From:

Kirstin Riesbeck

To:

Robert Meck — RES

Date:

Wed, Aug 13, 2003 11:16 AM

Subject:

Re: IAEA DS161 Member State Comments

Thank you!

>>> Robert Meck 08/13/03 11:12AM >>> Dear Kirstin:

At Cheryl Trottier's request, I am sending the combined agency, U.S. Member State comments on DS161. The commenters were: NRC, DOE, DOL (OSHA), EPA, and the States, represented by the CRCPD. These agencies are noted on the forms as commenters. The logic diagram on the .pdf file is an integral part of the comments and should be the last page of the comments.

In parallel, these comments are being reviewed by the DEDO.

Please contact me, if I can be of further assistance.

Bob Meck

Robert A. Meck, Ph.D. Senior Health Physicist T9-F31 U.S. Nuclear Regulatory Commission Washington, DC 20555-0001

Telephone: 301 415-6205 FAX: 301 415-5385 e-mail: ram2@nrc.gov

B-52

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

Comi	ments by Revie	ewer		Resolution				
Reviewer: C	Consolidated U	.S. Member State Co	omments					
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		A/NRC, DOE, EPA,	DOL					
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as	Rejected	Reason for modification/	
ļ		 			follows		rejection	
1	General		SDLs for artificial			1	İ	
	Applies to		radionuclides are based			İ	Í	
	entire		on clearance analyses.]		
	document		However, implementation					
			of SDLs is more complex.	!]	1	
1			Clearance analyses limit			į]	
j			the concentrations of					
1			radioactivity that enter			}	}	
			commerce from the			ļ		
]		practice. Limits are based				ĺ	
			on assessments of the		:	İ		
İ			doses from all subsequent]		
			diluting and concentrating					
[processes and uses. In				}	
}	ļ		contrast, implementation					
			of SDLs would allow the		1		ĺ	
[[same concentrations to be				}	
}			present in any or all					
			commodities. Generic				1	
1			dose assessments of					
			SDLs have not been					

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1 (continued)		· · ·	performed for radionuclides in commodities throughout general commerce as could arise in an intervention situation. Concentrating processes and exposures to many commodities could result in doses significantly greater than the dose criterion of 10 μ Sv in a		<u>.</u>		
2	Applies to NORM SDLs		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 attached sheet.). For reasons stated in Comment 1., above, a generic SDL assessment could give greater doses.				

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Comment	Para/Line	Proposed New	Reason	Accepted	Accepted but	Rejected	Reason for
No.	No.	Text			modified as		modification/
L					follows		rejection
3	General		The Basic Safety		<u></u>		
ľ	Applies to		Standards (BSS), a]
	entire		requirements document,				
	document		requires authorization of a	1			ł
]		practice to meet the				
		!	radiation protection	1			İ
		:	principles of justification (a				
			net benefit), optimization				<u> </u>
1			(ALARA), limitation of				<u> </u>
			individual dose, and dose				
1			constraint. In contrast,	}			
			DS161, a safety guide,				
	ĺ		prescribes a new criterion	1		i	l
]		that would require a		•		
	İ		practice to be authorized,	ľ		1	l
]		based only on the			ļ	
			concentration of				1
			radionuclides. There is an			ļ]
			administrative question as				1
ĺ	1		to whether the new "scope				
			defining levels" (SDLs) as				
	[a requirement for	}			l
1			authorization can be				1
l			established in a guidance				Í
ĺ	1		document.				1

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4	General- Applies to entire document		Clearance levels in units of Bq/cm² that implement the radiological criteria for clearance are missing. A large fraction of the commodities cleared from practices only have surficial radioactivity.							
5	General Applies to entire document		Transportation regulations specify both the allowed surficial and mass concentrations of radioactivity, thus compatibility with SDLs is needed.							
6	General Applies to entire document		Waste with no intrinsic value and that can only be disposed, is not a commodity, and, thus, SDLs would not apply to it.							

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7	1.2	Delete reference to human activities in this sentence. Change to readradionuclides are ubiquitous in the environment.	The presence of radionuclides from human activities is addressed in the next sentence.					
8	1.2/8	In the atmosphere and from	clarification					
9	1.2/10	of natural and artificial origin, is nearly always	clarification and accuracy of statement needed					
10	1.2/footnot e 3	add H-3, and C- 14 to list	Significant quantities of these radionuclides naturally occur on earth					
11	1.2/footnot e 4	Add: Some wastes are worthless and, thus, cannot be bought or sold, these are also included.	Clearance applies to worthless wastes that can be disposed in a landfill or incinerated.					

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Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
12	1.3/6	Add sentence to bullet on exclusion: "Unamenable to control through regulation" usually means that regulation cannot be justified, i.e., no net benefit.	Clarification of principle applied				
13	1.3/10	Add sentence: Exempted sources have such a low risk that regulation is unwarranted.	Clarification of rationale				
14	1.3/12	Add sentence: Continuation of regulation is unwarranted due to low risk.	Clarification of rationale.				

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Country/Orga Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection		
15	1.4/ALL	1.4. In addition, the ICRP recommendations and a number of international conventions have considerations that outline their scope of application. A summary of these considerations are: •The exemption from intervention, which involves the use of the ICRP concept of intervention exemption levels [6], is "	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.						

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15 (continued)	1.4/ALL (continued)	recommended specifically in the context of international trade in essential "commodities" such as food, in areas affected by significant incidents and 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					
16	1.5/ALL		Objective should relate SDLs to exclusion, exemption, and clearance.				

