2016 November 09

COMPLIANCE Regulatory Affairs 145-CNNO-16-0035-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 CNSC Draft REGDOC-3.1.2, Reporting Requirements for Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

The purpose of this letter is to provide comments on CNSC draft REGDOC-3.1.2, Reporting Requirements for Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills. The initial comments and feedback were developed in consultation with industry partners, Ontario Power Generation, Bruce Power, New Brunswick Power, McMaster University, Areva and Cameco.

CNL's version of the combined comments on the draft REGDOC is provided in Attachment A. The major themes of the comments are:

- In some cases all the reporting required will be addressed in the initial report suggest CNSC should review Table A to change where required the column Full Report in the table to: "Within 60 days after becoming aware of the event if required"
- 2. The draft REGDOC calls for an annual report as described here which is not required given that the CNSC staff are already provided all the information separately and therefore adds significant administrative burden with no benefit
- 3. No Impact statement was provided as required by the cabinet directive on regulatory management
- 4. REGDOC 3.1.2 should address all reporting requirements and should supersede all other current reporting requirements in the current regulatory framework

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If you have any questions regarding this submission, please contact me as indicated below.

Yours sincerely,

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SK/CvdW/mj

Attachment (1)

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Attachment A

Canadian Nuclear Laboratories comments on draft REGDOC-3.1.2, Reporting Requirements for Non-Power Reactor Class I Nuclear Facilities & Uranium Mines and Mills

#	Document section / excerpt of section	Industry issue	Suggested change (if applicable)	Major Comment/ request for clarification ¹	Impact on industry if major comment
1.	General	The Annual Report contents as outlined in Section 3, are very similar to that required for an Application, and add significant burden. This is contrary to the direction to reduce unnecessary burden. REGDOC-3.1.1 was developed to provide performance data necessary for the regulatory oversight while making use of existing practices. Reports should be limited to performance reporting. No impact statement has been provided.	Remove requirements for future Plan, changes, and facility descriptions.	Major	As written, this requires licensees to provide essentially a new application for each facility each year. This is a significant burden on licensees, with no improvement to safety or performance. Modifications to systems, documents etc. are provided to the regulator through other mechanisms, including the LCH notification process. Duplicative reporting adds significant burden in racking for no improvement in safety. Once established, industry expects the content requirements to remain unchanged, except though the REGDOC revision process. This will ensure consistency

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					between licensees and regulatory certainty.
2.	General	In some cases, all the reporting required will be addressed in the initial report; however, if a full report is required, it should be submitted 60 days following the submission of the preliminary report.	Suggested change: CNSC should review Table A to change where required the column Full Report in the table to "Within 60 days (if required)".	Major	Adds administrative burden with no benefit
3.	General	Quoting sections from many other regulatory documents and acts adds confusion to the document. The reader must carefully review all of the referenced documents to understand the intent of each section and sections from Appendix A Table A. Since the sections are often partially quoted, they will be interpreted differently by different readers and increases the likelihood that information is taken out of context.		Clarification	
4.	Preface, Pg i,	Guidance is meant to be guidance. If the licensee is required to meet guidance	Change to: "Licensees are expected to review and consider guidance.	Major	Licensees note that a simila statement appears in all REGDOCs. It puts an

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	Sixth paragraph: "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. An applicant or licensee may put forward a case to demonstrate that the intent of a requirement is addressed by other means and demonstrated with supportable evidence."	criteria (even by other means), then it is a requirement, not guidance.			unreasonable onus on licensees to demonstrate not just how requirements are met, but also how guidance is met.
5.	Preface	It is not clear how CNSC staff might use this document for assessment of new licence applications or how evaluations of specific problems or data during the review of applications will be conducted.	Delete.	Clarification	
6.	Table of Contents	Appendix A does not sufficiently reflect the hierarchical structure of Table A.	Expand Table of contents – Appendix A accordingly.	Clarification	
7.	Scope, Pg 1.	These reporting requirements go beyond just incorporating	Suggest using the wording from REGDOC-3.1.1 "incorporates and expands upon the	Clarification	

