lead to uncertainty for both licensees and the regulator. Unclear or imprecise language may lead CNSC personnel to interpret the document as setting additional requirements. In turn, this can unintentionally result in significant effort to justify how to apply the information in the REGDOC for regulatory compliance purposes.</p>

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			<p>to understand and promote a healthy safety culture.</p> <ul style="list-style-type: none"> Amend the 3rd paragraph to read, "... have further elaborated on leadership expectations and requirements in recognition of the key role leaders have in an organization." <p>If bullets are deemed necessary, ensure the wording is identical to the source document.</p>		
9.	3.3 Supply Chain	In keeping with this draft REGDOC's intent, industry believes the term 'information' is more appropriate than 'guidance' whenever possible.	Amend the 2 nd sentence of the 2 nd paragraph to read, "...this standard can also be used as <u>information guidance</u> for the other classes of licensees with respect to the implementation of supply chain management processes and requirements for their suppliers."	Clarification	

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<p>10.</p>	<p>3.3.1- Counterfeit, fraudulent and suspect items</p>	<p>The draft REGDOC’s definitions for counterfeit, fraudulent and suspect items (CFSI) can be strengthened to harmonize with international agencies and departments.</p>	<p>Harmonize the defined terms for CFSI to specifically align with the Electric Power Research Institute, Inc. (EPRI).</p> <ol style="list-style-type: none"> 1. Counterfeit items are items that are intentionally manufactured or altered to imitate a legitimate product without the legal right to do so. (Examples of a counterfeit item include one that has been fabricated in imitation of something else with purpose to defraud by passing the false copy for genuine or original or an item copied without the legal right or authority to do so.) 2. Fraudulent items are items that are intentionally misrepresented with intent to deceive. (Fraudulent items include items provided with incorrect identification or falsified or inaccurate certification.) 3. Suspect items are items suspected of being counterfeit or fraudulent. <p>For consistency, this definition should also be added <i>REGDOC-3.6, Glossary of CNSC Terminology</i>.</p>	<p align="center">MAJOR</p>	<p>The absence of common, defined terms decreases performance effectiveness between parties. The terms of this draft REGDOC are narrow in citing codes and standards and ignoring broader issue of legal rights of use and ownership. This is important since the TSSA Act and the Professional Engineering Act both identify liabilities and implications for public safety for the design which are uniquely tied to the Canadian Registration Number (CRN) Owner. This means a design owner is responsible for the protection of the public and environment in the event of a component issue or failure. As currently written, there is no relation in this draft REGDOC to legitimacy of ownership and, therefore, weakness in the ladder of accountability for public safety. Areas of weakness include:</p> <ol style="list-style-type: none"> 1. Misrepresenting themselves as the CRN Owner to TSSA or ANI 2. Using design or product information that was not legitimately provided to them 3. Producing a derivative work based on unlicensed information (see item 2) 4. Remaking/profiting from design or product information that was not legitimately provided to them 5. Reverse engineering a design or product owned by another company 6. Breach of patent or other IP mark <p>Underlying these definitions is the basic tenet that public safety and environmental protection can be compromised if a “fake” component or information finds its way into a power plant. In other words, CFSI is trying to address safety concerns stemming from the potential failure of an item or erroneous information that impacts an item’s ability to function during normal operations, abnormal or accident conditions. Therefore, the ability to pursue infringement must also factor in the weight of law, which is not explicit in the definitions as written in this REGDOC, and which may compromise licensees and vendors in managing international supply chains.</p> <p>Without the strength to shown causation to specific terms, a greater burden is placed on all parties to verify and validate information as being - or not being - CFSI. It also weakens the</p>
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					ability to leverage international cooperation from agencies like the US Office of Intellectual Property Enforcement Coordinator, which fosters alignment with a variety of US departments (including US NRC) and Canada (RCMP).
11.	4. Radiation Safety Oversight	This draft REGDOC is an informative document. However, this section includes several “should” statements which is inconsistent with the rest of the draft.	For clarity of intent, the CNSC is encouraged to reinforce the information-only nature of this REGDOC by changing the “should” references to “may,” or other informative language.	MAJOR	Even though this is an information-only REGDOC, the frequent references to “should” could be misconstrued by some as requirements.