

**Combined public review comments**

**Draft REGDOC-3.1.2, *Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills***

Version out for Public consultation July 11 to November 9, 2016

The following table is a compilation of the review comments received during Public Consultation and the dispositions. Since the REGDOC 3.1.2, *Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills*, originally provided for public review in July 2016, changes in approach are being incorporated into the draft regulatory document to accommodate CNSC licence improvement initiatives that are intended to help minimize administrative burden. Consequently, unlike the distributed draft, when completed, REGDOC-3.1.2, Volume I will be referenced in the licence conditions handbook, rather than the licence as had been originally proposed.

What this means is that the regulatory requirements found in section 29 of the *General Nuclear Safety and Control Regulations* allow for variations in what to report, as well as the timing of reports, however only if the alternate information is specified in the licence. Since REGDOC-3.1.2, Volume I will not be referenced in licences, no variation can be made to what is reported and the timing of the reports. Therefore, for the most part, the detailed or full reports were to be provided to the Commission within 21 days.

As REGDOC-3.1.2, Volume I will not be found in licences, the significance of an event is not a determining factor in whether the event needs to be reported nor when the event is to be reported. The Regulations do not refer to the significance of an event.

The detailed dispositions in the following table reflect the change in approach.

Combined public review comments

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	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
1	General	CNA, OPG, Bruce Power	As always, we appreciate the opportunity to provide comment on this draft document and share our experiences with the CNSC. (OPG, CNA, Bruce Power)  and encourage the CNSC to continue to engage licensees further as this suite of proposed REGDOCs is developed. (CNA)		
2	General	CNL CNA	In some cases all the reporting required will be addressed in the initial report – suggest CNSC should review Table A to change where required the column Full Report in the table to : “Within 60 days after becoming aware of the event if required”	It is agreed that the initial report may adequately provide sufficient information to be considered a “full report” and the accountability for the determination needs to remain with the licensees. Section 2 Guidance contains the following text for the application of Table A.  “If the licensee determines that investigation beyond the preliminary report is unlikely to yield further relevant details or identify additional corrective actions to prevent recurrence of the situation or event, then a full report may not be necessary. In this case, the preliminary report should include the information required by the full report.”  The text also further provides the following:  “If, after further investigation, the licensee concludes a situation or event was not reportable, the licensee should provide the CNSC with a written statement that includes a rationale to support the	

**Combined public review comments**

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				conclusion.”	
3	General	OPG CNA CNL	The draft REGDOC calls for an annual report as described here which is not required given that the CNSC staff are already provided all the information separately and therefore adds significant administrative burden with no benefit	<p>It is intended that the Annual Compliance Monitoring Report reduce administrative burden by permitting licensees to provide a single and summarized annual compliance report. Guidance has been added to the section on annual reporting as follows :</p> <p>“Each annual compliance monitoring report should act as a stand-alone document. If any of the information has been provided to the CNSC previously, such as in an event report, or in a separate or previous compliance report, the information does not need to be duplicated. In these cases a reference(s) pointing to the previous report(s) is adequate.”</p> <p>The appendix B is provided as a sample for consideration, but the final format and content can be determined by the type of facility and operation in question. The REGDOC is general to address a wide range of potential types of facilities with differing breadth of activities. A discussion with the licensing officer can be useful in determining the format and content to be used. The contents in Appendix B is to assist a licensee in writing their annual report in order to demonstrate performance in various areas and compliance to regulatory requirements.</p>	
4	General	OPG	No Impact statement was provided as required by the cabinet directive on regulatory management.	A “Request for information” was provided with the draft REGDOC. The previously issued	

Combined public review comments

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		CNA OPG Bruce Power CNL		supporting documents called "impact statements" have been updated and renamed to give licensees an opportunity to provide their feedback on the potential impact of implementation of the REGDOC for CNSC consideration.	
5	General	OPG CNA CNL	REGDOC 3.1.2 should address all reporting requirements (while referencing related regulatory documents) and should supersede all other current reporting requirements in the current regulatory framework	REGDOC-3.1.2 is not intended to replace other reporting requirements found in the CNSC regulatory framework.  As stated in the Preface of every regulatory document, 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  The duplication of reporting that may exist will be addressed during the implementation. The extent of the current reporting requirements may be superseded by the requirements of this document when published.	
6	General	CNA	Generally, industry sees the need for further discussions with the CNSC to clarify the proposed requirements.	A Stakeholder Workshop for continuing discussion is scheduled for September 27, 2017.	
7	General	CNA	While industry supports the CNSC's attempts to create succinct, clearly written regulatory documents, we have concerns that some elements of this discussion paper are limited in scope and are actually counter-productive to the		

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			CNSC's goals.		
8	General	CNA OPG Bruce Power CNL	<p>The Annual Report contents as outlined in Section 3, are very similar to that required for an Application, and add significant burden. This is contrary to the direction to reduce unnecessary burden. REGDOC-3.1.1 was developed to provide performance data necessary for the regulatory oversight while making use of existing practices. Reports should be limited to performance reporting.</p> <p>Industry would be happy to work with other stakeholders and CNSC to identify appropriate reporting requirements</p> <p>Remove requirements for future Plan, changes, and facility descriptions.</p> <p>The Annual Report should be reconsidered to focus on performance. Once established, industry expects the content requirements to remain unchanged, except through revision of the REGDOC process.</p> <p>Major Impact: As written, this requires licensees to provide essentially a new application for each facility each year. This is a significant burden on licensees, with no improvement to safety or performance.</p> <p>Modifications to systems, documents etc. are provided to the regulator through other mechanisms, including the LCH notification process. Duplicative reporting adds significant burden in racking for no improvement in safety.</p> <p>Once established, industry expects the content requirements to remain unchanged, except though the</p>	<p>The content in Appendix B of the REGDOC is to assist a licensee in writing their annual report in order to demonstrate performance in various areas and to demonstrate to the CNSC that they are meeting regulatory requirements and operating safely.</p> <p>It is intended that the Annual Compliance Monitoring Report reduce administrative burden by permitting licensees to provide a single and summarized annual compliance report.</p> <p>Guidance has been added to the section on annual reporting as follows :</p> <p>“Each annual compliance monitoring report should act as a stand-alone document. If any of the information has been provided to the CNSC previously, such as in an event report, or in a separate or previous compliance report, the information does not need to be duplicated. In these cases a reference(s) pointing to the previous report(s) is adequate.”</p> <p>The appendix B is provided as a sample for consideration, but the final format and content can be determined by the type of facility and operation in question. The REGDOC is general to address a wide range of potential types of facilities with differing breadth of activities. A discussion with the licensing officer can be useful in determining the format and content to be used.</p> <p>Future Plans has been removed from Appendix</p>	

**Combined public review comments**

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			REGDOC revision process. This will ensure consistency between licensees and regulatory certainty.	<p>B, as an item to add to an Annual Report.</p> <p>Documents in the CNSC regulatory framework undergo regular reviews and potential updates consistent with the practices of governments and standards development organizations.</p> <p>Individual comments are addressed in the responses below.</p> <p>A Stakeholder Workshop for continuing discussion is scheduled for September 27, 2017.</p>	
9	General	Cameco	<p>Cameco Corporation (Cameco) has reviewed and prepared the following comments on the draft REGDOC 3.1.2, <i>Reporting Requirements for Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills</i> (the REGDOC). The REGDOC sets out requirements and guidance for reports and notifications that licensees must submit to the Canadian Nuclear Safety Commission (CNSC) including the types of reports, their frequency and the applicable timeframe for reporting.</p> <p>Cameco welcomes the development of the REGDOC, which should be a useful resource for identifying our reporting requirements and the associated reporting timelines. The final REGDOC will help clarify and streamline Cameco's reporting requirements and provide clear expectations for what information is to be submitted to the CNSC. The following comments are intended to further improve the reporting requirements outlined in the draft REGDOC.</p>	<p>The comments received from Cameco are appreciated to assist with the development and improvement of the draft REGDOC. The specific comments provided are addressed throughout this table below.</p>	

Combined public review comments

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10	General	CNA OPG Bruce Power CNL	<p>In some cases, all the reporting required will be addressed in the initial report</p> <p>However if a full report is required, it should be submitted 60 days following the submission of the preliminary report.</p> <p>Suggested change :</p> <p>By CNA: CNSC should review Table A to change where required the column Full Report in the table to "Within 60 days after becoming aware of the event <i>if required</i>"</p> <p>By OPG and Bruce Power: CNSC should review Table A to change where required the column <b>Full Report</b> in the table to "Within 60 days <del>after becoming aware of the event</del> (<i>if required</i>)"</p> <p>Major impact: Adds administrative burden with no benefit</p>	<p>Feedback based on the experience of a range of licensees in terms of facility type and size is appreciated.</p> <p>See Preamble of this table for information on the timing of the reports.</p> <p>The regulations specifies when the full report must be submitted (ie 21 days after becoming aware of it,...).</p> <p>The document is revised and clarified so that the reporting timelines are consistent with those in the Regulations.</p> <p>It is agreed that the initial report may adequately provide sufficient information to be considered a "full report" and the accountability for the determination needs to remain with the licensees. Section 2 Guidance contains the following text for the application of Table A.</p> <p style="padding-left: 40px;">"If the licensee determines that investigation beyond the preliminary report is unlikely to yield further relevant details or identify additional corrective actions to prevent recurrence of the situation or event, then a full report may not be necessary. In this case, the preliminary report should include the information required by the full report."</p> <p>The text also further provides the following:</p> <p style="padding-left: 40px;">"If, after further investigation, the licensee</p>	

Combined public review comments

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				<p>concludes a situation or event was not reportable, the licensee should provide the CNSC with a written statement that includes a rationale to support the conclusion.”</p> <p>The text in Appendix A preamble contains the following bullet that provides the same intent as the suggestion for the use of “if required”.</p> <p>“for situations or events, the report is due immediately (where “immediately” means as soon as the licensee becomes aware that an event is reportable) and, if required, shall be updated with additional information in a full report within 21 days after becoming aware of the event”</p>	
11	General	CNA OPG Bruce Power CNL	<p>Quoting sections from many other regulatory documents and acts adds confusion to the document. The reader must carefully review all of the referenced documents to understand the intent of each section and sections from Appendix A Table A. Since the sections are often partially quoted, they will be interpreted differently by different readers and increases the likelihood that information is taken out of context.</p> <p>Impact: Clarification</p>	<p>Table A provides a tool to consolidate and include reporting requirements from the Act and regulations into a single document as best possible, and the text is therefore quoted directly and compiled in Table A.</p> <p>The only instance where text is partially quoted is the reference to the <i>Radiation Protection Regulations</i>, and where the inclusion of the full text would confuse the purpose of the REGDOC because of the amount of the requirements text in that document that would be needed.</p> <p>It is also standard practice in regulation and standards to refer to other documents to remain current and consistent, and to eliminate potential</p>	

Combined public review comments

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				errors in the transcription.	
12	General	Bruce Power	<p>The purpose of this letter is to comment on this document, which sets requirements and guidance for reports and notifications that licensees of Class I nuclear facilities and uranium mines and mills must submit to the CNSC.</p> <p>Its scope is very similar to <i>REGDOC-3.1.1, Reporting Requirements for Nuclear Power Plants</i>, which Bruce Power commented on extensively during its own development period. -The attached list of comments is based on our operating experience with <i>REGDOC-3.1.1</i> and a collaborative review of this particular draft with our industry peers. Let me highlight two key points that emerged from this collective review:</p> <ul style="list-style-type: none"> <li>•It is unclear what value is added by the requirement for an Annual Compliance Monitoring Report (Section 3) in <i>REGDOC-3.1.2</i>. Most requirements are similar to other required reporting.</li> <li>•In some cases, it is recommended that the reporting timelines for the unscheduled reporting (Table A.1) be based on the significance of the event. This allows the administrative burden of reporting to be managed as applicable.</li> </ul>	<p>Feedback based on the experience of a range of licensees in terms of facility type and size is appreciated.</p> <p>It is intended that the Annual Compliance Monitoring Report reduce administrative burden by permitting licensees to provide a single and summarized annual compliance report. Guidance has been added to the section on annual reporting as follows :</p> <p>“Each annual compliance monitoring report should act as a stand-alone document. If any of the information has been provided to the CNSC previously, such as in an event report, or in a separate or previous compliance report, the information does not need to be duplicated. In these cases a reference(s) pointing to the previous report(s) is adequate.”</p> <p>The appendix B is provided as a sample for consideration, but the final format and content can be determined by the type of facility and operation in question. The REGDOC is general to address a wide range of potential types of facilities with differing breadth of activities. A discussion with the licensing officer can be useful in determining the format and content to be used. The content in Appendix B is to assist a licensee in writing their annual report in order to demonstrate performance in various areas and compliance to regulatory requirements.</p>	

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				<p>The extent of the current reporting requirements may be superseded by the requirements of this document when published.</p> <p>See Preamble of this table for information on the timing of the reports.</p> <p>The regulations specifies when the full report must be submitted (ie 21 days after becoming aware of it,...).</p> <p>The document is revised and clarified so that the reporting timelines are consistent with those in the Regulations.</p>	
13	<p>General</p> <p>Table A,</p> <p>A.3b (g)</p> <p>D.8</p> <p>D.11</p>	Cameco	<p><b>Maintaining a Risk-Based Approach</b></p> <p>Cameco supports CNSC's intention in this REGDOC to "...establish a modern, risk-informed approach to reporting requirements" as described in the Preface. This approach, however, is contradicted by the Guidance subsection in Section 2 <i>Reporting Requirements</i> that describes reportable situations or events in Table A to include situations and events "regardless of their safety significance" and includes "...other types of notifications or situations ... even though they do not meet the definitions of an event."</p> <p>[A.3b (g)] An example in Table A of a non-risk-based reporting requirement is the Guidance associated with s.29(1)(g) of the <i>General Nuclear Safety and Control Regulations</i> (GNSCR) that makes the fact that union is in a legal strike position reportable whereas the GNSCR itself requires the reporting of "threatened or planned work disruption". In the absence of an indication from the union</p>	<p>The text provided in the Preface is standard general text that is provided when a REGDOC is intended to be applied to the licensing basis for a nuclear facility or activity.</p> <p>Text is revised in Guidance in section 2 to clarify that the Table A in Appendix A provides a list of situations and events to be reported. The phrase "regardless of their safety significance" has been removed. See the Preamble to this table regarding significance of events and reporting.</p> <p>The CNSC expectation for compliance with s.29(1)(g) of the GNSCR is that if a union is in a legal strike position, a report is made to the CNSC. The CNSC wants to be made aware of possible work disruptions before a work disruption occurs.</p>	

