UNRESTRICTED

2017 May 12

COMPLIANCE
Regulatory Affairs
145-CNNO-17-0017-L

Mr. Brian Torrie
Director General, Regulatory Policy Directorate
Canadian Nuclear Safety Commission
280 Slater Street
P.O. Box 1046, Station B
OTTAWA, Ontario K1P 5S9

Dear Mr. Torrie:

Canadian Nuclear Laboratories Comments on Draft REGDOC-1.5.1, Application Guide Certification of Radiation Devices or Class II Prescribed Equipment

Canadian Nuclear Laboratories (CNL) and industry partners have reviewed the draft document "REGDOC-1.5.1, Application Guide Certification of Radiation Devices or Class II Prescribed Equipment", and produced a set of consolidated comments, captured in Attachment A to this letter.

CNL believes that a stakeholder workshop on this REGDOC would be beneficial to discuss a number of implementation issues, given the different parties involved in certification of these items.

If you should have any questions regarding this submission, please contact me directly.

Yours sincerely,

Solly Karivelil, Manager
Regulatory Affairs
Phone: 613-584-3311, ext. 48021
Email: solly.karivelil@cnl.ca

SK/kam

Attachment (1)

c J. LeClair (CNSC)

Consultations (CNSC)

S. Cotnam	D. Cox	K. Daniels	J.D. Garrick
K. Kehler	H. Khartabil	K. McCarthy	T. Preisig
B. Sanderson	J. Stone	>CR CNSC Site Office	>CR Licensing

Canadian Nuclear Laboratories

Chalk River Laboratories
286 Plant Road
Chalk River, Ontario
Canada K0J 1J0
Telephone: 613-584-3311
Toll Free: 1-866-513-2325

Laboratoires Nucléaires Canadiens

Laboratoires de Chalk River
286, rue Plant
Chalk River (Ontario)
Canada K0J 1J0
Téléphone: 613-584-3311
Sans frais: 1-866-513-2325

Attachment A
Comments on Draft REGDOC-1.5.1, Application Guide Certification of Radiation Devices or Class II Prescribed Equipment

#	Document/ Excerpt of Section	Industry Issue	Suggested Change (*if applicable*)	Major Comment/ ***Request for Clarification***	Impact on Industry, *if major comment*
1.	**General**	Document should distinguish between CNSC and CNSC staff (e.g. "meet with the CNSC").		*Clarification*	
2.	**General**	The document provides CNSC contact information for application, however, it does not clarify the contact mechanism in a number of other situations where communication is advised (e.g., request for meeting with CNSC staff prior to submitting an application, notification of changes).	Suggest that the contact should be the designated Project Officer.	*Clarification*	
3.	**General**	The units used in an application have to be according to the SI system. In some situations the tech specs are not based on SI units.	There should be some official mechanism for "certified" conversion to a SI based document which can be enclosed with an application.	*Clarification*	
4.	**Preface**	The statement, *"Guidance contained in this document exists to inform the applicant, to elaborate further on requirements or to provide direction to licensees and applicants on how to meet requirements. It also provides more information about how CNSC staff evaluates specific problems or data during their review of licence applications. Licensees are expected to*	Delete the last phrase to read, "*Guidance contained in this document exists to inform the applicant, to elaborate further on requirements or to provide direction to licensees and applicants on how to meet requirements. It also provides more information about how CNSC staff evaluate specific problems or data during their review of licence applications.*	**MAJOR**	Some CNSC staff interpret this statement to mean that guidance within the REGDOC is a requirement. This is not true. Guidance is not a requirement. This has major impacts on licensees in the time spent in discussion with CNSC staff as to why guidance is not followed in certain cases.