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Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/rejection
17	1.5/3	Delete: "for the purposes of radiation protection in accordance with the BSS"	Radiation protection in accordance with the BSS requires justification, optimization, dose limitation, and dose constraint. For the authorization of a practice. Exceeding SDLs would require authorization of a practice, and this requirement is not addressed in the BSS. Additionally, clearance of concentrations of Ra-226 or other radionuclides at concentrations 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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No.	No.	Text			modified as		modification/
					follows		rejection
18	1.6/2	Delete: "but,	General application in				
		rather, they clarify	relation to commodities is		1		
	2.1/1	their scopes of	unanalyzed in the Safety				
		application in	report. Clearance				
		relation to	calculations were				,
		commodities."	performed for releases				
1			from an authorized				
1			practice. They took into				
			account dilutions and				
			concentration of		1		
			radioactivity due to	}			
j			processing. In contrast,				
			scope defining levels				
			would allow the same				
			level of radioactivity at any				
			stage of industrial				
			processing or consumer				
1			use. Doses to individuals,	i			
			especially consumers,				
1			could be much greater		1	[
1	1		than 10 μ Sv in a year.	Ī			ļ

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No.	No.	Text			modified as		modification/
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19	1.7/3	ADD	Some rationale needs to	1			1
	ł	SENTENCE: It is	be provided, so that	1			1
		acknowledged	regulatory authorities,				
		that this may	operators, industry, etc.			1	
		result in non-	do not appear to be	ļ			1
		comparable levels					
		for different types	guidance for control of	1			
		of commodities.	commodities.				
		Such					
		inconsistency is					1
		warranted					
		because of the					
	1	types of					
		radionuclides		1		ļ	
	ļ	involved and the					
		potential types of					
		uses of the					
ļ		commodities in					
i		question.	İ	ļ		1	1

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Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/rejection
20	1.8	This document only addresses volumetric contamination in commodities. Surficially-contaminated materials eligible for release from regulatory control are not addressed	This is a significant omission from the safety series publications list. There are significant inventories of metals and other materials that should be included in the "commodities" heading, but are excluded from the SDLs listing.				
21	Table 1	New text is needed to explain the Pb-210 and Po-210 values of 5 Bq/g	There is no explanation given for the Pb-210 and Po-210 values of 5 Bq/g				
22	3.1-3.4/ali	Explicit ranges of doses from realistic clearance scenarios need to be presented for NORM radionuclides.	A full disclosure of the doses from NORM is required for an informed comparison of risk consequences with the levels for artificial radionuclides.				

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23	3.1-3.4/all	Explicit ranges of doses from realistic clearance scenarios need to be presented for NORM radionuclides.	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 attached sheet.) For reasons given in Comment 1., above the doses attributable to SDL levels in many commodities could be even greater. Thus there is little support for the statement that "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."					

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			omments				
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Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
24	3.2/1	Revise sentence to: "The mechanism of exclusion	Consistent terminology with Section 1.3 should be used.				
25	3.2/8	Provide criteria and methods for determining "amenable to control."	The authority is left without guidance on how to determine amenability to control of exposures from materials containing radionuclides of natural origin.				
26	3.1/5, 3.5/4, 3.6I(B).	judged to be unlikely	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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27	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.	in the form of restricted access or other physical barriers rather than leave				

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Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/rejection
	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, and dose limitation.	Provide sound guidance established by the BSS.				

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29	3.3/13	Revise sentence to: "Decisions on which materials should be within the system of regulatory control may be based on an analysis of the worldwide distribution of the activity concentrations of naturally occurring radionuclides and an evaluation of the human tolerance to health risks associated with these exposures."	For example, concentrations of non-radiological environmental toxins, such as arsenic, are regulated on the basis of health risk.				

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30	3.3/14	of regulatory control and the degree of such control should be based on an analysis of the worldwide distribution of the activity concentrations of naturally occurring radionuclides and on the specific national circumstances (e.g., availability of resources).	Control can be institutional as in restriction of access or translocation of affected populations. The implications of the original language are too suggestive that remediation is the sole course of action.						
31	3.4/3	Scope defining levels for natural radionuclides are the total of the background and any added radioactivity.	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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32	3.5/3-4	with modeling considering a low	The indefinite article "a" is unnecessary.				
33	3.6/6	Change to read "selected set of exposure pathway scenarios"	Exposure pathways were evaluated on a nuclide-by-nuclide basis. All pathways for a scenario were not added to get a total exposure dose.				
34	Section 3.6, page 8	This section should state that certain scenarios encompassed skin contamination also.	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)				
35	Section 3.6, page 8	This section should state that the dose basis ranged from 10 µSv/a to 100 µSv/a	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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36	3.8/all	Revise section to state that the calculations apply to solids cleared from a practice. Similar analyses for liquids and gases have not been performed.	There is no rationale or 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.						

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Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
37	4.1/1	Change to read: "Materials and equipment [alternatively: Commodities and waste] cleared from an authorized practice with activity concentrations below the clearance levels should not be subject to regulatory controls from radiological protection considerations."	If the levels in DS161 were applied to all commodities, they would not necessarily meet the dose criterion of <10 µSv in a year. See reason above for paragraphs 1.6/2 and 2.1/1 (comment 20).				