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	First paragraph: "This regulatory document incorporates and clarifies requirements found in the NSCA and the regulations"	and clarifying the existing requirements.	requirements" which is more accurate.		
8.	1.1 para 2	The requirement to report is unclear as to safety significance.	Requirement to report situations or events of higher safety significance	Clarification	
9.	1.3 bullet 3	Missing provisions in the Act for extension of submission time for reports.	Add "section 44 of the NSCA and section 29, 30 and 31 of the GNSCR contain provisions where the submission time for full reports can be extended by the terms of a licence condition."	Clarification	
10.	1.3 subsection 7.5(4) of the Nuclear Security Regulations states that "every licensee shall provide a copy of the written record, together with a statement of actions taken as a result of the [yearly] threat and risk assessment, to the Commission within 60 days after completion of the assessment"; in addition, sections 21 and 36 and subsection 44(2) stipulate other situations requiring notification.	Section 7.3 of the Nuclear Security Regulations indicates that "Sections 7.4 – 38 apply in respect of high-security sites." While Appendix A Table A makes reference to applicability, the scope section does not limit how this regulation is applied. In effect the NSR are paraphrased in this document which could	Remove the bullet from section 1.3 or add disclaimer on limitation of scope for the reference.	Major	If not modified, sections of the Nuclear Security Regulations can be applied to facilities and sites they were not intended for.

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		allow the requirement to be taken out of context.			
11.	Page 2 last 2 bullets	Text is irrelevant to this document.	Delete.	Major	Unnecessary administrative burden since this document is specific to Class I facilities
12.	Section 2, Guidance paragraph 3: In addition to the list above, the licensee may be required to file facility-specific reports, as described in their licence conditions handbook (LCH).	Some Industry LCHs contain a comprehensive table of situations, events or dangerous occurrences which require reporting by the licensee to the CNSC. If the table will not be replaced with this REGDOC in the LCH, then it does not seem that this REGDOC is necessary.	REGDOC 3.1.2 should supersede all other current reporting requirements in the current regulatory framework.	Major	Duplicated burden and unnecessary inconsistency between licensees
13.	2, p. 3, 1a	Terminology revision	Replace "an event or a situation with "an event or a situation as set out in Table A of Appendix A"."	Clarification	
14.	2, p. 4, para. 1	Terminology revision.	Replace "licensing specialist" with "project officer".	Clarification	
15.	2, p. 4, last bullet	Terminology revision.	Replace "an unplanned spill or release" with an "unplanned spill or release that is reportable	Clarification	

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			under provincial or federal legislation".		
16.	Page 4 S2	Why 'immediate reporting' is applied to all types of events?	Replace by reporting timelines by safety significance, same as in REGDOC 3.1.1 (section 2 – items 1-8, and 10).	Major	Administrative burden on licensee and regulator due to immediate response requirement.
17.	2, p. 5	Public disclosure: some reportable events have no public interest element and should not be considered as an "input to their public disclosure protocol".	Delete paragraph, licensees should adhere to their own public information programs	Major	Administrative burden on licensee with no benefit .Expanding on licensing requirements
18.	2, p. 5 5th full para.	Public disclosure should not be required until after it is determined that an event is reportable.	Revise to require to defer any public disclosure as per the licensee public disclosure protocol.	Major	Administrative burden on licensee with no benefit .Expanding on licensing requirements
19.	2, p. 5 Last para.	CNSC's Guidance Document on Confidential Filings applies to licensing applications and related proceedings for which decisions authorized by the NSCA are made by the Commission and has no application to the reporting of other events.	Revise to clarify that not all reportable information is subject to a licensee's public disclosure protocol.	Major	