Combined public review comments

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			<p>that it intends to cause a work disruption, the reporting threshold of the regulation is not met and the Guidance appears to expand clear, risk-based regulatory requirements without a legal basis.</p> <p>[D.8] Another example in the Table A Guidance is s.29(1)(f) of the GNSCR. This lists reportable events that may have no risk when the regulation restricts reporting to situations where the failure of any component or system “could have a serious adverse effect...” or “... contribute to serious risk to...” If the intention is to require licensees to report all the enumerated events regardless of risk, then the Guidance creates non-risk-based reporting. If the intention is to limit reporting to the events specified in s.29(1)(f), then the Guidance creates confusion, is unnecessary and should be deleted.</p> <p>[D.11] Non-risk-based reporting may also be created in the “specific reporting provisions” described in Table A under the authority of s.24(5) of the <i>Nuclear Safety and Control Act</i> (NSCA) for situations and events “that can be reasonably assumed to be of regulatory interest that are not otherwise specified in this document ...” This language could capture minor and very low risks events and situations and is contrary to the Licence Conditions Handbook (LCH) concept of a “material violation”, which is defined to be a violation that “impacts the ability of the licensee to carry out its licenced activities in a way that takes into consideration the protection of the environment, health and safety of persons, maintenance of national security and measures required to implement international obligations to which Canada has agreed.”</p> <p><b>Issue/Suggestion:</b> We recommend that the REGDOC be revised to eliminate all references to reporting that is not</p>	<p>The bulleted listed under the guidance for [D.8] are examples of events that could result in serious adverse effects. The text does not state that the events will result in serious adverse effects.</p> <p>To clarify the intent, D.11 has been revised as follows:</p> <p>The licensee shall report on all other situations or events that are not otherwise specified in this document but are significant enough to be reasonably assumed to be of regulatory interest, including notifications and situation or event reports to other regulatory agencies within the scope covered by the objects of the Commission (see section 9 of the NSCA).The Guidance has been revised as:</p> <p>The licensee may submit copies of the report(s) or notification(s) prepared for other governing regulatory bodies to the CNSC..</p> <p>Reports may also include events or situations that could have been reportable but were not, due to fortuitous circumstances (near-miss events).</p>	

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			risk-based to be consistent with the intent of the REGDOC, the legislation and LCHs. We also recommend that all guidance that could be interpreted to expand reporting beyond the scope of regulatory requirements and to circumvent clear legislative intent should be deleted.		
14	General	Cameco	<p>We suggest that the REGDOC can be streamlined by simply listing the applicable Regulations within section 1.3, Relevant legislation, and then referring to Table A in Appendix A. The relevant provisions of the NSCA and associated Regulations are clearly described in Table A.</p> <p>We also recommend the following clarifications and/or corrections:</p>	<p>No change required, as it is the purpose of REGDOCs to clarify how to meet the requirements of the legislation. Further guidance is provided to provide examples of good practice that is being codified or otherwise captured to share across the industry.</p> <p>The text in Table A is provided as a convenience for text extracted from the various regulations for the legislated reporting requirements applicable to all, or where applicable to the various facility types. However, as the REGDOC does apply to a broad range of types of facilities that may also be unique in design, construction or operation, some may have specific additional reporting requirements because of the nature of the facility, operation, and identified performance issues.</p> <p>The recommendations for clarifications and/or corrections are addressed below for the applicable sections.</p>	
15	General	Cameco	<p><b>Summary</b></p> <p>We believe the draft REGDOC can be improved by maintaining a risk-based approach to reporting</p>	CNSC appreciates the suggestions for improving and streamlining the document. Specific	

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			requirements, integrating codes of practice, aligning reporting requirements with public disclosure, and incorporating opportunities to streamline the document.	suggestions are addressed below.	
16	General	AREVA	AREVA Resources Canada Inc. (AREVA) has reviewed and prepared comments on draft <i>REGDOC-3.1.2 Reporting Requirements for Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills</i> (REGDOC). AREVA supports the effort to establish a document that consolidates and clarifies reporting requirements, including the types of events that require reporting, reporting frequencies and applicable timeframes for providing reports to the Canadian Nuclear Safety Commission (CNSC). To assist in achieving the intention of the document AREVA has participated with industry discussions and is providing the following feedback to further improve the REGDOC.	Feedback based on the experience of a range of licensees in terms of facility type and size is appreciated.  Individual comments are addressed below.	
17	General 2, Guidance Page 4	AREVA	<u>Risk-informed approach</u> : The intention of the REGDOC described in the Preface is to establish a modern, risk-informed approach to reporting requirements. AREVA supports this intention but observes that many of the requirements for reporting which unnecessarily heighten the perception of risk in the nuclear industry are codified within the regulations made pursuant to the Nuclear Safety Control Act (NSCA), limiting the opportunity in the REGDOC to meet the desired intent, resulting in such unfortunate statements as "Table A of the REGDOC provides a list of situations and events that must be reported <u>regardless of their safety significance</u> ". The REGDOC should take the opportunity where available to risk-informed reporting.	Table A consolidates various legislated reporting requirements into a single location to assist licensees.  As the REGDOC will not be referenced in the licence the timelines specified in the Regulations must be adhered to. The REGDOC is revised and clarified so that the reporting timelines are consistent with those found in the Regulations. See Preamble to this table for information on the timing of the reports.	

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18	Preface	Cameco	Provide clarification on how the REGDOC "... will be used to assess new licence applications for nuclear facilities and activities."	No change is required. The text provided in the Preface is standard general text that is provided when a REGDOC is intended to be applied to the licensing basis for a nuclear facility or activity. The details of the application of the requirements and guidance are provided in the document, and the relevant licences and/or LCH when applicable.	
19	Introduction	Nordion	This document presents the types of reports, the frequency and the applicable timeline for reporting.  <b>Issue/Suggestion:</b> Clarify "frequency". It is interpreted that the frequency of reporting and the timeframe for reporting are the same.	Text has been revised to address the intent of the comment. The word "frequency" is removed to clarify the intent. The introduction is intended to provide general text for which the requirements are expanded upon in more detail in the body of the document.	Done
20	Introduction	Nordion	Paragraph 27(b) of the NSCA states that <i>"Every licensee and every prescribed person shall</i>  <i>(b) make the prescribed reports and file them in the prescribed manner [including a report on ...</i>  <i>(ii) any contravention of this Act in relation to an activity that is authorized by this Act and any measure that has been taken in respect of the contravention.]</i>  <b>Issue/Suggestion:</b> Nordion proposes providing examples for contraventions of the Act in relation to an activity that is authorized by this Act.	Text has been revised to address the intent of the comment. The following text has been added as Guidance:  "A licensee shall conduct its licensed activities in accordance with its licensing basis; therefore, the following are examples of when a licensee shall report to the Commission:  <ul style="list-style-type: none"> <li>• when the licensee determines it has contravened the regulatory requirements set out in the NSCA and regulations</li> <li>• when the licensee determines it has</li> </ul>	

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				<p>not carried out the safety and control measures described in the licence application and the documents supporting the application</p> <ul style="list-style-type: none"> <li>• when the licensee determines it has not carried out activities in accordance with documents directly referenced in the licence</li> </ul> <p>For the purpose of event reporting, not carrying out the safety and control measures described in the application and documents supporting the application is more appropriately considered in the context of systemic/programmatic/sustained failure in the implementation of a program.</p> <p>Another example of a situation referred to in paragraph 27 b) of the NSCA is when a licensee determines that they have carried out an activity in section 26 of the NSCA without the proper licence authorization.”</p>	
21	Preface p. 1	CAN OPG	The 6 <sup>th</sup> paragraph (states) <i>“Licensees are expected to review and consider guidance; should they choose not to follow it, they should explain how their chosen alternate approach meets regulatory requirements. An applicant or</i>	No change is required at this time, as this is standard Preface text in CNSC REGDOCs. It will be reviewed as part of the normal CNSC	

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		Bruce Power  CNL	<p><i>licensee may put forward a case to demonstrate that the intent of a requirement is addressed by other means and demonstrated with supportable evidence.</i></p> <p><b>Issue:</b> Guidance is meant to be guidance. If the licensee is required to meet guidance criteria (even by other means), then it is a requirement, not guidance.</p> <p><b>Suggestion:</b> Change to: <i>“Licensees are expected to review and consider guidance. ; <del>should they choose not to follow it, they should explain how their chosen alternate approach meets regulatory requirements. An applicant or licensee may put forward a case to demonstrate that the intent of a requirement is addressed by other means and demonstrated with supportable evidence.</del>”</i></p> <p><b>Major impact:</b> Licensees note that a similar statement appears in all REGDOCs. It puts an unreasonable onus on licensees to demonstrate not just how requirements are met, but also how guidance is met.</p>	<p>document review process for REGDOCs.</p> <p>The requirements are stated in the REGDOC, and the guidance text provides an example of a good practice that has been accepted by the CNSC. They have been captured in the document to assist licensees or licence applicants in meeting the requirements. However, the text is also provided to emphasize how the licensees can provide alternative means to meet the requirements in an objective-based manner.</p>	
22	Preface paragraph 4	OPG  Bruce Power  CNL	<p>The paragraph states: <i>“This document will be used to assess new licence applications for nuclear facilities and activities.”</i></p> <p><b>Issue:</b> It is not clear how CNSC staff might use this document for the assessment of new licence applications, or how evaluations of specific problems or data during the review of applications will be conducted.</p> <p><b>Suggestion:</b> Delete</p>	<p>No change is required at this time, as this is standard Preface text in CNSC REGDOCs. The text will be reviewed as part of the normal document review process for REGDOCs.</p>	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
			<b>Impact:</b> Clarification		
23	Table of contents	CNA OPG Bruce Power CNL	<b>Issue:</b> Appendix A does not sufficiently reflect the hierarchical structure of Table A  <b>Suggestion:</b> Expand Table of contents – Appendix A accordingly  <b>Impact:</b> Clarification	Text has been revised as suggested. Table of Contents has been updated.	Done
24	1.1 Purpose	Cameco	Clearly describe if and how reporting requirements currently outlined in a site's LCH will be updated once the REGDOC is published. Note if the REGDOC will supersede reporting requirements in an existing LCH and provide direction to licensees on how any transition in reporting will be completed.	No change required. REGDOCs are not written to include an implementation plan.  The duplication of reporting that may exist will be addressed during the implementation.  The extent of the current reporting requirements may be superseded by the requirements of this document when published.	
25	1.2 Scope, page 1	CNA OPG Bruce Power CNL	First paragraph (states): <i>"This regulatory document incorporates and clarifies requirements found in the NSCA and the regulations..."</i>  <b>Issue:</b> These reporting requirements go beyond just incorporating and clarifying the existing requirements.  <b>Suggestion:</b> Suggest using the wording from REGDOC-3.1.1 "...incorporates and expands upon the requirements..." which is more accurate.  <b>Impact:</b> Clarification	No change is required. REGDOCs provide more information on expectations and guidance to help clarify how to meet the requirements.	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

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26	1.1 para 2	CNA OPG Bruce Power CNL	<p><b>Issue:</b> The requirement to report is unclear as to safety significance</p> <p><b>Suggestion:</b> <i>Requirement to report situations or events of higher safety significance...</i></p> <p><b>Impact:</b> Clarification</p>	No change is required. The Purpose section provides a description of the purpose of the document, and the requirements, criteria and guidance are provided further in the body of the document with more clarity and detail.	
27	1.3 bullet 3	CNA OPG Bruce Power CNL	<p><b>Issue:</b> Missing provisions in the Act for extension of submission time for reports</p> <p><b>Suggestion:</b> <i>Add "section 44 of the NSCA and section 29, 30 and 31 of the GNSCR contain provisions where the submission time for full reports can be extended by the terms of a licence condition."</i></p> <p><b>Impact:</b> Clarification</p>	No change is required. See Preamble for information on the timing of the reports.	
28	1.3, page 3 last paragraph	CNA OPG Bruce Power CNL	<p><i>subsection 7.5(4) of the Nuclear Security Regulations states that "every licensee shall provide a copy of the written record, together with a statement of actions taken as a result of the [yearly] threat and risk assessment, to the Commission within 60 days after completion of the assessment"; in addition, sections 21 and 36 and subsection 44(2) stipulate other situations requiring notification</i></p> <p><b>Issue:</b> Section 7.3 of the Nuclear Security Regulations indicates that "Sections 7.4 – 38 apply in respect of high-security sites."</p> <p>While Appendix A Table A makes reference to</p>	No change required as this section provides a list of relevant legislation applicable to the requirements in this document. The scope section is intended to provide a high level description of the intent. The requirements are provided later in the document, and the guidance indicates application to high security sites.	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

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			<p>applicability, the scope section does not limit how this regulation is applied. In effect the NSR are paraphrased in this document which could allow the requirement to be taken out of context.</p> <p><b>Suggestion:</b> Remove the bullet from section 1.3 or add disclaimer on limitation of scope for the reference.</p> <p><b>Major impact:</b> If not modified, sections of the Nuclear Security Regulations can be applied to facilities and sites they were not intended for.</p>		
29	1.3 Page 2 last 2 bullets	CNA OPG Bruce Power CNL	<p><b>Issue:</b> Text is irrelevant to this document</p> <p><b>Suggestion:</b> Delete.</p> <p><b>Major impact:</b> Unnecessary administrative burden since this document is specific to Class I facilities</p>	No change required as this section provides a list of relevant legislation applicable to the requirements in this document. The requirements are provided later in the document. However, there are facilities licenced by the CNSC that include Class II facilities and prescribed equipment.	
30	2	Nordion	<p>Reporting Requirements state: <i>The following reporting requirements apply for Class I nuclear facilities (excluding power reactors) and uranium mines and mills:</i></p> <p><i>1. The licensee shall file a report to the Commission in response to:</i></p> <p><i>a. An event or a situation, or</i></p> <p><i>b. A dangerous occurrence as stipulated in section 35 of the PTNSR 2015</i></p> <p><b>Issue:</b> Point 1. A. "an event or a situation" is too generic.</p>	No change required. This section provides the high-level generic requirements for reporting. The document as a whole reflects the requirements from the Regulations, and details are provided later in the document.	

