



UNITED STATES
NUCLEAR REGULATORY COMMISSION
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FROM: John W. Craig
Assistant for Operations, OEDO

SUBJECT: U.S. MEMBER STATE COMMENTS ON IAEA DRAFT SAFETY GUIDE (DS-161) ON SCOPE DEFINING LEVELS IN COMMODITIES

Attached for your information are the proposed U.S. Member State comments on the IAEA Draft Safety Guide, DS-161, "Radionuclide Content in Commodities Not Requiring Regulation for Purposes of Radiation Protection." These comments were coordinated with RES, NMSS, and NRR staff, as well as the staff of the Departments of Energy, Labor (OSHA) and the Environmental Protection Agency through the Recycle Subcommittee of the Interagency Steering Committee for Radiation Standards (ISCORS). They have also been coordinated with the State (Illinois) regulatory representative to the ISCORS Recycle Subcommittee.

Attachment: As stated

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CFO (w/o attachment)
EDO R/F (w/attachment)

Title: Radionuclide Content in Commodities not requiring Regulation for Purposes of Radiation Protection DS161

Comments by Reviewer				Resolution			
Reviewer: Consolidated U.S. Member State Comments Page ___ of 23 Date: 22 August 2002 Country/Organizations: USA/NRC, DOE, EPA, DOL							
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/rejection
1	General-- Applies to the scope and use of the document	The U.S. recommends that the IAEA proceed with caution with respect to this Safety Guide on commodities. The effects of implementation of SDLs on other regulatory areas (e.g., the disposal of ordinary waste, transportation, and surficially-contaminated materials) have not been developed or elaborated. The SDLs add a requirement for authorization of a practice based only on concentration of radionuclides. Clarification is needed from the IAEA with regard to publication of SDLs in lieu of corresponding modifications in the requirements stipulated by the BSS.	USEFULNESS; SCOPE; COMPLETENESS; QUALITY CLARITY The U.S. has not yet established requirements for general clearance of materials or commodities. Even so, and although experience is limited, caution in proceeding is urged because of reservations about administrative, implementation, and technical aspects of this Safety Guide.				

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2	1.2/6	Delete: "...and some are present from human activities"	CLARIFY The presence of radionuclides from human activities is addressed in the next sentence				
3	1.2/9	Add: <i>from</i> before "routine"	CLARIFY				
4	1.2/10	Change "natural or artificial" to ... <i>natural and</i> artificial...	CLARIFY				
5	1.2/ footnote 3	Add H-3, and C-14 to list	CLARIFY Large quantities of these radionuclides naturally occur on earth.				
6	1.2/ footnote 4	Add: <i>Some wastes are worthless and, thus, cannot be bought or sold, thus, these are not commodities.</i>	CLARIFY; SCOPE				

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7	1.4/2-5	Replace lines 2-5 with: <i>...considerations that outline their scope of application. A summary of these considerations is: ...international trade in essential "commodities" such as food and in areas affected by significant incidents. They are established for temporary emergency application. These levels are frequently referred to as "action levels" and are not considered appropriate for routine situations; •The exemption....</i>	CLARIFY -- The changes to paragraph. 1.4 are needed because 1) the word "mechanism" is incorrect in the text (no mechanisms are addressed), and 2) the 1 st bullet may be misinterpreted to indicate that the avertable dose target level of 10 mSv/a is applicable to materials not requiring regulatory control. The reference needs to be qualified to avoid misapplication of large accident cleanup strategies to low activity commercial products.				
8	1.5/3	Delete: "for the purposes of radiation protection in accordance with the BSS"	CLARITY; QUALITY Clearance at the SDL of Ra-226 or at the SDLs of other radionuclides that could lead to an individual dose greater than 1 mSv in a year cannot be said to be for the purposes of radiation protection in accordance with the BSS.				