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20.	Section 2: Reporting Requirements, Pg 5 Final paragraph: "Each report should be unclassified and should not contain any proprietary business information so it can be made available to the public upon request. Information should be considered public for the most part. Any information considered classified, protected, proprietary or personal should be submitted in accordance with the CNSC's Guidance Document on Confidential Filings." AND Page 5 S3 Item 1	The Guidance Document on Confidential Filings only applies to submissions made to formal Commission hearings for licensing decisions. It doesn't apply to reports generated by the REGDOC.	Delete this reference.	Major	As written, this requirement may lead to an inadvertent public disclosure of classified, protected, proprietary or personal information. Creates confusion to refer to a document which has no application.
21.	S2 guidance	Significance level is not addressed, facility specific reports are unclear (scheduled/non-scheduled/annual/quarterly).	Make consistent with guidance from REGDOC 3.1.1.	Major	Inconsistency given the risk profile of the facility with existing LCH/licence/REGDOC 3.1.1
22.	Page 5 Para 2	"Licensees using this option" This is redundant - the requirements are captured in	Delete entire paragraph.	Major	Accountability should remain with the licensee

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		LCH/Licence. The REGDOC should specify the requirement which the licensee will define how compliance is achieved.			
23.	Page 5 Para 6	"If, after further investigation"	Delete sentence, and include "If, after further investigation, the licensee believes that the event was not reportable, the licensee will notify CNSC staff."	Major	Accountability should remain with the licensee
24.	Page 5 Para 7	"If the licensee determines"	Change the first sentence "a full report may not be necessary to" a full report is not necessary" Delete second sentence".	Clarification	
25.	2, p. 6, Guidance, para. 3	This paragraph applies to all notifications and reports and not just the annual compliance monitoring report.	Move to Section 2 Reporting Requirements.	Clarification	
26.	Page 6, Guidance	It is unclear whether Annual Reports provided by a licensee pursuant to REGDOC 3.1.1. can take the place of content required by draft REGDOC 3.1.2. For example, for licensees with multiple facilities under separate licences at a site, it is unclear whether the licensee	Revise the Guidance on page 6 to state "for sites with multiple facilities (under the same or different CNSC licences) or a licensee possessing a licence with multiple locations, the licensee may submit the information through other required reports applicable to	Major	Providing duplicative information serves no benefit, and increases the reporting burden placed on licensees. It may also lead to a configuration management issue.

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		can prepare a single report, for example a single Annual Environmental Report.	the SCA, or in a single consolidated annual compliance report.		
27.	Page 5 Section 3	"The licensee shall submit an annual compliance monitoring report" The licensee is provided with the flexibility of providing compliance monitoring in a format and frequency other than the annual report. (i.e. existing quarterly reports from the licensee may satisfy the requirement for compliance monitoring).	"Licensee shall submit compliance monitoring report(s)"	Clarification	
28.	Page 5 S3 Item 2	Sufficient details to provide CNSC staff with information to verify that licensees are meeting their regulatory requirements and are operating safely.	Further discussions between industry and CNSC staff are required to clarify requirements.	Major	Unclear requirements leading to inconsistencies in reporting
29.	Page 6 S3 Para after item 3	Each annual compliance monitoring report shall act as a stand-alone document. If information from any previous annual compliance monitoring	Delete the second sentence.	Clarification	

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		report is needed <u>f</u> or			
		completeness, the licensee			
		shall repeat it to the			
		appropriate level of detail.			
30.	Page 6	The licensee may be required	Delete the paragraph.	Clarification	
	Guidance	to submit additional			
	second and third para	compliance monitoring reports			
		(e.g., quarterly, monthly or			
		licensee-specific) as described			
		in their licence or LCH. For			
		example, other compliance			
		monitoring reports may be			
		required for new facilities or in			
		situations where additional			
		reporting is necessary (such as			
		following a reportable event).			
		Flexibility is allowed for			
		integrated/harmonized			
		reporting. For example, if a			
		licensee is required to submit			
		reports to regulatory bodies			
		other than the CNSC, then			
		sending a copy of the report to			
		the CNSC is acceptable			
		provided the copied report			
		contains all reporting			
		information required by the			