#	Document/ Excerpt of Section	Industry Issue	Suggested Change (*if applicable*)	Major Comment/ ***Request for Clarification***	Impact on Industry, *if major comment*
		review and consider guidance; should they choose not to follow it, they should explain how their chosen alternate approach meets regulatory requirements" gives the impression that the guidance is a requirement.	*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.~~'*		
5.	**Section 1.2**	There is the potential for excessive administrative burden related to the second paragraph, which reads, *"Once issued, the certificate applies to a specific model design and to specified operating conditions only."*	Industry requests the CNC to clearly indicate items that are exempted from this limitation such as changing a name, software upgrades or other minor modifications that improve operations without interacting or impacting the source assembly. Industry suggests using generic names without specific letters on devices with the same source assembly.	**MAJOR**	Adopting these suggestions will avoid unnecessary administrative burden related to changes/activities that are not radiologically relevant.
6.	**Section 2.1**	Clarity.	Amend 2nd paragraph to read, "*This certification for a Radiation Device or Class II Prescribed Equipment is not to be construed as a licence for use, servicing or installation."* In the 3rd paragraph, clarify if the expectation is to use the form for the application. If so, perhaps the wording should be changed from *"should"* to *"shall"*.	*Clarification*	

#	Document/ Excerpt of Section	Industry Issue	Suggested Change (*if applicable*)	Major Comment/ ***Request for Clarification***	Impact on Industry, *if major comment*
7.	**Section 2.1**	Similar to section 1.2, there is the potential for excessive administrative burden related to the final line in section 2.1, which reads, "*Once a certificate has been issued, it applies to a specific model design and to specific operating conditions only.*"	Delete this statement.	**MAJOR**	Unnecessary administrative burden related to changes/activities that are not radiologically relevant. The CNSC should continue to certify series of models.
8.	**Section 2.2**	No guidance is provided as to who is required to submit a renewal application. What is the CNSC's expectation? When existing manufacturers reject requests to submit a renewal application, what is the allowable timeframe to reject submitting an application? If they reject 2 weeks in advance of the certificate due date, does the interested applicant get a grace period for submitting an application? Will the CNSC give an extension to the expiry date of the certificate on those grounds? How licensees are made aware of this situation? Is there a penalty for late rejection? This is a current problem that should be corrected. Sufficient time should be allowed for all parties including manufacturers	Revisit this section to clearly establish the expectations regarding which party is required to submit a renewal application and answer the questions posed by industry regarding timeframes, grace periods, extensions, penalties and communication protocols. This could be one agenda item for a proposed workshop with the CNSC.	**MAJOR**	Currently, certification accountability lies with manufacturers and then licensees. However, in cases where there could be more than one licensee who possesses/uses the device, the accountability/liability process for maintaining the certification is unclear.

#	Document/ Excerpt of Section	Industry Issue	Suggested Change (*if applicable*)	Major Comment/ ***Request for Clarification***	Impact on Industry, *if major comment*
9.	**Section 2.2**	Clarity.	Change the second paragraph to read: "*For applicants wanting to submit a hard copy of their application ~~physically~~, print a copy of the completed form, sign and date it, and mail it to the CNSC's Directorate of Nuclear Substance Regulation at the address indicated below*:" Change the final sentence to read: "*Applicants should keep a complete copy of the application for ~~his~~ their records*."	*Clarification*	
10.	**Section 2.3.**	There is no discussion of extensions, which is what the CNSC has been processing for late submissions and charging a fee.	The option of a one-year extension should be available and automatically granted to users who make a request to keep using an existing device. As an extension, the payment should be a fraction of the regular fee.	**MAJOR**	Undue financial and administrative burden.
11.	**Section 2.4**	Clarify the certificate duration after renewal. What would be the basis for the duration to be shorter if there has been no change to the design?	Provide the bases for CNSC determination whether a shorter duration is appropriate.	*Clarification*	
12.	**Section 2.4**	As per the comment on section 2.3, there is no mention of a one-year extension to certification or the fee required to extend. Who is liable to ensure the certification is valid and extended as required until a renewal application has been processed?	Clarify which party is responsible for end of certification management. Further clarify the expectations of licensees versus manufacturers.	**MAJOR**	Undue financial and administrative burden.

