

**April 13, 2011**

**ATTACHED ARE COMMENTS  
FOR A NOVEMBER 20, 2010  
MEETING WITH IAEA**

**RASSC**  
**U.S Comments on DS379: Draft 4.05: International Basic Safety Standards**

COMMENTS BY REVIEWER					REVIEWER'S COMMENTS	
Reviewer: Country/Organization: U.S.A					Date: November 16, 2010	
Com ment No.	Para/Li ne No.	Comments/Proposed new text	Reason	Acce pted	Accepted, but modified as follows	Other
		<b>General Comments</b>				
1		The United States provides these comments on the technical edited version released on November 5, 2010. We find that there have been substantial changes, and that the draft goes well beyond what would be expected from editing, and substantially changes the technical content and provisions in a number of respects. A number of these "edits" change the result of careful negotiation and agreement. Significant additional discussion is needed to resolve the issues and assure a high degree of consensus on the text to be approved.				
2		There has been a fundamental change of terminology from "optimized" to "optimization of protection and safety is implemented". This needs to have a clear discussion and broad agreement, as the question has been debated numerous times before, and it seems remarkable that a change is now made by the editor.  Some specific instances are given in the specific comments below, but not every instance is identified.				
3		The graded approach has been modified throughout to say that the "stringency and scope of the application of ..." This is probably acceptable, assuming that everyone agrees that stringency and scope cover everything that is intended by the graded approach concept.				

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		<b>Specific Comments</b>				
		Section 1				
1	1.18	We have not commented before, but the paragraph states that radiation in medicine does more harm than good. There is no caveat that this statement is true when the use is appropriately justified (described in the following sentences, and properly administered. Such a caveat is probably important.				
2	1.19	What is the reason for deleting the parenthetical about comforters and carers of a patient, and replacing with a footnote? This would seem to be more than editorial, although the outcome may be the same. Does this change the definition of public?				
3	1.20	What is the reason for deleting the parenthetical about individuals in biomedical research, and re0placing with a footnote? This would seem to be more than editorial, although the outcome may be the same. Does this change the definition of medical exposure?				
4	1.22	Are practical and practicable really the same thing?				
5	1.22	Adding security in the first bullet is probably a good thing.				
6	1.28	Last sentence. Not only is it doses initially received, it may be the doses that are initially projected to be received. This needs to be added. Draft 4.0 was ambiguous on this point, but with the editing, it is now necessary.				
7	1.33	The word synergistic was replaced by the word aggravated in the third line. This is not an appropriate word change. The effects of smoking and radon exposure are synergistic.				

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8	1.35	In line 2, the word “initiator” has been substituted for the word “trigger”. This has a very different connotation, and is not considered an appropriate editorial change. If the term trigger is considered wrong, then an alternative might be “indicator of the need for an investigation”.				
9	1.36	It is not obvious why the last sentence was deleted. This was important information, and its deletion is not considered to be editorial.				
10	1.31	NOTE that paragraph numbering has been altered, and is not consistent.  Line 7. It is not obvious why “other species” was substituted for “flora and fauna”.				
11	1.41	The statement that IAEA issues guidance is not the same as the statement that nuclear security recommendations complementary to ...				
12	1.48	Are there really any instances where there are now associated explanation text, beyond the shall statements. The second sentence was added, presumably as the boiler plate of the new agency format. But it would not seem to be appropriate in this case.				
13	1.53	In line 3, it would appear from the text that Section 2 only deals with protection of the environment. This is obviously wrong. Section 2 contains general requirements that apply to all exposure situations. This must be fixed.				
		Section 2				

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14	R 1	It is not obvious that application of the principles for an exposure situation is the same as applying the principles in an exposure situation. Why was this adjustment made, and is it appropriate?				
15	2.9	It appears in the last line that protection strategy is now being used as a defined term, replacing a strategy for protection. Is this appropriate, and will it be recognized?				
16	2.10	A significant modification has been introduced, changing from "optimized" to "optimization of protection and safety is implemented". After all the debate and discussion, the editor makes a unilateral change? The footnote has also been modified. As such, the footnote is now circular. Assuming, for the moment, that the revised text is accepted, the footnote should be revised to read: "means that <b>the process of optimization of protection and safety has been applied, taking into account relevant factors, to determine the optimum protection and safety for that particular circumstance and time</b> , and the result of that process has been implemented."				
17	2.14	The second sentence is a significant new addition. Although taken from the safety fundamentals, it is in part duplicative of text in the first sentence, and then goes beyond the previous discussions and agreements by reference to populations remote to the present facilities and activities. If everyone agrees that it is appropriate to include the populations remote to the present facilities and activities, then this should be added to a modified first sentence, not adding an additional requirement statement.				
18	2.25	The editing makes it appear that this paragraph was deleted. In fact, the paragraph is now 2.26. The change in numbering and sequence makes cross reference and checking very difficult.				