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		CNSC. This option allows the licensee to avoid duplication of effort and to minimize administrative burden.			
31.	Page 6 4	Current licensees have differing reporting requirements in their LCHs. This REGDOC should supersede all the requirements in the LCHs ".	This REGDOC should supersede all the requirements in the LCHs.	Major	Duplicated burden and unnecessary inconsistency between licensees
32.	Page 6 4.1	A preliminary report or immediate notification of a situation or event, or of a dangerous occurrence as stipulated in section 35 of the PTNSR 2015, shall contain the following information: (1-4)	Add to the end of the first paragraph the following"as available."	Clarification	
33.	Section 4.2: Full reports, Pg 7 Under Guidance: "Licensees should include information that allows the report to be reviewed efficiently; for example: - identify updates and new or additional information from that provided previously	Bullets 1 and 3 were determined to be unnecessary during the development of REGDOC-3.1.1.	Remove bullets 1 and 3.	Major	As written, the inclusion of these bullets is inconsistent with REGDOC-3.1.1 and could generate regulatory confusion/uncertainty.

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	 identify any further missing information and the date that the missing information will be provided to the CNSC Identify the target completion date for each action that the licensee proposes to take to re-establish normal operations or to prevent a recurrence." 				
34.	Page 7 4.2 item 11	Any actions that the licensee has taken to inform the public and target audience about the situation or event.	Delete, this action is already achieved through the public information program of the licensee on an as needed basis. Not all the reportable events are required to be disclosed to the public.	Major	If not modified, this will set requirements in excess of the Public Information and Disclosure RD/GD document.
35.	Section 4.3: Action level reports, Pg. 8	Action Level Reports are discussed in Section 4.3 and Table A #13.	Delete the subsection.	Clarification	
36.	Page 9	"Immediate reporting" should not be applied to all types of events. Events with low safety significance should not require immediate reporting.	Replace by reporting timelines by safety significance, same as in REGDOC 3.1.1 (section 2 – items 1-8, and 10).	Major	Administrative burden on licensee and regulator due to immediate response requirement.

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37.	Appendix A Table A: A.1	Additional guidance is provided in REGDOC-3.1.1 on a non-compliance situation. This should be included. This section of the REGDOC should be consistent with REGDOC 3.1.1.	Add as 1.a: Guidance Regulations made pursuant to the NSCA, orders of the CNSC, a designated officer or an inspector, and licence conditions have their origins from the NSCA. Therefore, it is understood that a contravention of a regulation made pursuant to the NSCA, of an order or of a licence condition is a contravention of the NSCA.	Clarification	
38.	Appendix A	Requirements of GNSCR 9(4) missing.	Add as 1.b: General Nuclear Safety and Control Regulations (GNSCR): 9. (4) Every person who carries on an activity without a licence in accordance with subsection (1) or (2) shall immediately notify the Commission of that fact.	Clarification	
39.	Table A	Timing for preliminary report does not distinguish between	Specify: High safety significance situations or events require an immediate preliminary report.	Major	Adds administrative burden with no benefit

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		significant and non-significant events.	Where reporting of lower significance events is required allow for 5 day reporting.		
40.	No. 1	27(b) is immediate but it should depend on significance level. The timing of reporting should be commensurate with the risk.	Change to: immediate for significant or 5 business day for low significant levels. Full report due in 60 days (if required) Requirements should be different for 27(b) and 29(1).	Major	Adds administrative burden with no benefit
41.	Appendix A Table A section 3a) A contingency plan may include: i. any situation or event (flood, fires, earthquakes, etc.) that requires the implementation of an emergency plan, or the use of any abnormal operating procedures or emergency operating procedures, or the mobilization of resources in response to the situation or event	Subsection i. indicates any situation or event, however subsection ii. characterizes the same examples as "unusual external events".	Use consistent terminology "unusual external events" throughout.	Clarification	