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9	1.5/5	Insert after "...scope-defining levels.": <i>The relationship of scope defining levels to exclusion, exemption, and clearance is explained.</i>	SCOPE; COMPLETENESS; CLARITY Objective should relate SDLs to established situations where radioactivity or exposures are not regulated, namely, exclusion, exemption, and clearance.				
10	1.7/1	No change to first sentence	SCOPE; CLARITY The U.S. strongly agrees that the scope of the Safety Guide should exclude foodstuffs and drinking water as revised.				
11	1.7/1	Insert after the last sentence: <i>IAEA will cooperate with the FAO/CAC to develop radionuclide concentrations in foodstuffs for non-intervention and post-intervention situations after the first year of intervention.</i>	CLARITY Clarification of scope and relationship to addressing specifically foodstuffs in GC(44)/RES/15				

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12	1.6/2	Delete: "but, rather, they clarify their scopes of application in relation to commodities."	CLARITY; QUALITY General application in relation to commodities is unanalyzed in the Safety report. Clearance calculations were performed for releases from an authorized practice. They took into account dilutions and reconcentration of radioactivity due to processing. In contrast, scope- defining levels be much greater than 10 μ Sv in a year.				
13	1.7/3	Add sentences at end: <i>"It is acknowledged that this may result in non-comparable levels for different types of commodities. Such inconsistency is warranted because of the types of radionuclides involved and the potential types of uses of the commodities in question."</i>	CLARITY Some rationale needs to be provided, so that regulatory authorities, operators, industry, etc. do not appear to be capricious in setting guidance for control of commodities.				

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14	1.8	Add paragraph: <i>Waste with no intrinsic value and that can only be disposed, is not a commodity, because it cannot be bought or sold, and, thus, SDLs would not apply to it.</i>	SCOPE; CLARITY; COMPLETENESS Worthless waste such as ordinary waste is valueless, and because it cannot be bought or sold, it is not a commodity.				
15	1.10/1	Renumber to: 1.9	QUALITY; CLARITY; Paragraph 1.9 is missing.				
16	2.1/1	Insert after "content in": <i>and on...</i> (IAEA to supply surficial SDLs)	USEFULNESS; COMPLETENESS; SDLs only in units of Bq/g are not practical to implement. A large fraction of the commodities cleared from practices only have surficial radioactivity.				

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17	3.4/3	Insert after the first sentence: <i>"The SDL for K-40 was selected at two and one-half times the highest value for an individual country because [IAEA supply reason] [9]. The Pb-210 and Po-210 values of 5 Bq/g were selected because [IAEA supply the reason] [9]. H-3 and C-14 values were based on [IAEA supply reason] [9]."</i>	QUALITY; COMPLETENESS; CLARITY With reference to K-40, Section 3.4 of the referenced Safety Report [9] refers to table one for population weighted averages, however Table I in this Section is a list of daughter radionuclides. A population weighted average would not explain a factor of 2.5 above the highest value. There is no explanation given for the Pb-210 and Po-210 values of 5 Bq/g or the basis for the H-3 and C-14 values.				
18	3.4/6	Insert a table of doses calculated from both low probability and realistic scenarios in the application of the NORM SDLs to clearance. See attached sheet, Table XXX.	COMPLETENESS; QUALITY; CLARITY A full disclosure of the doses from NORM is required for an informed comparison of risk consequences with the levels for artificial radionuclides and with the 1 mSv public dose limit of the BSS.				

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19	3.4/3-6	Delete sentence: "Doses to individuals as a consequence of the use of these scope defining levels are unlikely to exceed about 1 mSv in a year in most cases, excluding the contribution from the emanation of radon. Add text: <i>Low probability scenarios for clearance were assessed to ensure that doses would be unlikely to exceed 1 mSv in a year. However, some doses attributable to the SDLs for NORM for clearance exceed 1 mSv in a year. (See Table XXX, attached sheet.) The doses attributable to SDL levels in many commodities could be even greater.</i>	QUALITY; CLARITY; COMPLETENESS				
20	3.2/1	Revise sentence to: " <i>The mechanism of exclusion...</i> "	CLARITY Consistent terminology with Section 1.3 should be used.				

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21	3.2/8	Provide criteria and methods for determining "amenable to control."	COMPLETENESS; CLARITY; USEFULNESS The authority is left without guidance on how to determine amenability to control of exposures from materials containing radionuclides of natural origin.				
22	3.1/5, 3.5/4,	Change to read: "...a probability of the dose to any individual approaching 1 mSv in a year as judged to be unlikely. ..."	USEFULNESS, COMPLETENESS, CLARITY. There is no indication of the criterion used to judge the probability of a 1 mSv dose in a year nor is there an indication that uniformity from nuclide to nuclide was sought in the target low probability. There is no quantitative evaluation of the probability of the 1 mSv dose.				