#	Document/ Excerpt of Section	Industry Issue	Suggested Change (*if applicable*)	Major Comment/ ***Request for Clarification***	Impact on Industry, *if major comment*
		What is the process for extensions?			
13.	**Section 2.4**	As written, the recertification process does not address current issues with manufacturers, outdated contacts and responsibility for design.	This topic warrants further discussion at a proposed workshop. Specific items include: The re-certification process should be re-defined for cases when the manufacturer is un- available, or unwilling, to submit an application form for renewal. The initial letter should be sent to a current contact and not the person who applied 15 years ago. CNSC should be responsible for maintaining a contact list. Also, users are not experts on the design or software. An alternative may be a survey from the regulator asking safety questions -- if the authority is satisfied with the answers, the certificate could be renewed for 5 years with the potential to repeat the process at least three times. If the regulator is not satisfied with the survey responses, an agreement with the licensee should be made on a timeline to stop using the device. Licensees should not take responsibility for the design.	**MAJOR**	It is not reasonable to expect that one of the users apply for recertification considering that, in many cases, the only available information is in the CNSC's possession, especially for obsolete designs that are not commercialized at the time of the renewal.

#	Document/ Excerpt of Section	Industry Issue	Suggested Change (*if applicable*)	Major Comment/ ***Request for Clarification***	Impact on Industry, *if major comment*
14.	**Section 2.4**	Expiry of certificates should be extended following notification to licensees.	The certificate expiry day should be extended 6 months after licensees are notified that the manufacture/vendor is not applying for the renewal.	**MAJOR**	Users will need time to track the technical information, prepare the application form and submit it several months before the expiry day.
15.	**Section 2.4**	Certificate information should be more readily available.	The CNSC should provide licensees increased visibility regarding the status of renewals prior to expiry. The website should be updated regularly (weekly) to ensure users know the status of the recertification process. This would be another area for discussion at a proposed workshop.	**MAJOR**	Any delays in the process can impact licensees so that they could have invalid equipment.
16.	**Section 2.4**	Advance notification of expiry should be provided to manufacturers.	At least one year before expiry, the authority should contact manufacturers about their intention to initiate the re-certification process or let it lapse.	**MAJOR**	Undue financial and administrative burden.
17.	**Section 3**	This section requires that supporting documentation "*specify to which section of the application form the information pertains.*" It is not clear if this means it is sufficient that the supporting document title/number be properly referenced on the application form, or if the supporting document itself must make a declaration of which section	Revise to: "*When preparing an application package, ensure that the information provided on the form and in the attached supporting documents is clear, precise, accurate and complete. If attaching or appending supporting documentation, please specify on the application form the supporting documentation being references. The*	**MAJOR**	This requirement as written represents a significant administrative burden to the applicant. Typically, the supporting documentation is developed during the development lifecycle of the device. Without the suggested revision, applicants will be required to go back through the documentation and provide cross-reference on approved documentation, or developing a stand-alone cross-reference matrix. By

#	Document/ Excerpt of Section	Industry Issue	Suggested Change (*if applicable*)	Major Comment/ ***Request for Clarification***	Impact on Industry, *if major comment*
		on the application it pertains to. The latter can be problematic as support documentation can pertain to a number of different sections of the application.	*International System of Units (SI) should be used throughout the application."*		providing the documents references on the application form, the application form becomes the cross-reference document.
18.	**Section 3.1 A1**	Clarify amendment conditions.	The conditions that require amendments of the certificate should be indicated.	*Clarification*	
19.	**Section 3.2**	The application form does not clearly indicate if no changes have been made to the equipment since its original certification.	Add a statement to say: *"For renewal applications, if no changes have been made to the equipment since its original certification, indicate 'no change."*	**MAJOR**	Information should be in CNSC records. It is redundant to provide an exhaustive list of information during renewals with no benefit if no change has been made.
20.	**Section 3.2, Part B7**	Additional clarity required.	This section needs a note on how to handle devices that contain more than one nuclear substance and one or more of those substances are less than the Exemption Quantity (EQ) or between EQ and 10*EQ.	*Clarification*	
21.	**Section 3.3, Part C**	Additional clarity regarding no changes to equipment for renewals. See comment 19 on section 3.2.	Same comment as above regarding no change for renewals.	*Clarification*	
22.	**Section 3.3, Part C1**	As part of the application, the CNSC is requesting the "*expected lifetime of use of the prescribed equipment allowed by the design"*. This should be "as applicable" as there may be devices and prescribed equipment that do not have a design	Revise to: "*the expected lifetime of use of the equipment allowed by the design, as applicable*." This would be another item for a potential workshop	**MAJOR**	The requirement to provide a design lifetime will result in significant expense on licensees in cases where design lifetime of the device/prescribed equipment does not apply.