**Combined public review comments**  
**Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills**  
Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
			<p>The regulations specify that this is in relation to an event or situation that is likely to result in the exposure of persons or the environment.</p> <p><b>Suggestion:</b> Language should be added to specify which events or situations require reporting.</p>		
31	2	Nordion	<p>Reporting Requirements state:</p> <p style="text-align: center;"><i>2. as required, licensees shall provide other notifications or reports, including a failure to comply with section 26 of the PTNSR 2015</i></p> <p><b>Issue:</b> Point 2. This language is generic. A specific example is given in section 26 of the PTNSR 2015.</p> <p><b>Suggestion:</b> Nordion suggests listing specific notification or reports and removing generic language.</p>	<p>No change required. This section provides the high-level general requirements for reporting. The document as a whole reflects the requirements from the Regulations, and details are provided later in the document.</p>	
32	2	Nordion	<p>Reporting Requirements state:</p> <p style="text-align: center;"><i>A preliminary report or notification that must be submitted immediately may be provided in person, by telephone, by email or by fax.</i></p> <p><b>Suggestion:</b> Nordion suggest rewording as: <i>"A preliminary report or notification that must be submitted immediately may be provided in person, by telephone, by e-mail or by fax unless specified otherwise by the regulations (refer to Table A)."</i></p>	<p>No change required. The regulations do not provide this level of detail.</p>	
33	2,	Nordion	Reporting Requirements, Guidance	Text has been revised to address the intent of the comment. The section is revised to clarify the	Done

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

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	Guidance		<p>Text states:</p> <p><i>For an emergency involving a nuclear facility or nuclear substances the licensee should contact the CNSC Duty Officer emergency telephone number.</i></p> <p><i>An emergency includes:</i></p> <ul style="list-style-type: none"> <li>• <i>any accident involving a nuclear reactor, nuclear fuel facility, or nuclear substances</i></li> <li>• <i>lost or damaged nuclear substances</i></li> <li>• <i>any threat, theft, smuggling, vandalism or terrorist activity involving a nuclear facility or nuclear substances</i></li> <li>• <i>an unplanned spill or release</i></li> <li>• <i>a worker injury that requires offsite medical response</i></li> <li>• <i>any event that requires activation of a site emergency response plan</i></li> </ul> <p><b>Issue:</b></p> <p>For the purposes of providing examples of an emergency to Class 1 Nuclear Facilities and Uranium Mines and Mills, Nordion recommends removing <i>“any accident involving a nuclear reactor and nuclear fuel facility”</i> from the example list.</p> <ul style="list-style-type: none"> <li>• <i>“Any accident involving a nuclear substance”</i> is vague. For example, a dropped vial of Y-90 inside a hot cell during processing of a nuclear substance. Such “accidents” do</li> </ul>	<p>intent as follows.</p> <p>“Licensees shall report any of the following events to the CNSC, directly through the Duty officer: an event or incident that triggers actions under emergency response programs, even if it is a false alarm; an event such as a spill, a release or an injury that could trigger stakeholder interest; an event that falls under the requirements of subsection 29(1) of the <i>General Nuclear Safety and Control Regulations</i>.”</p>	

Combined public review comments

Draft REGDOC-3.1.2, *Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills*

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
			<p>not trigger the licensee's emergency response plan and should not require reporting to the Duty Officer. A recommendation is to specify <i>"any accident that triggers actions under emergency response programs"</i> to the bullet.</p> <ul style="list-style-type: none"> <li>• Nordion's practice for missing packages is to contact the Director, Transport Licensing and Strategic Support Division (SSD) and not the Duty Officer after a 24 period to allow for missed flights or sorting issues. Nordion suggests defining a wait time before considering a package lost. Clarification is recommended on the requirement, in particular when lost packages do not trigger emergency response such as missing Type A quantity packages. For all situations where Nordion has reported a missing package, the package has been found within a few days and always within the carrier's facility.</li> <li>• In addition, the reporting to the Duty Officer requirement is also for damaged packages. Again, this should specify damaged packages that trigger emergency response or could result in an exposure to the public or release to the environment. Nordion's large Type B containers regularly sustain minor damage (scrapes, dents) during transport. These do not affect the integrity of the package.</li> <li>• Clarify theft. As worded <i>"any theft, ...involving a nuclear facility"</i> it could mean any theft, whereas, the regulations are more specific: <ul style="list-style-type: none"> <li>• NSCA 27(b)(a) – theft or loss of a nuclear substance, prescribed equipment, or prescribed information</li> </ul> </li> </ul>		

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
			<p>that is used in carrying on any activity that is authorized by the NSCA</p> <ul style="list-style-type: none"> <li>•GNSCR 30(1) – theft, ... of safeguards equipment or samples collected for the purpose of a safeguards inspection</li> <li>•NSRDR 38(1) – the nuclear substance or radiation device is lost or stolen</li> <li>• Nordion recommends developing a threshold relative to impact and risk to clarify guidance.</li> <li>• As worded, this could mean any spill, such as a minor spill that is handled internally using Chemical Spill Response procedures. Nordion has defined a chemical spill that would require contacting the Duty Officer as a chemical spill that triggers ERP activation, or results in any releases to the environment, injury to workers, or evacuation of the building.</li> <li>• As worded, this could mean any worker injury, whereas, worker injuries vary in severity. The regulations specify “serious illness injury incurred or possibly incurred as a result of the licensed activity” (GNSCR 29(1)).</li> </ul>		
34	Section 2, p. 3, 1a	CNA OPG Bruce Power	<p><b>Issue:</b> Terminology revision</p> <p><b>Suggestion:</b> Replace “<i>an event or a situation</i>” with “<i>an event or a situation as set out in Table A of Appendix A</i>”.</p> <p><b>Impact:</b> Clarification</p>	No change required. This section provides the high-level general requirements for reporting. The document as a whole reflects the requirements from the Regulations, and details are provided later in the document. Additionally, the same intent for this proposal is provided in	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

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		CNL Cameco		item 5 of this section.	
35	Section 2, p.4	CNA Bruce Power CNL OPG	<p><b>Issue:</b> Why is 'immediate reporting' applied to all types of events?</p> <p><b>Suggestion:</b> Replace by reporting timelines by safety significance, same as in REGDOC 3.1.1 (section 2 – items 1-8, and 10)</p> <p><b>Major impact:</b> Administrative burden on licensee and regulator due to immediate response requirement.</p>	No change required. See Preamble to this table for information on the timing of the reports.	
36	Section 2, Guidance p.4	CNA Bruce Power CNL <u>OPG</u>	<p><b>Issue:</b> Significance level is not addressed, facility specific reports are unclear</p> <p><b>Suggestion:</b> Make consistent with guidance from REGDOC-3.1.1 (scheduled/non-scheduled/annual/quarterly)</p> <p><b>Major impact:</b> There is inconsistency with existing LCH/licence, and with the published REGDOC 3.1.1. This is especially problematic given the risk profile of the facility</p>	<p>No change required. See Preamble for information on the timing of the reports plus significance level of the event.</p> <p>The extent of the current reporting requirements may be superseded by the requirements of this document when published.</p> <p>The REGDOC is general to address a wide range of potential types of facilities with differing breadth of activities and therefore facility-specific reports will continue to be necessary.</p>	
37	Section 2, Guidance para.1, p.4,	CNA OPG Bruce Power	<p><b>Issue:</b> Terminology revision</p> <p><b>Suggestion:</b> Replace "<i>licensing specialist</i>" with "<i>project officer</i>"</p> <p><b>Impact:</b> Clarification</p>	Text has been revised to address the intent of the comment. Text is revised generically to "point of contact" as the terminology is different based on the licensing program for the type of facility.	Done

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

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		CNL Cameco			
38	Section 2, Guidance para 3, p.4	CNA OPG Bruce Power CNL	<p>The text states: <i>"In addition to the list above, the licensee may be required to file facility-specific reports, as described in their licence conditions handbook (LCH)."</i></p> <p><b>Issue:</b> Some Industry LCHs contain a comprehensive table of situations, events or dangerous occurrences which require reporting by the licensee to the CNSC. If the table will not be replaced with this REGDOC in the LCH, then it does not seem that this REGDOC is necessary.</p> <p><b>Suggestion:</b> REGDOC 3.1.2 should supersede all other current reporting requirements in the current regulatory framework</p> <p><b>Major impact:</b> Duplicated burden and unnecessary inconsistency between licensees</p>	<p>No change required. The duplication of reporting that may exist will be addressed during the implementation.</p> <p>The extent of the current reporting requirements may be superseded by the requirements of this document when published.</p> <p>The REGDOC is general to address a wide range of potential types of facilities with differing breadth of activities and therefore facility-specific reports will continue to be necessary. These will be found in licensee's documentation referenced in the LCH or found directly in the LCH.</p>	
39	Section 2, Guidance, para 6, last bullet, p. 4,	CNA OPG Bruce Power CNL Cameco	<p><b>Issue:</b> Terminology revision</p> <p><b>Suggestion:</b> Replace <i>"an unplanned spill or release"</i> with an <i>"unplanned spill or release that is reportable under provincial or federal legislation"</i></p> <p><b>Impact:</b> Clarification</p>	<p>Text is revised to address the intent of the comment.</p> <ol style="list-style-type: none"> <li>Licensees shall report any of the following events to the CNSC, directly through the Duty officer: an event or incident that triggers actions under emergency response programs, even if it is a false alarm; an event such as a spill, a release or an injury that could trigger stakeholder interest; an event that falls under the</li> </ol>	Done

Combined public review comments

Draft REGDOC-3.1.2, *Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills*

Version out for Public consultation July 11 to November 9, 2016

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				requirements of subsection 29(1) of the <i>General Nuclear Safety and Control Regulations</i> .	
40	2, Guidance, para 6	Nordion	<p>Reporting Requirements, Guidance</p> <p>Text states:</p> <p><i>For an emergency involving a nuclear facility or nuclear substances, the licensee should contact the CNSC Duty Officer emergency telephone number.</i></p> <p><b>Note:</b> <i>If an emergency is reported to the CNSC duty officer, a preliminary report or immediate notification is not required.</i></p> <p><b>Issue:</b></p> <p>It is our interpretation that the call to the Duty Officer is the preliminary report or immediate notification. Removal of this note is suggested.</p>	<p>Text is revised to address the intent of the comment.</p> <p>“Licensees shall report any of the following events to the CNSC, directly through the Duty officer: an event or incident that triggers actions under emergency response programs, even if it is a false alarm; an event such as a spill, a release or an injury that could trigger stakeholder interest; an event that falls under the requirements of subsection 29(1) of the <i>General Nuclear Safety and Control Regulations</i>.”</p> <p>Contacting the Duty officer and provision of the required information is considered a preliminary report.</p>	Done
41	Section 2, guidance, para 7, p.5	CNA Bruce Power CNL	<p>Text states: <i>“Licensees using this option...”</i></p> <p><b>Issue:</b> Redundant - the requirements are captured in LCH/Licence. the REGDOC should specify the requirement which the licensee will define how compliance is achieved</p>	<p>Text is revised to address the intent of the comment.</p> <p>The sentence “Licensees using this option are required to submit...” has been deleted from the text, as the licensee is accountable to comply</p>	Done

Combined public review comments

Draft REGDOC-3.1.2, *Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills*

Version out for Public consultation July 11 to November 9, 2016

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		OPG	<p><b>Suggestion:</b> Delete entire paragraph</p> <p><b>Major impact (CNA &amp; Bruce Power):</b> Accountability should remain with the licensee</p> <p><b>Major impact (OPG):</b> Accountability for determining how requirements are met should remain with the licensee.</p>	<p>with the NSCA and regulations.</p> <p>See Preamble to this table for information on the timing of the reports.</p>	
42	Section 2 Guidance, para 6	AREVA	<p><b>Issue: <u>Duty Officer Reporting:</u></b> AREVA appreciates that flexibility in developing facility reporting schemes has been identified in Section 2 and believes that development of these schemes will better risk-inform reporting to the Commission.</p> <p>We observe in the guidance on page 4 of the draft the CNSC has identified events which should be considered emergencies. To better risk-inform reporting we recommend the CNSC take the opportunity to better consider emergency situations. We have typically considered events which are immediately dangerous to life or health (IDLH) as emergencies.</p> <p>We observed that the CNSC has broadened the regulatory reporting requirement by perhaps paraphrasing General Nuclear Safety and Control Regulations (GNSCR) Section 29(1)(c) and Nuclear Substances and Radiation Devices Regulations (GNSCR) Section 29(1)(c) and Nuclear Substances and Radiations Devices Regulations (NSRDR) Section 38(1)(e), identifying "an unplanned spill or release" as an emergency requiring reporting. Our experience is that, while these events are unfortunate, they seldom constitute an emergency. Reporting many of these events</p>	<p>Text is revised as follows for clarification.</p> <p>"Licensees shall report any of the following events to the CNSC, directly through the Duty officer: an event or incident that triggers actions under emergency response programs, even if it is a false alarm; an event such as a spill, a release or an injury that could trigger stakeholder interest; an event that falls under the requirements of subsection 29(1) of the <i>General Nuclear Safety and Control Regulations</i>."</p> <p>Contacting the Duty officer and provision of the required information is considered a preliminary report. This information is found in Section 2 Guidance.</p>	Done

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

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			<p>unduly heightens the perception of risk in the nuclear industry when most such events result n no impact to the environment or the health and safety of persons. Similarly, the “activation of a site emergency plan” is rarely the result of an emergency as the threshold for activating emergency personnel on site is very precautionary.</p> <p><b>Suggestion:</b> We recommend that the REGDOC take the opportunity to provide additional guidance around the GNSCR section 29(1)(d) requirement to reduce valueless reporting. Reporting burden is a disincentive to low response thresholds. Subsequent to receiving the expectation that ‘when an event or incident triggers actions under emergency response programs, even if it is a false alarm, ... licensees are required to report to the CNSC directly through the Duty Officer (Tadros to Huffman), June 2016 it should be observed that most alarms from our McClean Lake facility which trigger response programs are false alarms.</p>		

