From: Jirovec, Marie <personal information redacted>
Sent: January 31, 2020 9:36 AM
To: Torrie, Brian (CNSC/CCSN)
Cc: Murthy, Kavita (CNSC/CCSN); Consultation (CNSC/CCSN); Forms / Formulaires (CNSC/CCSN); Boyle, Phillip; Brewer, Sarah; Cotnam, Shaun; Garrick, David; Gull, Michael; Holder, Shaun; Parnell, Scott; Schruder, Kristan; Senaratne, Uditha PM; Vickerd, Meggan; Wegner, Kevin; Williams, Cynthia; Karivelil, Solly; CNLRPD Site Office / Bureau régional de CNLRPD (CNSC/CCSN); >CR Licensing
Subject: CNL Comments on Draft REGDOC-1.6.2, Developing and Implementing an Effective Radiation Protection Program for Nuclear Substances and Radiation Devices Licences.
Attachments: 145-CNNO-20-0003-L - Comments on REGDOC 1.6.2.pdf

UNRESTRICTED / ILLIMITÉE

Good morning Mr. Torrie,

Please find attached a letter from Solly Karivelil titled *Canadian Nuclear Laboratories Comments on Draft REGDOC-1.6.2, Developing and Implementing an Effective Radiation Protection Program for Nuclear Substances and Radiation Devices Licences.*

Marie Jirovec
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2020 January 31

145-CNNO-20-0003-L

Mr. Brian Torrie
Director General, Regulatory Policy Directorate
Canadian Nuclear Safety Commission
280 Slater Street
P.O. Box 1046, Station B
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COMPLIANCE
Regulatory Affairs

Dear Mr. Torrie:

CANADIAN NUCLEAR LABORATORIES COMMENTS ON DRAFT REGDOC-1.6.2, DEVELOPING AND IMPLEMENTING AN EFFECTIVE RADIATION PROTECTION PROGRAM FOR NUCLEAR SUBSTANCES AND RADIATION DEVICES LICENCES

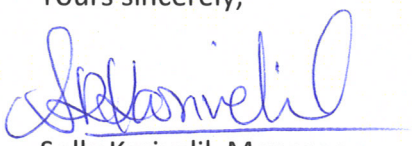
Canadian Nuclear Laboratories (CNL) has reviewed the proposed Industry comments on draft REGDOC-1.6.2, *Developing and Implementing an Effective Radiation Protection Program for Nuclear Substances and Radiation Devices Licences*, and has consulted with its industry partners to produce a set of consolidated comments, which are presented in Attachment A.

The draft REGDOC moves away from successful past practice of providing reasonable parameters for licensees to operate within. As currently written, it does not accommodate all licensees. It should reflect the range, size and complexities across the spectrum of licensees in the Industry. In many instances, the REGDOC alters already safe limits to levels that will require significant effort and resources with no corresponding benefit to nuclear safety.

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

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

Yours sincerely,



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Attachment (1)

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ATTACHMENT A

CANADIAN NUCLEAR LABORATORIES COMMENTS ON DRAFT COMMENTS ON DRAFT REGDOC-1.6.2, DEVELOPING AND IMPLEMENTING AN EFFECTIVE RADIATION PROTECTION PROGRAM FOR NUCLEAR SUBSTANCES AND RADIATION DEVICES LICENCES