#	Document/ Excerpt of Section	Industry Issue	Suggested Change (*if applicable*)	Major Comment/ ***Request for Clarification***	Impact on Industry, *if major comment*
		lifetime, but could last indefinitely with proper care and repair. For example, self-shielded irradiators with non-moveable sources, industrial irradiators, or accelerators could fit in this category.			
23.	**Section 3.4, Part D4**	Additional clarity sought regarding servicing. What if the manufacturer goes out of business or is no longer available at the time of renewal? Or, what if it was indicated that only the manufacturer can perform this function -- what would be the path forward for applicants submitting a renewal application? If users have a solid radiation protection program as deemed by the CNSC, that licensee should be allowed to service its own equipment if the regulator provides them with the process indicated on the certification process. Some exceptions may apply based on the complexity of the device.	Remove from Section 3.4 D4 the last half of the last sentence to read: *"Provide the procedure for source replacement if applicable"~~, and indicated if this can only be performed by the manufacturer"~~.* Revise to allow licensees with mature radiation protection program to service their own equipment under some scenarios.	*Clarification*	
24.	**Section 3.4, Part D5**	This section deals with transport of radioactive material. It seems to be related to devices which also act as the approved	Clarify section D5 to specify that this information is only needed if the device also acts as the transport package.	**MAJOR**	For devices that do not act as transport packages, this requirement adds a significant and duplicate administrative burden on the

#	Document/ Excerpt of Section	Industry Issue	Suggested Change (*if applicable*)	Major Comment/ ***Request for Clarification***	Impact on Industry, *if major comment*
		transport package. However, this is not always the case. The transport of the radioactive material should not be a part of the device registration but should remain separate as part of the Packaging and Transport Regulations, unless the device itself also acts as the transport package In addition, this section states such information is not required for particle accelerators that do not contain radioactive materials. This should be expanded to cover all devices/prescribed equipment that does not contains radioactive material when shipped (such as external beam therapy machines, industrial irradiators, etc.).			applicant.
25.	**Section 3.4, Part D6**	This section, as with Part D7, seems to be directed to devices/prescribed equipment that also acts as the transport containers. However, there seems to be no exclusion for devices/prescribed equipment that is shipped without radioactive material.	Add exclusion to this section for devices/prescribed equipment shipped without radioactive material incorporated.	**MAJOR**	For devices that do not act as transport packages, this requirement adds a significant and duplicate administrative burden on the applicant.
26.	**Section 3.6 F3**	*Include a copy of the following documents, if applicable:* • *United States Nuclear Regulatory Commission registration*	Clarify the intent and requirement of this section. This is another agenda item for a potential	*Clarification*	

#	Document/ Excerpt of Section	Industry Issue	Suggested Change (*if applicable*)	Major Comment/ ***Request for Clarification***	Impact on Industry, *if major comment*
		This requirement makes sense if the device was first certified in a foreign country, and more specifically the country of origin. However, it is not clear how this requirement will be implemented for Canadian made products that also have, or are in the process of obtaining, foreign registrations. Would all foreign registrations need to be submitted for a renewal application?	workshop.		
27.	**F3 include a copy of the following documents, if applicable: United States Nuclear Regulatory Commission registration**	This requirement makes sense if the device was first certified in a foreign country, and more specifically the country of origin. However, it is not clear how this requirement will be implemented for Canadian made products that also have, or are in the process of obtaining, foreign registrations. Would all foreign registrations need to be submitted for a renewal application?	This is another agenda item for a workshop Clarify the intent and requirement of this section.	*Clarification*	