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

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43	Section 2, para 11, page 5	OPG CNL Nordion	<p>Text states: "If, after further investigation...."</p> <p><b>OPG CNL Suggestion:</b> Delete sentence, and replace with: <i>"If, after further investigation, the licensee believes that the event was not reportable, the licensee will notify CNSC staff."</i></p> <p><b>Nordion Suggestion:</b> <i>"If, after further investigation, the licensee concludes a situation or event, which was initially reported to the CNSC, was not reportable, the licensee ..."</i></p> <p><b>Major impact:</b> Accountability for determining reportability should clearly remain with the licensee.</p>	<p>No change required. It is agreed that the initial report may adequately provide sufficient information to be considered a "full report" and the accountability for the determination needs to remain with the licensees. Guidance text is provided for that clarification. Section 2 Guidance contains the following text for the application of Table A.</p> <p>If the licensee determines that investigation beyond the preliminary report is unlikely to yield further relevant details or identify additional corrective actions to prevent recurrence of the situation or event, then a full report may not be necessary. In this case, the preliminary report should include the information required by the full report.</p> <p>The text is also further revised to clarify the normal practice for this section as follows:</p> <p style="padding-left: 40px;"><i>"If, after further investigation, the licensee concludes a situation or event was not reportable, the licensee should provide the CNSC with a written statement that includes a rationale to support the conclusion."</i></p> <p>A record of the disposition needs to be maintained.</p>	
44	Section 2 Page 5 3 <sup>rd</sup> last para	CNA OPG Bruce	<p>Text states: "If the licensee determines..."</p> <p><b>Suggestion:</b> Change the first sentence <i>"a full report may not be necessary"</i> to <i>"a full report is not necessary"</i>.</p>	<p>It is agreed that the initial report may adequately provide sufficient information to be considered a "full report" and the accountability for the determination needs to remain with the licensees. Guidance text is provided for that</p>	Done

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
	(para 12)	Power CNL Cameco	Delete second sentence ”  <b>Impact:</b> Clarification	clarification. Section 2 Guidance contains the following text for the application of Table A.  “If the licensee determines that investigation beyond the preliminary report is unlikely to yield further relevant details or identify additional corrective actions to prevent recurrence of the situation or event, then a full report may not be necessary. In this case, the preliminary report should include the information required by the full report.”  The text has been revised to address the intent of the comment as follows:  “If, after further investigation, the licensee concludes a situation or event was not reportable, the licensee should provide the CNSC with a written statement that includes a rationale to support the conclusion.  A record of the disposition needs to be maintained.”	
45	Section 2, Guidance, second last paragraph (13), P.5	CNA OPG Bruce Power CNL	<b>Issue:</b> Public disclosure: some reportable events have no public interest element and should not be considered as an “input to their public disclosure protocol”. Public disclosure should not be required until after it is determined that an event is reportable.  <b>Suggestion:</b> Delete paragraph. Licensees should adhere	No change required as this is already normal practice in developing the public disclosure protocols that all Class I facilities develop. RD/GD-99.3 describes how the licensees work with their respective target audiences to determine what should be included in the public information program and disclosure protocol. The information is a suggested input for	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
		<a href="#">Areva</a>	<p>to their own public information programs.</p> <p>Alternatively, revise to defer any public disclosure to the licensee public disclosure protocol.</p> <p><b>Major impact:</b> Administrative burden on licensee with no benefit. This requirement is expanding on licensing requirements.</p>	<p>consideration in developing a proactive (rather than reactive) public disclosure protocol and public information program to address the potential for public interest. .This demonstrates the licensee's transparency and openness with the public.</p> <p>Additionally, with regards to when an event or situation is suggested as an input to the public information program, the draft document is not intended to be prescriptive on how it is applied. It does not preclude an agreement with the target audience as defined in RD/GD-99.3 about when such an event is included in the protocol for disclosure. If it makes sense that it is best to determine if an event is reportable, it can be included in the public disclosure protocol.</p>	
46	Section 2, Guidance, Para 13, p.5	Cameco	<p><b>Aligning Reporting Requirements and Public Disclosure</b></p> <p>On page 5 of the REGDOC, the statements "[l]icensees should use the situation or event. . .as an input to their public disclosure protocol" and "[e]ach report should be unclassified . . .so that it can be made available to the public upon request" both fail to recognize the distinction between information that relates to a legitimate public interest and information that must be reported and has no public interest. For example, section 29(1)(i) of the GNSCR requires the reporting of any death at a nuclear facility. If a death is due to natural causes, and is unrelated</p>	<p>No change required as this is already normal practice in developing the public disclosure protocols that all Class I facilities develop. REGDOC 3.2.1 describes how the licensees work with their respective target audiences to determine what should be included in the public information program and disclosure protocol. The information is a suggested input for consideration in developing a proactive (rather than reactive) public disclosure protocol and public information program to address the potential for public interest. This demonstrates the licensee's transparency and openness with</p>	Done

**Combined public review comments**

**Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills**

Version out for Public consultation July 11 to November 9, 2016

	<b>Section or Para. #</b>	<b>Reviewer</b>	<b>Reviewer's Comment and Proposed Change</b>	<b>Response</b>	<b>Done?</b>
			<p>to a public health or safety or environmental protection issue, then the death should not be publicly disclosed as part of a licensee's public disclosure protocol as it does not relate to a licensing decision or to a public health and safety or environmental issue.</p> <p>The REGDOC also states that reports should be made in accordance with CNSC's Guidance Document on Confidential Filings when this document only applies to licensing applications and related proceedings for which decisions authorized by the NSCA are made by the Commission. This guidance document has no application to the reporting of events or situations that are not required by the NSCA or do not trigger a Commission decision, such as the reporting of the death of a worker by natural causes. The REGDOC should be revised to make it clear that not all reported information is subject to a licensee's public disclosure protocol.</p> <p>Closely related is the statement on page 5, "[i]f, after further investigation, the licensee concludes a situation or event was not reportable, the licensee may provide the CNSC with a written statement that includes a justification of their conclusion." Cameco suggests that the REGDOC should include a complementary policy deferring all requirements for public disclosure until after a conclusion has been reached on whether a situation or event was, in fact, reportable.</p>	<p>the public.</p> <p>Additionally, with regards to when an event or situation is suggested as an input to the public information program, the draft document is not intended to be prescriptive on how it is applied. It does not preclude an agreement with the target audience as defined in RD/GD-99.3 about when such an event is included in the protocol for disclosure. If it makes sense that it is best to determine if an event is reportable, it can be included in the public disclosure protocol.</p> <p>Text has been revised to address the intent of the comment as found in comment 47.</p> <p>The management of REGDOC 3.2.1 for public information and disclosure will determine what and how the suggested reports would be addressed. This REGDOC 3.2.1 deals with requirements for reporting, and not those for public disclosure.</p>	
47	2, Guidance,	Nordion	Reporting Requirements, Guidance	Text has been revised to address the intent of the comment on confidential filings:	Done

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
	para 14		<p>Text states:</p> <p><i>Each report should be unclassified and should not contain any proprietary business information so it can be made available to the public upon request. Information should be considered public for the most part. Any information considered classified, protected, proprietary or personal should be submitted in accordance with the CNSC's Guidance Document on Confidential Filings [1].</i></p> <p><b>Issue:</b></p> <p>Nordion is concerned with the wording of this statement as this REGDOC draft requires the reporting of security breaches and other security related events that may contain sensitive and/or Prescribed Information. This information must be protected and only distributed on a need to know basis. It cannot be open to public access without jeopardizing security.</p>	<p>The following text remains in Guidance:</p> <p>`` Each report should be unclassified and should not contain any proprietary business information so it can be made available to the public upon request. Information in the licensee reports should, for the most part, be considered public. ``</p> <p>The following text has been added to Reporting Requirements:</p> <p>``The licensee shall mark all reports made or filed under this regulatory document with an appropriate protection and classification and shall file reports under the appropriate security precautions``</p> <p>The text in Section 3 has been revised to state:</p> <p>``(note: any classified, protected, proprietary or personal information shall be submitted to the CNSC separately and marked with an appropriate protection and classification and filed under the appropriate security precautions)``</p>	
48	Section 2, Guidance, final para (14), p.5	CNA OPG Bruce	<p>Reporting Requirements</p> <p>Text states: <i>“Each report should be unclassified and should not contain any proprietary business information so it can be made available to the public upon request. Information should be considered public for the most part.</i></p>	Text has been revised to address the intent of the comment, as found in comment 47.	Done

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
	and section 3, item 1, p.5	Power CNL	<p><i>Any information considered classified, protected, proprietary or personal should be submitted in accordance with the CNSC's Guidance Document on Confidential Filings."</i></p> <p><b>Issue:</b> The Guidance Document on Confidential Filings only applies to submissions made to formal Commission hearings for licensing decisions. It doesn't apply to reports generated by the REGDOC.</p> <p><b>Suggestion:</b> Delete this reference, and replace the last sentence with: <i>"Any information considered ...classified should be submitted in accordance with the licensee security and information management protocols."</i></p> <p><b>Major impact:</b> As written, this requirement may lead to an inadvertent public disclosure of classified, protected, proprietary or personal information.</p> <p>Creates confusion to refer to a document which has no application.</p>		
49	Section 3, page 5	OPG Bruce Power CNL	<p><b>Text states:</b> <i>"The licensee shall submit an annual compliance monitoring report..."</i></p> <p><b>Issue:</b> The licensee is provided with the flexibility of providing compliance monitoring in a format and frequency other than the annual report.(i.e. existing quarterly reports from the licensee may satisfy the requirement for compliance monitoring).</p> <p><b>Suggestion:</b> <i>"Licensee shall submit compliance</i></p>	No change required. The duplication of reporting that may exist will be addressed during the implementation, as necessary.	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
			<p><i>monitoring report(s)...</i></p> <p><b>Impact:</b> Clarification</p>		
50	Section 3, item 2, Page 5	CNA OPG Bruce Power CNL	<p>Text states: <i>"Sufficient details to provide CNSC staff with information to verify that licensees are meeting their regulatory requirements and are operating safely"</i></p> <p><b>Issue:</b> Vague statement. (Bruce Power)</p> <p>Suggestion: Further discussions between industry and CNSC are required to clarify requirements</p> <p><b>Major impact:</b> Unclear requirements leading to inconsistencies in reporting</p>	<p>Text has been revised to address the intent of the comment:</p> <p>"Sufficient detail to demonstrate and verify that licensees are meeting their regulatory requirements and are operating safely."</p>	Done
51	Section 3, Page 6 Para after item 3	CNA OPG Bruce Power CNL	<p>Text states: <i>"Each annual compliance monitoring report shall act as a stand-alone document. If information from any previous annual compliance monitoring report is needed <u>for completeness</u>, the licensee shall repeat it to the appropriate level of detail."</i></p> <p><b>Issue:</b> The second sentence is redundant if the report is to be a standalone document. [Second sentence is a duplicate of effort]</p> <p><b>Suggestion:</b> Delete the second sentence</p> <p><b>Impact:</b> Clarification</p>	<p>Text has been revised to address the intent of the comment, as follows:</p> <p>"Each annual compliance monitoring report should act as a stand-alone document. If any of the information has previously been provided to the CNSC (for example, in an event report or in a separate or previous compliance report), this information does not need to be duplicated. In these cases, a reference(s) pointing to the previous report(s) is adequate."</p> <p>and the text has been moved into the Guidance.</p>	Done

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
52	Page 6 Guidance, 2 <sup>nd</sup> and 3 <sup>rd</sup> para	OPG  Bruce Power  CNL	<p>Text says: "The licensee may be required to submit additional compliance monitoring reports (e.g., quarterly, monthly or licensee-specific) as described in their licence or LCH. For example, other compliance monitoring reports may be required for new facilities or in situations where additional reporting is necessary (such as following a reportable event). Flexibility is allowed for integrated/harmonized reporting. For example, if a licensee is required to submit reports to regulatory bodies other than the CNSC, then sending a copy of the report to the CNSC is acceptable provided the copied report contains all reporting information required by the CNSC. This option allows the licensee to avoid duplication of effort and to minimize administrative burden."</p> <p><b>Issue:</b> The suggested flexibility is not applicable to annual reporting</p> <p><b>Suggestion:</b> Delete the paragraph</p> <p><b>Impact:</b> Clarification</p>	<p>The duplication of reporting that may exist will be addressed during the implementation.</p> <p>The extent of the current reporting requirements may be superseded by the requirements of this document when published.</p> <p>Text has been revised to address the intent of the comment. The third paragraph stays to accept reports that may be needed for other jurisdictions and eliminating burden. The paragraph has been moved from section 3, under Guidance, to section 2, as the flexibility applies to all reporting and not only annual reporting.</p>	Done
53	3, Guidance, para 4, p.6	AREVA	<p><b>Issue: Annual Compliance Monitoring Report:</b> The REGDOC identifies annual reports "should include all of the information listed in Appendix B, as applicable". Annual reporting for uranium mines and mills is prepared according to the document CNSC-Saskatchewan Harmonized Annual Reporting Requirements, August 2010, issued jointly by the Canadian Nuclear Safety Commission, Saskatchewan Ministry of Environment and Saskatchewan Ministry of Labour Relations and Workplace Safety. AREVA appreciates that the flexibility is allowed for integrated/harmonized reporting and considers the jointly issued requirements as the appropriate vehicle for defining</p>	<p>No change required. The recommendation to remove the information related to improvement plans and significant future activities, found in Appendix B under Other Matters of Regulatory Interest, is agreed to, and the section has been removed.</p> <p>Appendix B is based on the modernized regulatory framework and SCA framework, which in turn are anchored in the NSCA and regulations. Additionally, the information is required for annual reporting to the</p>	

