



2019 February 15

145-CNNO-19-0009-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 Waste Nuclear Substance Licensees, Class II Nuclear Facilities and Users of Prescribed Equipment, Nuclear Substances and Radiation Devices

Canadian Nuclear Laboratories (CNL) has reviewed the second draft of proposed REGDOC-3.1.3, Reporting Requirements for Waste Nuclear Substance Licensees, Class II Nuclear Facilities and Users of Prescribed Equipment, Nuclear Substances and Radiation Devices, and is presenting a set of comments for the first draft in Attachment A and additional comments for the second draft in Attachment B.

CNL appreciates the opportunity to provide comments during the development of this regulatory document. However, due to the diversity of CNL's various licensed sites, the major concern remains that effective implementation of REGDOC-3.1.3 may prove to be challenging without much greater alignment of requirements with those of REGDOC-3.1.2. Please give due consideration as to how such alignment might best be achieved.

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

Yours sincerely,

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Attachments (2)

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Attachment A

Canadian Nuclear Laboratories Comments on Draft REGDOC-3.1.3, Reporting Requirements for Waste Nuclear Substance Licensees, 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 <i>REGDOC-3.1.1</i> and <i>REGDOC-3.1.2</i>	Clarification	
3.	General	Licensees wonder if the CNSC has considered producing an interpretation document to accompany <i>REGDCOC-3.1.3</i> .	Provide an interpretation document as per <i>REGDOC-3.1.1</i> .	Clarification	
4.	General	<i>REGDOC-3.1.3</i> 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 <i>REGDOC-3.1.1</i> .	Clarification	
6.	2	The 4 th paragraph under Guidance is relevant to a preliminary report and inconsistent with <i>REGDOC-3.1.2</i> .	Move to section 3.1 and reword as follows to be consistent with <i>REGDOC 3.1.2</i> : "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	Clarification	

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			format (for example, a database). The date of filing of a report is the date it is received by the Commission.”		
7.	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	
8.	2	In the 13 th 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 should be clarified (consistent with <i>REGDOC 3.1.1 and REGDOC 3.1.2</i>).	Clarification	
9.	2	The 15 th paragraph under Guidance is a requirement, not guidance.	Move as new No. 8 under section 2, using “shall” instead of “should”	Clarification	

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10.	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.
11.	3.1	The information specified in 2a, 2b, 2c and 4 is not required by the <i>CNSC PTNSR, 2015</i> . The regulations section 37(4) only indicates the circumstance of the failure-to-comply or of the dangerous occurrence.	Delete or make consistent with <i>REGDOC-3.1.2</i> .	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 <i>CNSC PTNSR, 2015</i> . Further, item 11 is already captured under <i>RD 99.3</i> and not required under <i>REGDOC 3.1.1</i> or <i>REGDOC-3.1.2</i>	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 <i>REGDOC-3.1.2</i> and <i>REGDOC-3.1.1</i> .	Replace the guidance of section 3.2 with the guidance in section 4.2 of <i>REGDOC-3.1.2</i> .	Clarification	



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			<p>Otherwise:</p> <ul style="list-style-type: none"> 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.” 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	Revise this section with the full	MAJOR	This adds potential burden to Licensees without

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		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.	(21-day) reporting requirements stated in the Regulations.		providing additional pertinent information to the required report.
15.	3.4	The example in the 1 st sentence is misleading and not appropriate in many situations. This is also not found in the <i>CNSC, PTNSR, 2015</i> .	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 the situation.	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.
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	Please delete "separately."	Clarification	

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		administrative burden on the licensees to provide two submissions where previously one submission was sufficient.			
17.	Appendix A	<p>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.</p> <p>Also, paragraphs 2 and 3 are incorrectly placed.</p>	<p>Delete paragraphs 1 and 4.</p> <p>Move paragraphs 2 and 3 to section 2 Guidance.</p>	Clarification	
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 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.