#	Document section / excerpt of section	Industry issue	Suggested change (if applicable)	Major Comment/ request for clarification ¹	Impact on industry if major comment
	ii. the occurrence of any unusual external events (flood, fires, earthquakes, etc.) at or near the site that require further inspection to verify its effect on any structures, systems and components.				
42.	No. 3 a)	Timing of reports should depend on significance level of situation or event.	Change to: immediate for significant or 5 business day for low significant levels. Full report due in 60 days (if required) Requirements should be different for 27(b) and 29(1).	Major	Adds administrative burden with no benefit
43.	No.3a)	In cases of some external events there may no additional information available or required.	Suggested change: Change full report in the table to "Within 60 days after becoming aware of the event if required".	Major	Adds administrative burden with no benefit
44.	No. 3 b)	Timing of reports should depend on significance level of situation or event.	Change to: immediate for significant or 5 business day for low significant levels. Full report due in 60 days (if required)	Major	Adds administrative burden with no benefit

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			Requirements should be different for 27(b) and 29(1)		
45.	No. 4	60 days is required for full report.	Add "if required".	Clarification	
46.	Table A: B.4	Add in geographical limits for site boundary.	Guidance Any death within the exclusion zone or the licensed area (whichever is larger) or as defined in the LCH, regardless of cause, or any death resulting from an injury or illness, regardless of time intervening between injury or illness and death, will be reported.	Clarification	
47.	No. 5	60 days is required for full report.	Add "if required".	Clarification	
48.	Table A, No. 8	Guidance for s. 29(1)(f) of GNSCR: lists enumerated events that may have no serious adverse effects.	Remove enumerated list.	Major	If intention is to require reporting of all enumerated events then it would create administrative burden; if the intention is to only require reporting of events with a serious adverse effect then it creates uncertainty.
49.	No. 9	Title of the section includes Class II equipment.	Is it applicable?	Clarification	

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50.	No. 9 a) and b)	60 days is required for full report.	Add "if required".	Clarification	
51.	No. 9 c)	Concerns Class II equipment.	Is it applicable?	Clarification	
52.	Table A: D.9	In many cases, these sources or devices are held under a separate licence and may not be included under the Class I or UMM licence. Reporting for devices must be done in accordance with the appropriate licence and Nuclear Substance and Radiation Devices Regulations.	Clarify that these reporting requirements only apply if these are held under the Class I or UMM licence.	Major	Adds administrative burden with no benefit
53.	Table A: D.10	No reference to an appropriate clause in the NSCA or Regulations is provided. This should Reference NSCA 24(5).	Add: Applicable section(s) of the NSCA or regulations made under the NSCA: NSCA: 24. (5) A licence may contain any term or condition that the Commission considers necessary for the purposes of this Act, including a condition that the applicant provide a financial guarantee in a form that is acceptable to the Commission.	Clarification	

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54.	Appendix A Table A section 11 Specific Reporting Provisions The licensee shall report on all other situations or events that are not otherwise specified in this document but can be reasonably assumed to be of regulatory interest, including notifications and situation or event reports to other regulatory agencies within the scope covered by the objects of the Commission (see section 9 of the NSCA).	This section provides no useful information but acts as a catch all. The table could in consist of only section 11 and cover everything. Additionally, Section 24(5) of the NSCA, this section on Specific reporting provisions, and the Guidance paragraph do not seem to be related.	Change wording to add: Subject to the opinion of the licensee, the licensee shall report on all other situations or events that are not otherwise specified in this document but can be reasonably assumed to be of regulatory interest, including notifications and situation or event reports to other regulatory agencies within the scope covered by the objects of the Commission (see section 9 of the NSCA).	Major	Adds administrative burden and uncertainty with no benefit
55.	No. 10, 11	Timing of reports should depend on significance level of situation or event.	Change to: immediate for significant or 5 business day for low significant levels. Full report due in 60 days (if required) Requirements should be different for 27(b) and 29(1).	Major	Adds administrative burden with no benefit
56.	12b	The guidance has a typographic error. Refers to a section that does not exist in this table.	Fix error.	Clarification	

