October 3, 2002

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FROM: John W. Craig /RA/
Assistant for Operations, OEDO

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

Attached for your information are the revised staff comments provided to IAEA on IAEA DS-161, "Radionuclide Content in Commodies Not Requiring Regulation for the Purpose of Radiation Protection. The comments were coordinated with DOE, DOL, and EPA.

Attachment: As stated

cc: W. Travers, EDO (w/attachment)
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OIP (w/o attachment)
CIO (w/o attachment)
CFO (w/o attachment)
EDO R/F (w/attachment)

E-2

Non-Public

File: ML022760543
Memo: ML022760545
Attach: ML022760558

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

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __of 21 Date: 1 October 2002 Country/Organizations: USA/NRC, DOE, EPA, DOL				Resolution			
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. does not object to establishing for commodities concentration levels of artificial radionuclides based on a criterion of less than 10 µSv in a year to an individual. Nor does the U.S. object to a separate criterion applied to naturally occurring radionuclides based on practicality of implementation and with a reference to concentrations occurring in nature. However, the U.S. recommends that the IAEA proceed with caution with respect to this Safety Guide on commodities.	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.				
2	General--Applies to the scope and use of the document	The SDLs need to be reviewed in the context of other regulatory areas. These include the Code of Conduct on the Safety and Security of Radioactive Sources, including security concerns for detection of illicit trafficking, source	USEFULNESS; SCOPE; COMPLETENESS; QUALITY CLARITY There are other concerns besides radiological protection. These have to be taken into account for implementation. Sensitive monitors readily detect				

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		safety in trans-boundary shipments, the implications for exceeding the surface contamination requirements for transportation of materials, and harmonization with EC clearance levels.	some radionuclides at the SDLs. Caution must be taken in consideration of detection of illicit trafficking, source safety in trans-boundary shipments. Other regulatory requirements can cause more restrictive levels to be implemented.				
3	General	Implementation of the SDLs would appear to add a requirement, for authorization of a practice based only on concentration of radionuclides. This requirement departs from the principles applied in the BSS. The BSS requires justification, optimization, dose limitation, and constraint of practices. Authorization based only on SDLs would bypass these present criteria. The document should emphasize that it is intended as guidance, not as a requirements level document.	SCOPE; COMPLETENESS; QUALITY; CLARITY				

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4	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				
5	1.2/9	Add: *from* before "routine"	CLARIFY				
6	1.2/10	Change "natural or artificial" to ...natural *and* artificial...	CLARIFY				
7	1.2/ footnote 3	Add H-3, and C-14 to list	CLARIFY Large quantities of these radionuclides naturally occur on earth.				
8	1.2/ footnote 4	Add: *Some wastes are worthless and, thus, cannot be bought or sold, thus, these are not commodities.*	CLARIFY; SCOPE				
9	1.4/2-5	Replace lines 2-5 with: *...considerations that outline their scope of application. A summary of these considerations is:* •The exemption from intervention...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*	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 1st bullet may be misinterpreted to indicate that the intervention avertable dose target level of 10 mSv/a is applicable to materials not requiring regulatory				

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		frequently referred to as "action levels" and are not considered appropriate for routine situations; •The exemption....	control. The reference needs to be qualified to avoid misapplication of large accident cleanup strategies to low activity commercial products.				
10	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. See attached Table 1.				
11	1.5/4	Qualify the objective by adding text to read: "...below which regulation for the purposes of radiation protection in accordance with the BSS *generally* should not be required."	SCOPE, ACCURACY, CLARITY For reasons explained in comment number 33, when SDLs are applied in situations other than clearance, such as intervention, or even for clearance of some materials other than metals or rubble, there is a potential for the dose criterion of 10 μSv in a year to be exceeded.				