**Combined public review comments**  
**Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills**  
Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
			<p>what is applicable for mines and mills annual reporting.</p> <p><b>Suggestion:</b></p> <ul style="list-style-type: none"> <li>•AREVA recommends that the annual compliance reporting requirements address only previous year's compliance and regulatory requirements. The CNSC should remove requirements for forward-looking statements related to future improvement plans and significant changes.</li> <li>•Table A of the REGDOC has identified various reporting requirements which are anchored in regulations; Appendix B would benefit from similarly identifying the requirements for compliance reporting which are anchored in regulation or licence conditions for the purposes of regulatory compliance.</li> </ul>	<p>Commission. Section 3, item 2 is modified to further clarify the basis.</p> <p style="padding-left: 40px;">“The licensee shall submit an annual compliance monitoring report that includes:</p> <p style="padding-left: 40px;">sufficient details to demonstrate and verify that licensees are meeting their regulatory requirements and are operating safely”</p>	
54	Section 2/3, Guidance, para. 3, P.6,	CNA OPG Bruce Power CNL	<p><b>Issue:</b> This paragraph applies to all notifications and reports and not just the annual compliance monitoring report.</p> <p><b>Suggestion:</b> Move to Section 2 Reporting Requirements</p> <p><b>Impact:</b> Clarification</p>	Text has been revised to address the intent of the comment. The harmonized reporting is moved to section 2, Guidance.	Done
55	Section 2/3, Guidance, para. 3,	Cameco	<p><b>Suggestion:</b> <i>Annual Compliance Monitoring Report.</i> move this paragraph to Section 2, Reporting Requirements because flexibility, avoiding duplication and minimizing administrative burden apply to all notifications and reports in addition to the annual</p>	Text has been revised to address the intent of the comment. The harmonized reporting is moved to section 2, Guidance.	Done

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
			monitoring reports.		
56	Section 3, Guidance, page 6	CNA OPG Bruce Power CNL	<p><b>Issue:</b> It is unclear whether Annual Reports provided by a licensee pursuant to REGDOC 3.1.1 can take the place of content required by draft REGDOC 3.1.2. For example, for licensees with multiple facilities under separate licences at a site, it is unclear whether the licensee can prepare a single report, for example a single Annual Environmental Report.</p> <p><b>Suggestion:</b> Revise the Guidance on page 6 to state <i>“for sites with multiple facilities (under the same <u>or different CNSC licences</u>) or a licensee possessing a licence with multiple locations, the licensee may submit the information through other required reports applicable to the SCA, or in a single consolidated annual compliance report.</i></p> <p><b>Major impact:</b> Providing duplicative information serves not benefit, and increases the reporting burden placed on licensees. It may also lead to a configuration management issue.</p>	<p>The licensees can provide the information in single or multiple reports. The information in Appendix B of the REGDOC are items that CNSC staff will look for when they review the report and therefore should be included as applicable, to demonstrate the licensee's compliance with regulatory requirements<sup>1</sup>.</p> <p>If a licensee produces a report applicable to an SCA, the other report can be submitted as information for the SCA and the other report referenced in the annual compliance monitoring report-. There is no reason to duplicate the information.</p> <p>Text has been revised to address the intent of the comment. The guidance has been revised as suggested:</p> <p>``For sites with multiple facilities (under the same or different CNSC licences) or a licensee possessing a licence with multiple locations, the licensee may submit the information through other required reports applicable to the SCA, or in a single consolidated annual compliance report.``</p>	Done
57	Section 4,	CNA	<b>Issue:</b> Current licensees have differing reporting	No change required. The duplication of reporting	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
	Page 6	Bruce Power CNL OPG	requirements in their LCHs. <b>Suggestion:</b> This REGOC should supersede all the requirements in the LCHs <b>Major impact:</b> Duplicated burden and unnecessary inconsistency between licensees	that may exist will be addressed during the implementation, as necessary.  The extent of the current reporting requirements may be superseded by the requirements of this document when published.	
58	Section 4.1, Page 6	CNA Bruce Power CNL OPG	Text states: <i>A preliminary report or immediate notification of a situation or event, or of a dangerous occurrence as stipulated in section 35 of the PTNSR 2015, shall contain the following information: (1-4)</i>  <b>Issue:</b> Not all information may be available at the time of a preliminary report or immediate notification.  <b>Suggestion:</b> Add to the end of the first paragraph the following " ...as available ."  <b>Impact:</b> Clarification	No change required. The guidance explains that: "Preliminary reports should contain enough information that CNSC staff have an understanding of the effects of the event on the health, safety and security of Canadians and the environment." Any further information beyond the preliminary report of immediate notification can be provided in subsequent reports or updates. In addition, point 4 states :“for situations and events, any preliminary information <u>that is available</u> regarding the effect on the health, safety and security of persons or the environment.”	
59	Section 4.2 Page 7 item 11	CNA CNL OPG Bruce	Text states: <i>Any actions that the licensee has taken to inform the public and target audience about the situation or event</i>  <b>Issue:</b> Delete, this action is already achieved through the public information program of the licensee on an as needed basis. Not all the reportable events are required to	No change required, and it is agreed that not all reportable events need to be disclosed to the public beyond the public information and disclosure program. The text does not provide a requirement for informing the public. It is to include in the report, any actions taken to inform	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
		Power	<p>be disclosed to the public.</p> <p><b>Suggestion:</b> Delete</p> <p><b>Major impact:</b> If not modified, this will set requirements in excess of the Public Information and Disclosure RD/GD document.</p>	the public, if it has been done.	
60	4.2, Guidance	Nordion	<p>Full reports, Guidance</p> <p>Text states: <i>identify the target completion date for each action that the licensee proposes to take to reestablish normal operations or to prevent a recurrence</i></p> <p><b>Issue:</b> Nordion's practice is to issue Corrective Preventive Actions (CAPAs) following investigation of an event and identification of root causes. The action is then captured as per the CAPA non-conformance system which is a staged process. Target completion dates are determined stage by stage following completion of the previous stage. Therefore, identifying target completion dates may be a challenge. Nordion recommends removal of the requirement to identify the target completion dates in the full report.</p>	No change required, as this is guidance. This section is intended to clarify that the actions taken or proposed should be associated with a planned completion date. The CAPA system is not precluded, and dates can be updated/ revised as needed.	
61	Section 4.2, Guidance Page 7	CNA OPG Bruce Power	<p>Text states: <i>"Licensees should include information that allows the report to be reviewed efficiently; for example:</i></p> <ul style="list-style-type: none"> <li>• <i>identify updates and new or additional information from that provided previously</i></li> <li>• <i>identify any further missing information and the date that the missing information will be provided to the</i></li> </ul>	No change required. The items listed are guidance for the effective and efficient review or the information provided, including in follow-up updates. Bullets 1 and 2 are essentially the same as a requirement in REGOC-3.1.1, except that they are guidance in this document. Specifically for bullet 1, the intent is that any	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
		CNL	<p>CNSC</p> <ul style="list-style-type: none"> <li>• <i>Identify the target completion date for each action that the licensee proposes to take to re-establish normal operations or to prevent a recurrence.</i></li> </ul> <p><b>Issue:</b> Bullets 1 and 3 were determined to be unnecessary during the development of REGDOC-3.1.1.</p> <p><b>Suggestion:</b> Remove bullets 1 and 3</p> <p><b>Major impact:</b> As written, the inclusion of these bullets is inconsistent with REGDOC-3.1.1 and could generate regulatory confusion/uncertainty.</p>	<p>updates should highlight the changes from the previous reports as it may not need to be reviewed fully again.</p> <p>No change required for bullet 3, as this is guidance. This section is intended to clarify that the actions taken or proposed should be associated with a targeted completion date. Dates can be revised or updated as needed.</p>	
62	4.3	AREVA	<p>Action Level Reporting:</p> <p><b>Suggestion:</b> Section 4.3 should acknowledge that action level reporting schemes are described in codes of practices established for radiation and environmental protection at uranium mines and mills.</p>	<p>No change required. The suggested information is already included in the Uranium Mines and Mills Regulations that are referenced in the Glossary definition for Action level.</p> <p>Text has been revised to address the intent of the comment. The addition of legislative references and text from UMM Regulations are added into section 1.3 and was already stated in Table A, item 13.</p>	Done
63	4.3, Page 8	Cameco	<p><b>Incorporating Codes of Practice</b></p> <p>The REGDOC should be revised to refer to codes of practice when describing radiation protection and environmental protection action levels. For instance, Section 4.3 Action level reports can be strengthened by adding the following statement: "Uranium mines and mills</p>	<p>No change required. The suggested information is already included in the Uranium Mines and Mills Regulations that are referenced in the CNSC Glossary definition for Action level.</p> <p>The addition of legislative references and text from UMM Regulations are added into section</p>	Done

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
			<p>licensees are to follow the reporting procedures referenced in the environmental protection program code of practice if an action level is reached (refer to UMMR 4(2) for the contents of a proposed code of practice)."</p> <p>In addition, the reporting time period in Table A, Section 13a, could be updated to refer to the code of practice, which may or may not be 60 days.</p>	1.3 and was already stated in Table A, item 13.	
64	Section 4.3, Page 8	OPG Bruce Power CNL	<p><b>Issue:</b> Action Level Reports are discussed in Section 4.3 and Table A.1 item 13.</p> <p><b>Suggestion:</b> Delete the subsection (4.3)</p> <p><b>Impact:</b> Clarification</p>	<p>This section describes a specific section to be included in the full report described in section 4.2.</p> <p>Text has been revised to address the intent of the comment. The text is clarified with the addition of the following bullet to section 4.2: "the information specified in section 4.3 Action level reports"</p>	Done
65	Section 4.3, Page 8	Cameco	<p><b>Suggestion:</b> Action level reports: the text here is a duplication of Table A of Appendix A, Entry 13 and, as such, we suggest s. 4.3 be deleted.</p>	<p>This section describes a specific section to be included in the full report described in section 4.2.</p> <p>Text has been revised to address the intent of the comment. The text is clarified with the addition of the following bullet to section 4.2:</p> <p>"the information specified in section 4.3 Action level reports"</p>	Done
66	4.4	Nordion	<p>Specific reports under the Packaging and Transport of Nuclear Substances Regulations, 2015</p> <p>Text states: Expert assessment of a dangerous occurrence</p>	No change required. However, for information the Oxford Canadian dictionary defines the term "expert " is any person who is very	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
			<p>in packaging and transport</p> <p>As per subsection 36(2) of the PTNSR 2015, in the event of a dangerous occurrence in the packaging or transport of radioactive material or a nuclear substance, the consignor, carrier or consignee must have an expert in radiation protection assess the situation. The expert must report the results of the assessment to the Commission as soon as feasible.</p> <p><b>Issue:</b></p> <p>Further guidance is needed on what an “expert assessment” entails and who is considered an expert.</p> <p>Clarification in the guidance is needed to answer the following questions:</p> <p>Is the expert assessment a separate communication or is it part of the full report?</p> <p>Can consignors or consignees act as the expert for assessments?</p> <p>Are there exceptions to including an expert assessment for reporting of dangerous occurrences?</p>	<p>knowledgeable about or skillful in a particular area . Therefore an expert in radiation is any person who is knowledgeable about radiation protection</p> <p>There is no requirement for a full report for this expert assessment of a dangerous occurrence.</p> <p>The application of this requirement is detailed in the PTNSR-2015, section 36.</p>	
67	Appendix A, p.9	Nordion	<p>Reports, Notifications and Timing</p> <p><b>Issue:</b> Nordion proposes stipulating that “days” are calendar days.</p>	<p>No change required. “Days” are defined in the <a href="#">Interpretation Act</a> .The Glossary has been revised to include “days”.</p>	
68	Appendix A, p.9	CNA	<p><b>Issue:</b> [Why is ‘immediate reporting’ applied to all types of</p>	<p>No change required. See Preamble for</p>	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
		Bruce Power  OPG  CNL	events?] ["Immediate reporting" should not be applied to all types of events.] Events with low safety significance should not require immediate reporting  <b>Suggestion:</b> Replace by reporting timelines by safety significance, same as in REGDOC 3.1.1 (section 2 – items 1-8, and 10)  <b>Major impact:</b> Administrative burden on licensee and regulator due to immediate response requirement.	information on the timing of the reports plus significance level of the event.  The regulations specifies when the full report must be submitted (ie 21 days after becoming aware of it,...).  The document is revised and clarified so that the reporting timelines are consistent with those in the Regulations.	
69	Appendix A, p.9	AREVA	<b>Issue: Reporting Timelines:</b> Section 29(2) of the GNSCR specifies that a full report regarding a situation referred to in section 29(1) must be provided within 21 days, unless otherwise specified in the licence. Table A of the REGDOC identifies situations and events for which a report or notification is required under Section 29 of the GNSCR as requiring a full report within 60 days.  Clarification is required as to whether reference of the REGDOC in a facility's licence satisfies the specification clause allowing licensees to adopt reporting periods stated in the REGDOC.	No change required.  See Preamble for information on the timing of the reports plus significance level of the event.  The regulations specifies when the full report must be submitted (ie 21 days after becoming aware of it,...).  The document is revised and clarified so that the reporting timelines are consistent with those in the Regulations.	
70	Table A  General comment	Nordion	Situations and events for which a report or notification is required, including the timing  <b>Issue:</b>  Provide a summary of how the events, notifications or filings of records are arranged in the table (i.e. by Safety	No change required. Table A is part of Appendix A and reflects the requirements structure and text of the governing Act and Regulations to assure that it is complete and accurate. The SCA framework will be considered in future revisions for the various CNSC reporting	

