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February 24, 2017

Mr. Brian Torrie
Director General
Regulatory Policy Directorate
Canadian Nuclear Safety Commission
280 Slater St.
Ottawa ON
K1P 5S9

Re: Nordion feedback on draft RegDoc 1.4.1, "Class II Nuclear Facilities and Prescribed Equipment License Application Guide"

Dear Mr. Torrie,

Nordion is pleased with the opportunity to comment on the CNSC's proposed RegDoc 1.4.1, "Class II Nuclear Facilities and Prescribed Equipment License Application Guide". We have reviewed CNSC's proposal and have a number of comments and suggestions which we have attached to this letter.

Should you have any questions, please don't hesitate to contact me at 613-592-3400 x2539, or at richard.wassenaar@nordion.com.

Sincerely,

Richard Wassenaar, PhD, MCCPM
Sr. Manager, Transport Licensing and Gamma Radiation Safety

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Nordion (Canada) Inc. Responses to Proposed RegDoc 1.4.1

#	Document section/ excerpt of section	Comment or Concern	Suggested change (if applicable)
1	General	Nordion is pleased to see a move to electronic application forms. Electronic forms are helpful when preparing an application and this will be an administrative assistance.	It would be useful if a single form was available that could automatically remove or block out non-applicable sections based on the selected use type of the license being applied for.
2	General	In the accompanying "Request for Information on the Proposed Implementation of REGDOC-1.4.1, *License Application Guide: Class II Nuclear Facilities and Prescribed Equipment*", the potential impact of the new RegDoc is to "reduce administrative burden" and to have "guidance for applicants provided in one convenient location". However, the previous set up with three different RD/GD's was not an administrative challenge since each RD/GD was for a specific license use. So licensee's only need to pull the correct RD/GD. The previous RD/GD documents were also shorter and more concise, ranging from about 21 to 46 pages. The proposed RegDoc is over 100 pages. The CNSC seems to be moving to consolidating many smaller documents into mega-documents. Although this provides the information all in one location, it can also make for a new document that is difficult to navigate and find the information that is needed. In this document, which is meant to encourage consolidated licensing, the application forms are still separated based on use type.	The CNSC should reconsider whether there is a strong need to move to consolidation of RD/GD-289, RD/GD-120, and RD/GD-207.

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3	**Preface** **Page i** **Paragraph 6**	From RD-1.4.1: "*Guidance in this document elaborates on regulatory requirements and provides direction to applicants on how to meet requirements. Applicants are expected to review and consider guidance given in this document; should they choose not to follow it, they should explain how their chosen alternate approach would meet regulatory requirements. An applicant may put forward a case to demonstrate that the intent of a regulatory requirement is addressed by its alternate approach and submit evidence to support it.*" Guidance should be that, guidance. If licensees are expected to follow it, it should not be called guidance. By default, licensees must always show that their proposed approach meets the requirements or intent of the regulations. As such, much of this paragraph seems at best redundant, and at worst, an increased administrative burden.	Delete second half of paragraph: *Guidance in this document elaborates on regulatory requirements and provides direction to applicants on how to meet requirements. Applicants are ~~expected~~ **encouraged** to review and consider guidance given in this document; ~~should they choose not to follow it, they should explain how their chosen alternate approach would meet regulatory requirements. An applicant may put forward a case to demonstrate that the intent of a regulatory requirement is addressed by its alternate approach and submit evidence to support it.~~*

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4	B.1.4	Nordion has concern with the text: *"Dose targets that meet the recommendations in the CNSC guide G-129 rev. 1, Keeping Radiation Exposures and Doses "As Low As Reasonably Achievable (ALARA)" will normally be accepted by the CNSC as being ALARA without further justification. This guide is available on the CNSC's website. The guide G-129 recommends that doses should be at or below:* *• 1 mSv/yr for NEWs* *• 0.05 mSv/yr for non-NEW staff and members of the public* *Submit a cost-benefit analysis to justify any annual dose in excess of those recommended in guide G-129."* This seems to be a misrepresentation of G-129, which states the 1 mSv and 50 uSv annual limits are those at which CNSC may (not will, but may) accept without further ALARA assessment. G-129 does not state these are actual recommended levels nor does it require a cost-benefit analysis. The requirement of a cost-benefit analysis seems to be a new administrative burden. The additional cost-benefit analysis is likely to poses a significant time and resource burden to licensees currently meeting the ALARA principle but not meeting the "recommended" dose levels.	Remove the following text: "*The guide G-129 recommends that doses should be at or below:* *• 1 mSv/yr for NEWs* *• 0.05 mSv/yr for non-NEW staff and members of the public* *Submit a cost-benefit analysis to justify any annual dose in excess of those recommended in guide G-129."* This allows RegDoc 1.4.1 to continue to reference G-129, without adding additional requirements. This aligns the wording with what was present in the previous documents being superseded.
5	2.1.2	The proposed RegDoc states: "*Applicants should be aware that all information submitted is subject to the provisions of the Access to Information Act and the Privacy Act.*" However, there are exemptions to this rule, which are clarified	The CNSC should further clarify in section 2.1.2 that applicants can apply for public non-disclosure of information that falls within the exemptions listed in the Access to Information Act.

#	Document section/ excerpt of section	Comment or Concern	Suggested change (if applicable)
		in section A.1.5 of the proposed document.	
6	D.1.5	It is unclear whether "should" is being interchanged with "shall" as some of the guidance provided here seems to be regulatory requirements in the GNSCR If the CNSC is not clear on what is guidance and what is regulatory requirement, issues will arise as licensees may not implement "guidance", even though CNSC staff/inspectors may consider it to be regulatory requirement.	CNSC should clarify what are guidance statements and what are regulatory requirements throughout the entire document. In general, there appears to be a lot of "should" statements.
7	D.2.9	This section in several places states that only workers trained in TDG may handle packages or source transfer containers. Nordion has several concerns: 1) Source transfer containers is used in the draft document, but it is not defined. Does the CNSC mean this the same as containers authorized for transport? 2) TDG is only applicable when receiving or shipping a container. So packaging a container for shipment requires TDG. However, moving a container within a licensed facility from, for example, the shipping area to the facility room where it will be used does not require TDG-trained personnel. 3) If the source transfer container is not used for shipping, then TDG training is not required for handling.	Clarify the term "source transfer container". Rewrite to clarify that TDG training is required only when performing duties related to packaging, shipping or receiving of material.