	Document/ Excerpt of Section	Industry Issue	Suggested Change *(if applicable)*	Major Comment/ *Request for Clarification*[1]	Impact on Industry, *if major comment*
1.	**Preface**	Licensees appreciate the effort to reduce verbiage by directing readers to *REGDOC-3.5.3, Regulatory Fundamentals* for information on a graded approach. However, users might benefit from a brief description of how a graded approach could apply to this specific REGDOC since it isn't immediately clear which types of licensees this draft is truly intended for.	Draw language from REGDOC-3.5.3, to offer additional context. Amend to read, "Regulatory document REGDOC-1.6.2 … provides guidance to nuclear substances and radiation devices licensees and applicants on the development, implementation, management and assessment of their radiation protection programs. It applies to the full range of licensees, from operators of Class 1 nuclear facilities with well-established radiation protection programs, to new applicants seeking to use nuclear materials for medical, industrial or research purposes. Licensing and compliance activities related to REGDOC-1.6.2 will vary widely depending on the type of licenses already held or those being sought. This aligns with the CNSC's graded approach, which is driven primarily by an assessment of the risk associated with the activities being regulated and the performance history of the licensee. For information on the implementation of regulatory documents and ~~on~~ the graded approach, see REGDOC-3.5.3, Regulatory Fundamentals."	**MAJOR**	Insufficient context on a graded approach can make it difficult for licensees to interpret compliance expectations related specifically to their facility.
2.	**Preface**	As with other recent draft REGDOCs, this document uses the term "must" to express requirements. This is a departure from other nuclear standards, which traditionally use only "shall." It also uses "should," "may" and "can" to describe various levels of guidance, which inadvertently generates more confusion than clarity.	Industry encourages the CNSC to only use "shall" statements to express requirements and "may" to discuss guidance in this and all other regulatory documents.	**MAJOR**	On its surface, the use of different words to express requirements or guidance appears inconsequential. It is not. Readers of recent draft REGDOCs have found it increasingly difficult to determine what is truly obligatory and what is optional.

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3.	**1.2**	The Scope could more explicitly say which types of licensees this document is intended to guide. If it is not truly meant for licensees with rigorous, site-wide licences, Certified Health Physicists and well-established Radiation Protection Programs, it should simply exempt them. Otherwise, it should overtly identify Class I licensees as those who may wish to consult the REGDOC for information. As currently written, the 2nd sentence grammatically implies that it is nuclear substances and radiation devises – not licensees – who may wish to consult the document for information. A slight edit is needed to correct the intent.	Amend the 2nd sentence to exempt Class 1 licensees. Otherwise, edit it to read, "Current operators of Class I facilities or uranium mines and mills with nuclear substances and radioactive devices licensed under other classes of licence meet the requirements for a radiation protection program. Given this, they may wish to consult this document for information."	Clarification	
4.	**2.**	Licensees believe the 1st paragraph should be edited for improved clarity. Specifically: *1)* The REGDOC should recognize that some licensees, such as NPPs, are required to have health physicists whose training exceeds the requirements for an RSO and can fill that role. *2)* The phrase "not delegating accountability" to the RSO is contrary to "acting as a signing authority" in section 3.2 and does not clearly delineate applicant and RSO responsibilities.	Amend the 1st paragraph to read, "…The applicant authority should delegate duties for the day-to-day oversight of the RPP~~, but not accountability,~~ to an individual known as the radiation safety officer (RSO). A Health Physicist can be delegated as an RSO without additional training or certification. More details on applicant authority responsibilities can be found in REGDOC-1.6.1, Licence Application Guide: Nuclear Substances and Radiation Devices [1]."	**MAJOR**	Without the suggested amendments, this section could create uncertainty regarding the responsibilities and training of RSOs. As written, it does not accommodate all licensees. It should reflect the range, size and complexities across the spectrum of licensees in the industry.
5.	**2 and 3.6.1**	It is not a regulatory requirement to use the supplied forms to appoint an RSO (or any person) under section 15 of the General Nuclear Safety and Control Regulations.	Remove all mention of an RSO except in reference to the Class II Nuclear Facilities and Prescribed Equipment Regulations. Remove all mention to a requirement to fill out specific forms when notifying the Commission.	**MAJOR**	This adds requirements to licensees that have not gone through a regulatory impact analysis.
6.	**3.1**	Licensees have concerns with the following: 1) The 1st paragraph does not recognize that in some larger organizations, the applicant authority may not always have direct, day-to-day supervisory responsibilities for the RSO in their wider organization. Also, the last sentence of the 1st	Amend the 1st paragraph to read, "The applicant authority, or those who directly supervise the RSO, should ensure that competing duties or priorities are not assigned to the RSO that might detract significantly from their ability or availability to manage the RPP. The responsibilities of an RSO are ~~not an adjunct to another~~	**MAJOR**	For large organizations, no single person or alternate(s) or site specific individual can manage the duties and authorities as described. The industry has Radiation Protection Program Manager(s) for the administration of the RPP and qualified Health Physics staff who help oversee the implementation of the RP Program. As

