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COMPLIANCE
Regulatory Affairs
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Mr. Brian Torrie
Director General, Regulatory Policy Directorate
Canadian Nuclear Safety Commission
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OTTAWA, Ontario K1P 5S9

Dear Mr. Torrie:

Canadian Nuclear Laboratories Comments on Draft REGDOC-1.4.1, Licence Application Guide: Class II Nuclear Facilities and Prescribed Equipment

Canadian Nuclear Laboratories (CNL) has reviewed the Draft REGDOC -1.4.1, Licence Application Guide: Class II Nuclear Facilities and Prescribed Equipment and has consulted with industry partners to produce a set of consolidated comments, which are presented in Attachment A.

In general we found that incorporating feedback from reviews of related REGDOCs has produced a more clearly-written licence application guide for Class II Nuclear Facilities and Prescribed Equipment.

The major themes of the consolidated comments are:

1. Wording should be consistent across all REGDOCs when the requirement being expressed is meant to be the same.
2. Wording for regulatory requirements should be exactly as written in the regulations to avoid imprecise interpretations and potential confusion.
3. There needs to be clear delineation between requirements and guidance.

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

Yours sincerely,

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Attachment A
Integrated Comments on Draft REGDOC-1.4.1, Licence Application Guide: Class II Nuclear Facilities and 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**	We appreciate the CNSC's efforts to incorporate several 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.		**Major**	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.
2.	**General**	The regulations list the information required to be submitted in a licence application. This REGDOC lists even more information without clear rationale.	Remove additional requirements or provide clear justification as to their benefit.	**Major**	Additional requirements increase regulatory burden and cost for licensees without a clear, compensatory benefit.
3.	**Preface 6th paragraph, 2nd sentence**	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."*	Revise to clearly and simply say, *'Applicants are expected to review and consider guidance.'*	**Major**	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 meant to be guidance. If the licensee is required to meet guidance criteria (even by other means), then it is a requirement, not guidance.

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4.	**Preface**	Under **Important note,** indirect references are not automatically part of the licensing basis.	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."	**Major**	Cascading references are not included in the licensing basis. As written, the note is not aligned with INFO 0795 and could cause confusion.
5.	**1.5 Terminology**	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)?		Clarification	
6.	**A.1.8 Submitting an application**	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.	Delete the first two sentences in section A.1.8.	Clarification	
7.	**2.2 Amending a licence**	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.	Do not 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.	**Major**	Paraphrasing existing regulatory requirements creates confusion since saying something differently implies something different is required.

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8.	**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.	**Major**	There are other mechanisms to ensure adequate regulatory review of licensee performance and to allow for public involvement other than artificial licence renewal periods.
9.	**3. Completing an application 3rd paragraph, 6th sentence**	The sentence, "*The applicant shall resubmit sections 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 listed in the current licence appendix* • *information submitted with previous applications* 2) Point (b) under Section 5 of the General Regulation, which says an *"application for the renewal of a licence shall contain … a statement identifying the changes in the information that was previously submitted."*	Clarify why moving to a new licensing phase justifies having to resubmit information that was previously provided OR delete this requirement.	**Major**	Unnecessary administrative burden.