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38	4.1/3	Delete sentence beginning, "Where commodities have an activity concentration above the scopedefining levels but below the exemption levels," or specify additional safety criteria and applied only to applied to clearance that would be required to equalize the prerequisite conditions of exemption.	must be met before the exemption concentrations can be applied. These conditions are summarized as:				

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39	4.2/3-4	In general,	As originally worded, the				
		countries should	sentence implied that	i			
		coordinate their	measurement along the			1	}
		regulatory	material flow path would				
		strategy and	not be necessary. The				
		implementation	entrance of orphaned	ļ		[1
		with their	sources or related				
		neighboring	contaminated material			l	
		States, including	either incidentally or				
		their monitoring	deliberately would seem			l	
		programs for	to necessitate some				
		commodities, in	degree of monitoring or				ľ
		order to avoid	continuity of control	-		ŀ	
		unnecessary	measure to avoid such				
		nuisance alarms	downstream			1	
		at boundary	contamination scenarios.			l	
		transfer points.		}		}	

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39 (continued)	4.2/3-4 (continued)	The IAEA and other international nuclear material safety organizations should be used to harmonize the control of such commodities and the attendant transboundary interactions.					
40	4.2/8-9	appropriate techniques and equipment to ensure that detection levels are calibrated to detect materials having contamination at or above scope defining levels.	Original wording implies that detection equipment and techniques would result in nuisance alarms, because calibration would pick up levels below the scope defining levels. That is clearly counterproductive and constitutes poor guidance.				

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41	4.5/all	This section appears to contradict some possible scenarios with NORM at the levels in Table I	An individual dose from the realistic scenario with the level of Ra-226 at 0.5 Bq/g yields 1.85 mSv/a. This is above the public dose limit. So, would limitation and control of occupational exposure be required just below this scope defining level? If so it would be a contradiction with the concept of scope defining level.		ionovo		rejeouori	
42	4.6/5	residues in the environment or vice versa. (Guidance	This underscores the guidance that intervention exemption or exclusion levels are not routinely appropriate for clearance of commodities.					

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43	4.7/1	Change to read: Deliberate dilution, as opposed to dilution that takes place in normal operations when radioactivity is not a consideration, in order to meet clearance levels	Distinction should be make from normal operations and processes and dilution for the purpose of meeting a specified concentration level.					

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44	4.7/3	Change to read: "the processing of commodities containing either artificial or natural radionuclides"	While 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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45	4.7/5	defining levels. This may occur in cases where water recycle from sanitation systems results in re-concentration of diluted agents. In such cases	The text was unclear as to circumstances where SDL-compliant releases could results in nontrivial impacts.				

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46	4.7/7	ADD SENTENCE: 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.	The risk that a neighboring country rejecting commodities, when the two regulatory implementations are inconsistent should be explicitly recognized in the guidance.				

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47	References	Reference 13 is EC's RP-122, but the supporting Draft Safety Report references EC RP-89. Which reference is correct?	The Safety Guide and Safety Report should have similar references.			,		

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Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection		
1	General Applies to entire document		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						Deleted: Limits
			based on assessments of the doses from all subsequent diluting and concentrating processes and uses. In contrast,						(acted as Elimo
			implementation of SDLs would allow the same concentrations to be present in any or all commodities. Generic						Deleted: 30
]		dose assessments of SDLs have not been						Inserted: 30
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		A/NRC, DOE, EPA,						
Comment	Para/Line	Proposed New	Reason	Accepted	Accepted but	Rejected	Reason for	
No.	No.	Text			modified as follows		modification/ rejection	
1			performed for					
(continued)			radionuclides in					
			commodities throughout					
			general commerce as could arise in an		1	 		
			intervention situation.					
1			Concentrating processes	-		1		
			and exposures to many			ļ		
1			commodities could result			l		
Į.			in doses significantly			}		
Ì			greater than the dose			1		
			criterion of 10 μ Sv in a					
			year.					
2	Applies to		Although the NORM SDLs					
	NORM		are not dose based, it is					
ļ	SDLs		problematic that some			ļ	ļ	
1			NORM SDLs applied to			1		
			clearance could result in			ł		
			doses greater than the		_			
1			BSS public dose limit of 1 mSv in a year (See					
			attached sheet.). For				1	
İ			reasons stated in			1	\	
			Comment 1., above, a			-		
]		generic SDL assessment				}	
			could give greater doses.					

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| Page 2 of <u>30</u>

Reviewer: C Pageof 3	0 Date	.S. Member State C : 17 August 2002	i	Resolution				
Country/Orga	<u>anizations: US</u>	A/NRC, DOE, EPA,	DOL	l				
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection	
3	General Applies to entire document		The Basic Safety Standards (BSS), a requirements document, requires authorization of a practice to meet the radiation protection principles of justification (a net benefit), optimization (ALARA), limitation of individual dose, and dose constraint. In contrast, DS161, a safety guide, prescribes a new criterion that would require a practice to be authorized, based only on the concentration of radionuclides. There is an administrative question as to whether the new "scope defining levels" (SDLs) as a requirement for authorization can be established in a guidance document.					

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Reviewer: C		.S. Member State C	omments		Resol	ution	
Pageof 3 Country/Orga		: 17 August 2002 A/NRC, DOE, EPA,	DOL			-	
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
4	General Applies to entire document		Clearance levels in units of Bq/cm² that implement the radiological criteria for clearance are missing. A large fraction of the commodities cleared from practices only have surficial radioactivity.				
5	General Applies to entire document		Transportation regulations specify both the allowed surficial and mass concentrations of radioactivity, thus compatibility with SDLs is needed.			,	
6	General Applies to entire document		Waste with no intrinsic value and that can only be disposed, is not a commodity, and, thus, SDLs would not apply to it.				

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Comments by Reviewer					Resolution			
		.S. Member State Co						
Pageof 30 Date: 17 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	
7	1.2	Delete reference to human activities in this sentence. Change to readradionuclides are ubiquitous in the environment.	The presence of radionuclides from human activities is addressed in the next sentence.					
8	1.2/8	In the atmosphere and from	clarification					
9	1.2/10	of natural and artificial origin, is nearly always	clarification and accuracy of statement needed					
10	1.2/footnot e 3	add H-3, and C- 14 to list	Significant quantities of these radionuclides naturally occur on earth					
11	1.2/footnot e 4	Add: Some wastes are worthless and, thus, cannot be bought or sold, these are also included.	Clearance applies to worthless wastes that can be disposed in a landfill or incinerated.					