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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 <i>REGDOC-3.1.1</i> . 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.
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 <i>GNSCRs</i> directly through the duty officer and as stated on page 3 of <i>REGDOC-3.1.3</i> .	Clarify the appropriate contact.	Clarification	

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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 <i>REGDOC 3.1.2, VI</i> . 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 <i>REGDOCs 3.1.1 & 3.1.2</i> . 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 <i>REGDOC 3.1.2</i> .
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 <u>prior to</u> the contingency plan is not being <u>fully implemented.</u> "	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	

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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 3 rd 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 <i>REGDOC 3.1.2, VI</i> .	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 <i>REGDOC 3.1.2, VI</i>	Add guidance, contact details and ensure timeline is consistent with <i>REGDOC 3.1.2, VI</i> .	Clarification	
30.	Table A Item 11	The person to whom licensees should send the notification is not specified in #11.	Indicate project officer or CNSC point of contact	Clarification	
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 <i>REGDOC-3.1.2 VI</i> .	Clarification	
32.	Table A	For 15, the applicability of the Guidance	Clarify.	Clarification	

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	Item 15	statement is not clear for an event when <i>GNSR 29(1)</i> is not triggered, since the full report column unconditionally stipulates requirement of 21-day reporting.			
33.	Table A Item 17	For 17, licensees believe the intent of <i>GNSCR 29(1)(e)</i> 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 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?	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 protection as outlined in this regulatory document (REGDOC 2.12.3 <i>Security Measures for Sealed Sources</i>). 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	MAJOR	Potential reporting anomalies

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			be documented in the licensee's Site Security Plan."		
34.	Table A Item 19	For 19, the 3 rd 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 <i>REGDOC-3.1.2 VI</i>) 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 <i>REGDOC-3.1.2</i>	Add the sentence "Applicable section(s) of NSCA or regulations made under NSCA"	Clarification	
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	Clarification	

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			package) Notify duty officer (if the material is not contained)		
39.	Table A Item 22h	The example for 22h) is misleading and not appropriate in many situation. This is also not found in the <i>CNSC, PTNSR, 2015</i> . (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.

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

#	Document/ Excerpt of Section	Industry Issue	Suggested Change <i>(if applicable)</i>	Major Comment/ Request for Clarification	Impact on Industry, if major comment
1.	Pg. 1, last para.	<p>The statements:</p> <p>“Class I licensees who use nuclear substances or prescribed equipment should consult either REGDOC 3.1.1, Reporting Requirements for Nuclear Power Plants, version 2...”</p> <p>In addition, “Nothing contained in this document is to be construed as relieving any licensee from any other pertinent requirements. It is the licensee’s responsibility to identify and comply with all applicable regulations and licence conditions.”</p> <p>Create some ambiguity. Does it mean that the default for Class I licensees is REGDOC 3.1.1, or not?</p>	<p>Clarify which guidance applies where.</p> <p>“Class I licensees who use nuclear substances or prescribed equipment should consult either REGDOC 3.1.1 or REGDOC 3.1.2, <u>unless specifically directed otherwise, in their PROL.</u>”</p>	<p><i>Clarification</i></p>	

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		For example, the introduction of REGDOCs 3.1.3 combined with the integration of Bruce Power’s WNSL, Class II, etc. licences into its site wide PROL has led to a lack of clarity in reporting requirements.			
2.	2.6: “The following reporting requirement applies to licensees holding a waste nuclear substance licence (WNSL). The licence shall report: a. Any failure to monitor or control the release of a hazardous substance as required by any federal or provincial regulation, or a licence, permit or certificate issued by a municipal,	Under Reporting Requirements, there is a separate reporting requirement that applies to licensees holding a waste nuclear substance licence (WNSL) – should this not just be a reportable condition in Appendix A?	Move to Appendix A with the other reportable conditions, so that it is clearly assessed as part of the reportability assessment for an event.	<i>Clarification</i>	

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	provincial, or other federal authority.				
3.	Section 3.4, pg. 8	<p>REGDOC 3.1.1 stipulates that annual reports must be filed with the CNSC on <u>May 1st</u>, with the exception of the research and development reports. For example, the BP LCH does not specify a timeline for reporting in association with what was previously WNSL.</p> <p>REGDOC 3.1.3 does not specify reporting timelines except in the case of PTNSR, which stipulate, that the person who performs the characterization must file an annual report to the CNSC by <u>April 30</u> that contains a summary of radiation detections for the calendar year before the date of the report.”</p>	Clarify reporting timelines (e.g., what they are and where they are). In keeping with REGDOC 3.1.1, it is recommended aligning to a date of May 1 st .	<i>Clarification</i>	
4.	Section 4, pg. 8-9	REGDOC 3.1.1 stipulates that annual reports be filed with the CNSC on <u>May 1st</u> , with the exception of the research and development reports.	Improve licence integration and consistency of reporting requirements. File all annual reports by May 1 st .	<i>Clarification</i>	