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12	1.5/5	Insert after "...scope-defining levels.": *The relationship of scope defining levels to exclusion, exemption, and clearance is explained.*	SCOPE; COMPLETENESS; CLARITY Objective should relate SDLs to established situations where radioactivity or exposures are not regulated, namely, exclusion, exemption, and clearance.				
13	1.6/1	Add text to read: "The scope-defining levels *for artificial radionuclides are based on clearance of metals and rubble. However, they may also serve as a reference metric for radiation protection guidance applied to commodities in general. The scope-defining levels for naturally occurring radionuclides are based on practical considerations with natural concentrations as a reference. They may serve as a reference metric for radiation protection guidance applied to commodities. The scope-defining levels* do not limit the application of the BSS..."	USEFULNESS, SCOPE, COMPLETENESS, QUALITY, CLARITY, ACCURACY				

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14	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.				
15	1.7/1	Insert after the last sentence: *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.*	CLARITY Clarification of scope and relationship to addressing specifically foodstuffs in GC(44)/RES/15				
16	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 μSv in a year.				

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17	1.7/3	Add sentences at end: *"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."*	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.				
18	1.8	Add paragraph: *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.*	SCOPE; CLARITY; COMPLETENESS Worthless waste such as ordinary waste is valueless, and because it cannot be bought or sold, it is not a commodity.				
19	1.10/1	Renumber to: *1.9*	QUALITY; CLARITY; Paragraph 1.9 is missing.				
20	2.1/1	Insert after "content in": *and on...* (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.				
21	3.4/3	Insert after the first sentence: *"The SDL for K-40*	QUALITY; COMPLETENESS; CLARITY				

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		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]."	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.				
22	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 1.	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.				
23	3.4/3-6	Delete sentence: "Doses to individuals as a consequence of the use of	QUALITY; CLARITY; COMPLETENESS				

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		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: *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 1, attached sheet.) The doses attributable to SDL levels in many commodities could be even greater.*					
24	3.2/1	Revise sentence to: *"The mechanism of exclusion..."*	CLARITY Consistent terminology with Section 1.3 should be used.				
25	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				

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			origin.				
26	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.				
27	3.6I(B)/All	Change to: *"Concentrations were also derived for a 1 mSv/a dose criterion for relatively unlikely scenarios."*	USEFULNESS, COMPLETENESS, CLARITY Same reasoning as in the previous comment.				
28	3.2/8	Add sentence: *"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."*	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				

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			the implication that a remediation is necessarily warranted.				
29	3.3/13	After sentence ending: '...consideration and control." Add: *"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."*	COMPLETENESS, QUALITY, RELEVANCE, USEFULNESS, CLARITY, SCOPE. Provide sound guidance established by the BSS.				
30	3.3/14	Revise sentence to: "... *control may be based on an* ...radionuclides, *socio-economic considerations and an evaluation of the human tolerance to 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				
31	3.4/3	Add sentence after [1, 10]: "*Scope defining levels for natural radionuclides are the total of the background and any added radioactivity."*	CLARITY; COMPLETENESS The text is not clear that the total amount of a naturally occurring radionuclide is included in				

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			the SDL and not just the incrementally added amount.				
32	3.4/3	Insert after levels [1,10]. *"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 1, attached sheet.). For reasons stated in Comment 33, a generic SDL assessment could give even greater doses."*	CLARITY				
33	3.5/1	Add text at beginning of 3.5: *"SDLs for artificial radionuclides are based on clearance analyses and are most appropriately applied to clearance of metals and rubble. However, clearance analyses are not sufficient to assess doses from all potential applications of SDLs. The authority should be aware that the criterion of less than a 10 μSv dose to an individual in a year and a*	SCOPE; COMPLETENESS; QUALITY; CLARITY, ACCURACY The technical basis needs to be broadened. Clearance levels only apply to practices. Assessments for clearance levels limit the amount of radioactivity introduced into commerce from a practice by taking into account dilution or				

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		very low probability of approaching 1 mSv in a year may not be met for materials other than metals and rubble. In addition, it might not be met in intervention situations or other situations where large quantities of materials or equipment and relatively large quantities of radioactivity are involved. In these situations, the authority is advised to make a case-specific analysis to ensure that the dose criterion is met.	reconcentration from all subsequent handling, distribution, and manufacturing processes. In contrast, SDLs also allow additional amounts of radioactivity to enter general commerce from intervention and from natural sources, as well as from clearance. Implementation of SDLs would allow the same clearance concentrations to be present in any and all commodities. Thus, with SDLs the commodities from intervention and natural sources would tend to cause less dilution and more reconcentration than accounted for in the clearance assessments. Generic dose assessments of SDLs have not been performed for radionuclides in commodities throughout general commerce as could arise in an				

