

November 8, 2016

Canadian Nuclear Safety Commission
P.O. Box 1046 Station B
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Subject: Nordion Comments on Draft REGDOC 3.1.2 Reporting Requirements for Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

Nordion (Canada) Inc. has reviewed the Draft REGDOC 3.1.2 Reporting Requirements for Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills and would like to submit the following comments. Please refer to the attached Summary of Nordion Comments on Draft REGDOC 3.1.2.

Sincerely,



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Encl.: Summary of Nordion Comments on Draft REGDOC 3.1.2.



Summary of Nordion Comments on Draft REGDOC 3.1.2

Section	Title	Text from REGDOC-3.1.2	Nordion's Comments
1	Introduction	This document presents the types of reports, the frequency and the applicable timeframe for reporting.	Clarify "frequency". It is interpreted that the frequency of reporting and the timeframe for reporting are the same.
1	Introduction	<p>-paragraph 27(b) of the NSCA states that "Every licensee and every prescribed person shall</p> <p>(b) make the prescribed reports and file them in the prescribed manner [including a report on...</p> <p>(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.]</p>	Nordion proposes providing examples for contraventions of the Act in relation to an activity that is authorized by this Act.
2	Reporting Requirements	<p>The following reporting requirements apply for Class I nuclear facilities (excluding power reactors) and uranium mines and mills:</p> <p>1. the licensee shall file a report to the Commission in response to:</p> <p>a. an event or a situation, or</p> <p>b. a dangerous occurrence as stipulated in section 35 of the PTNSR 2015</p>	Point 1. a. "an event or a situation" is too generic. 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. Language should be added to specify which events or situations require reporting.
2	Reporting Requirements	2. as required, licensees shall provide other notifications or reports, including a failure to comply with section 26 of the PTNSR 2015	Point 2. This language is generic. A specific example is given in section 26 of the PTNSR 2015. Nordion suggests listing specific notification or reports and removing generic language.
2	Reporting Requirements	A preliminary report or notification that must be submitted immediately in person, by telephone, by email or by fax	Nordion suggest rewording as: "A preliminary report or notification that must be submitted immediately may be provided in person, by telephone, by email or by fax unless specified otherwise by the regulations (refer to Table A)."



Section	Title	Text from REGDOC-3.1.2	Nordion's Comments
2	Reporting Requirements Guidance	<p>For an emergency involving a nuclear facility or nuclear substances, the licensee should contact the CNSC Duty Officer emergency telephone number. An emergency includes:</p> <ul style="list-style-type: none"> • any accident involving a nuclear reactor, nuclear fuel facility, or nuclear substances <ul style="list-style-type: none"> • lost or damaged nuclear substances 	<p>For the purposes of providing examples of an emergency to Class 1 Nuclear Facilities and Uranium Mines and Mills, Nordion recommends removing “any accident involving a nuclear reactor and nuclear fuel facility” from the example list.</p> <p>“Any accident involving a nuclear substance” is vague. For example, a dropped vial of Y-90 inside a hot cell during processing of a nuclear substance. Such “accidents” do not trigger the licensee’s emergency response plan and should not require reporting to the Duty Officer. A recommendation is to specify “any accident that triggers actions under emergency response programs” to the bullet.</p> <p>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.</p> <p>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</p>



Section	Title	Text from REGDOC-3.1.2	Nordion's Comments
		<ul style="list-style-type: none"> • any threat, theft, smuggling, vandalism or terrorist activity involving a nuclear facility or nuclear substances • an unplanned spill or release • a worker injury that requires offsite medical response • any event that requires activation of a site emergency response plan 	<p>sustain minor damage (scrapes, dents) during transport. These do not affect the integrity of the package.</p> <p>Clarify theft. As worded "any theft,...involving a nuclear facility" it could mean any theft, whereas, the regulations are more specific: NSCA 27(b)(a) – theft or loss of a nuclear substance, prescribed equipment, or prescribed information that is used in carrying on any activity that is authorized by the NSCA GNSCR 30(1) – theft, ... of safeguards equipment or samples collected for the purpose of a safeguards inspection NSRDR 38(1) – the nuclear substance or radiation device is lost or stolen Nordion recommends developing a threshold relative to impact and risk to clarify guidance.</p> <p>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.</p> <p>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)).</p>



