

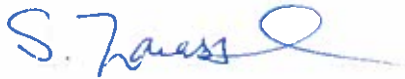
November 2, 2018

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

Subject: Nordion Comments on Draft REGDOC 3.1.3 Reporting Requirements for Class II Nuclear Facilities and Users of Prescribed Equipment, Nuclear Substances and Radiation Devices

Nordion (Canada) Inc. has reviewed the Draft REGDOC 3.1.3 Reporting Requirements for Class II Nuclear Facilities and Users of Prescribed Equipment, Nuclear Substances and Radiation Devices 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 3.1.3.

Sincerely,



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Nordion (Canada), Inc.

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

Encl.: Summary of Nordion Comments on Draft REGDOC 3.1.3.



Summary of Nordion Comments on Draft REGDOC 3.1.3

#	Document Section/ Excerpt of Section	Industry Issue	Suggested Change (if applicable)	Major Comment/ Request for Clarification	Impact on Industry, if Major Comment
1.	General	The use of "notification" and "report" is not clear throughout the current version of this draft. For example, Table A includes instances where notification is required to the duty officer followed by further reporting. However, in the guidance under section 3.1, notification "refers to the obligation to inform the CNSC of situations where no further reporting (such as a full report) is required."	Clearly define the difference between "notification" and "report."	MAJOR	Licenseses may inadvertently be non-compliant with respect of notification and reporting of events.
2.	General	The terms "quickly," "immediately" and "as soon as is practicable/ feasible" are used interchangeably in this draft.	Remove the term "quickly" to be consistent with REGDOC-3.1.1 and REGDOC-3.1.2.	Clarification	
3.	General	REGDOC-3.1.3 uses the term "classified" and "classification" in a few places. Licensees cannot classify documents on behalf of the government of Canada, nor does the REGDOC provide any guidance on what classification is appropriate for the government of Canada (note that licensees may classify documents according to an internal process, but this process need not align with the government of Canada classification for sensitive information).	Replace "classified" and "unclassified" with prescribed or personal information, as appropriate.	Clarification	
4.	2	The 6 th paragraph under Guidance is a requirement, not guidance.	Move as new No. 7 under section 2, using "shall" instead of "should"	Clarification	
5.	3.1 & 3.2	Industry has significant privacy concerns with : <ul style="list-style-type: none"> Providing the "names of the persons involved in the situation," as indicated in the 5th paragraph under Guidance. Normally, only job titles, positions and organizations are provided. The 9th requirement listed under 3.2, which reads, "for dangerous occurrences (under the PTNSR 2015), the names of persons involved and the details of the packaging and packages" 	Remove references to names of the persons.	MAJOR	Inappropriate filing of a person's name involved in a situation may violate their right to privacy.

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6.	3.2	This section adds additional requirements not currently found in the requirements for 21-day reports as stated in the Regulations, and possibly require additional effort which may be onerous to licensees. We currently believe that the current 21-day report requirements within the Regulations provide all the pertinent details related to an event, and should be duplicated here.	Revise this section with the full (21-day) reporting requirements stated in the Regulations.	MAJOR	This adds potential burden to Licensees without providing additional pertinent information to the required report.
7.	Appendix A	Paragraphs 1 and 4 contain duplicate material. Information from the 1 st paragraph has already been listed in Section 2 Guidance paragraphs 2 & 3 and in the Section 3 preamble. Information from the 4 th paragraph has already been listed in Section 2 Guidance, paragraph 4. Also, paragraphs 2 and 3 are incorrectly placed.	Delete paragraphs 1 and 4. Move paragraphs 2 and 3 to section 2 Guidance.	Clarification	
8.	Table A (general)	The term "notify" regularly appears in the Preliminary event reports column. (Please see comment #1 for a related issue)	Licensees strongly suggest that a 4 th column be added to clearly distinguish between a notification where no further reporting is required and a preliminary report that may require a full report. The table should reflect the guidance wording (i.e. definition of notification) in the 1 st paragraph of section 3.1.	MAJOR	Licensees may inadvertently be non-compliant with respect of notification and reporting of events.
9.	Table A (general)	There are differences between requirements, such as reporting timing, in this draft and the already approved REGDOC-3.1.1. For instance, the requirement for preliminary reports does not distinguish between significant and non-significant events as is the accepted practice under REGDOC-3.1.1.	Align with approved REGDOC-3.1.1. Specify that high safety-significant situations or events require an immediate preliminary report, but allow for 5-day reporting for events of lower significance. For most situations, change the full report requirement in the table to "Within 60 days (if required)"	MAJOR	Differing requirements between event reporting REGDOCs can inadvertently lead to errors or confusion for licensees who hold more than one type of licence. The contracted timelines in this draft add additional administrative burden with no corresponding increase in nuclear safety.