Combined public review comments

Draft REGDOC-3.1.2, *Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills*

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
			and Control Area).	REGDOCs.	
71	Table A  General comment	Nordion	<p>Situations and events for which a report or notification is required, including the timing</p> <p><b>Issue:</b> Nordion proposes capturing reporting requirements for emergency situations (e.g. large-scale event, natural event, radiation emergency, terrorism, fire, chemical spill, first aid, transportation, and crisis) in the summary table, Table A.</p> <p>In addition, Nordion proposes including the requirement to notify the Duty Officer within 15 minutes as per REGDOC 2.10.1, "Nuclear Emergency Preparedness and Response" in this draft document.</p> <p>Furthermore, Nordion proposes including reporting requirements in the case of false alarms.</p>	<p>Table A, item 3 guidance for contingency plans is intended to include the suggested emergency situations, but these are provided for guidance purposes only.</p> <p>The guidance section on Duty Officer has been revised to clarify the intended as follows.</p> <p style="padding-left: 40px;">"Licensees shall report any of the following events to the CNSC, directly through the Duty officer: an event or incident that triggers actions under emergency response programs, even if it is a false alarm; an event such as a spill, a release or an injury that could trigger stakeholder interest; an event that falls under the requirements of subsection 29(1) of the <i>General Nuclear Safety and Control Regulations</i>."</p> <p>In addition the following text has been added to the REGDOC as proposed :</p> <p style="padding-left: 40px;">"Additional requirements are established in REGDOC-2.10.1, <i>Nuclear Emergency Preparedness and Response</i> . These requirements ensure that the CNSC is notified within 15 minutes of the emergency</p>	Done

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
				response organization being activated."	
72	Table A throughout	OPG Bruce Power CNL	<p><b>Issue:</b> Timing for preliminary report does not distinguish between significant and non-significant events</p> <p><b>Suggestion:</b> Specify: High safety significance situations or events require an immediate preliminary report.</p> <p>Where reporting of lower significance events is required, allow for 5 day reporting</p> <p><b>Major impact:</b> Adds administrative burden with no benefit.</p>	<p>No change required.</p> <p>See Preamble to this table for information on the timing of the reports plus significance level of the event.</p> <p>The regulations specifies when the full report must be submitted (ie 21 days after becoming aware of it,...).</p> <p>The document is revised and clarified so that the reporting timelines are consistent with those in the Regulations.</p>	
73	Table A throughout:  B.3a) B.3.b) (Bruce Power)	Bruce Power  OPG CNL	<p><b>Issue:</b> For full reports:</p> <p>-in some cases, there may be no additional information available or required.</p> <p>-The due date for submission of the full report should be based on the date of the preliminary report was submitted.</p> <p><b>Suggestion:</b> For most situations, change the full report requirement in the table to ["within 60 days][after becoming aware of the event] (if required)"</p> <p><b>Major impact:</b> Adds administrative burden with no benefit.</p>	<p>No change required. The regulations specifies when the full report must be submitted (ie 21 days after becoming aware of it,...).</p> <p>It is agreed that the initial report may adequately provide sufficient information to be considered a "full report" and the accountability needs to remain with the licensees. Guidance text is provided for that clarification. Section 2 Guidance contains the following text for the application of Table A.</p> <p>If the licensee determines that investigation beyond the preliminary report is unlikely to yield further relevant details or identify additional corrective actions to prevent recurrence of the situation or event, then a full report may not be necessary. In this case, the preliminary report should include the information required by the full report.</p>	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
				<p>The text also further provides the following:</p> <p style="padding-left: 40px;">“If, after further investigation, the licensee concludes a situation or event was not reportable, the licensee should provide the CNSC with a written statement that includes a rationale to support the conclusion.”</p> <p>The text in Appendix A preamble contains the following bullet that provides the same intent as the suggestion for the use of “if required”.</p> <p style="padding-left: 40px;">“for situations or events, the report is due immediately (where “immediately” means as soon as the licensee becomes aware that an event is reportable) and, <u>if required</u>, shall be updated with additional information in a full report within 21 days after becoming aware of the event”</p>	
74	Appendix A Table A: A1	CNA OPG Bruce Power CNL	<p><b>Issue:</b> Additional guidance is provided in REGDOC-3.1.1 on a non-compliance situation. This should be included. This section of the REGDOC should be consistent with REGDOC 3.1.1</p> <p><b>Suggestion:</b> Add as 1.a :</p> <p><b>Guidance</b></p> <p><i>Regulations made pursuant to the NSCA, orders of the</i></p>	Guidance has been added to Table A:A1. See the guidance added found in item 20 of this Table.	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
			<p><i>CNSC, a designated officer or an inspector, and licence conditions have their origins from the NSCA. Therefore, it is understood that a contravention of a regulation made pursuant to the NSCA, of an order or of a licence condition is a contravention of the NSCA.</i></p> <p>Impact: Clarification</p>		
75	Table A No. 1	Nordion	<p>Contravention of the Nuclear Safety and Control Act (NSCA) in relation to an activity that is authorized</p> <p>Text states:</p> <p><i>Applicable section(s) of NSCA or regulations made under the NSCA:</i></p> <p><i>NSCA:</i></p> <p><i>27. Every licensee and every prescribed person shall [...]</i></p> <p><i>(b) make the prescribed reports and file them in the prescribed manner, including a report on</i></p> <p><i>(ii) any contravention of this Act in relation to an activity that is authorized by this Act and any measure that has been taken in respect of the contravention</i></p> <p><b>General Nuclear Safety and Control Regulations (GNSCR):</b></p> <p><b>29. (1) Every licensee who becomes aware of any of the following situations shall immediately make a</b></p>	<p>No change required. See Preamble to this table for information on the timing of the reports.</p> <p>The regulations specifies when the full report must be submitted (ie 21 days after becoming aware of it,...).</p> <p>The document is revised and clarified so that the reporting timelines are consistent with those in the Regulations.</p>	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
			<p><b>preliminary report</b> to the Commission of the location and circumstances of the situation and of any action that the licensee has taken or proposes to take with respect to it:</p> <p>(a) a situation referred to in paragraph 27(b) of the NSCA</p> <p><b>Issue:</b></p> <p>The 60 day timeframe for the full report contradicts what the GNSCR indicates. As per Section 29(2) of the GNSCR and page 2 of this draft regulatory document, licensees are to file a full report within 21 days after becoming aware of the event.</p>		
76	Appendix A Table A (new 1.b proposed)	CNA OPG Bruce Power CNL	<p><b>Issue:</b> Requirements of GNSCR 9(4) missing.</p> <p><b>Suggestion:</b> Add as 1.b :</p> <p><i>General Nuclear Safety and Control Regulations (GNSCR):</i></p> <p><i>9. (4) Every person who carries on an activity without a licence in accordance with subsection (1) or (2) shall immediately notify the Commission of that fact.</i></p> <p><b>Impact:</b> Clarification</p>	No change required. GNSCR 9.(4) only applies to the persons who are authorized to carry on the identified activities without a licence as identified in subsection 9(1) and 9(2) of the GNSCR.	
77	Appendix A, Table A: A.1.	OPG CNL CNA	<p><b>Issue:</b> 27(b) is indicated as "Immediate" reporting, but it should depend on significance level. The timing of reporting should be commensurate with the risk.</p> <p><b>Suggestion:</b> Change to: immediate for significant or 5 business day for low significant levels. Full report due in</p>	<p>See Preamble to this Table for information on the timing of the reports plus significance level of the event.</p> <p>The regulations specifies when the full report must be submitted (ie 21 days after becoming aware of it,...).</p>	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
			60 days (if required).  Requirements should be different for 27(b) and 29(1).  <b>Major impact:</b> Adds administrative burden with no benefit.	The document is revised and clarified so that the reporting timelines are consistent with those in the Regulations.	
78	Table A  B.	Nordion	Management system, human performance, conventional health and safety, financial status  Text states:  <i>Management system, human performance, conventional health and safety, financial status</i>  <b>Issue:</b>  Suggest replacing management system and human performance with emergency management as the implementation of a contingency plan is more applicable to this safety and control area.	Text has been revised to address the intent of the comment. Title for Table A, items B is changed to better reflect the listed items. The title is changed to: "Contingency plan, conventional health and safety, financial status"	Done
79	Table A  No. B.3	Nordion	Contingency plan  Text states:  <i>(d) a situation or event that requires the implementation of a contingency plan in accordance with the licence;</i>  <b>Issue:</b>  Nordion suggests providing more information regarding a contingency plan. Is reporting to the Duty Officer of a situation or event that requires implementation of a contingency plan only required if the licensee has a	No change required as Table A, B.3a), item (d) has guidance of what should be included and events that are considered occurrences that should be addressed (or not).  For clarity regarding when a report/notification to the Duty Officer is required, text has been revised to address the intent of the comment. The following has been added to Section 2 Guidance:  "Licensees shall report any of the	Done

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
			contingency plan referenced in their license?	following events to the CNSC, directly through the Duty officer: an event or incident that triggers actions under emergency response programs, even if it is a false alarm; an event such as a spill, a release or an injury that could trigger stakeholder interest; an event that falls under the requirements of subsection 29(1) of the <i>General Nuclear Safety and Control Regulations</i> .”	
80	Table A  No. B.3	Nordion	<p>Contingency plan</p> <p>Text states:</p> <p><i>A contingency plan may include:</i></p> <p><i>i. any situation or event (flood, fires, earthquakes, etc.) that requires the implementation of an emergency plan, or the use of any abnormal operating procedures or emergency operating procedures, or the mobilization of resources in response to the situation or event</i></p> <p><b>Issue:</b></p> <p>Nordion suggests the following wording: “<i>A contingency plan may be required for:</i>” to replace “<i>A contingency plan may include:</i>”.</p> <p>“<i>Any situation or event</i>” is broad and requires clarification.</p>	<p>The text has been revised to address the intent of the comment, as follows:</p> <p><i>“Examples of when a contingency plan may be implemented:”</i></p> <p>For clarity regarding when a report/notification to the Duty Officer is required, the following clarification is added to Section 2 Guidance.</p> <p>“Licensees shall report any of the following events to the CNSC, directly through the Duty officer: an event or incident that triggers actions under emergency response programs, even if it is a false alarm; an event such as a spill, a release or an injury that could trigger stakeholder interest; an event that falls under the</p>	Done

Combined public review comments

Draft REGDOC-3.1.2, *Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills*

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
			<p>Does any situation or event in this statement mean any unusual external event or natural event as provided in brackets? Or does it mean any situation or event?</p> <p>If it is any situation or event, the Duty Officer could be contacted for any number of issues that are not emergencies, but for which abnormal or emergency operating procedures were used, or for which mobilization of resources was required.</p>	<p>requirements of subsection 29(1) of the <i>General Nuclear Safety and Control Regulations</i>."</p>	
81	Appendix A Table A B.3a	CNA OPG CNL	<p>Text states: <i>A contingency plan may include:</i></p> <p><i>i. any situation or event (flood, fires, earthquakes, etc.) that requires the implementation of an emergency plan, or the use of any abnormal operating procedures or emergency operating procedures, or the mobilization of resources in response to the situation or event</i></p> <p><i>ii. the occurrence of any unusual external events (flood, fires, earthquakes, etc.) at or near the site that require further inspection to verify its effect on any structures, systems and components</i></p> <p><b>Issue:</b> Subsection i. indicates any situation or event, however subsection ii. characterizes the same examples as "unusual external events"</p> <p><b>Suggestion:</b> Use consistent terminology "<i>unusual external events</i>" throughout</p> <p><b>Impact:</b> Clarification</p>	<p>The text has been revised to address the intent of the comment, as follows: "Examples of when a contingency plan may be implemented:"</p> <p>Additionally, the text for i and ii is revised as follows:</p> <p>``i. a situation or event (flood, fires, earthquakes, etc.) that requires the implementation of an emergency plan, or the use of any abnormal operating procedures or emergency operating procedures, or the mobilization of resources in response to the situation or event</p> <p>ii. the occurrence of a situation or event (flood, fires, earthquakes, etc.) at or near the site that require further inspection to verify its effect on any structures, systems</p>	Done

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
				and components``	
82	Table A: B.3a) & B.3.b)  D.10 & D.11  F.17	OPG  CNL  Bruce Power  OPG  CNA	<p><b>Issue:</b> Timing of reports should depend on significance level of situation or event.</p> <p><b>Suggestion:</b> Change to: <i>immediate for significant or 5 business day for low significant levels. Full report due in 60 days, if required.</i></p> <p>Requirements should be different for 27(b) and 29(1) (CNA)(CNL)</p> <p><b>Major impact:</b> Adds administrative burden with no benefit.</p>	<p>See Preamble for information on the timing of the reports plus significance level of the event. The regulations for the most part specify when reports must be submitted.</p> <p>For D.10 the timing for the Preliminary report has been changed to: Immediate (significant) and Five days (non – significant). The full report is due within 21 days after becoming aware of the event.</p> <p>For D.11, the CNSC should be notified as soon as the report is filed to another agency.</p> <p>For D.11, a full report need only be submitted upon request.</p>	
83	Table A: B.3a)	OPG	<p><b>Issue:</b> Industry needs clarity around what should be reported.</p> <p><b>Suggestion:</b> Add the following Guidance to the table:</p> <p><i>Reportable situations include:</i></p> <ul style="list-style-type: none"> <li>•Activation of the site nuclear emergency plan, or</li> <li>•Use of emergency operating procedures (including evacuation of an area, meeting the entry conditions to an AIM, etc.), or</li> <li>•Sounding emergency alarm, mobilizing the site Emergency Response Team (ERT) or offsite emergency</li> </ul>	<p>The text has been revised to address the intent of the comment. Clarifying that the situations are examples.</p>	Done

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
			<p><i>responders in response to an unexpected occurrence that creates a hazard to the safe operation of the nuclear power plant, to the environment or to the health and safety of persons.</i></p> <p><b>Impact:</b> Clarification</p>		
84	Table A No.B.4	Nordion	<p>Serious illness, injury or death, Guidance</p> <p>Text states:</p> <p><i>Illnesses and injuries that do not result directly from the licensed activity, such as illness from a pre-existing condition or injuries that may occur in any office environment (e.g., a back strain due to ergonomic configuration of a desk) do not need to be reported.</i></p> <p><b>Issue:</b></p> <p>This statement does not align with the guidance on the CNSC's new reporting structure provided in the CNSC letter dated Sept. 19, 2016. According to the guidance, an illness or injury un-related to the licensed activity would still require reporting to the Duty Officer if it triggers ERP activation or if offsite medical response is required due to the fact that it could draw stakeholder interest.</p> <p>In addition, reporting would be required as per the GNSCR for a first aid emergency unrelated to the licensed activity if it was a serious illness, injury or fatality (e.g. window washer falling from a significant height) or if multiple employees required hospitalization.</p>	<p>The text has been revised to address the intent of the comment. The guidance has been updated as follows:</p> <p>For 29(1)(h). Illnesses and injuries that do not result directly from the licensed activity, such as illness from a pre-existing condition or injuries that may occur in any office environment (e.g., a back strain due to ergonomic configuration of a desk) do not need to be reported.</p> <p>For 29(1)(i). ...This requirement does not make any distinction for cause of death as a factor in determining if the situation or event is reportable.</p> <p>The text has been revised to address the intent of the comment. The section referring to the duty officer is revised to clarify the intent as follows.</p> <p>“Licensees shall report any of the following events to the CNSC, directly through the Duty officer: an event or incident that triggers actions under emergency response programs, even if it is a false alarm; an event such as</p>	Done