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		<p>The current Bruce Power LCH indicates that in the case of the Class II licence “The licensee is required to submit to the Commission the annual compliance report by <u>March 31</u> of each year. The report shall include activities covering the nuclear substances and prescribed equipment of the Class II Nuclear facility as listed in this section of the LCH.” Also, in the case of the Annual Compliance report for Nuclear Substances and Prescribed Equipment, “The licensee is required to submit to the Commission the annual compliance report by <u>March 31</u> of each year.”</p>			
5.	4. Annual Compliance Report	<p>The use of the word ‘separately’ in item #1 might suggest the need for an additional compliance report to some readers. The entire Annual Compliance Report (ACR) is considered “protected B when completed.”</p>	<p>For clarity, industry suggests a simple amendment to Item #1 to read, “information that can be made available to the public (note: any classified, protected, proprietary or personal information shall be submitted to the CNSC in accordance</p>	<i>Clarification</i>	

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		However, as currently written, the item could be interpreted to require licensees to provide two submissions where previously one submission has sufficed. This would require additional administrative resources with no corresponding benefit to nuclear safety.	with the appropriate security precautions and marked with appropriate protection and classification)”		
6.	Appendix A	Licensees appreciate the value of simplification and the CNSC’s reason to omit the list of nuclear substances for licence condition 2406 “for ease of reading.” However, in this instance, licensees believe the list should be cited for clarity. If REGDOC-3.1.3 is to define requirements, then it should explicitly list the relevant nuclear substances.	Include the relevant list of substances.	<i>Clarification</i>	
7.	4 and Appendix B	Inconsistent wording: Guidance, 3 rd para “...the report <u>should</u> include all of the information...”	Recommending changing to “may”.	<i>Clarification</i>	

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		Appendix B, 1 st para “...the report <u>may</u> include all information...”			
8.	Appendix B	<p>There are consistency issues around the reporting requirements for WNSLs in cases where, for example, Bruce Power’s WNSL has been integrated into its PROL, which currently states:</p> <p>“For REGDOC 3.1.1 Section 3.1, Quarterly report on safety performance indicators: Bruce Power’s quarterly report on Safety Performance Indicators (SPIs) is to include contributions from the licensed support activities at the Central Maintenance and Laundry Facility (CMLF) for SPI 1, Collective Radiation Exposure and SPI 5, Environmental Releases – Radiological.”</p> <p>How does this Appendix apply to a consolidated license?</p>	Improve licence integration and clarify reporting requirements where WNSL has been integrated into PROL.	<i>Clarification</i>	

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9.	Appendix B, Table of contents	Safety analysis is missing from the list of SCAs.	Add Safety analysis as subsection 3.4. (Note that this is not applicable to all WNSL's, for example at OPG's RWOS-1 site).	<i>Clarification</i>	
10.	Appendix B (generic comment)	For the structure and content shown for the Annual Compliance Monitoring Report for WNSL, OPG already provides the relevant/applicable information for many of the listed Safety and Control Areas (SCA's) in the Quarterly Operations Report submitted under the site waste license where the WNSL is located.	Exemption for licensees that already provide this information to the CNSC in other required regulatory submissions.	MAJOR	Duplication of effort required by the Licensee, with no value added.
11.	Appendix B – Operating Performance	Requirement for “an assessment of how well the licensee conducted operations ...” This requirement has not been seen anywhere else in reporting REGDOC's.	Remove requirement as it is believed that this is captured by CNSC Type II Compliance Inspection findings and in Performance Indicator reporting, as applicable.	MAJOR	Onerous for Licensee to conduct self-assessment to meet this one requirement of the Annual Compliance Report that should be captured in CNSC Type II Compliance Inspections and other metrics (such as the Quarterly Operations reports that are already submitted).
12.	Abbreviations p. 61	This is inconsistent with REGDOC-3.1.2 requirements, where such a table is not provided.	Remove the table and leave in a reference to REGDOC-3.6, Glossary of CNSC Terminology. The abbreviations currently missing from REGDOC-3.6 should be added to its next revision.	<i>Clarification</i>	