2018 November 02

145-CNNO-18-0029-L

Mr. Brian Torrie
Director General, Regulatory Policy Directorate
Canadian Nuclear Safety Commission
280 Slater Street
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COMPLIANCE
Regulatory Affairs

Dear Mr. Torrie:

Canadian Nuclear Laboratories Comments on Draft REGDOC-3.1.3, Reporting Requirements for Class II Nuclear Facilities and Users of Prescribed Equipment, Nuclear Substances and Radiation Devices

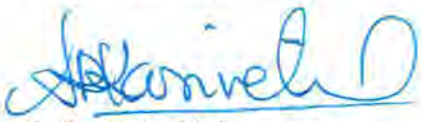
Canadian Nuclear Laboratories (CNL) has reviewed the proposed REGDOC-3.1.3, Reporting Requirements for Class II Nuclear Facilities and Users of Prescribed Equipment, Nuclear Substances and Radiation Devices, and has consulted with its industry partners to produce a set of consolidated comments, which are presented in Attachment A.

One of the major themes of the comments, echoed by our industry peers, relates to inconsistencies between the reporting requirements of the CNSC Regulations and the proposed REGDOC. There is an associated concern regarding whom the formal point of contact should be for event notifications. Furthermore, this document should be better aligned with the reporting requirements of REGDOC-3.1.2. This will then assist all licensees with obligations to report under the requirements of both documents.

CNL appreciates the opportunity to provide comments during the development of this regulatory document.

If you require further information or should have any questions regarding this submission, please contact me directly.

Yours sincerely,



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Attachment (1)

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ATTACHMENT A
Canadian Nuclear Laboratories Comments on draft REGDOC-3.1.3, Reporting Requirements for Class II Nuclear Facilities and Users of Prescribed Equipment, Nuclear Substances and Radiation Devices

#	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**	Licensees 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**	Licensees wonder if the CNSC has considered producing an interpretation document to accompany *REGDCOC-3.1.3.*	Provide an interpretation document as per *REGDOC-3.1.1*.	Clarification	
4.	**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	Replace "classified" and "unclassified" with prescribed or personal information, as appropriate.	Clarification	

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		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).			
5.	**2**	There is redundant language for requirements of the submission in bullets 4 and 6; "4. All reports filed by the licensee shall contain the name and address …. & 6. A full report, preliminary report or notification shall: …."	Amalgamate requirements and clearly delineate between information required for each submission type. Consider a simplified table as found in *REGDOC-3.1.1.*	Clarification	
6.	**2**	The 4th paragraph under Guidance is relevant to a preliminary report and inconsistent with *REGDOC-3.1.2*.	Move to section 3.1 and reword as follows to be consistent with *REGDOC 3.1.2*: "A preliminary report or notification that must be submitted immediately may be provided in person, by telephone, by email or by fax. Full reports may be filed by email, by fax or by regular mail. All information (including supporting information such as data for air/water monitoring) may be submitted in electronic format (for example, a database). The date of filing of a report is	Clarification	

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			the date it is received by the Commission."		
7.	**2**	The 6th paragraph under Guidance is a requirement, not guidance.	Move as new No. 7 under section 2, using "shall" instead of "should"	Clarification	
8.	**2**	In the 13th paragraph under Guidance, it is not clear whether a preliminary report can be submitted as a combined preliminary/full report in this case.	Move to section 3.1 and the concept of combined report clarified (consistent with *REGDOC- 3.1.1 and REGDOC-3.1.2*).	Clarification	
9.	**2**	The 15th paragraph under Guidance is a requirement, not guidance.	Move as new No. 8 under section 2, using "shall" instead of "should"	Clarification	
10.	**3. 1 & 3.2**	Industry has significant privacy concerns with : • 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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11.	**3.1**	The information specified in 2a, 2b, 2c and 4 is not required by the *CNSC PTNSR, 2015*. The regulations section 37(4) only indicates the circumstance of the failure-to-comply or of the dangerous occurrence.	Delete or make consistent with *REGDOC-3.1.2.*	**MAJOR**	This imposes additional requirement not found in the regulations and adds additional regulatory burden with no apparent impact on safety.
12.	**3.2**	The information specified in items 4 and 11 are not required by section 38 of the *CNSC PTNSR, 2015*. Further, item 11 is already captured under *RD 99.3* and not required under *REGDOC-3.1.1* or *REGDOC-3.1.2*	Delete sections 4 and 11.	**MAJOR**	This imposes additional requirement not found in the regulations and adds additional regulatory burden with no apparent impact on safety.
13.	**3.2**	The Guidance in this section contains redundant language and is inconsistent with guidance in *REGDOC-3.1.2* and *REGDOC-3.1.1*.	Replace the guidance of section 3.2 with the guidance in section 4.2 of *REGDOC-3.1.2*. Otherwise: • Remove the following sentences to avoid redundancy: ~~"This report is generally required within 21 days after the preliminary report of the event. There should be sufficient information included to allow for efficient review of the report. "~~	Clarification	

