

February 27, 2017

NK21-CORR-00531-13443 NK29-CORR-00531-14001 NK37-CORR-00531-02735

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 REGDOC-1.4.1,
<u>Licence Application Guide: Class II Nuclear Facilities and Prescribed Equipment</u>

The purpose of this letter is to comment on this draft Regulatory Document, which instructs licensees on how to apply for licences related to Class II nuclear facilities and prescribed equipment.

Following a collaborative review of the document with our industry colleagues, Bruce Power has compiled a series of observations, suggestions and requests for clarification, which we have attached to this letter for your consideration.

Let me highlight two points from those comments:

- We appreciate the CNSC's efforts to include many suggestions in this draft REGDOC that were made during the comment period of REGDOC 1.1.3, Licence Application Guide: Licence to Operate a Nuclear Power Plant.
 Incorporating feedback from reviews of related documents has produced a more clearly-written guide for Class II licences than initial drafts for other REGDOCs.
- The Preface of this draft REGDOC includes the phrase, "Applicants are expected to review and consider guidance given in this document; should they choose not to follow it, they should explain how their chosen alternate approach would meet regulatory requirements." This is an area where feedback from earlier reviews has not been properly addressed and remains an ongoing source of significant concern since it puts an unreasonable onus on licensees to demonstrate not just how requirements are met, but also how guidance is met. 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.



Thank you again for allowing us the opportunity to share our thoughts on this draft document. If you require further information or have any questions regarding this submission, please contact Maury Burton, Manager, Nuclear Regulatory Affairs, at (519)361-2673, ext.15291, or maury.burton@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

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1.5 Terminology	Preface	General General Preface 6 th paragraph, 2 nd sentence	Document/ Excerpt of Section
What is meant by the opening phrase: "For the purpose of this guide"? Is this section to explain terms that are different from what may have been established in other glossaries (e.g. the CIINFR and REGDOC-3.6)?	Under Important note, indirect references are not automatically part of the licensing basis	We appreciate the CNSC's efforts to incorporate several suggestions in this draft REGDOC that were made during the comment period of <i>REGDOC 1.1.3</i> , <i>Licence Application Guide: Licence to Operate a Nuclear Power Plant.</i> The regulations list the information required to be submitted in a licence application. This REGDOC lists even more information without clear rationale. It is unreasonable to say, "Applicants are expected to review and consider guidance given in this document; should they choose not to follow it, they should explain how their chosen alternate approach would meet regulatory requirements."	Industry Issue
	Revise to say, "Important note: When directly referenced in a licence or in a licence application, this document is part of the licensing basis for a regulated facility or activity."	Remove additional requirements or provide clear justification as to their benefit. Revise to clearly and simply say, 'Applicants 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 licensee may put forward a case to demonstrate that the intent of a specification is addressed by other means and demonstrated with supportable evidence	Suggested Change (if applicable)
Clarification	MAJOR	MAJOR MAJOR	Major Comment/ request for clarification
	Cascading references are not included in the licensing basis. As written, the note is not aligned with INFO 0795 and could cause confusion.	Incorporating feedback from reviews of related REGDOCs has produced a more clearly-written guide for Class II facilities and prescribed equipment than initial drafts for other REGDOCs. Additional requirements increase regulatory burden and cost for licensees without a clear, compensatory benefit. This is an area where feedback from earlier reviews has not been properly addressed and remains an ongoing source of significant concern. A similar statement appears in all REGDOCs and puts an unreasonable onus on licensees to demonstrate not just how requirements are met, but also how guidance is met. Guidance is required to meet guidance. If the licensee is required to meet guidance criteria (even by other means), then it is a requirement, not guidance.	Impact on Industry, if MAJOR Comment

Excerpt of Section	Suggested Change (if applicable)	Major Comment/ request for clarification
A.1.8 Submitting The following sentences are unnecessarily prescriptive: "A.1.8 Applicant or licensee representative Provide the name and title of the person who submitted the application on behalf of the applicant. This person should have authority to act on behalf of the applicant" Licensee's existing communication protocols adequately govern how applications are submitted.	nt. of	
2.2 Amending a Why is this wording in this section different than GNSCR section 6? This section is missing subsection 6(a) and changes the wording to subsection 6(c). Different wording for the same requirements is unnecessary and will cause confusion.	Don't paraphrase existing regulatory requirements, it is advantageous for applicants to see the same wording across different REGDOCs when the requirement being expressed is meant to be the same. REGDOC-3.1.1 is a good example of using the same wording as in the regulations.	
2.5 Licence period What is the basis for time periods cited in the sentence, "Consolidated operating licences and operating licences are typically valid for a 10-year period. All other licences are typically valid for five years;"? Other jurisdictions have 20- and 40-year licences and/or licences granted for the life of the facility.	Licences should be granted for the life of a facility.	· ·
3. Completing an application A.1 through A.3 at each licensing phase" seems inconsistent with the intent of statements in: 1) Section 2.2 of this REGDOC (recognizing section 2.2 is for an amendment) which says: If information previously submitted to the CNSC as part of a licence application has not changed, the applicant can refer to: information submitted with previous applications 2) Point (b) under Section 5 of the General	justifies having to a new licensing phase justifies having to resubmit information that was previously provided OR delete this requirement n	nt nt