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23	3.6I(B)/All	Change to: <i>"Concentrations were also derived for a 1 mSv/a dose criterion for relatively unlikely scenarios."</i>	USEFULNESS, COMPLETENESS, CLARITY Same reasoning as in the previous comment.				
24	3.2/8	Add sentence: <i>"Some locations are naturally antagonistic to human health and can be addressed by physical isolation or restricted access; there may be little benefit from remediation."</i>	COMPLETENESS, CLARITY, QUALITY, RELEVANCE. There may be little point to remediation of naturally hazardous areas that may also have high radionuclide content. The guidance should encourage controls in the form of restricted access or other physical barriers rather than leave silent the implication that a remediation is necessarily warranted.				

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25	3.3/13	After sentence ending: "...consideration and control." Add: <i>"Decisions for existing, as well as future, NORM industries including fertilizers, coal ash, ores, mineral sands, and slag, need to be based on the radiological principles of justification, optimization, dose limitation and dose constraint."</i>	COMPLETENESS, QUALITY, RELEVANCE, USEFULNESS, CLARITY, SCOPE. Provide sound guidance established by the BSS.				
26	3.3/14	Revise sentence to: "...control may be based on an ...radionuclides, socio-economic considerations and an evaluation of the health risks associated with these exposures."	CLARITY, USEFULNESS, RELEVANCE. For example, concentrations of non-radiological environmental toxins, such as arsenic, are regulated on the basis of health risk. Also the strategy for remediation needs to consider available resources				
27	3.4/3	Add sentence after [1, 10]: <i>"Scope defining levels for natural radionuclides are the total of the background and any added radioactivity."</i>	CLARITY; COMPLETENESS The text is not clear that the total amount of a naturally occurring radionuclide is included in the SDL and not just the incrementally added amount.				

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28	3.4/3	Insert after levels [1,10]. <i>“Although the NORM SDLs are not dose based, it is problematic that some NORM SDLs applied to clearance could result in doses greater than the BSS public dose limit of 1 mSv in a year (See Table XXX, attached sheet.). For reasons stated in Comment 29, a generic SDL assessment could give even greater doses.”</i>	CLARITY				

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29	3.5/1	Add text at beginning of 3.5: <i>“SDLs for artificial radionuclides are based on clearance analyses. However, implementation of SDLs is more complex. Clearance levels only limit the concentrations of radioactivity that enter commerce from the practice. These levels are based on assessments of the doses from all subsequent diluting and reconcentrating processes and uses. In contrast, implementation of SDLs would allow the same concentrations to be present in any or all commodities. Generic dose assessments of SDLs have not been performed for radionuclides in commodities throughout general commerce as could arise in an intervention situation. Reconcentrating processes and exposures to many commodities could result in doses significantly greater than the dose criterion of 10 μ Sv in a year.</i>	SCOPE; COMPLETENESS; QUALITY; CLARITY				

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29 (continued)	3.5/1	<i>many commodities could result in doses significantly greater than the dose criterion of 10 μ Sv in a year."</i>					

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30	3.6/6	Change to read "...selected set of exposure pathway scenarios..."	CLARITY, RELEVANCE, QUALITY COMPLETENESS Exposure pathways were evaluated on a nuclide-by-nuclide basis. All pathways for a scenario were not added to get a total exposure dose.				
31	3.6/5	Insert sentence after "...solid materials.": <i>"It should be noted that the assumptions in the four calculations varied among the different scenarios that were evaluated. For example, only 2 of the 3 scenarios addressed skin contamination."</i>	COMPLETENESS, CLARITY, QUALITY, USEFULNESS, RELEVANCE. The draft Safety Report indicates that skin contamination was evaluated for metal and concrete processing (scenarios II and III), but not for typical exposure situations (scenario I)				
32	3.7/2	Add sentence after "I, II, and III.": <i>"Although the dose basis in the calculations ranged from 10 μSv/a to 100 μSv/a, the concentrations in Table 1 were increased by a factor 10 to account for the conservatism in metal and concrete scenarios."</i>	CLARITY, USEFULNESS, COMPLETENESS, QUALITY, RELEVANCE. The draft Safety Report section 3.3, states that values in Table 1 of the draft Safety Guide were increased by a factor 10 to account for the conservatism in metal and concrete scenarios.				