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Comments by Reviewer					Resolution			
Reviewer: Consolidated U.S. Member State Comments Pageof 30								
		SA/NRC, DOE, EPA,	DOL					
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection	
12	1.3/6	Add sentence to bullet on exclusion: "Unamenable to control through regulation" usually means that regulation cannot be justified, i.e., no net benefit.	Clarification of principle applied					
13	1.3/10	Add sentence: Exempted sources have such a low risk that regulation is unwarranted.	Clarification of rationale		-			
14	1.3/12	Add sentence: Continuation of regulation is unwarranted due to low risk.	Clarification of rationale.					

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Comr	nents by Revi		Resol	ution	· · · · · · · · · · · · · · · · · · ·			
Reviewer: C	Reviewer: Consolidated U.S. Member State Comments							
Pageof 3	0 Date	: 17 August 2002						
Country/Orga	anizations: US	SANRC, DOE, EPA,	DOL					
Comment	Para/Line	Proposed New	Reason	Accepted	Accepted but	Rejected	Reason for	
No.	No.	Text			modified as		modification/	•
					follows		rejection	
15	1.4/ALL	1.4. In addition,	The changes to					
		the ICRP	paragraph. 1.4 are				l	
		recommendations	needed because 1) the					
		and a number of	word "mechanism" is					
		international	incorrect in the text (no					•
		conventions have	mechanisms are					
		considerations	addressed), and 2) the 1 st			ŀ		
		that outline their	bullet may be					
		scope of	misinterpreted to indicate					
		application. A	that the avertable dose					
.1		summary of these	target level of 10 mSv/a is					
11		considerations is:	applicable to materials not					Deleted: are
		•The exemption	requiring regulatory				ļ	
		from intervention,	control. The reference				l	
		which involves	needs to be qualified to					
		the use of the	avoid misapplication of				İ	
		ICRP concept of	large accident cleanup				1	
1		intervention	strategies to low activity					
1		exemption levels	commercial products.					
L	ł	[6], is "	<u> </u>	<u> </u>		<u> </u>		

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	nents by Revi		Resolution				
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Pageof 3		: 17 August 2002					
Country/Orga	anizations: US	A/NRC, DOE, EPA,	DOL				
Comment	Para/Line	Proposed New	Reason	Accepted	Accepted but	Rejected	Reason for
No.	No.	Text			modified as follows		modification/ rejection
15	1.4/ALL	recommended					
(continued)	(continued)	specifically in the					
ļ		context of		'			Ì
Į į		international trade		ļ ·			
1		in essential					
		"commodities"					
		such as food, in		ł			1
		areas affected by					
		significant incidents and are		ļ			
		established for					
1		temporary				 	1
		emergency				ł	
}		application.					
		These levels are					
1		frequently		\		l .	1
}		referred to as]			
İ	}	"action levels"		1			
		and are not				f	
Į		considered					ļ
1		appropriate for]]	
	Ì	routine situations;		Ì		1	
		•The exemption					
16	1.5/ALL		Objective should relate				
1	1		SDLs to exclusion,				
			exemption, and clearance.	<u> </u>			

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	Comments by Reviewer				Resol	lution		1	
Reviewer: Consolidated U.S. Member State Comments							1		
Pageof 3	0 Date	e: 17 August 2002							
Country/Org		SA/NRC, DOE, EPA,		ļ _			·,		
Comment	Para/Line	Proposed New	Reason	Accepted	Accepted but	Rejected	Reason for	ļ	
No.	No.	Text			modified as follows		modification/ rejection		
17	1.5/3	Delete: "for the purposes of	Radiation protection in accordance with the BSS						
	ļ	radiation	requires justification,			}	}	}	
		protection in	optimization, dose						
ļ		accordance with	limitation, and dose					ľ	
İ		the BSS"	constraint for the						Deleted: .
ł	}		authorization of a practice.	ì		1		"	Deleted: F
ļ	İ		Exceeding SDLs would	ļ		ļ			
			require authorization of a						
		İ	practice, and this	1	ļ	ļ			
1	}		requirement is not	•			İ		
ļ	ļ		addressed in the BSS.				ļ		
1			Additionally, clearance of concentrations of Ra-226				,		
ļ	į		or other radionuclides at	1		1	1	1	
			concentrations that could			ł	Ī		
			lead to an individual dose						
ř			greater than 1 mSv in a	1		Ì	1		
\	\		year cannot be said to be	Ì		1	1	1	
			for the purposes of		•				
			radiation protection in	1					
i	1		accordance with the BSS.				l	į į	

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Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Pageof 30					Resol	ution	
Country/Orga	anizations: US	SA/NRC, DOE, EPA,	DOL				
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
18	1.6/2 2.1/1	Delete: "but, rather, they clarify their scopes of application in relation to commodities."	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 concentration of radioactivity due to processing. In contrast, scope defining levels would allow the same level of radioactivity at any stage of industrial processing or consumer use. Doses to individuals, especially consumers, could be much greater than 10 µSv in a year.				