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| applicable to accelerators; can a licensee Wishing to | replace their Class II gamma irradiator go directly into | replace their Class II gamma irradiator go directly into | the commissioning phase if they plan on using their | the conning bridge it they plan on using their
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| replace their Class II gamma irradiator go directly into the commissioning phase if they plan on using their existing facility? A.1 Applicant Information Individual who is responsible for the licensed activity (applicant authority), doesn't seem to be stated | the commissioning phase if they plan on using their existing facility? A.1 Applicant The GNSCR 15b requirement, to identify an individual who is responsible for the licensed activity person (the applicant authority), doesn't seem to be stated A.1.8 is referring to the applicant authority, then | A.1 Applicant Information (applicant authority), doesn't seem to be stated A.1.8 is referring to the applicant authority, then | A.1 Applicant The GNSCR 15b requirement, to identify an individual who is responsible for the licensed activity person (the applicant authority), doesn't seem to be stated A.1.8 is referring to the applicant authority, then | A.1 Applicant The GNSCR 15b requirement, to identify an individual who is responsible for the licensed activity person (the applicant authority), doesn't seem to be stated A.1.8 is referring to the applicant authority, then
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*	Document/ Excerpt of Section	Industry Issue	Suggested Change (if applicable)	Major Comment/ request for clarification	Impact on Industry, if MAJOR Comment
14.	B.1.4 Design dose targets 6 th paragraph	It is unnecessary to state that not meeting regulatory requirements won't be accepted.	Delete the statement: "The CNSC will not accept dose targets greater than the dose limits for NEWs and members of the public as specified in section 13 of the Radiation Protection Regulations under any circumstance."	Clarification	
15.	Section B.2.5.2	 Industry seeks clarification regarding the intent of the last two bullets, which indicates radiation monitoring devices shall: produce audible and visible alarms when detecting abnormally high radiation dose rates. have alarm thresholds appropriate to each area being monitored so they are not activated by dose rates expected under normal operating conditions 	Align with Cli 15(6)	Clarification	
		FAGMs in the RCF are activated when the entrance door is opened and they are measuring expected dose rates. Licensees meet the requirement of the Class II Regulations (Section 15(6)). The wording in the bullets is not consistent with the Regulations.			
16.	D.1.3 Organizational management	Items from this section, highlighted below, are beyond the objectives of the NSCA and blur the distinction between requirements and guidance.	There needs to be clear delineation between requirements and guidance. There are several areas in this document where the delineation isn't clear.	MAJOR	Applicants need clear direction as to what is a regulatory requirement and what is guidance. It is inappropriate to mix the two in a manner that makes it difficult for an applicant to determine
		including: o management's accountability and responsibility for safety o developing a learning driven safety culture including encouragement of a questioning attitude, promotion of a "no-blame" environment, and willingness to change	The last two bullets, which have been highlighted for this note, should be clearly identified as guidance.		which is which.

#		17.	18.
Document/ Excerpt of Section		D.1.5 Reporting requirements	D.1.7 Control of records
Industry Issue	including balancing production pressure and safety and staff taking responsibility for their own safety	This is an example that supports comment #16. Industry's concerns with this section are: 1) The items listed for the procedure are from GNSCR 29(2), so the "should" statement ought to be a "shall." 2) There is inconsistency in language between what is written here and what is contained in the GNSCR passages from which it is drawn. For instance, if the 1st bullet under the policy section is drawn from GNSCR3(k), why would the CNSC not use those exact words? 3) The 3 rd bullet under the policy section is a clear example of a requirement and guidance being bundled together in a way that confuses which is which The need to keep a record is a requirement while the format is guidance. 4) Reference to GNSCR 27 isn't cited for the requirement to keep a record. 5) Reference to GNSCR 29(2) isn't cited for the	Why isn't GNSCR 27, Records and Reports, cited in the 1 st bullet, which reads: • "The applicant's commitment to maintain records including those specified under section 24 of the CNSC Radiation Protection Regulations and those specified in Section 21(1) of the Class II Nuclear Facilities and Prescribed Equipment Regulations."
Suggested Change (if applicable)		Separate or otherwise clarify which statements are guidance and which are citing regulatory requirements. Provide the basis when regulatory requirements are cited. It is noted this is done generally in App A, but it should be done for each requirement. Rewrite to say: "The policy should specify: the job title of the person responsible for filling the report – GNSCR 3(k) the occurrences or events that should be reported to the CNSC in accordance with section 29(1) of the General Nuclear Safety and Control Regulations – GNSCR 29(1) the requirement for keeping a record of the report – GNSCR 27 - and the format of the report – guidance The procedure shall require a description of – GNSCR 29(2):	
Major Comment/ request for clarification		MAJOR	Clarification
Impact on Industry, if MAJOR Comment		Applicants need clear direction as to what is regulatory requirement and what is guidance. It is inappropriate to mix the two in a manner that makes it difficult for an applicant to determine which is which. Also, if references in a REGDOC are drawn from specific GNSCR sections, the CNSC can avoid imprecise interpretations and potential confusion by reproducing the GNSCR language, which is already accepted and understood by licensees. Paraphrasing has the potential to confuse.	

