CD# N-CORR-00531-18298

OPG Comments on Draft REGDOC 3.1.2 Reporting Requirements for Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills

The purpose of this email is to provide Ontario Power Generation's (OPG) comments on draft REGDOC 3.1.2 Reporting Requirements for Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills.

OPG appreciates the opportunity to comment on the draft document, which we reviewed in conjunction with other licensees.

OPG's general comments are that:

- i. No impact statement was provided, as required by the cabinet directive on regulatory management.
- ii. REGDOC 3.1.2 should address all reporting requirements, and should supersede all other current reporting requirements in the current regulatory framework.
- iii. The draft REGDOC calls for an annual report as described here, which industry believes is not required given that the CNSC are already provided all the information separately. Therefore, this adds significant administrative burden with no benefit. OPG sees the need for further discussions with the CNSC to clarify requirements.

OPG's detailed comments are contained in the attachments to this email.

If you have any questions or concerns, please contact Ms. Leslie Mitchell, Manager, Regulatory Programs, Strategy and Support, at (905) 839-6746 ext 5198, or by e-mail at <a href="mailto:leslie.j.mitchell@opg.com<mailto:leslie.j.mitchell@opg.com">leslie.j.mitchell@opg.com.

Doug Coleman Manager, Darlington Regulatory Affairs

On behalf of: Robin Manley

VP, Nuclear Regulatory Affairs and Stakeholder Relations Ontario Power Generation

	Document section / excerpt of section	Industry issue	Suggested change (if applicable)	Major Comment/ request for clarification	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 regulatory oversight while making use of existing practices. Reports should be limited to performance reporting. No impact statement has been provided.	Industry would be happy to work with other stakeholders and CNSC to identify appropriate reporting requirements. The Annual Report should be reconsidered to focus on performance. Once established, industry expects the content requirements to remain unchanged, except though revision of the REGDOC process. 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 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 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 after becoming aware of the event (if required)"	Major	Adds administrative burden with no benefit, and is inconsistent with the practice of REGDOC-3.1.1.

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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,Page i 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	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.	Change to: "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."	Major	Licensees note that a similar statement appears in all REGDOCs. It puts an unreasonable onus on licensees to demonstrate not just how requirements are met, but also how guidance is met.

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	supportable evidence."				
5.	Preface	It is not clear how CNSC staff might use this document for the 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, Page 1. First paragraph: "This regulatory document incorporates and clarifies requirements found in the NSCA and the regulations"	These reporting requirements go beyond just incorporating and clarifying the existing requirements.	Suggest using the wording from REGDOC-3.1.1: "incorporates and expands upon the requirements" which is more accurate.	Clarification	
8.	Page 1, 1.1 Purpose, paragraph 2.	The requirement to report is unclear as to safety significance.	Requirement to report situations or events of higher safety significance	Clarification	
9.	Page 1, 1.3 Relevant Legislation, 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	

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10.	Page 3, 1.3 Relevant Legislation, last bullet. 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 allow the requirement to be taken out of context.	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.
11.	Page 2, 1.3 Relevant Legislation, last 2 bullets.	Text is irrelevant to this document.	Delete	Major	Unnecessary administrative burden since this document is specific to Class I facilities.

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12.	Page 4, Section 2 Reporting requirements, 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 contains 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 supercede all other current reporting requirements in the current regulatory framework.	Major	Duplicated burden and unnecessary inconsistency between licensees.
13.	Page 3, Section 2, 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.	Page 4, Section 2, Guidance paragraph 1.	Terminology revision.	Replace "licensing specialist " with "project officer"	Clarification	
15.	Page 4, last bullet.	Terminology revision.	Replace "an unplanned spill or release" with an "unplanned spill or release that is reportable under provincial or federal legislation."	Clarification	
16.	Page 4, Section 2	"Immediate reporting" should not be applied to all types of events. Suggested change would align with REGDOC 3.1.1 (section 2 – items 1-8, and 10).	Replace with reporting timelines by safety significance, similar to those provided in REGDOC 3.1.1, i.e., Immediate for significant or 5 business day for low significant levels.	Major	Administrative burden on licensee and regulator due to immediate response requirement.