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Reviewer: C Pageof 3	0 Date	J.S. Member State Co e: 17 August 2002	Resolution				
Country/Orga Comment No.	Para/Line No.	SA/NRC, DOE, EPA, Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
19	1.7/3	ADD SENTENCE: 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.	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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Comments by Reviewer					Reso	lution	
Reviewer: C Pageof 3	Consolidated U 30 Date	J.S. Member State Co e: 17 August 2002 SA/NRC, DOE, EPA,					
Comment No.	Para/Line No.	Proposed New Text	· Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
20	1.8	This document only addresses volumetric contamination in commodities. Surficially-contaminated materials eligible for release from regulatory control are not addressed	This is a significant omission from the safety series publications list. There are significant inventories of metals and other materials that should be included in the "commodities" heading, but are excluded from the SDLs listing.				
21	Table 1	New text is needed to explain the Pb-210 and Po-210 values of 5 Bq/g	There is no explanation given for the Pb-210 and Po-210 values of 5 Bq/g				
22	3.1-3.4/all	Explicit ranges of doses from realistic clearance scenarios need to be presented for NORM radionuclides.	A full disclosure of the doses from NORM is required for an informed comparison of risk consequences with the levels for artificial radionuclides.				

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Com	ments by Revi	iewer			Resol	ution			
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Pageof 3	Pageof 30								
		SA/NRC, DOE, EPA,			A second and lead	Delegand	December 1		
Comment	Para/Line	Proposed New	Reason	Accepted	Accepted but	Rejected	Reason for		
No.	No.	Text			modified as follows	 	modification/ rejection		
23	3.1-3.4/all	Explicit ranges of	Low probability scenarios						
		doses from	for clearance were	, ,	ĺ	1	[
		realistic clearance	assessed to ensure that	1 1		1	İ		
	ł	scenarios need to	doses would be unlikely to	Į į		{	<u> </u>		
		be presented for	exceed 1 mSv in a year.	i !			1		
		NORM radionuclides.	However, some doses attributable to the SDLs	! !				l	
	· ·	radionuciides.	for NORM for clearance	[]	1		
	1		exceed 1 mSv in a year.	!		1	<u> </u>	1	
			(See attached sheet.) For	1		1	Ì	Ì	
	1		reasons given in	ļ		ļ			
			Comment 1., the doses	,		1			Deleted: above
	}	1	attributable to SDL levels		[1		[
		}	in many commodities	1	ĺ		1	1	
		1	could be even greater.	1	l	}	1		
		}	Thus there is little support	ļ !	ĺ	1		1	
	į		for the statement that	,		}	}	}	
	ļ	1	"Doses to individuals as a	!	ĺ				
	Į	ļ	consequence of the use of	[l	ļ	ļ	\	
	}]	these scope defining	!	İ	į			
			levels are unlikely to	 	1		[l	
		}	exceed about 1 mSv in a	j	ł]			
	ĺ	(year in most cases,	!	1	-	ļ	ļ	
	1		excluding the contribution from the emanation of	,		}		}	Deleted: 30
		-	radon."			1		/	Inserted: 30
			Tadon.		L		<u> </u>	/; ا	Deleted: 30

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Com	nonte by Boyi	OWOr		ı - · · · · · · · · · · · · · · · · · ·	Reso	ution	
Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments					Heso:	duon	
Pageof 3		e: 17 August 2002					
		SA/NRC, DOE, EPA,	ŀ				
						5	
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
24	3.2/1	Revise sentence to: "The mechanism of exclusion	Consistent terminology with Section 1.3 should be used.				
25	3.2/8	Provide criteria and methods for determining "amenable to control."	The authority is left without guidance on how to determine amenability to control of exposures from materials containing radionuclides of natural origin.				
26	3.1/5, 3.5/4, 3.6I(B).	judged to be unlikely	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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Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Pageof 30					Resolution					
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection			
27	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.								

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		nsolidated U.S. Member State Comments						1	
Pageof 3	0 Date	e: 17 August 2002							
Country/Org	anizations: US	SA/NRC, DOE, EPA,	DOL	<u> </u>					
Comment	Para/Line	Proposed New	Reason	Accepted	Accepted but	Rejected	Reason for	ł	
No.	No.	Text	Ì	1	modified as	1	modification/	1	
	<u> </u>				follows		rejection	_	
28	3.3/13	After sentence	Provide sound guidance			1			
		ending:	established by the BSS.						
		'consideration			į		į		
	l .	and control." Add							
		: "Decisions for							
		existing, as well]		
	1	as future, NORM	ł						
	ľ	industries	ļ						
		including]]				
		fertilizers, coal							
		ash, ores, mineral		1					
		sands, and slag,	ì	1	[
	į	need to be based	(1	ł	1			
		on the				1			
		radiological							
		principles of				1			
		justification,		ļ			-		
	İ	optimization, dose	{		<u> </u>				
]	1	limitation and]			1		j	
	1	dose constraint.	l			<u> </u>			

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Reviewer: C Pageof 3	0 Date	ewer J.S. Member State C E: 17 August 2002 SA/NRC, DOE, EPA,		Resol	ution		
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
29	3.3/13	Revise sentence to: "Decisions on which materials should be within the system of regulatory control may be based on an analysis of the worldwide distribution of the activity concentrations of naturally occurring radionuclides and an evaluation of the human tolerance to health risks associated with these exposures."	For example, concentrations of non-radiological environmental toxins, such as arsenic, are regulated on the basis of health risk.				

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	ments by Rev			Resolution			
· ·		J.S. Member State Co					
Pageof 30 Date: 17 August 2002 Country/Organizations: USA/NRC, DOE, EPA, DOL			[•		
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as	Rejected	Reason for modification/
					follows	[rejection
30	3.3/14	of regulatory control and the degree of such control should be based on an analysis of the worldwide distribution of the activity concentrations of naturally occurring radionuclides and on the specific national circumstances (e.g., availability	Control can be institutional as in restriction of access or translocation of affected populations. The implications of the original language are too suggestive that remediation is the sole course of action.				
31	3.4/3	of resources). Scope defining levels for natural radionuclides are the total of the background and	The text is not clear that the total amount of a naturally occurring radionuclide is included in the SDL and not just the				
		any added radioactivity.	incrementally added amount.				

