May 11, 2017

NK21-CORR-00531-13568
NK29-CORR-00531-14194
NK37-CORR-00531-02773

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

Dear Mr. Torrie:

Bruce Power comments on draft REGDOC-1.5.1,
Application Guide: Certification of Radiation Devices or Class II Prescribed Equipment

The purpose of this letter is to provide feedback on this draft Regulatory Document, which serves as a guide to prepare and submit applications for certification of radiation devices and Class II prescribed equipment.

Bruce Power appreciates the CNSC's effort to seek stakeholder input and participated in a collaborative review of this draft along with our industry colleagues at Ontario Power Generation, New Brunswick Power, Canadian Nuclear Laboratories, Nordion and the Canadian Nuclear Association.

That collective evaluation generated the series of comments and requests for clarification detailed in Appendix A, which is attached to this letter. It also highlighted the need for a workshop with the CNSC to discuss expectations in several areas of this current draft, including:

- A review of section 2 to clarify the role of licensees versus manufacturers to submit renewal applications. This is a current challenge for industry, which has faced instances where a manufacturer is either unavailable, or unwilling, to apply for a certification renewal for a radiation device or piece of prescribed equipment important to a licensee's day-to-day operations. Industry wants to better understand the CNSC's expectations and its willingness to consider extensions to certificate expiry dates in these circumstances.
- The need for the CNSC to maintain an up-to-date contact list to ensure recertification letters are sent to current contacts and not the person who applied for the original certificate 15 or 25 years earlier.
- Methods the CNSC could use to provide licensees with increased visibility regarding the status of renewals prior to expiry. This could include regular updates on the CNSC website to ensure devise users know the status of the recertification process.

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Bruce Power looks forward to participating in a potential workshop, which we have found to be an effective way to address issues early and help the CNSC produce more effective Regulatory Documents.

If you require further information or have any questions regarding this submission, please contact Steve Cannon, Senior Strategist, Nuclear Oversight and Regulatory Affairs, at (519)-361-6559, or steve.cannon@brucepower.com.

Yours truly,

Frank Saunders
Vice President Nuclear Oversight and Regulatory Affairs
Bruce Power

cc: CNSC Bruce Site Office (Letter only)
K. Lafrenière, CNSC Ottawa
K. Owen-Whitred, CNSC Ottawa

Attach.

Attachment A

Bruce Power comments on draft REGDOC-1.5.1, Application Guide: Certification of Radiation Devices or Class II Prescribed Equipment

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Bruce Power 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*** [1]	Impact on Industry, *if major comment*
1.	**General**	The document should distinguish between CNSC and CNSC staff (e.g. "meet with the CNSC")		*Request for Clarification*	
2.	**General**	The document provides CNSC contact information for an 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 the contact should be the project officer.	*Request for 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 an SI based document which can be enclosed to an application.	*Request for 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 evaluate specific problems or data during their review of licence applications. 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'* gives the impression that the guidance is a requirement.	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. 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.~~'*	**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.

5.	**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 CNSC 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.	**2.1**	Clarity	Amend 2nd paragraph to read, "This certification for a Radiation Device or Class II Prescribed Equipment is not to be constructed as a licence for use, servicing or installation."	*Request for Clarification*	
7.	**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.
8.	**2.2**	No guidance is provided as to who is required to submit a renewal application, which is a current problem. 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 two 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 are licensees made aware of this situation? Is there a penalty for late rejection?	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. Sufficient time should be provided for all parties, including manufacturers This is a subject that industry requests be discussed during a workshop with the CNSC.	**MAJOR**	The current [informal] process for 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.

9.	**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."	*Request for Clarification*	
10.	**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.	**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?	The CNSC should clarify who Is responsible for end-of-certification management and should further clarify the expectations of licensees versus manufacturers.	*Request for Clarification*	
12.	**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? What is the process for extensions?	The CNSC should clarify who Is responsible for end-of-certification management and should further clarify the expectations of licensees versus manufacturers.	**MAJOR**	Undue financial and administrative burden.
13.	**2.4**	As written, the recertification process does not address current issues with manufacturers, outdated contacts and responsibility for design.	This is another agenda item for a stakeholder's workshop. Some suggestions for consideration include : - The re-certification process should be re-defined for cases when the manufacturer is unavailable, 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	**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.

			years ago. CNSC should be responsible for maintaining a contact list. - Users are not experts on 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 could be made on a timeline to stop using the device. Licensees should not take responsibility for the design.		
14.	**2.4**	Expiry of certificates should be extended following notification to licensees.	The certificate expiry day should be extended six 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.	**2.4**	Certificate information should be more readily available.	This is another suggested agenda item for a workshop: - The website should be updated regularly (weekly) to ensure users know the status of the recertification process. The CNSC should provide licensees increased visibility regarding the status of renewals prior to expiry.	*Request for Clarification*	Any delays in the process can impact licensees so they could have invalid equipment.
16.	**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. The survey process suggested earlier should start at this point.	**MAJOR**	Undue financial and administrative burden.
17.	**3**	This section requires supporting documentation to specify "which section of the application form the information pertains."	When preparing an application package, ensure 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	**MAJOR**	This requirement 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

		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 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.	specify on the application form the supporting documentation being references. The International System of Units (SI) should be used throughout the application.		documentation and provide cross-reference on approved documentation, or developing a stand-alone cross-reference matrix. By providing the documents references on the application form, the application form becomes the cross-reference document.
18.	**3.1**	Clarify amendment conditions.	The conditions that require amendments of the certificate should be indicated.	*Request for Clarification*	
19.	**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.	**3.2 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 EQ or between EQ and 10EQ.	*Request for Clarification*	
21.	**3.3 C**	Additional clarity regarding no changes to equipment for renewals See comment on section 3.2	Same comment regarding no change for renewals.	*Request for Clarification*	

22.	**3.3, 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 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.	This is another item for discussion during a workshop. Industry suggests revising it to read, the "expected lifetime of use of the equipment allowed by the design, as applicable."	**MAJOR**	The requirement to provide a design lifetime will result in significant expense to licensees in cases where design lifetime of the device/prescribed equipment does not apply.
23.	**3.4 D4**	Additional clarity is 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?	Industry suggests the CNSC: 1. Suggest changing the last sentence in D4 to read, "Provide the procedure for source replacement, if applicable~~, and indicate if this can only be performed by the manufacturer~~." 2. Allow licensees with solid radiation protection program as deemed by the CNSC to service their 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.	*Request for Clarification*	
24.	**3.4 D5**	This section deals with transport of radioactive material. It seems to be related to devices which also act as the approved 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 also acts as the transport package	Clarify section D5 to specify 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 applicant.

		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.).			
25.	**3.4 D6**	This section 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 an 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.	**3.6 F3**	The requirement to "include a copy of the following documents, if applicable, to:...the United States Nuclear Regulatory Commission registration" 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?	The clarification of the intent and requirement of this section is another suggested agenda item for a CNSC workshop with industry.	*Request for Clarification*	