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33	3.8/1	Replace first sentence by: <i>"The calculations were performed for clearance of solids from an authorized practice. Similar analyses for liquids and gases have not been performed."</i>	QUALITY, CLARITY, USEFULNESS, SCOPE, RELEVANCE. There is no rationale, basis or analyses presented to support the assertions that the calculations for solids are, in fact, appropriate for liquids or gases. Counter examples might include large storage tanks or pipelines.				
34	4.1/1	Change to read: <i>"Materials and equipment [alternatively: Commodities] cleared from an authorized practice with activity concentrations below the clearance levels should not be subject to regulatory controls from radiological protection considerations."</i>	QUALITY, RELEVANCE, COMPLETENESS, SCOPE CLARITY. If the SDLs in DS161 were applied to all commodities, they would not necessarily meet the dose criterion of <10 µSv in a year. See reasons in comments 28 and 29.				

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35	4.1/3	Delete sentence beginning: "Where commodities have..." - OR - Specify additional safety criteria applied only to clearance that would be required to be equivalent to the prerequisite conditions of exemption.	CLARITY, COMPLETENESS, RELEVANCE QUALITY. Exemption can be applied at higher levels than clearance, because prerequisite conditions must be met before the exemption concentrations can be applied. These conditions are summarized as: applicable to moderate quantities, sufficiently low risk to individuals and the collective dose to be of no regulatory concern and inherently safe.				

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36	4.2/3-4	Replace third sentence by: <i>"In general, countries should coordinate their regulatory strategy and implementation with their neighboring States, including their monitoring programs for commodities, in order to avoid unnecessary nuisance alarms at boundary transfer points. The IAEA and other international nuclear material safety organizations should be used to harmonize the control of such commodities and the attendant trans-boundary interactions."</i>	CLARITY, COMPLETENESS, RELEVANCE, USEFULNESS, QUALITY. As originally worded, the sentence implied that measurement along the material flow path would not be necessary. The entrance of orphaned sources or related contaminated material either incidentally or deliberately would seem to necessitate some degree of monitoring or continuity of control measure to avoid such downstream contamination scenarios.				
37	4.2/8-9	Insert: <i>".... appropriate techniques and equipment to ensure detection of radioactivity concentrations at the scope defining levels."</i>	CLARITY, RELEVANCE QUALITY. Original wording raises concerns that detection equipment and techniques would result in nuisance alarms. It could be counterproductive and constitute poor guidance.				

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38	4.3/1	Insert as first sentence: <i>“Transportation regulations specify both the allowed surficial and mass concentrations of radioactivity. For most radionuclides on surface contaminated objects, SDLs will exceed the transportation limits for surface contamination without packaging.”</i>	RELEVANCE; USEFULNESS; SCOPE; COMPLETENESS; QUALITY; CLARITY Actual mass to surface ratios for clearance from nuclear facilities would require SDLs to be in the range of 0.06 – 0.1 Bq/g, to not require packages for transportation. Table I shows generally higher values for SDLs.				
39	4.3/3	Change “should not be attributed to radiation protection considerations” to: <i>“may require special exemption.”</i>	QUALITY; CLARITY Doses could exceed 1 mSv in a year.				

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40	4.5/3	Insert after the first sentence: <i>"For clearance scenarios, individual doses from NORM at SDLs may be greater than 1 mSv in a year. For example, the realistic clearance scenario with the level of Ra-226 at 0.5 Bq/g yields 1.9 mSv/a. This is above the public dose limit. So, in these cases, limitation and control of occupational exposure would be required even below this scope defining level. The authority must be aware of these possible situations."</i>	QUALITY, COMPLETENESS, USEFULNESS, CLARITY, RELEVANCE				
41	4.6/5	Add after "... residues in the environment": <i>or vice versa.</i> (Guidance....	CLARITY, SCOPE, COMPLETENESS RELEVANCE This underscores the guidance that intervention exemption or exclusion levels are not routinely appropriate for clearance of commodities.				