19.	*
D.1.7 Control of records	Document/ Excerpt of Section
There are several examples in this section where regulatory requirements have been mixed with guidance, which again supports comment #16. It is difficult to separate requirements from guidance and the regulatory basis isn't cited.	Industry Issue
The procedure should identify the records to be kept, such as: • personnel records, including: - the names of the persons operating or servicing the prescribed equipment or handling nuclear substances - guidance the training received by each person working with or servicing the prescribed equipment or handling nuclear substances, including the date and subject of training - CIINFR 21(2)(b) • operating and performance records, including: - prescribed equipment workload - CIINFR 21(2)(a) - any other record required by operational and servicing procedures - guidance • facility and prescribed equipment records, including: - the results of radiation surveys required by the Regulations or the licence - CIINFR 21(6)?? - the inspections, verifications, and tests of the prescribed equipment - CIINFR 21(2)(c) the transfer of prescribed equipment, including the date of transfer, the licence number of the organization to whom the equipment was transferred, and the model and serial number of the equipment - CIINFR 21(2)(c) - the facility plans and drawings, and design specifications - guidance - the facility commissioning test procedures and test results - guidance	Suggested Change (if applicable)
MAJOR	Major Comment/ request for clarification
While we appreciate the CNSC's efforts to pull items together in a single document, it has resulted in occasionally burying new requirements within these guidelines and confusing guidance with requirements.	Impact on Industry, if MAJOR Comment

23.		22.	21.	20.		*
Section D.1.2		Appendix D: Licensed Activities	Appendix D: Licensed Activities	Appendix A: Licensing Expectations and Regulatory Requirement Cross-reference		Document/ Excerpt of Section
Clarify the exemption from certification for Class I licensees is still applicable (Cll 15.12)	Also, according to the table for a licence to operate a fixed installation—general, you only need to include "use" as a licensed activity if the check source is listed on the licence. If the check source isn't listed on the licence, do you need a licence?	 This table isn't clear. As currently written it: Doesn't include the construction phase Lists "Abandon" as an activity rather than a phase Lists "Service" as a phase rather than an activity 	The notes do not align with industry's current licences. Licensees are allowed to possess, use, service and store. Note 3 suggests licensees can only have "use" if check sources are included under this licence (not the case). Note 5 does not describe licensees' situation for "store." Also, it is confusing to have notes that aren't referenced in the table.	This appendix is very useful, but still more of a summary. It would be useful to have each specific regulatory requirement noted in the body of the guide.		Industry Issue
Align with CII 15.12		Update the table to address comments #21 and #22.	Clarify terminology used for licensed activities	Add specific regulatory requirements to the body of the guide to help differentiate between requirement and guidance.	 if applicable, the quality assurance program for the design and testing of experimental targets - guidance the list of laboratories, rooms and other locations designated for the use or storage of nuclear substances - guidance 	Suggested Change (if applicable)
Clarification		Clarification	Clarification	Clarification		Major Comment/ request for clarification
						Impact on Industry, if MAJOR Comment

26.	25.	24.	*
26. Glossary	25. Appendix F: Survey Meter Calibration	24. Section D.3.1	Document/ Excerpt of Section
Industry is pleased to see the Glossary definitions are consistent with REGDOC-3.6.and suggest these be italicised, or otherwise highlighted, in the written text to draw attention to REGDOC 3.6.	These "shalls" in this appendix ought to be "shoulds." Or, is this implied by stating these are expectations? Industry does not calibrate survey meters exactly as described here and alternative approaches may be just as acceptable.	Industry does not include "education" as a qualification requirement for RCF Authorized Users. This should not be specified.	Industry Issue
Highlight defined terms in the text of the document	Confirm that appendices are recommended practices by changing "shall" to "should."	Remove "education"	Suggested Change (if applicable)
Clarification	MAJOR	Clarification	Major Comment/ request for clarification
	Changing acceptable practices creates regulatory cost and burden with no improvement to safety.		Impact on Industry, if MAJOR Comment