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			intervention situation and from natural sources. Less dilution and more sources for reconcentrating processes and exposures from more commodities could result in doses greater than the dose criterion of 10 μ Sv in a year."				
34	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.				
35	3.6/5	Insert footnote after "...solid materials.": *"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. More restrictive clearance levels for 20 artificial radionuclides*	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). Previous IAEA dose assessments for				

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		were not used. These more restrictive clearance levels applied to skin exposure and clearance of commodities other than metals and rubble."	clearance of "all materials [other than metals or rubble]" should be included for completeness and transparency.				
36	3.7/2	Resolve discrepancy between DS161 and supporting draft Safety Report, Section 3.3, end of 10th paragraph and Table III of the same report on whether a factor of 10 was multiplied with clearance levels. The statement in the Safety Report appears to be in error and should be deleted.	CLARITY, USEFULNESS, COMPLETENESS, QUALITY, RELEVANCE. The draft Safety Report section 3.3, end of 10th paragraph, 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. This statement appears in error upon examination of the levels for clearance				
37	3.8/1	Replace first sentence by: *"The calculations were performed for clearance of solids from an authorized practice. Similar analyses for liquids and gases have not been performed. "*	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				

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			might include large storage tanks or pipelines.				
38	4.1/1	Change to read: *"Materials and equipment [alternatively: Commodities] cleared from an authorized practice with activity concentrations below those derived from clearance scenarios in the Safety Report should not be subject to regulatory controls from radiological protection considerations."*	QUALITY, RELEVANCE, COMPLETENESS, SCOPE CLARITY. If the SDLs in DS161 were applied to all commodities, they would not necessarily meet the dose criteria. See comment 33.				
39	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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40	4.2/3-4	Replace third sentence by: *"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."*	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.				
41	4.2/8-9	Insert: "…. appropriate techniques and equipment *to ensure detection of radioactivity concentrations at the scope defining levels."*	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.				
42	4.3/1	Insert as first sentence: "*Transportation regulations specify both the allowed surficial and mass*	RELEVANCE; USEFULNESS; SCOPE; COMPLETENESS; QUALITY; CLARITY Actual mass to surface				

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		concentrations of radioactivity. For most radionuclides on surface contaminated objects, SDLs will exceed the transportation limits for surface contamination without packaging."	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.				
43	4.3/3	Change "should not be attributed to radiation protection considerations" to: "*may require special exemption."*	QUALITY; CLARITY Doses could exceed 1 mSv in a year. See Table 1, attached sheet.				
44	4.5/3	Insert after the first sentence: *"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."*	QUALITY, COMPLETENESS, USEFULNESS, CLARITY, RELEVANCE				

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45	4.6/5	Add after ".... residues in the environment": *or vice versa.* (Guidance....	CLARITY, SCOPE, COMPLETENESS RELEVANCE This underscores the guidance that intervention exemption or exclusion levels are not routinely appropriate for clearance of commodities.				
46	4.7/1	Change first sentence to read: "*Deliberate dilution, as opposed to dilution that takes place in normal operations when radioactivity is not a consideration*, in order to meet SDLs ..."	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.				
47	4.7/3	Change to read: "the processing of commodities containing *either artificial or* 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				

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			situations for processing generic commodities, such an analysis may not be feasible. See comments 33, 43, and 44. Thus, with scope defining levels the regulatory authority cannot assure the stated dose criteria will be met.				
48	4.7/5	Insert sentence after: "...defining levels.": "*This may occur in cases where water in purification systems results in re-concentration of diluted agents.* In such cases..."	CLARITY AND QUALITY The text was unclear as to circumstances where SDL-compliant releases could results in nontrivial impacts.				
49	4.7/7	Add sentence at end: "*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.*"	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 1. NORM SDLs APPLIED TO CLEARANCE SCENARIOS

NUCLIDE	SDL Bq/g	Table I-IV	Low Prob Dose µSv	Low Prob > 1 mSv	Table I-III	Realistic Dose µSv	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 µSv/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 µSv/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