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	ments by Revi			Resolution			
Reviewer: Consolidated U.S. Member State Comments							
Pageof 30 Date: 17 August 2002 Country/Organizations: USA/NRC, DOE, EPA, DOL							
							
Comment	Para/Line	Proposed New	Reason	Accepted	Accepted but	Rejected	Reason for
No.	No.	Text			modified as follows		modification/ rejection
32	3.5/3-4	with modeling	The indefinite article "a" is				
	ĺ	considering a low	unnecessary.		1		•
33	3.6/6	Change to read	Exposure pathways were				
		"selected set of	evaluated on a nuclide-by-		<u>"</u>		
		exposure	nuclide basis. All				ł
{		pathway	pathways for a scenario				
1	İ	scenarios"	were not added to get a				
			total exposure dose.				
34	Section	This section	Draft Safety Report		1:		1
	3.6, page 8	should state that	indicates that skin				
		certain scenarios	contamination was				İ
		encompassed	evaluated for metal and				
ł	l	skin	concrete processing		;]	<u>}</u>
		contamination	(scenarios II and III), but				
]	also.	not for typical exposure				
35	Section	This section	situations (scenario I)				
33	3.6, page 8	should state that	Draft Safety Report section 3.3, states that				ļ
Ì	5.0, page 0	the dose basis	values in Table 1 of the				
<u> </u>	Í	ranged from 10	Draft Safety Guide were				
	l	μ Sv/a to 100	increased by a factor 10				j
Į	1	μSv/a to 100	to account for the				<u> </u>
		10114	conservatism in metal and		1]
	1	ĺ	concrete scenarios				ł

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Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Pageof 30					Reso	lution	
Comment No.	comment Para/Line Proposed New Reason		Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection	
36	3.8/all	Revise section to state that the calculations apply to solids cleared from a practice. Similar analyses for liquids and gases have not been performed.	There is no rationale or 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.				

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	nents by Rev		Resolution					
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Country/Organizations: USA/NRC, DOE, EPA, DOL				<u> </u>	· · · · · · · · · · · · · · · · · · ·			
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification rejection	
37	4.1/1	Change to read: "Materials and equipment [alternatively: Commodities and waste] cleared from an authorized practice with activity concentrations below the clearance levels should not be subject to regulatory controls from radiological protection considerations."	If the levels in DS161 were applied to all commodities, they would not necessarily meet the dose criterion of <10 µSv in a year. See reason above for paragraphs 1.6/2 and 2.1/1 (comment 20).					

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Comments by Reviewer					Reso	lution			
Reviewer: Consolidated U.S. Member State Comments									
Pageof 30									
Country/Orga	anizations: US	ANRC, DOE, EPA,	DOL						
Comment	Para/Line	Proposed New	Reason	Accepted	Accepted but	Rejected	Reason for		
No.	No.	Text			modified as follows		modification/ rejection		
38	4.1/3	Delete sentence	Exemption can be applied		10110113		rejection		
		beginning,	at higher levels than				<u> </u>		
		"Where	clearance, because				:		
		commodities have	prerequisite conditions						
		an activity	must be met before the	Į			į		
		concentration	exemption concentrations	1			ĺ	ł	
		above the scope-	can be applied. These					1	
			conditions are			•		1	
		below the	summarized as:			ľ		{	
		exemption levels,"	applicable to moderate					1	
]]		OR specify	guantities, sufficiently low						Deleted: or
.]		additional safety	risk to individuals and the	1		ŀ		i	
[]		criteria applied	collective dose to be of no	ļ				'	Deleted: and
il		only to clearance	regulatory concern and			 	ļ	·	Deleted: applied to
		that would be	inherently safe.	{			ľ		
		required to be		L					Deleted: equalize
!		equivalent to the		l	İ		}		
		prerequisite			1		1		
		conditions of]		1		
	<u> </u>	exemption.	<u> </u>	<u> </u>	<u> </u>	l]	

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Reviewer: C Pageof 3	0 Date	ewer J.S. Member State C e: 17 August 2002 GA/NRC, DOE, EPA,			Reso		
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
39	4.2/3-4	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.	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.				

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Reviewer: Consolidated U.S. Member State Comments Pageof 30							
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
39 (continued)	4.2/3-4 (continued)	The IAEA and other international nuclear material safety organizations should be used to harmonize the control of such commodities and the attendant transboundary interactions.					
40	4.2/8-9	appropriate techniques and equipment to ensure that detection levels are calibrated to detect materials having contamination at or above scope defining levels.	Original wording implies that detection equipment and techniques would result in nuisance alarms, because calibration would pick up levels below the scope defining levels. That is clearly counterproductive and constitutes poor guidance.				

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Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Pageof 30				Reso	lution		
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
41	4.5/all	This section appears to contradict some possible scenarios with NORM at the levels in Table I	An individual dose from the realistic scenario with the level of Ra-226 at 0.5 Bq/g yields 1.85 mSv/a. This is above the public dose limit. So, would limitation and control of occupational exposure be required just below this scope defining level? If so it would be a contradiction with the concept of scope defining level.				
42	4.6/5	residues in the environment or vice versa. (Guidance	This underscores the guidance that intervention exemption or exclusion levels are not routinely appropriate for clearance of commodities.				