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10.	Table A (general)	Specific numbered licence conditions have been listed throughout.	Identify where these licence conditions are identified (reference) or provide some explanation in the REGDOC as to their applicability.	Clarification	
11.	Table A (general)	Why is the phrase "point of contact if known" noted for some events and not others like 20b), 20 c)?	Clarify.	Clarification	
12.	Table A (general)	The person to whom licensees should send the report (CNSC point of contact) does not align with the CNSC expectation to report events that fall under the reporting requirements of subsection 29(1) of the GNSCRs directly through the duty officer and as stated on page 3 of REGDOC-3.1.3.	Clarify the appropriate contact.	Clarification	
13.	Table A Item 1	The guidance for Item 1 regarding non-compliances found during internal audits is inappropriate. Internal audits are used by the licensee for self-monitoring, while the regulator should be evaluating licensee's performance through inspections.	Delete or reword the guidance to align with REGDOC 3.1.2, VI. Confirm that "non-compliances found during internal audits" means non-compliances with regulatory requirements (i.e. licence or regulatory violations). It should not be as broad as any non-compliance. For example, does this mean all non-compliances found during audits should be reported even if they are not a violation of a licence condition or a regulatory violation?	MAJOR	This ratchets reporting requirements contained in REGDOCs 3.1.1 & 3.1.2. Requiring licensees to report non-compliances identified in an internal audit is contrary to the purpose of conducting audits and inconsistent with the guidance section in REGDOC 3.1.2.
14.	Table A Item 3a	"Quickly" is not sufficiently defined as referenced in the guidance of 3a).	Reward to: "... if the situation is resolved quickly and prior to the contingency plan is not being fully implemented."	Clarification	
15.	Table A Items 6a, 8f	The person to whom licensee should send the report is not identified in 6a). For 8f), the document only indicates "the Commission" where elsewhere, it specifies either the point of contact or the duty officer.	Indicate CNSC point of contact.	Clarification	



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16.	Table A Item 8a	8a) is missing the word "event" in the 3 rd column "Within 21 days after becoming aware of the ..."	Add "event"	Clarification	
17.	Table A Item 9c	9c) would benefit from the note included in the equivalent event in REGDOC 3.1.2, VI.	Include the same note.	Clarification	
18.	Table A Item 10	Guidance is missing from Item #10 and the person to whom licensees should send the report is not identified. The timing does not align with that in REGDOC 3.1.2, VI	Add guidance, contact details and ensure timeline is consistent with REGDOC 3.1.2, VI.	Clarification	
19.	Table A Item 11	The person to whom licensees should send the notification is not specified in #11.	Add contact details.	Clarification	
20.	Table A Item 13a	The timeframe for submission of the full report is not indicated.	Indicate within 21 days of the notification date, or if the licence specifies a different time period, within that time period.	Clarification	
21.	Table A Item 15	For 15, the applicability of the Guidance statement is not clear for an event when GNSR 29(1) is not triggered, since the full report column unconditionally stipulates requirement of 21-day reporting.	Clarify.	Clarification	
22.	Table A Item 19	For 19, the 3 rd column repeats "...Notify CNSC point of contact."	Delete.	Clarification	
23.	Table A Item 21	For 21, the note in Guidance regarding submission of full report (as in REGDOC-3.1.2 VI) is not included.	Suggest adding note to Guidance: "If a licensee submits this full report, the licensee is not required to also submit a full report under subsection 29(1) of the GNSCR within 21 days or under section 16 of the RPR within 21 days."	Clarification	
24.	Table A Item 22	For 22, there is a missing sentence from Guidance in REGDOC-3.1.2	Add the sentence "Applicable section(s) of NSCA or regulations made under NSCA"	Clarification	
25.	Table A Item 22a	Although the guidance for 22a) is understood, the wording: "The severity of the accident does not matter" is not appropriate.	Delete the guidance statement.	Clarification	



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26.	Table A Item 22e	Align conditions for 22e) with 22d)	Suggest including similar conditions for submission of Preliminary Report to that of 22d): Notify CNSC point of contact (if the material is contained in the internal package) Notify duty officer (if the material is not contained)	Clarification	
27.	Table A Item 23	For 23, the guidance provided and the preliminary event reports do not match up. Industry agrees the reporting can be done to the CNSC point of contact if there is no contamination or the package has reached its destination.	Add information to indicate the CNSC point of contact can be notified if there is no contamination or the package has reached its destination as an alternative to notifying the duty officer in the preliminary event reports column.	MAJOR	Can lead to confusion on how the report is to be done and result in incorrect reporting.