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
				a spill, a release or an injury that could trigger stakeholder interest; an event that falls under the requirements of subsection 29(1) of the <i>General Nuclear Safety and Control Regulations</i> .”	
85	Table A: B.4 B.5 D.9 a) and D.9 b) F.16	OPG CNL Bruce Power	<b>Issue:</b> 60 days is required for full report but no further information may be available. <b>Suggestion:</b> Add “ <i>if required</i> ” and delete “ <i>after becoming aware of the event.</i> ” (Bruce Power) <b>Impact:</b> Clarification. [Add administrative burden with no benefit] (Bruce Power).	The regulations specifies when the full report must be submitted (ie 21 days after becoming aware of it,...).  The text has been revised to address the intent of the comment. The document is revised and clarified so that the reporting timelines are consistent with those in the Regulations.  It is agreed that the initial report may adequately provide sufficient information to be considered a “full report” and the accountability for the determination needs to remain with the licensees. Guidance text is provided for that clarification. Section 2 Guidance contains the following text for the application of Table A. If the licensee determines that investigation beyond the preliminary report is unlikely to yield further relevant details or identify additional corrective actions to prevent recurrence of the situation or event, then a full report may not be necessary. In this case, the preliminary report should include the information required by the full report.	Done

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
				<p>The text is also further revised to clarify the normal practice for this section as follows:</p> <p style="padding-left: 40px;">“If, after further investigation, the licensee concludes a situation or event was not reportable, the licensee should provide the CNSC with a written statement that includes a rationale to support the conclusion.”</p>	
86	Table A: B.4	OPG  Bruce Power	<p><b>Issue:</b> Add in geographical limits for site boundary.</p> <p><b>Suggestion:</b> Add the following Guidance:</p> <p><i>Any death within the exclusion zone or the licensed area (whichever is larger) or as defined in the LCH, regardless of cause, or any death resulting from an injury or illness, regardless of time intervening between injury or illness and death, will be reported.</i></p> <p><b>Impact:</b> Clarification</p>	No change required, as not all types of facilities covered by this document have exclusion zones.	
87	Table A: D.8	CNA  OPG  Bruce Power	<p><b>Issue:</b> Guidance for s.29(1)(f) of GNSCR lists enumerated events that may have no serious adverse effects.</p> <p><b>Suggestion:</b> Remove enumerated list.</p> <p><b>Major impact:</b> If intention is to require reporting of all enumerated events then it would create administrative burden; if the intention is to only require reporting of events with a serious adverse effect then it creates uncertainty.</p>	No change required. This list is provided as examples in guidance, and the event would only be reported if the event could result in serious adverse effects.	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
88	Table A D.9	CNA CNL Bruce Power	<b>Issue:</b> Title of the section includes Class II equipment.  Is it applicable?  <b>Impact:</b> Clarification	No change required. The title including Class II equipment is applicable. There are Class I facilities that include Class II prescribed equipment.	
89	Table A No. 9a), b) and d)	Nordion	Nuclear substances, radiation devices, exposure devices and Class II equipment  Text states:  <i>Subsection 38(2) of the NSRDR stipulates the content to be included in the report.</i>  <b>Issue:</b>  Suggested wording: Subsection 38(2) of the NSRDR stipulates the content to be included in the full report.	The text has been revised to address the intent of the comment. Text revised to include "...full report."	Done
90	Table A: D.9	OPG Bruce Power CNA	<b>Issue:</b> In many cases, these sources or devices are held under a separate licence and may not be included under the Class I or UMM licence. Reporting for devices must be done in accordance with the appropriate licence and Nuclear Substance and Radiation Devices Regulations.  <b>Suggestion:</b> Clarify that these reporting requirements only apply if these are held under the Class I or UMM licence.  <b>Major impact:</b> Adds administrative burden with no benefit [by potentially requiring duplicative reporting].	No change required. As described in the Purpose, "This regulatory document sets out requirements and guidance for reports ...that <b>licensees of class I nuclear facilities ... and of uranium mines and mills ...</b> "	
91	Table A:	CNA	<b>Issue:</b> No reference to an appropriate clause in the NSCA or Regulations is provided. This should Reference NSCA	No change required. This reporting requirement is an expectation of the Commission, and	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
	D.10	OPG Bruce Power CNL	<p>24(5).</p> <p><b>Suggestion:</b> Add: <i>Applicable section(s) of the NSCA or regulations made under the NSCA:</i></p> <p><i>NSCA:</i></p> <p><i>24. (5) A licence may contain any term or condition that the Commission considers necessary for the purposes of this Act, including a condition that the applicant provide a financial guarantee in a form that is acceptable to the Commission.</i></p> <p><b>Impact:</b> Clarification</p>	therefore should be part of a reporting program.	
92	Table A: D.10	Cameco	<b>Suggestion:</b> the reporting of the discovery of counterfeit, fraudulent or suspect items does not include a legal authority for this requirement. In the absence of such an authority, this provision should be deleted.	No change required. This reporting requirement is an expectation of the Commission, and therefore should be part of a reporting program.	
93	Appendix A Table A D.11	CNA OPG CNL	<p>Text states: <i>Specific reporting provisions</i></p> <p><i>The licensee shall report on all other situations or events that are not otherwise specified in this document but can be reasonably assumed to be of regulatory interest, including notifications and situation or event reports to other regulatory agencies within the scope covered by the objects of the Commission (see section 9 of the NSCA).</i></p> <p><b>Issue:</b> This section provides no useful information but acts</p>	<p>The text has been revised to address the intent of the comment.</p> <p>It is expected that the licensee identify and determine the situations or events to be of regulatory interest to CNSC or of public interest, because they may require follow-up by the CNSC.</p> <p>This is also intended to cover reports provided to</p>	Done

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
			<p>as a catch all. The table could in consist of only section 11 and cover everything.</p> <p>Additionally, Section 24(5) of the NSCA, this section on Specific reporting provisions, and the Guidance paragraph do not seem to be related.</p> <p><b>Suggestion:</b> Change wording to add: <i>Subject to the opinion of the licensee, the licensee shall report on all other situations or events that are not otherwise specified in this document but can be reasonably assumed to be of regulatory interest, including notifications and situation or event reports to other regulatory agencies within the scope covered by the objects of the Commission (see section 9 of the NSCA).</i></p> <p>Suggestion: Change wording of "Specific reporting provision" to add: Subject to the opinion of the licensee, the licensee shall report on all other situations or events that are not otherwise specified in this document but can be reasonably assumed to be of regulatory interest, including notifications and situation or event reports to other regulatory agencies within the scope covered by the objects of the Commission</p> <p><b>Major CAN, CNL and Bruce Power impact:</b> Adds administrative burden and uncertainty with no benefit</p> <p><b>Major OPG impact:</b> Adds administrative burden and uncertainty with no benefit, without clarity on accountability for determining when this clause is used.</p>	<p>other government agencies for any licenced activity under the NSCA.</p> <p>To clarify the intent, D.11 has been revised as follows:</p> <p>The licensee shall report on all other situations or events that are not otherwise specified in this document <u>but are significant enough to be</u> reasonably assumed to be of regulatory interest, including notifications and situation or event reports to other regulatory agencies within the scope covered by the objects of the Commission</p> <p>The Guidance has been revised as:</p> <p>``The licensee may submit copies of the report(s) or notification(s) prepared for other governing regulatory bodies to the CNSC.</p> <p>Possible reports could also include events or situation that could have been reportable but were not, due to fortuitous circumstances (near-miss events). ``</p>	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
94	Table A: No E.12a) Full report column	Bruce Power	<p><b>Issue:</b> If a full report is required, it should be submitted 60 days following the submission of the preliminary report</p> <p><b>Suggestion:</b> Delete “after becoming aware of the event” and add “if required”</p> <p><b>Major impact:</b> Adds administrative burden with no benefit</p>	<p>No change required. The regulations specifies when the full report must be submitted (ie 21 days after becoming aware of it,...).</p> <p>The document is revised and clarified so that the reporting timelines are consistent with those in the Regulations.</p>	
95	Table A: E.12a)  Guidance	Cameco	<p><b>Suggestion:</b> replace the reference to 23 with 23b)</p>	<p>The text has been revised to address the intent of the comment. The reference has been changed from 23 to 24 in the table.</p>	Done
96	Table A: E.12b)	OPG  Bruce Power  CNL	<p><b>Issue:</b> The Guidance has a typographic error. Refers to a section that does not exist in this table.</p> <p><b>Suggestion:</b> Fix error. This should likely point to Item 12a.</p> <p><b>Impact:</b> Clarification</p>	<p>The text has been revised to address the comment.</p>	Done
97	Appendix A  Table A  E.13a & E.13b	CNA  CNL  OPG	<p>Text states: <i>Licence condition:</i></p> <p><i>The licensee shall implement and maintain an environmental protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within X days.</i></p> <p><i>Note: In the specific licence condition, “X days” will be</i></p>	<p>No change required. This licence conditions in 13a and 13b will be found in all Class I and Uranium Mines and Mill licences in the future, if not already. The licence conditions include notification to the CNSC and therefore have been added to Appendix A of the REGDOC.</p> <p>The text codifies current practice for action levels, but provides more clarity and consistent</p>	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
			<p><i>replaced with a specified period.</i></p> <p><b>Issue:</b> [If a facility does not have this condition written in their LCH in this manner, does the licensee have to follow the LCH condition on EPP and this REGDOC?] (CNA) (CNL) [This appears to be defining a Licence Conditions within a Regulatory Document.] (OPG)</p> <p>This example also exists in table section 13a) and all of 13b</p> <p><b>Suggestion:</b> Remove last paragraph of Table A E.13.a and all of Table A: E13.b</p> <p><b>Major impact:</b> This REGDOC is inappropriately setting license conditions.</p>	<p>approach.</p> <p>The CNSC's expectation for reporting action level exceedances is that a full report shall be provided to the CNSC within 21 days.</p>	
98	Appendix A Table A Preamble to No. E.13	CNA CNL OPG	<p><b>Issue:</b> No requirements are identified and adds no value. [The guidance should clarify the specific reporting provision]. (OPG)</p> <p><b>Suggestion:</b> Remove the preamble to section 13 a and 13 b</p> <p><b>Impact:</b> Clarification. Adds [confusion in its existing position][no value] and complicates the table.</p>	<p>The text has been revised to address the intent of the comment.</p> <p>``The guidance paragraph is maintained as it is intended to provide background information to support the requirements in the other parts of E.13. However, the regulatory basis text has been removed.``</p>	Done
99	Appendix A Table A E.13a	CNA Bruce Power CNL	<p><b>Issue:</b> Reporting times for uranium mines and mills action levels are set out in code of practice [and this should be recognized in the specific reporting provision (OPG) (Bruce Power)]</p> <p><b>Suggestion:</b> Add the following guidance: <i>Uranium mines</i></p>	<p>No change required as the suggested information is provided in the pre-amble text in E.13.</p>	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
		OPG	<p><i>and mills licensees are to follow the reporting procedures referenced in the environmental protection program code of practice if an action level is reached (refer to UMMR 4(2) for the contents of a proposed code of practice)"</i></p> <p><b>Major impact:</b> Leads to uncertainty in requirements</p> <p><b>Bruce Power impact:</b> Clarification</p>		
100	Appendix A Table A E.14	OPG CNL	<p><b>Issue:</b> REGDOC-3.1.1 App A 22 clarifies that single missed sample where justified is not considered failure to monitor.</p> <p><b>Suggestion:</b> Add to Guidance:</p> <p><i>For item b), a failure to collect an individual sample where justified, is not considered failure to monitor. For the purpose of event reporting, failure to monitor is more appropriately considered in the context of programmatic failure.</i></p> <p><b>Impact:</b> Clarification</p>	<p>The text has been revised to address the intent of the comment. It is reasonable that it is considered more of a programmatic failure for the scenario described. Added the following text to the guidance:</p> <p>“For item b), a failure to collect an individual sample where justified, is not considered failure to monitor. For the purpose of event reporting, failure to monitor is more appropriately considered in the context of programmatic failure.”</p>	Done
101	Appendix A Table A E.14	CNA OPG Bruce Power CNL	<p><b>Issue:</b> Reporting time should be based on significance level of the environmental impact</p> <p><b>Suggestion:</b> Change to: <i>immediate for significant or 5 business day for low significant levels. Full report due in 60 days (if required)</i></p> <p><b>Major impact:</b> Adds administrative burden with no benefit</p>	<p>See Preamble to this table for information on the timing of the reports.</p> <p>The regulations specifies when the full report must be submitted (ie 21 days after becoming aware of it,...).</p> <p>The document is revised and clarified so that the reporting timelines are consistent with those in the Regulations.</p>	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

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102	Appendix A Table A E.15	CNA OPG Bruce Power CNL	<p><b>Issue:</b> In many cases, these sources or devices are held under a separate licence and may not be included under the Class I or UMM licence. Reporting for devices must be done in accordance with the appropriate licence and Nuclear Substance and Radiation Devices Regulations</p> <p><b>Suggestion:</b> Clarify that these reporting requirements only apply if these are held under the Class I or UMM licence</p> <p><b>Major impact:</b> Duplication of reporting requirements</p>	<p>It is confirmed that this draft of REGDOC-3.1.2 applies to licensees of Class I nuclear facilities (excluding power reactors) and of uranium mines and mills as indicated in the document title, Purpose, and original press release.</p> <p>However, it should be noted that any references in the draft is for Class II equipment that may be used at Class I facilities (excluding nuclear power plants) and uranium mines and mills, and are not intended for Class II facilities.</p> <p>The text has been revised to address the intent of the comment. To provide clarification, the following guidance text is added to Table A, line item 9c:</p> <p style="padding-left: 40px;">“19.(2) applies to Class II prescribed equipment used by licensees as described in the Purpose, and not to Class II facility licensees. The heading of this line item in the Table reflects the title of the applicable Regulation from which the requirements text originates only, and not the applicable facility.”</p>	Done
103	Appendix A Table A E.15	CNA OPG CNL	<p><b>Issue:</b> A requirement for Class II Facilities should not be included in this document. ?</p> <p><b>Suggestion:</b> Delete requirement.</p> <p><b>Major Impact:</b> Duplication of reporting requirements</p>	<p>It is confirmed that this draft of REGDOC-3.1.2 applies to licensees of Class I nuclear facilities (excluding power reactors) and of uranium mines and mills as indicated in the document title, Purpose, and original press release.</p> <p>However, it should be noted that any references</p>	Done