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19	2.28	The editing has removed an important point. The arrangements were to be adequate, but this has been removed. Now it just has to be in place.				
20	2.31 (3)	The “as necessary” has been removed. With this change, does it mean that every country has to establish the infrastructure for emergency exposure and existing exposure situations? The “as necessary” was intended to give this some flexibility in situations where significant issues were not likely to arise, and this has now been removed.				
21	2.34	The editing on this paragraph removes the option of providing information, as it now requires the actual provision of the lessons learned. The paragraph also now seems confusing, and seems to imply that the same mechanisms used to interact with licensees are to be used in interacting with other national and international organizations.				
22	2.41	The editor is proposing a possible alternative construction for this, and probably a number of other paragraphs. This should be carefully considered, as the previous “registrants and licensees” was specific to the types of authorizations that are to be granted by a regulatory body. To say “authorized parties” would seem to significantly weaken the requirement.				
23	2.42 (a)	Footnote has been added, which is essentially a modified definition, and different from the previous definition found in the glossary. The revised glossary has been modified to match the footnote. If this is a defined phrase, why is there both a footnote and a glossary entry? Further, note that the definition implies that the consumer product is exempted, which might not be the case.				

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24	2.50	With the change from “aspects” to “elements”, a new question is raised. Is it the elements that are to be commensurate with the complexity and risk, or is it the implementation? The latter is more appropriate, as there may be licensing, inspection, etc, which are elements, but which are implemented in a manner commensurate with the complexity and risk. This should be modified.				
		Section 3				
25	3.4 (d)	Note U.S. comment on this point has been accommodated and incorporated by the editor.				
26	R 6	The editor has inserted the phrase “in accordance with a graded approach”. This seems duplicative of the actually requirement text, and would seem to be unnecessary. It is not at all obvious how this addition helps with the clarity of the text.				
27	R 9 Etc.	“Registrants and licensees” is highlighted, presumably because of the earlier question about whether this phrase should be replaced by “authorized parties”.				
28	3.15 (e)	As the earlier paragraph 3.9(d) requires a safety assessment when exposures greater than the levels specified by a regulatory body are expected, a question is now raised about the requirement in 3.15(e) is related to the requirement in 3.15(c) for a safety assessment. It would seem that there are two requirements for the same thing. Certainly the assessment of potential exposure should have been part of the safety assessment. This is a new issue, not necessarily generated by the editor, but which was latent in the existing text. Discussion and resolution is necessary.				

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29	3.18	The revision by the editor is appropriate, but removes the shall statement about normally being considered not justified. As edited, the sentence is now a simple declarative, and the "shall" statement is the second sentence. The U.S. should support this revision.				
30	3.19	The "shall" statement has been removed. Does this mean that this paragraph is no longer considered a requirement? This edit would seem to have major implications for a very sensitive topic in previous secretariat meetings.				
31	3.20	Like paragraph 3.18, the first sentence is now a declarative, and the second sentence is the "shall" statement". This is appropriate, and should be supported by the U.S.				
32	3.20 Bis	Consistent with the changes to 3.18 and 3.20, it is suggested that the "shall be" statement in the first sentence be changed to "is normally". Then the same logic of the other paragraphs would apply, with the "shall" statement being the operational requirement in the second sentence.				
33	3.21 3.22	Here again is the question of "optimized" vs. "optimization of protection and safety is implemented". This needs to have a clear discussion and broad agreement, as the question has been debated numerous times before, and it seems remarkable that a change is now made by the editor.				
34	3.30 (b)	Without saying the term, this is a specific requirement to assess potential exposure. This should be clarified, so that the requirements are coherent.				
35	3.39 (c)	Agree with the revision. It is assumed that the double bracket highlight text is a note to the reader, and will be eliminated from the final text.				