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10.	**3. Completing an application Table 2, first note**	Industry seeks clarification on this note. Is the option to bypass the construction licensing phase only applicable to accelerators? Can a licensee wishing to replace their Class II gamma irradiator go directly into the commissioning phase if they plan on using their existing facility?	This should apply to Class II facilities with gamma irradiators as well.	Clarification	
11.	**A.1 Applicant information**	The GNSCR 15b requirement, to identify an individual who is responsible for the licensed activity (**applicant authority**), does not seem to be stated anywhere is this section (assuming section A.1.8 is referring to the GNSCR 15a person (the signing authority).)	Add the requirement to identify the GNSCR 15b person (the applicant authority) OR, if section A.1.8 is referring to the applicant authority, then add the requirement to identify the GNSCR 15a person (the signing authority).	Clarification	
12.	**A.2 Licenced activities and locations 1st sentence**	This needs to be limited to the activities associated with the application, not necessarily all of them (e.g. some activities might be covered by other licences).	Rewrite to say, 'Identify the activities associated with the application ~~applicant's operations~~ as they relate to the *Canadian Nuclear Safety Commission Cost Recovery Fees Regulations*.'	Clarification	
13.	**B.1.4 Design dose targets 4th paragraph**	Industry has concerns with the passage that reads: *"The guide G-129 recommends that doses should be at or below:* *• 1 mSv/yr for NEWs* *• 0.05 mSv/yr for non-NEW staff and members of the public* *Submit a cost-benefit analysis to justify any annual dose in excess of those recommended in guide G-129."*	Delete the requirement to submit cost benefit analysis when not meeting the guidance doses.	**Major**	Applicants should not have to submit cost benefit analysis to justify not meeting guidance dose targets. Justification of the adequacy of the ALARA program should be sufficient. Industry also notes under the Potential impacts and Implementation sections of the "Request for Information" from the CNSC that this REGDOC *"will not*

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		As per comments #2 and #3, having a requirement to justify not meeting guidance makes guidance the same as a requirement.			*impose additional burden on applicants"* and *"does not impose any new requirements."* The passage in B.1.4 challenges those statements.
14.	**B.1.4 Design dose targets 6th 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* 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	Align with CII 15(6)	Clarification	

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		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. • *the management's commitment to safety including:* ○ *management's accountability and responsibility for safety* ○ *developing a learning driven safety culture including encouragement of a questioning attitude, promotion of a "no-blame" environment, and willingness to change* ○ *promoting the value placed on safety culture including balancing production pressure and safety and staff taking responsibility for their own safety*	There needs to be clear delineation between requirements and guidance. There are several areas in this document where the delineation isn't clear. The last two bullets, which have been highlighted for this note, should be clearly identified as guidance.	**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 which is which.

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17.	**D.1.5 Reporting requirements**	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 3rd 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 procedural items.	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**	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.
18.	**D.1.7 Control of records**	Why isn't GNSCR 27, Records and Reports, cited in the 1st bullet, which reads: • *"The applicant's commitment to maintain records including those specified under section 24 of the CNSC*		Clarification	

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		Radiation Protection Regulations and those specified in Section 21(1) of the Class II Nuclear Facilities and Prescribed Equipment Regulations."			
19.	**D.1.7 Control of records**	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.	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 names and job categories of nuclear energy workers – RPR 24* – *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)*	**Major**	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.

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			– *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(4)* – *the facility plans and drawings, and design specifications – guidance* – *the facility commissioning test procedures and test results - 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*		

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			or storage of nuclear substances - guidance		
20.	**Appendix A: Licensing Expectations and Regulatory Requirement Cross-reference**	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.	Add specific regulatory requirements to the body of the guide to help differentiate between requirement and guidance.	Clarification	
21.	**Appendix D: Licensed Activities**	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 are not referenced in the table.	Clarify terminology used for licensed activities.	Clarification	
22.	**Appendix D: Licensed Activities**	This table is not clear. As currently written it: • Does not include the construction phase • Lists "Abandon" as an activity rather than a phase • Lists "Service" as a phase rather than an activity Also, according to the table for a licence to operate a fixed installation– general, the application only needs to include "use" as a licensed activity if the check source is listed on	Update the table to address comments #21 and #22.	Clarification	

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		the licence. If the check source is not listed on the licence, is the licence required?			
23.	**Section D.1.2**	Clarify the exemption from certification for Class I licensees is still applicable (CII 15.12).	Align with CII 15.12.	Clarification	
24.	**Section D.3.1**	Industry does not include "education" as a qualification requirement for RCF Authorized Users. This should not be specified.	Remove "education"	Clarification	
25.	**Appendix F: Survey Meter Calibration**	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.	Confirm that appendices are recommended practices by changing "shall" to "should."	**Major**	Changing acceptable practices creates regulatory cost and burden with no improvement to safety.
26.	**Glossary**	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.	Highlight defined terms in the text of the document.	Clarification	