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		paragraph says, "… not an adjunct to another job task; …" This may create confusion for smaller licensees since an RSO may have numerous job tasks, as recognized in the 4th paragraph. What is important is that the RSO has sufficient time and resources to complete the applicable job tasks. 2) Many of the duties listed for an RSO in Appendix A – and referenced in the 3rd paragraph of this section -- would to be delegated to other staff.	~~job task; they are an~~ essential ~~element for~~ to ensur~~e~~~~ing~~ the safe use of nuclear substances and radiation devices." Amend the 2nd paragraph to read, "~~As best practice, the applicant authority should provide~~The RSO should be given ~~with~~ a description of ~~the~~ their duties~~, as well as and guidance regarding the number of hours they the RSO should be dedicating to them~~. The ability of the RSO to manage the RPP should be evaluated by an appropriate level of management and/or the applicant authority at defined intervals~~, in order~~ to identify where additional time or other assistance is needed. Amend the 1st sentence of the 3rd paragraph to read, "The RSO typically ensures the non-exhaustive lists of tasks described in appendix A are performed."		currently written, all these staff would need to be designated as an RSO and some larger licensees with complex, well-established RPP programs may be required to structure themselves in inefficient, ineffective ways to ensure the RSO reports directly to an applicant authority. Without the suggested edits, the implication would be significant cost and administrative effort s with no corresponding improvement to nuclear safety.
7.	**3.2**	Licensees, especially those with well-established regulatory frameworks and processes, believe it is not appropriate to require an RSO to be the signing authority for all radiation safety matters. This is more appropriate as guidance.	Amend the 2nd paragraph to read, "In particular, the RSO may act as signing authority on all matters of radiation safety, the CNSC licence and the obligations of the licensee and ~~must~~ have necessary authority to: 1. communicate directly with the applicant authority ~~2. act as signing authority on all matters of radiation safety, the CNSC licence and the obligations of the licensee~~ 2. immediately stop any work, task or undertaking that the RSO considers unsafe or which may contravene the NSCA, its regulations or the CNSC licence 3. implement and enforce any changes to any work, task or undertaking which are necessary to ensure that the licensee remains compliant or returns to compliance 4. modify any policy and any procedure, and ensure that the changes are properly documented and communicated to workers	**MAJOR**	For large corporations, there may already be a framework for existing regulatory relations and processes.

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8.	**3.6**	The draft does not make it clear that an RSO with all the stated qualifications is not subject to rejection by the Commission or its staff.	Include language that confirms RSOs are appointed by licensees to best meet their individual organizational structures and business needs. While RSOs are selected to satisfy CNSC qualifications, their appointments are not subject to refusal by the Commission or its staff.	**MAJOR**	There is no appeal mechanism for a nominated RSO within the Class II Nuclear Facilities and Prescribed Equipment Regulations. Appeals of an administrative decision-maker may be taken to a provincial court unless other mechanisms are present. In this case, they are not.
9.	**3.6.1**	Licensees believe the REGDOC should provide an appropriate threshold/frequency for notifying the CNSC regarding alternate RSOs.	Amend the 2nd sentence of the 2nd paragraph, to read, "The CNSC should be notified in the case of short-term absences of more than 21 days."	Clarification	
10.	**3.6.2**	It's not appropriate to expect a similar level of experience, training and authority for site RSOs who manage sites with lower hazard profiles or less complex RPPs.	Rephrase the 2nd sentence of the 2nd paragraph to read, "The site RSO should have ~~similar levels of~~ experience, training and authority commensurate with the complexity of the RPP and hazards at their site ~~as the corporate RSO~~."	**MAJOR**	As currently written, the REGDOC does not allow industry to train or qualify staff to a level that is appropriate to the hazard profile they manage.
11.	**4.**	REGDOC 1.6.2 refers to REGDOC 2.7.1, Radiation Protection, which is under development and should not be referenced until it is published.	Remove the reference to REGDOC 2.7.1, Radiation Protection	**MAJOR**	As per industry feedback on other drafts, it's inappropriate to reference non-published REGDOCs. Citing REGDOC-2.7.1 prior to publication could generate confusion since the CNSC has not yet dispositioned licensee comments on that draft document.
12.	**5**	The last paragraph inappropriately lists safety culture among the management system components to include in an RPP. Safety culture is ***not*** a component of a management system. It is an outcome of, and promoted by, a management system.	To be consistent with other REGDOCs and promote a better understanding of safety culture, the CNSC is strongly urged to: • Delete 'safety culture' from the list of management system components • Move subsection 5.1 to precede section 4 • Add subsection 4.1 and provide a linking statement to say activities that promote safety culture should be considered in designing the management system.	**MAJOR**	Section 5 is inconsistent with *REGDOC-2.1.1, Management System* causes confusion and mischaracterizes the relationship between safety culture and the management system.
13.	**5.1**	This section does not align with the content of *REGDOC-1.6.1,* which provides guidance on the application requirements for a nuclear substance and radiation device license.	Remove this section so requirements align with *REGDOC-1.6.1*. Otherwise, clearly state that it contains ideas a licensee may implement, but the content cannot be used for compliance verification.	**MAJOR**	This section is inconsistent with an existing REGDOC which will generate compliance confusion.