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17.	Page 5, Section 2, second last paragraph, re public disclosure.	Public disclosure: some reportable events have no public interest element and should not be considered as an "input to their public disclosure protocol". Public disclosure should not be required until after it is determined that an event is reportable.	Delete paragraph. Licensees should adhere to their own public information programs. Alternatively, revise to defer any public disclosure to the licensee public disclosure protocol.	Major	Administrative burden on licensee with no benefit. This requirement is expanding on licensing requirements.
18.	Page 5, Section 2, 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." Applies also to Page 5, Section 3 Item 1,	The Guidance Document on Confidential Filings only applies to submissions made to formal Commission hearings for licensing decisions. It does not apply to reports generated by the REGDOC.	Delete this reference, and replace the last sentence with: "Any information consideredclassified should be submitted in accordance with the licensee security and information management protocols."	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.

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19.	Page 4 and 5, Section 2, Guidance.	Significance level for unscheduled reporting is not addressed, and requirements for facility specific scheduled reports are unclear	Make consistent with guidance from REGDOC 3.1.1	Major	There is inconsistency with existing LCH/licence, and with the published REGDOC 3.1.1. This is especially problematic given the risk profile of the facility.
20.	Page 5, Paragraph 2.	"Licensees using this option" Redundant - the requirements from this REGDOC should be captured in LCH/Licence. The REGDOC should specify the requirement which the licensee will define how compliance is achieved.	Delete entire paragraph.	Major	Accountability for determining how requirements are met should remain with the licensee.
21.	Page 5, Paragraph 6.	"If, after further investigation"	Delete sentence, and replace with: "If, after further investigation, the licensee believes that the event was not reportable, the licensee will notify CNSC staff."	Major	Accountability for determining reportability should clearly remain with the licensee.
22.	Page 5, Paragraph 7.	"If the licensee determines"	Change the phrase in the first sentence "a full report may not be necessary" to: "a full report is not necessary." Delete the second sentence.	Clarification	
23.	Page 6, Guidance, Paragraph 3.	This paragraph applies to all notifications and reports, not just the Annual Compliance Monitoring Report.	Move this paragraph to Section 2, Reporting Requirements.	Clarification	

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24.	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 can prepare a single report, for example a single Annual Environmental Report.	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 the SCA, or in a single consolidated annual compliance report.	Major	Providing duplicative information serves no benefit, and increases the reporting burden placed on licensees. It may also lead to a configuration management issue.
25.	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	
26.	Page 5, Section 3, 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 the CNSC are required to clarify requirements.	Major	Unclear requirements will lead to inconsistencies in reporting.

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27.	Page 6 Section 3, paragraph after item 3. Each annual compliance monitoring report shall act as a stand-alone document. If information from any previous annual compliance monitoring report is needed for completeness, the licensee shall repeat it to the appropriate level of detail.	The second sentence is redundant if the report is to be a standalone document.	Delete the second sentence.	Clarification	
28.	Page 6, Guidance, second and third paragraph. (re other required compliance reporting).	The suggested flexibility is not applicable to annual reporting.	Delete the paragraph.	Clarification	
29.	Page 6, Section 4.	Licensees currently have differing reporting requirements in their LCHs. This REGOC should supersede all the requirements in the LCHs for unscheduled reporting.	This REGOC should supersede all the requirements in the LCHs.	Major	Duplicated burden and unnecessary inconsistency between licensees.
30.	Page 6, Section 4.1	Not all information may be available at the time of a preliminary report or immediate notification.	Add to the end of the first paragraph "the following information as available."	Clarification	

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31.	Page 7, Section 4.2, Full reports. 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 - 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."	Bullets 1 and 3 were determined to be unnecessary during the development of REGDOC-3.1.1. The full report replaces the preliminary report in its entirety.	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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32.	Page 7, Section 4.2, item 11.	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.	Delete. "any actions that the licensee has taken to inform the public and target audience about the situation or event."	Major	If not modified, this will set requirements in excess of the Public Information and Disclosure RD/GD document.
33.	Page 8, Section 4.3: Action level reports.	Action Level Reports are discussed in Section 4.3 and Table A item 13.	Delete the subsection.	Clarification	
34.	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.
35.	Appendix A Table A: A.1	Additional guidance is provided in REGDOC-3.1.1 on a non-compliance situation. This wording should be included here. 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	

