

October 30, 2018

Canadian Nuclear Safety Commission  
P.O. Box 1046 Station B  
280 Slater Street  
Ottawa, ON  
K1P 5S9

**Subject: Nordion Comments on Draft REGDOC 2.1.1 Management System**

Nordion (Canada) Inc. has reviewed the Draft REGDOC 2.1.1 Management System and would like to submit the following comments developed along with other industry licensees. Please refer to the attached Summary of Nordion Comments on Draft REGDOC 2.1.1.

Sincerely,



Shannon Lacasse  
Facility Nuclear Compliance and Training Specialist  
Nordion (Canada), Inc.

cc: M. Young - CNSC  
R. Wassenaar – Nordion

Encl.: Summary of Nordion Comments on Draft REGDOC 2.1.1.



A Sotera Health company

Summary of Nordion Comments on Draft REGDOC 2.1.1

#	Document/ Excerpt of Section	Industry Issue	Suggested Change (if applicable)	Major Comment/ Request for Clarification <sup>1</sup>	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 N286, <i>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"> <li>The last sentence in the 2<sup>nd</sup> paragraph to read, "... along with supplemental information on various <del>and emerging</del> issues related to management systems."</li> <li>The final sentence of the 3<sup>rd</sup> paragraph to read, "However, it provides <u>additional clarifications</u> <del>more specific direction</del> for those requirements."</li> <li>The 4<sup>th</sup> paragraph to read, "Guidance contained in this document exists to inform the applicant, elaborate further on requirements or provide <u>information direction</u> to licensees and applicants on how to meet requirements."</li> </ul>	<p><b>MAJOR</b></p>	<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>	<p><b>MAJOR</b></p>	<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>

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3.	1.1 Purpose	To some readers, the 3 <sup>rd</sup> 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 N286-12 through the CSA Group's standard process.	Industry recommends removing the 3 <sup>rd</sup> bullet.	Clarification	
4.	2. Management system Information	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.	For clarity, industry recommends simplifying the 1 <sup>st</sup> 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 N286-12 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 N286-12, 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	



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6.	2. Management System Information (and 3.1 Leadership)	CAN/CSA-ISO 9001:15 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 ISO 9001:2015	For precision, change all references to CAN/CSA-ISO 9001:16 to ISO 9001:2015	Clarification	
7.	2. CSA N286-12 Structure and Principles	This section extensively references N286-12, but either paraphrases or does not quote the referenced passages verbatim. This increases the likelihood for confusion or misinterpretation.  For instance, the 2 <sup>nd</sup> sentence of the 2 <sup>nd</sup> paragraph says "... licensees are expected 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.	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 N286-12 Section 4.1.2 for the list of 12 principles and the Commentary 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 <sup>nd</sup> sentence of the 2 <sup>nd</sup> paragraph should read, "... licensees are expected to define design, plan and control their activities in order to meet all requirements ..."	<b>MAJOR</b>	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.
8.	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 <sup>nd</sup> sentence of the 2 <sup>nd</sup> 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	