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

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				<p>in the draft is for Class II equipment that may be used at Class I facilities (excluding nuclear power plants) and uranium mines and mills, and are not intended for Class II facilities.</p> <p>The text has been revised to address the intent of the comment. To provide clarification, the following guidance text is added to Table A, line item 9c:</p> <p>“19.(2) applies to Class II prescribed equipment used by licensees as described in the Purpose, and not to Class II facility licensees. The heading of this line item in the Table reflects the title of the applicable Regulation from which the requirements text originates only, and not the applicable facility.”</p>	
104	Table A No. 16	Nordion	<p>Theft or loss of nuclear substance, prescribed equipment or prescribed information</p> <p>Suggestion: Add NSRDR 38(1)(a).</p>	<p>The text has been revised to address the intent of the comment. The following text has been added:</p> <p><b>”NSRDR</b></p> <p>38 (1) Every licensee who possesses or uses a nuclear substance or a radiation device and becomes aware of any of the following situations shall notify the</p>	Done

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
				<p>Commission immediately of the location and circumstances of the situation and of any action that the licensee has taken or proposes to take with respect to it:</p> <p>(a) the nuclear substance or the radiation device is lost or stolen;"</p> <p>Also added reference to this Regulation and text in section 1.3.</p>	
105	Appendix A Table A F.16 & F.17	CNA OPG Bruce Power CNL	<p><b>Issue:</b> Reporting is not required where there is not a hazard to health safety and security of persons as found in REGDOC-3.1.1 A27</p> <p><b>Suggestion:</b> Add to guidance:</p> <p><i>Immediate reporting is required only where a hazard to the health, safety and security of persons and the environment or to the security of the nuclear facility exists.</i></p> <p><b>Major impact:</b> Adds administrative burden with no benefit</p>	<p>F.16. No change required. Reporting needs to be done in accordance with the regulation.</p> <p>F.17. The text has been revised to address the intent of the comment. Deleted the note as the item addresses all security.</p>	Done
106	Table A No. 17	Nordion	<p>Actual or attempted breach of security or act of sabotage</p> <p>Text states:</p> <p>GNSCR:</p> <p><i>29. (1) Every licensee who becomes aware of any of the following situations shall immediately make a preliminary report to the Commission of the location and</i></p>	<p>The text has been revised to address the intent of the comment. Deleted the note on cyber security.</p>	Done

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
			<p><i>circumstances of the situation and of any action that the licensee has taken or proposes to take with respect to it:</i></p> <p><i>(e) an attempted or actual breach of security or an attempted or actual act of sabotage at the site of the licensed activity;</i></p> <p><i>Guidance</i></p> <p><i>Includes any damage to any building or equipment that might affect the security of the facility or site, and includes actual or attempted theft, loss or unauthorized movement of nuclear substances or prescribed information. Examples include but are not limited to:</i></p> <ul style="list-style-type: none"> <li><i>• unauthorized access to a facility or site</i></li> <li><i>• attempted or actual breach against electronic systems and/or subsystems</i></li> <li><i>• discharge of firearms or the application of use-of-force options</i></li> </ul> <p><i>Note: "Security" includes cybersecurity (such as hacker attacks on computer systems).</i></p> <p><b>Issue:</b></p> <p>The language regarding cybersecurity requires clarification. Corporate network firewalls stop numerous probes, exploits and other types of hacker attacks daily. These should not and cannot reasonably be reported. We suggest the language be altered to state "successful"</p>		

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

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			hacker attacks or attacks that are a risk to the protection of Prescribed Information or critical safety or security systems and that require response actions to stop them.		
107	Appendix B	Nordion	<p>Sample Structure and Content for an Annual Compliance Monitoring Report</p> <p><b>Issue:</b></p> <p>Does this sample structure and content replace the draft guide document "Annual Reporting Requirements for Nuclear Processing and Research Facilities: Compliance Monitoring and Operational Performance" (E-DOCS-<a href="#">#3471152</a>)?</p>	<p>No change required. The appendix B is provided as a sample for consideration, but the final format and content can be determined by the type of facility and operation in question. The REGDOC is general to address a wide range of potential types of facilities with differing breadth of activities. A discussion with the licensing officer can be useful in determining the format and content to be used.</p> <p>The content is very similar to the draft guide document ( E-DOCS # 3471152), but there are some slight differences, such as the inclusion of financial guarantees in Appendix B. A discussion with the project officer can be useful in determining the format and content to be used.</p> <p>The content in Appendix B is to assist a licensee in writing their annual report in order to demonstrate performance in various areas and compliance to regulatory requirements.</p>	
108	Appendix B	CNA OPG Bruce Power	<p><b>Issue:</b> The guidance is too detailed.</p> <p>For example: Significant future activities or financial guarantee reporting should not be included in the Annual Compliance Monitoring report.</p>	<p>No change required. The appendix B is provided as a sample for consideration, but the final format and content can be determined by the type of facility and operation in question. The REGDOC is general to address a wide range of potential types of facilities with differing breadth</p>	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

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		CNL	<p><b>Suggestion:</b> Remove the section from the Appendix. Make it more general and consistent with licensees LCH requirements.</p> <p><b>Major impact:</b> Adds administrative burden with no benefit</p>	<p>of activities. A discussion with the licensing officer can be useful in determining the format and content to be used. The content in Appendix B is to assist a licensee in writing their annual report in order to demonstrate performance in various areas and compliance to regulatory requirements.</p> <p>The information related to improvement plans and significant future activities, found in Appendix B under Other Matters of Regulatory Interest, has been removed from the document.</p> <p>Maintaining a valid Financial guarantee is a licensee's regulatory requirement and therefore a licensee's annual compliance monitoring report should include confirmation that the financial guarantee is maintained and is valid.</p>	
109	Appendix B P 44	CNA Bruce Power CNL	<p><b>Issue:</b> Annual Compliance Monitoring Report sample includes analyses of five year trends in effluent and environmental monitoring results annually. This is provided in the EPRs.</p> <p>See general comment on the need for an annual report</p> <p><b>Suggestion:</b> Remove reference to five year trend analysis.</p> <p><b>Major impact:</b> It would create significant costs to perform the in-depth analysis for effluent and environmental trends carried out in accordance with CSA N288 series on an</p>	<p>No change required. The appendix B is provided as a sample for consideration, but the final format and content can be determined by the type of facility and operation in question. The REGDOC is general to address a wide range of potential types of facilities with differing breadth of activities. A discussion with the licensing officer can be useful in determining the format and content to be used. The content in Appendix B is to assist a licensee in writing their annual report in order to demonstrate performance in various areas and compliance to regulatory</p>	

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

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			annual basis.	requirements.  The intent is to discuss emerging trends over the five year period. A statistical analysis approach per CSA N288 series is not expected unless it has been identified through the licensee's commitment to comply with the CSA standards.	
110	Glossary	CNA OPG CNL  Bruce Power	<b>Issue:</b> The definition of 'safety significance' conflicts with the definition in the International Atomic Energy Agency's (IAEA's) document SF-1, Fundamental Safety Principles [IAEA Safety Standards Series, 2006] where the term is restricted to radiation risks. The term is only used once in the REGDOC on p. 4.  <b>Suggestion:</b> Delete definition of 'safety significance' and replace with 'risk' on p. 4. or remove reference to the IAEA SF-1  <b>Bruce Power Suggestion:</b> Remove reference to the IAEA SF-1  <b>Impact:</b> Clarification	The text has been revised to address the intent of the comment. The definition is removed, and the text in guidance in section 2 is revised to:  "Table A in appendix A provides a list of situations and events to be reported,"	Done
111	Glossary	Cameco	The definition of 'safety significance' conflicts with the definition in the International Atomic Energy Agency's (IAEA's) document SF-1, <i>Fundamental Safety Principles</i> [IAEA Safety Standards Series, 2006] where the term is restricted to radiation risks. The REGDOC definition broadens this since an event, situation, or dangerous occurrence may not be exclusively radiological in nature. Considering this and the fact that 'safety significance' is	The text has been revised to address the intent of the comment. The definition is removed, and the text in guidance in section 2 is revised to:  "Table A in appendix A provides a list of situations and events to be reported."	Done

Combined public review comments

Draft REGDOC-3.1.2, *Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills*

Version out for Public consultation July 11 to November 9, 2016

	Section or Para. #	Reviewer	Reviewer's Comment and Proposed Change	Response	Done?
			only used once in Section 2 <i>Reporting Requirements</i> ,  Suggestion: the phrase be replaced with the term 'risk' and removed from the glossary.		
112	Request for information	Cameco	Cameco has reviewed the potential impacts and implementation of this REGDOC as part of the request for information. If the suggestions in this submission are incorporated into the next version of the REGDOC, then we do not anticipate additional time or effort would be required to meet these requirements and guidance. The REGDOC closely follows what we currently report. As noted in the Request for Information on the Proposed Implementation of REGDOC 3.1.2., for the most part, this REGDOC brings together existing requirements for types of reports and notifications, and for the timing of each report and notification, which are spread throughout the NSCA and the regulations made under the NSCA.	No change required. We appreciate the review and feedback for the Request for Information to help determine the potential impact on licensees. It is intended to capture current practice for the core reporting elements common to most facility types.	
Comments on Comments received					
113	General	Winnipeg Regional Health Authority	I was shocked to see the CNSC announcement 20 DEC asking for comments on comments submitted for this draft REGDOC that in JUL was published as being for Class I nuclear facilities excluding power reactors as now being advertised for non-power Class I nuclear facilities <b>and potentially Class II facilities!</b>  The title of this draft REGDOC is misleading if not outright deceptive if there is an intention to apply it to Class I facility licensees. Of course many Class II licensees such as hospitals and cancer centres did not comment initially in the summer and fall because the title of the draft REGDOC	The text has been revised to address the intent of the comment. CNSC staff agree that REGDOC-3.1.2 does not include Class II facilities, and the CNSC website has been corrected to delete references to Class II facilities on the REGDOC-3.1.2 History Page as follows:  ``REGDOC-3.1.2, <i>Reporting Requirements for Non-Power Reactor Class I Facilities and Uranium Mines and Mills</i> is currently being developed. When	Done

Combined public review comments

Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Version out for Public consultation July 11 to November 9, 2016

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			<p>and verbiage that was published at the time said nothing about potential impact to Class II licensees.</p> <p>Elements with the CNSC recently seem to be finding ways to add needlessly to licensee administrative burden. What I am getting at here is the requirement in the draft REGDOC for submission of an Annual Compliance Monitoring Report - Class II licensees are already submitting Annual Compliance Reports and some have been forced to operate RD/GD-99.3 Public Information Programs even though hospitals and cancer treatment centres are clearly exempt from that requirement in RD/GD-99.3. Now there is a possibility that submission of and Annual Compliance Monitoring Report may be added to our reporting burden.</p> <p>With regard to “comments on comments”, the comments submitted by the six licensees and/or industry associations seem accurate. I fully support AREVA’s recommendation that the Annual Report should be limited to asking about past compliance and not be asking about forward-looking issues as well as the comments from Bruce Power suggesting that as written the Annual Report would almost take the work of doing a licence application – every year as well as contributing nothing to safety or performance.</p> <p>In summary, Draft REGDOC-3.1.2 <b>should not</b> apply to Class II facilities!</p> <p>4<sup>th</sup> para from 11 JUL news release:</p> <p>“This draft sets out requirements and guidance for reports and notifications that licensees of Class I nuclear facilities</p>	<p>published, REGDOC-3.1.2 will set out common requirements and guidance for annual compliance and event reporting for all non-power reactor Class I facilities, uranium mines and mills <b>and potentially Class II facilities.</b>”</p> <p>It is confirmed that this draft of REGDOC-3.1.2 applies to licensees of Class I nuclear facilities (excluding power reactors) and of uranium mines and mills as indicated in the document title, Purpose, and original press release. Any references in the draft is for Class II equipment that may be used at Class I facilities (excluding nuclear power plants) and uranium mines and mills, and are not intended for Class II facilities.</p> <p>To provide clarification, the following guidance text is added to Table A, line item 9c:</p> <p>“This applies to Class II prescribed equipment used by licensees as described in the Purpose, and not to Class II facility licensees. The heading of this line item in the Table reflects the title of the applicable Regulation from which the requirements text originates only, and not the applicable facility.”</p> <p>If reporting for Class II facilities is being considered, it would be addressed in a separate project, and be specifically identified for those</p>	

**Combined public review comments**

**Draft REGDOC-3.1.2, Reporting Requirements, Volume I: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills**

Version out for Public consultation July 11 to November 9, 2016

	<b>Section or Para. #</b>	<b>Reviewer</b>	<b>Reviewer's Comment and Proposed Change</b>	<b>Response</b>	<b>Done?</b>
			<p>(excluding power reactors) and uranium mines and mills must submit to the CNSC. This document presents the types of reports, their frequency and the applicable timeframe for reporting.”</p> <p>2<sup>nd</sup> sentence from CNSC web-site 20 DEC:</p> <p>“When published, REGDOC-3.1.2 will set out common requirements and guidance for annual compliance and event reporting for all non-power reactor Class I facilities, uranium mines and mills and potentially class II facilities.”</p>	<p>facilities in the title, scope and communications. It is expected that the public and stakeholders will be consulted shortly to solicit input with regards to any potential need and approach for reporting for Class II facilities.</p>	