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42	4.7/1	Change first sentence to read: <i>"Deliberate dilution, as opposed to dilution that takes place in normal operations when radioactivity is not a consideration, in order to meet SDLs ..."</i>	CLARITY, RELEVANCE, USEFULNESS Distinction should be made between dilution from normal operations and processes and dilution for the purpose of meeting a specified concentration level.				
43	4.7/3	Change to read: "the processing of commodities containing <i>either artificial or</i> natural radionuclides"	CLARITY, RELEVANCE, SCOPE USEFULNESS. Although the analyses for clearance scenarios take subsequent processing of the cleared materials and the processing of resultant byproducts into account, no such analysis has been done for similar levels in all commodities. Because of endless combinations of situations for processing generic commodities, such an analysis is not feasible. See comment 20. Thus, with scope defining levels the regulatory authority cannot assure adequate public safety.				

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44	4.7/5	Insert sentence after: "...defining levels.": <i>"This may occur in cases where water recycle from sanitation systems results in re-concentration of diluted agents. In such cases..."</i>	CLARITY AND QUALITY The text was unclear as to circumstances where SDL-compliant releases could results in nontrivial impacts.				
45	4.7/7	Add sentence at end: <i>"It should be acknowledged that what one Regulatory Authority establishes as the scope of application of these SDLs may not be acceptable to Member States to which these commodities may be exported. Again, the system of commodity control should be integrated and coordinated within and outside the borders of the Member State."</i>	COMPLETENESS, RELEVANCE, CLARITY, SCOPE The risk that a neighboring country rejecting commodities, when the two regulatory implementations are inconsistent should be explicitly recognized in the guidance.				

TABLE XXX. NORM SDLs APPLIED TO CLEARANCE SCENARIOS

NUCLIDE	SDL Bq/g	Table I-IV	Low Prob Dose μ Sv	Low Prob > 1 mSv	Table I-III	Realistic Dose μ Sv	Realistic > 1 mSv
H-3	100.0	2.1E+01	2.1E+03	2.1	1.1E+00	1.1E+02	
C-14	1.0	2.2E+02	2.2E+02		1.1E+01	1.1E+01	
K-40	5.0	3.5E+03	1.8E+04	17.5	1.7E+02	8.5E+02	
Pb-210	5.0	3.4E+04	1.7E+05	170.0	1.7E+03	8.5E+03	8.5
Bi-210	0.5	7.9E-01	4.0E-01		4.0E-01	2.0E-01	
Po-210	5.0	2.0E+02	1.0E+03		1.2E+01	6.0E+01	
Ra-223	0.5	1.2E+01	6.0E+00		1.0E+00	5.0E-01	
Ra-224	0.5	4.4E+00	2.2E+00		6.9E-01	3.5E-01	
Ra-226	0.5	7.5E+04	3.8E+04	37.5	3.7E+03	1.9E+03	1.9
Ra-228	0.5	3.2E+04	1.6E+04	16.0	1.6E+03	8.0E+02	
Th-227	0.5	2.1E+01	1.1E+01		5.5E-01	2.8E-01	
Th-228	0.5	4.0E+02	2.0E+02		1.1E+01	5.5E+00	
Th-230	0.5	1.5E+02	7.5E+01		7.6E+00	3.8E+00	
Th-231	0.5	6.7E-03	3.4E-03		3.4E-03	1.7E-03	
Th-232	0.5	1.1E+03	5.5E+02		5.4E+01	2.7E+01	
Th-234	0.5	2.2E-01	1.1E-01		3.4E-02	1.7E-02	
Pa-231	0.5	1.0E+04	5.0E+03	5.0	5.1E+02	2.6E+02	
U-234	0.5	2.8E+02	1.4E+02		1.4E+01	7.0E+00	
U-235	0.5	2.8E+02	1.4E+02		1.4E+01	7.0E+00	
U-238	0.5	2.7E+02	1.4E+02		1.3E+01	6.5E+00	

SDL is Scope Defining Level from DS 161

Table I-IV is the Safety Report limiting μ Sv/a per Bq/g from a low probability scenario

Low Prob Dose is the low probability dose for clearance at the SDL

Low Prob > 1 mSv is the low probability dose in mSv for clearance at the SDL

Table I-III is the Safety Report limiting μ Sv/a per Bq/g from a realistic scenario

Realistic Dose is the realistic dose for clearance at the SDL

Realistic > 1 mSv is the realistic dose in mSv for clearance at the SDL