Section	Title	Text from REGDOC-3.1.2	Nordion's Comments
2	Reporting Requirements Guidance	<p>For an emergency involving a nuclear facility or nuclear substances, the licensee should contact the CNSC Duty Officer emergency telephone number. An emergency includes:</p> <ul style="list-style-type: none"> • any accident involving a nuclear reactor, nuclear fuel facility, or nuclear substances • lost or damaged nuclear substances • any threat, theft, smuggling, vandalism or terrorist activity involving a nuclear facility or nuclear substances • an unplanned spill or release • a worker injury that requires offsite medical response • any event that requires activation of a site emergency response plan 	<p>Based on this one section, it is not clear when licensees are required to call the Duty Officer. The guidance provided by the CNSC in the letter dated Sept. 19, 2016 was as follows:</p> <p>“It is the CNSC’s expectation that when an event or incident triggers actions under emergency response programs, even if it is a false alarm, or when an event occurs that could trigger stakeholder interest, such as a spill, a release or an injury; or an event occurs that fits under the requirements of the <i>General Nuclear Safety and Control Regulations</i>, subsection 29(1), licensees are required to report to the CNSC directly through the Duty Officer.”</p> <p>It is suggested that the table in Appendix A specify who to contact for the notifications and preliminary reports.</p> <p>In addition, according to the guidance in the letter, licensees are expected to contact the Duty Officer when an EHS event occurs that could trigger stakeholder interest. This is not mentioned in the Regulatory document.</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>
2	Reporting Requirement Guidance	<p>Note: If an emergency is reported to the CNSC duty officer, a preliminary report or immediate notification is not required.</p>	



Section	Title	Text from REGDOC-3.1.2	Nordion's Comments
2	Reporting Requirements Guidance	If, 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.	Nordion suggests the following wording to provide clarity: "If, after further investigation, the licensee concludes a situation or event, which was initially reported to the CNSC, was not reportable, the licensee ...".
2	Reporting Requirements Guidance	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].	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.
4.2	Full Reports Guidance	Identify the target completion date for each action that the licensee proposes to take to reestablish normal operations or to prevent a recurrence	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.



Section	Title	Text from REGDOC-3.1.2	Nordion's Comments
4.4	Specific reports under the Packaging and Transport of Nuclear Substances Regulations, 2015	Expert assessment of a dangerous occurrence in packaging and transport 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.	Further guidance is needed on what an "expert assessment" entails and who is considered an expert. Clarification in the guidance is needed to answer the following questions: Is the expert assessment a separate communication or is it part of the full report? Can consignors or consignees act as the expert for assessments? Are there exceptions to including an expert assessment for reporting of dangerous occurrences?
Appendix A	Reports, Notifications and Timing	N/A	Nordion proposes stipulating that "days" are calendar days.
Table A General comment	Situations and events for which a report or notification is required, including the timing	N/A	Provide a summary of how the events, notifications or filings of records are arranged in the table (i.e. by Safety and Control Area).



Section	Title	Text from REGDOC-3.1.2	Nordion's Comments
Table A General comment	Situations and events for which a report or notification is required, including the timing	N/A	<p>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>



Section	Title	Text from REGDOC-3.1.2	Nordion's Comments
Table A No. 1	<p>Contravention of the <i>Nuclear Safety and Control Act</i> (NSCA) in relation to an activity that is authorized</p>	<p>Applicable section(s) of NSCA or regulations made under the NSCA:</p> <p>NSCA:</p> <p>27. Every licensee and every prescribed person shall [...]</p> <p>(b) make the prescribed reports and file them in the prescribed manner, including a report on (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</p> <p>General Nuclear Safety and Control Regulations (GNSCR):</p> <p>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 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>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>
Table A B.	<p>Management system, human performance, conventional health and safety, financial status</p>	<p>Management system, human performance, conventional health and safety, financial status</p>	<p>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.</p>



Section	Title	Text from REGDOC-3.1.2	Nordion's Comments
Table A No. 3	Contingency plan	(d) a situation or event that requires the implementation of a contingency plan in accordance with the licence;	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 contingency plan referenced in their license?
Table A No. 3	Contingency Plan Guidance	A contingency plan may include: 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	<p>Nordion suggests the following wording: "A contingency plan may be required for:" to replace "A contingency plan may include:".</p> <p>"Any situation or event" is broad and requires clarification. 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>



Section	Title	Text from REGDOC-3.1.2	Nordion's Comments
Table A No. 4	Serious illness, injury or death Guidance	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>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>
Table A No. 9a), b) and d)	Nuclear substances, radiation devices, exposure devices and Class II equipment	Subsection 38(2) of the NSRDR stipulates the content to be included in the report.	Suggested wording: Subsection 38(2) of the NSRDR stipulates the content to be included in the <u>full</u> report.
Table A No. 16	Theft or loss of nuclear substance, prescribed equipment or prescribed information	N/A	Add NSRDR 38(1)(a).



Section	Title	Text from REGDOC-3.1.2	Nordion's Comments
Table A No. 17	Actual or attempted breach of security or act of sabotage	<p>GNSCR:</p> <p>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 circumstances of the situation and of any action that the licensee has taken or proposes to take with respect to it:</p> <p>(e) an attempted or actual breach of security or an attempted or actual act of sabotage at the site of the licensed activity;</p> <p>Guidance</p> <p>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.</p> <p>Examples include but are not limited to:</p> <ul style="list-style-type: none"> • unauthorized access to a facility or site • attempted or actual breach against electronic systems and/or subsystems • discharge of firearms or the application of use-of-force options <p>Note: "Security" includes cybersecurity (such as hacker attacks on computer systems).</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" 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.</p>



Section	Title	Text from REGDOC-3.1.2	Nordion's Comments
Appendix B	Sample Structure and Content for an Annual Compliance Monitoring Report	N/A	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-#3471152)?