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Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Pageof 30				Reso				
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection	
43	4.7/1	Change to read: Deliberate dilution, as opposed to dilution that takes place in normal operations when radioactivity is not a consideration, in order to meet clearance levels	Distinction should be made between dilution from normal operations and processes and dilution for the purpose of meeting a specified concentration level.					 Deleted: make

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	ments by Revi		ammonto		Reso	lution	
Pageof 3	0 Date	J.S. Member State Co e: 17 August 2002 SA/NRC, DOE, EPA,					
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/rejection
44	4.7/3	Change to read: "the processing of commodities containing either artificial or natural radionuclides"	While 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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Reviewer: C Pageof 3	0 Date	J.S. Member State Co : 17 August 2002			Resol	ution	
Country/Orga		SA/NRC, DOE, EPA,	DOL				
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
45	4.7/5	defining levels. This may occur in cases where water recycle from sanitation systems results in re-concentration of diluted agents. In such cases	The text was unclear as to circumstances where SDL-compliant releases could results in nontrivial impacts.				

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| Page 28 of 30

Comi Reviewer: C Pageof 3		ewer J.S. Member State Co e: 17 August 2002	omments	Resolution				
		SA/NRC, DOE, EPA,	DOL					
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection	
46	4.7/7	ADD SENTENCE: 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.	The risk that a neighboring country rejecting commodities, when the two regulatory implementations are inconsistent should be explicitly recognized in the guidance.					

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Reviewer: C Pageof 3	0 Date	ewer .S. Member State Co : 17 August 2002 A/NRC, DOE, EPA,			Resol	ution	
Country/Orga Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
47	References	Reference 13 is EC's RP-122, but the supporting Draft Safety Report references EC RP-89. Which reference is correct?	The Safety Guide and Safety Report should have similar references.				

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Reviewer:	(Comments by Reviewer			Res	olution	
Page 1 of 3		Date: uclear Regulatory Commis	ssion				
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
1	Table 1	New text is needed to explain the Pb-210 and Po-210 values of 5 Bq/g	There is no explanation given for the Pb-210 and Po-210 values of 5 Bq/g				
2	References	Reference 13 is EC's RP-122, but the supporting Draft Safety Report references EC RP-89. Which reference is correct?	The Safety Guide and Safety Report should have similar references.				
3	Section 3.6, page 8	This section should state that certain scenarios encompassed skin contamination also.	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)				

Resolution Comments by Reviewer Reviewer: Page 2 of 3 Date: Country/Organization: USA/Nuclear Regulatory Commission **Proposed New Text** Reason for Comment Para/Line Reason Accepted Accepted Rejected but modified No. No. modification/ as follows rejection Section 3.6, This section should 4 **Draft Safety Report** section 3.3, states that page 8 state that the dose basis ranged from 10 values in Table 1 of the uSv/a to 100 uSv/a Draft Safety Guide were increased by a factor 10 to account for the conservatism in metal and concrete scenarios

Reviewer: Page 3 of 3 Country/Orga	I	Comments by Reviewer Date: uclear Regulatory Commission	on		Res	olution	
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
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Title: Radionuclide Content in Commodities not requiring Regulation for Purposes of Radiation Protection DS161

Reviewer: (G. Gnugnoli	Comments by Review	wer	Resolution				
Page 1 of 6		Date: August 9, 2002 A/Nuclear Regulatory Commission						
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection	
General			The basis for new scope defining levels should be established by means of a safety requirements document. This approach is trying to supersede the Basic Safety Standards (BSS).					
General	Through out docume nt.	When incremental doses are meant, it should indicate that these are above background explicitly.	Language is too vague throughout the document regarding total dose exposure or incremental dose above natural background.					
General	Through out docume nt.	SDLs should specify total concentration or concentrations above background levels, specifically for naturally-occurring radionuclides.	See above reason.		,			

Page 2 of		Comments by Review Date SA/Nuclear Regulatory Commission	wer : August 9, 2002	Resolution				
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection	
	1.4/ALL	1.4. In addition, the ICRP recommendations and a number of international conventions have considerations that outline their scope of application: A summary of these considerations are: •The exemption from intervention, which involves the use of the ICRP concept of intervention exemption levels [6], is recommended specifically in the context of international trade in essential "commodities" such as food, in areas affected by significant incidents and 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	The suggested changes to para. 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.					

Comments by Reviewer Resolution Reviewer: G. Gnuanoli Page 3 of 6 Date: August 9, 2002 Country/Organization: USA/Nuclear Regulatory Commission Comment Para/Line **Proposed New Text** Accepted Reason Accepted but Rejected Reason for No. No. modified as modification/ follows rejection 1.7/3 ADD SENTENCE: It is Some rationale needs to be provided. so that regulatory authorities, acknowledged that this may result in noncomparable levels operators, industry, etc... do not appear for different types of to be capricious in setting guidance for commodities. Such control of commodities. inconsistency is warranted because of the types of radionuclides involved and the potential types of uses of the commodities in question. 1.8 This document only addresses This is a significant omission from the volumetric contamination in safety series publications list. There commodities. Surficiallyare significant inventories of metals contaminated materials eligible and other materials which should be for release from regulatory included in the "commodities" heading. control are not addressed. but are excluded from the SDLs listing. Perhaps referring to SS No. 111-P-1.1 could provide a temporary benchmark to use for surficial cases. 3.1/5.there is little chance that an If the term "low probability" is used, 3.5/4. then an estimate should be provided. individual... 3.6I(B). For example, to have the same level of risk, the low probability would need to be on the order of 1%. Then perhaps the figure of 1% should be used to characterize this low probability.

Reviewer: (Page 4 of Country/Or	6	Comments by Review Date SA/Nuclear Regulatory Commission	ver : August 9, 2002		Resolu	tion	
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
**	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.	There may be little point to remediation of naturally poisonous areas which may 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.				
	3.3/14	of regulatory control and the degree of such control should be based on an analysis of the worldwide distribution of the activity concentrations of naturally occurring radionuclides and on the specific national circumstances (e.g., availability of resources).	Control can be institutional as in restriction of access or translocation of affected populations. The implication of the original language are too suggestive that remediation is the sole course of action.				
	3.5/3-4	with a modeling considering a low probability (1%) of the dose to any individual approaching 1mSv in a year.	The indefinite article "a" is unnecessary. Using a probability of 1% results in the same level of risk.				