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57.	Appendix A Table A section 13a and 13 b for example: Licence condition: The licensee shall implement and maintain an environmental protection program, which includes a set of action levels. When the licensee becomes aware that an action level has been reached, the licensee shall notify the Commission within X days. Note: In the specific licence condition, "X days" will be replaced with a specified period.	If a facility does not have this condition written in their LCH in this manner, does the licensee have to follow the LCH condition on EPP and this REGDOC? This example also exists in table section 13a and all of 13b.	Remove last paragraph of 13.a and all of 13.b	Major	This REGDOC is inappropriately setting license conditions.
58.	Preamble to No. 13	No requirements are identified and adds no value	Remove the preamble to section 13 a) and 13 b)	Major	Adds no value and complicates the table.
59.	Table A, No. 13a	Reporting times for uranium mines and mills action levels are set out in code of practice.	Add the following guidance: Uranium mines and mills licensees are to follow the reporting procedures referenced in the environmental protection program code of practice if an action level is reached (refer to UMMR 4(2) for the contents of a proposed code of practice)"	Major	Leads to uncertainty in requirements
60.	Table A: E.14	REGDOC-3.1.1 App A 22 clarifies that a single missed	Add to Guidance:	Clarification	

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		sample where justified is not	For item b), a failure to collect		
		considered failure to monitor.	an individual sample where		
			justified is not considered		
			failure to monitor. For the		
			purpose of event reporting,		
			failure to monitor is more		
			appropriately considered in the		
			context of programmatic failure.		
61.	Table A: E.14	Reporting time should be	Change to: immediate for	Major	Adds administrative burden
		based on significance level of	significant or 5 business day for	·	with no benefit
		the environmental impact.	low significant levels. Full		
			report due in 60 days (if		
			required).		
62.	Table A: E.15	In many cases, these sources	Clarify that these reporting	Major	Duplication of reporting
		or devices are held under a	requirements only apply if these	,	requirements
		separate licence and may not	are held under the Class I or		·
		be included under the Class I	UMM licence.		
		or UMM licence. Reporting for			
		devices must be done in			
		accordance with the			
		appropriate licence and			
		Nuclear Substance and			
		Radiation Devices Regulations.			
63.	No. 15	A requirement for Class II	Delete requirement.	Major	Duplication of reporting
		Facilities should not be			requirements
		included in this document.			· .

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64.	No. 16	60 days is required for full report.	Add "if required".	Clarification	
65.	Table A: F.16 and 17	Reporting is not required where there is not a hazard to health safety and security of persons as found in REGDOC-3.1.1 A27.	Add to guidance: Immediate reporting is required only where a hazard to the health, safety and security of persons and the environment or to the security of the nuclear facility exists.	Major	Adds administrative burden with no benefit
66.	No. 17	Timing of reports should depend on significance level of situation or event.	Change to: immediate for significant or 5 business day for low significant levels. Full report due in 60 days (if required).	Major	Adds administrative burden with no benefit
67.	Appendix B	The guidance is too detailed For example: Significant future activities or financial guarantee reporting should not be included in the Annual Compliance Monitoring report.	Remove the section from the Appendix. Make it more general and consistent with licensees LCH requirements.	Major	Adds administrative burden with no benefit
68.	Appendix B	The guidance is too detailed See general comment on the need for an annual report.		Major	Adds significant administrative burden with no benefit
69.	Appendix B, p. 42	Annual Compliance Monitoring Report sample includes analyses of five year trends in	Remove reference to five year trend analysis.	Major	It would create significant costs to perform the in-depth analysis for effluent and

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		effluent and environmental monitoring results annually. This is provided in the EPRs. See general comment on the need for an annual report.			environmental trends carried out in accordance with CSA N288 series on an annual basis.
70.	Glossary	The definition of 'safety significance' conflicts with the definition in the International Atomic Energy Agency's (IAEA's) document SF-1, Fundamental Safety Principles [IAEA Safety Standards Series, 2006] where the term is restricted to radiation risks. The term is only used once in the REGDOC on p. 4.	Delete definition of 'safety significance' and replace with 'risk' on p. 4. or remove reference to the IAEA SF-1.	Clarification	