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			• Amend the 4th bullet to remain consistent with *REGDOC-3.1.1* so it reads, "identify the target completion date for the actions that the licensee has taken or proposes to take, including actions identified and taken to restore the effectiveness …"		
14.	**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.
15.	**3.4**	The example in the 1st sentence is misleading and not appropriate in many situations. This is also not found in the *CNSC, PTNSR, 2015*.	Amend to read, "As per subsection 36(2) of the PTNSR 2015, the consignor, carrier or consignee must have an expert in radiation protection ~~(e.g., a radiation safety officer)~~ assess	**MAJOR**	In many transport incidents, the person providing the assessment is not the radiation safety officer but the transportation expert most familiar with the packaging and potential exposures.

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			the situation.		
16.	**4**	Industry has concerns with the term 'separately' in the phrase; "any classified, protected, proprietary, or personal information shall be submitted to the CNSC separately in accordance with …" This requirement is not logical. First, the entire ACR is considered "protected when completed" so the entire ACR must be submitted separately from the ACR itself (a logical impossibility). Secondly, this raises an additional administrative burden on the licensees to provide two submissions where previously one submission was sufficient.	Please delete "separately."	Clarification	
17.	**Appendix A**	Paragraphs 1 and 4 contain duplicate material. Information from the 1st paragraph has already been listed in Section 2 Guidance paragraphs 2 & 3 and in the Section 3 preamble. Information from the 4th 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	

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18.	**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 4th 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 1st paragraph of section 3.1.	**MAJOR**	Licensees may inadvertently be non-compliant with respect of notification and reporting of events.
19.	**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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20.	**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	
21.	**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	
22.	**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	
23.	**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	**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.*

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			should be reported even if they are not a violation of a licence condition or a regulatory violation?		
24.	**Table A Item 3a**	"Quickly" is not sufficiently defined as referenced in the guidance of 3a).	Reword to: "… if the situation is resolved ~~quickly and~~ prior to the contingency plan ~~is not~~ being fully implemented."	Clarification	
25.	**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	
26.	**Table A Item 6b**	Should 6b) also specify the requirement to request a licence amendment now that the CNSC is including the revision number in the licences?	Clarify.	Clarification	
27.	**Table A Item 8a**	8a) is missing the word "event" in the 3rd column "Within 21 days after becoming aware of the …"	Add "event"	Clarification	
28.	**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	
29.	**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	
30.	**Table A**	The person to whom licensees should send the	Indicate project officer or CNSC	Clarification	

#	Document Section/ Excerpt of Section	Industry Issue	Suggested Change *(if applicable)*	Major Comment/ Request for Clarification	Impact on Industry, if Major Comment
	Item 11	notification is not specified in #11.	point of contact		
31.	**Table A Item 12b**	For 12b), the examples should not be considered reportable events unless there are other indications of an overexposure. For example, entering a radiography/restricted area will not necessarily result in a dose limit exceedance. If licensees can promptly confirm the dose limit was not exceeded (i.e. reviewing workers electronic dosimeter or survey results), there should be no need to report.	Delete the examples and use guidance provided in section 12.1.b in *REGDOC-3.1.2 VI.*	Clarification	
32.	**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	
33.	**Table A Item 17**	For 17, licensees believe the intent of *GNSCR 29(1)(e)* is being stretched to include the examples provided. In particular, leaving a source unattended should not be an example of an "attempted or actual breach of security" or an "attempted or actual act of sabotage." Industry questions this interpretation and seeks clarity as to what is meant by "being left unattended". Licensees assume this means the source has been left unattended outside of an approved storage	Industry encourages the CNSC to insert the following guidance for high-security sites in Part A of this draft REGDOC: "If high-risk radioactive sources are stored at a high-security nuclear site (e.g., nuclear power plant) some of the security requirements that are in place will provide the required level of	**MAJOR**	Potential reporting anomalies

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		location. However, does it also mean "unattended outside of a secured area"? For example, does this include an unattended source that has been left inside the Protected Area of a high security facility or within a building with approved security controls fully intact?	protection as outlined in this regulatory document (REGDOC 2.12.3 *Security Measures for Sealed Sources)*. In cases of high-security nuclear sites, the expectation is that licensees would provide the required details as to how they meet all of the applicable requirements. It is expected this information would be documented in the licensee's Site Security Plan."		
34.	**Table A Item 19**	For 19, the 3rd column repeats "…Notify CNSC point of contact."	Delete.	Clarification	
35.	**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	
36.	**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	

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37.	**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	
38.	**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	
39.	**Table A** Item 22h	The example for 22h) is misleading and not appropriate in many situation. This is also not found in the *CNSC, PTNSR, 2015*. (Please see related comment #15)	Delete, "(e.g., a radiation safety officer)"	**MAJOR**	In many transport incident the person providing the assessment is not the radiation safety officer but the transportation expert who is most familiar with the packaging and potential exposures.
40.	**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.