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36	3.42 (a)	The inclusion of "initial" and "casualties" is a significant change on the tone and implications of the requirement. With this change, the requirement only reaches to very significant exposures, rather than the potential for medical counseling for exposures.				
37	3.52 (b)	The insertion of the word "any" in front of information leads to a question of who is responsible for obtaining and then reporting this information. This would appear to be a case where the requirement might never be acceptably complied with. Although it might appear as an editorial change, the any previously applied to the word "radiation generator", while now it applies to "information".				
38	3.54	What information is now to be provided? Previously it was appropriate information requested by the regulatory body. The modifier "appropriate" has been removed.				
39	3.59	This paragraph has been substantially modified, introducing a new set of conditions called interim destinations. This could be read to say that the licensee is still responsible after properly transferring the source to another licensee who may be doing recycling of the source, etc. This would seem to be inappropriate, and inconsistent with other BSS requirements.				
40	3.71	What is the rationale for deleting the word "appropriate" in the first line?				
41	3.73 (a)	This is an entirely new requirement not previously discussed on agreed upon by the member states or RASSC. It may be a reasonable addition, although it would seem that the general provisions for what a regulatory body is to require would have been sufficient. No rationale is provided for the suggested change.				

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42	3.73 (c)	The insertion of “providers of” should be before the word individual, not after. It is not individual providers, but individual monitoring services.				
43	3.77 (b)	Why was a new requirement added which is a simple repetition of requirements already in place to establish requirements? This is not an appropriate place for such an insertion.				
44	3.82	The timing of the requirement has been changed from “as soon as feasible” to “as soon as possible”. It is not immediately obvious that these are the same. It may be possible to do something, but doing that notification might put protection and safety at risk, and thus it might not be feasible.				
45	R 24	The requirement is highlighted, but no question has been asked. A rather substantial modification has been introduced, delimiting the arrangements to those related to classification of areas and controlling occupational exposure. This is certainly more precise, and may be appropriate.				
46	3.87 3.88	Support the deletion of “potential exposure” and the replacement.				
47	R 25	It is not obvious why certain text is highlighted. The editorial changes suggested seem reasonable.				

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48	3.102 3.104	The question posed by the highlight is the confusion between exposure records and dose assessment.  Dose assessments will lead to entries in exposure or dose records for a particular individual.  Records should include the necessary information to calculate effective dose, and the initial measurements, since effective dose is not appropriate for dose reconstruction for epidemiology.				
48	3.105 (a)	There is a note that information on their exposure records is not the same as access to their records. Individuals should be able to have access to their own records.				
50	R 28	The editorial change is appropriate, but it would seem that there are now two requirements.				
51	3.112	It is not clear why the parenthetical has been added. This would seem to be un-needed duplication. If the intention is to list direct radiation sources in addition to the discharges, then a different sentence construction needs to be considered.				
52	3.134 (d)	The insertion of "independent" in front of assessments adds a new requirement. This has not been previously discussed, and would seem to add significantly to the requirement, unless some qualifier ("as appropriate") is included.				
53	3.166	The edit added at the end of the stem of the requirement does not make any sense. Some words are missing, or the addition should be removed.				
54	3.168	A licensee may have a complex program with many different attributes. This is not the same as having a large program. The substitution of "large" for "complex" needs to be reconsidered.				

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55	3.173	The change in language from “signs in appropriate languages” to “signs in languages that are understood and accepted by the public” could be considered as a substantial change in the requirement. It could be that certain ethnic groups would not accept use of a particular language, even if it is the most appropriate for the overall population being served. Who would be the judge of compliance?				
		Section 5				
56	5.3 (a)	A substantial addition has been made to the footnote, to add a connection for air crew. The addition is very difficult to follow because it is a long series of negatives.				
57	5.13	The substitution of “discharge” for carry out is not inappropriate, but in the context of this document the word discharge is used to describe a release of radioactive material. It is suggested that a different word be found.				
58	5.31	It is not clear what “humans” was changed to workers. While it is true that in most all circumstances the individuals going into space are doing so as part of their job, there have been and likely will continue to be individuals who seek to go into space as a tourist. Such an individual would not be a worker, but the exceptional circumstances of space should logically apply equally to those individuals, since they go into space with an understanding of the risks involved.				
		Schedules				
59	Table IV-1	Several new footnotes have been added without review. These need to be carefully reviewed for correct content.				
		Glossary				

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60		A number of new terms and definitions have been added. There has not been time to check if these are from the current IAEA glossary, or if additional changes have been introduced.				
61		Many terms have been modified. Review is needed, and there has not been time to do this.				
62		All terms need to be carefully reviewed for correctness.				