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14.	**5.2.1**	Section 5.2 indicates self-assessments are a 'should.' However, 5.2.1 says self-assessments are 'vital.' These two statements are inconsistent and imply that self-assessments are a 'shall.'	Align 5.2.1 with 5.2 to ensure it's clear that self-assessments are a 'should' rather than a 'shall.' For clarity, amend the first two sentences to read, "~~Self-assessments, such as internal audits or inspections, are vital in evaluating the implementation and effectiveness of the RPP.~~ If self-assessments are performed, they are generally conducted by …"	Clarification	
15.	**5.2.2**	Clarity is required on the following points: 1) As with 5.2.1, the 1st sentence of the 1st paragraph implies that independent audits are a 'shall.' 2) It's unclear what "should be based on" means in the 1st sentence of the last paragraph.	Amend: 1) The 1st sentence of the 1st paragraph to read, "Independent assessments are often referred to as external audits and may be ~~are~~ planned and conducted ~~carried out~~ by an external organization at defined frequencies." 2) The 1st sentence of the last paragraph to read, "Independent assessments should be informed by ~~based on~~ the results of self-assessments."	Clarification	
16.	**5.2.3**	As currently written, this section implies that management reviews are a 'shall' and reviews need to be conducted ***by*** the Applicant Authority, not on their behalf.	Amend the 1st sentence to read, "Management reviews may be ~~are~~ conducted ~~by the applicant authority~~ at a set frequency and their results provided to the applicant authority ~~as an oversight activity~~ to assess the effectiveness of the RPP and ~~to~~ proactively make improvements as required."	**MAJOR**	Without these slight edits, the REGDOC inappropriately suggests the applicant authority must conduct the actual review rather than analyze its results.
17.	**5.3**	The requirement to submit a detailed report for events determined to be systematic does not align with the reporting requirements of the General Nuclear Safety and Control Regulations. Reporting requirements are already covered by the suite of applicable REGDOCs (3.1.1, 3.1.2 and 3.1.3) and corrective action processes are well established to resolve issues.	Licensees strongly urge the CNSC to delete the 2nd and 3rd paragraphs and their supporting bullets. Reporting requirements and corrective actions need to align with the GNSCR, applicable REGDOCs and well-established processes.	**MAJOR**	This section confuses event reporting, which is already well covered by existing REGDOCs. Similarly, the corrective action process is well understood and monitored by licensees and there is no need to reference it here.
18.	**5.4**	Licensees should have the flexibility to document their RPP in a way that best suits their organizational need. This may not necessarily be a safety manual.	Amend the 3rd sentence to read, "The specific details of the RPP are ~~usually~~ documented, ~~in a radiation safety manual, which is submitted as part of the licence application. The radiation safety manual should be~~ signed	**MAJOR**	For many licensees, there may already be an existing framework for regulatory relations and processes.

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			~~and dated by the RSO and applicant authority~~ to confirm its contents were ~~that the published version of the manual was~~ reviewed and approved."		
19.	**Appendix A:**	The phrase "lowest level of contamination" in the fitness for service section is unhelpful since the potential dose consequences will vary from site to site due to different radionuclides and measurement capabilities.	For clarity, amend the final bullet under fitness for service to read, • "maintain a sufficient supply of radiation monitoring instruments that are capable of detecting the nuclear substances in use ~~at the lowest level of contamination"~~	Clarification	
20.	**Appendix B**	Some licensees have ALARA Committees instead of Radiation Safety Committees, which serve the same purpose.	Clarify that an ALARA Committee is considered equivalent to a Radiation Safety Committee.	Clarification	

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