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36.	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	
37.	Table A	Timing for preliminary report does not distinguish between significant and non-significant events.	Specify: High safety significance situations or events require an immediate preliminary report. Where reporting of lower significance events is required allow for 5 day reporting.	Major	Adds administrative burden with no benefit.
38.	Table A: A. 1.	27(b) is indicated as "Immediate" reporting, 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.
39.	Table A: B.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	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	

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	operating procedures, or the mobilization of resources in response to the situation or event 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.				
40.	Table A: B.3a)	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.
41.	Table A: B.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.
42.	Table A: B.3a)	Industry needs clarity around what should be reported.	 Add the following Guidance to the table: Reportable situations include: Activation of the site nuclear emergency plan, or Use of emergency operating procedures (including evacuation of an area, meeting the entry 	Clarification	

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			conditions to an AIM, etc.), or Sounding emergency alarm, mobilizing the site Emergency Response Team (ERT) or offsite emergency responders in response to an unexpected occurrence that creates a hazard to the safe operation of the nuclear power plant, to the environment or to the health and safety of persons.		
43.	Table A: B.3b)	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.
44.	Table A: B.4	60 days is required for full report but no further information may be available.	Add "if required"	Clarification	
45.	Table A: B.4	Add in geographical limits for site boundary.	Add the following 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	
46.	Table A: B.5	60 days is required for full report but no further information may be available.	Add "if required"	Clarification	

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47.	Table A: D.8	Guidance for s.29(1)(f) of GNSCR lists enumerated events that may have no serious adverse effects.	Remove enumerated list.	Major	If the 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.
48.	Table A: D.9.a) and 9.b)	60 days is required for full report but no further information may be available.	Add "if required"	Clarification	
49.	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 by potentially requiring duplicative reporting.
50.	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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51.	Table A: D. 10	Timing of reports should depend on significance level of situation or event.	Change to: immediate for significant or 5 business day for lower significant levels. Full report due in 60 days, if required.	Major	Adds administrative burden with no benefit.
52.	Table A: D.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 as written. The decision must be with the licensee on when to use. 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, without clarity on accountability for determining when this clause is used.
53.	Table A: E.12b)	The Guidance has a typographic error. Refers to a section that does not exist in this table.	Fix error. This should likely point to Item 12a.	Clarification	

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54.	Table A: E.13a) and E.13 b) 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.	This appears to be defining a Licence Conditions within a Regulatory Document. This example also exists in table section 13a) and all of 13b).	Remove last paragraph of Table A E.13.a) and all of Table A: E13.b).	Major	This REGDOC is inappropriately setting licence conditions.
55.	Table A: Preamble to E.13	No requirements are identified and adds no value. The guidance should clarify the specific reporting provision.	Remove the preamble to section 13 a and 13 b.	Major	Adds confusion in its existing position and complicates the table.
56.	Table A: E.13a	Reporting times for uranium mines and mills action levels are set out in code of practice and this should be recognized in the specific reporting clause.	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.

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57.	Table A: E.14	REGDOC-3.1.1 App A 22 clarifies that single missed sample where justified is not considered failure to monitor.	Add to Guidance: For item b), a failure to collect 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.	Clarification	
58.	Table A: E.14	Reporting time should be based on significance level of the environmental impact.	Change wording 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.
59.	Table A: E.15	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	Duplication of reporting requirements.
60.	Table A: E.15	A requirement for Class II facilities should not be included in this document.	Delete requirement.	Major	Duplication of reporting requirements.
61.	Table A: F.16 and F.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.

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62.	Table A: F.17	Timing of reports should depend on significance level of situation or event.	Change wording 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.
63.	Appendix B.	The guidance is too detailed. 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 performance reporting needs.	Major	Adds administrative burden with no benefit.
64.	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 draft REGDOC on p. 4.	Delete the definition of 'safety significance' in the Glossary, and replace with the word 'risk' on p. 4, or remove the reference to the IAEA SF-1.	Clarification	