Comments by Reviewer Resolution Reviewer: G. Gnuanoli Page 5 of 6 Date: August 9, 2002 Country/Organization: USA/Nuclear Regulatory Commission Comment Para/Line **Proposed New Text** Reason Accepted Accepted but Rejected Reason for No. No. modified as modification/ follows rejection 4.2/3-4 In general, countries should As originally worded, the sentence coordinate their regulatory implied that measurement along the strategy and implementation material flow path would not be with their neighboring States. necessary. The entrance of orphaned including their monitoring sources or related contaminated programmes for commodities, in material either incidentally or order to avoid unnecessary deliberately would seem to necessitate nuisance alarms at boundary some degree of monitoring or transfer points. The IAEA and continuity of control measure to avoid other international nuclear such downstream contamination material safety organizations scenarios. should be used to harmonize the control of such commodities and the attendant transboundary interactions. 4.2/8-9 appropriate techniques and Original wording implies that detection equipment to ensure that equipment and techniques would result detection levels are calibrated to in nuisance alarms, because calibration would pick up levels below the SDLs. detect materials having That is clearly counterproductive and contamination at or above scope constitutes poor guidance. defining levels. 4.6/5 This underscores the guidance thatresidues in the environment or vice versa. (Guidance.... intervention exemption or exclusion levels are not routinely appropriate for

clearance of commodities.

Reviewer: (G. Gnugnoli	Comments by Review	ver		Resolu	tion	
Page 6 of 6		Date: August 9, 2002 SA/Nuclear Regulatory Commission					
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
	4.7/5	defining levels. This may occur in cases where water recycle from sanitation systems results in re-concentration of diluted agents. In such cases	The text was unclear as to circumstances where SDL-compliant releases could results in nontrivial impacts.				
	4.7/7	ADD SENTENCE: 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.	The risk that a neighboring country rejecting commodities, when the two regulatory implementations are inconsistent, should be explicitly recognized in the guidance.				

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

Comments by Reviewer					Resolution				
Reviewer: C Pageof 3		J.S. Member State Co : 10 August 2002							
		VNRC, DOE, EPA, DC							
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection		
1	General Applies to entire document	Revise draft Safety Guide to address only clearance criteria and clearance levels.	The basis for new scope defining levels should be established by means of a safety requirements document. This approach is trying to supersede the Basic Safety Standards (BSS).						
2	General Applies to entire document	Revise draft Safety Guide to address only clearance criteria and clearance levels.	There is no coherent overarching principle of radiation protection applicable to "scope defining levels." See comment above.						

Comments by Reviewer					Resolution				
Pageof 3	1 Date:	.S. Member State Con 10 August 2002 VNRC, DOE, EPA, DC							
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection		
3	General Applies to entire document	Revise draft Safety Guide to address only clearance criteria and clearance levels.	The concept that the same levels can be used for clearance levels and levels defining the necessity for authorization is flawed. Application of the radiological protection principles of justification, optimization, and dose limitation is a necessary prerequisite for authorization of a practice under the requirements of the Basic Safety Standards.						

		wer I.S. Member State Co 10 August 2002	mments	Resolution				
	anizations: USA	VNRC, DOE, EPA, DO)L	<u> </u>				
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection	
4	General Applies to entire document	Revise draft Safety Guide to address only clearance criteria and clearance levels.	Clearance levels for artificial radionuclides were derived specifically and distinctly for clearance of commodities or other materials from a practice. Generic analyses of the requirements of authorization that take into account the principles of radiation protection have not been presented and compared with clearance levels.					
5	General Applies to entire document	Revise draft Safety Guide to address only clearance criteria and clearance levels.	Clearance levels in units of Bq/cm² that implement the radiological criteria for clearance are missing.					

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Pageof 31					Resol	ution	
Country/Orga Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
6	General Applies to entire document	Revise draft Safety Guide to address only clearance criteria and clearance levels.	Consideration of both the mass and surface concentration levels of transportation requirements have not been taken into account.				
7	General Applies to entire document	Revise draft Safety Guide to address only clearance criteria and clearance levels.	The document needs to limit its scope to clearance criteria and levels specifically and distinctly for clearance of commodities or other materials and equipment from a practice				

	ments by Revie	wer I.S. Member State Co	mments		Resol	ution	
Pageof 31 Date: 10 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
8	General Applies to entire document	Revise draft Safety Guide to address only clearance criteria and clearance levels.	Introduction of "scope defining levels" adds a new term to the existing structure of radiation protection and thereby adds to complexity and confusion concerning implementation of exclusion, exemption, and clearance.				
9	General Applies to entire document	The document needs to clearly and explicitly distinguish and identify when doses and levels are incremental above background and when they include background	Language is too vague throughout the document regarding total dose exposure or incremental dose above natural background—and similarly for concentration levels.				

Reviewer: C Pageof 3	1 Date:	wer J.S. Member State Col 10 August 2002 VNRC, DOE, EPA, DO		Resolution				
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection	
10	1.2	Delete reference to human activities in this sentence. Change to readradionuclides are ubiquitous in the environment.	The presence of radionuclides from human activities is addressed in the next sentence.					
11	1.2/8	In the atmosphere and from	clarification					
12	1.2/10	of natural and artificial origin, is nearly always	clarification and accuracy of statement needed					
13	1.2/footnote 3	add H-3, and C-14 to list	Significant quantities of these radionuclides naturally occur on earth					
14	1.2/footnote 4	Add: Some wastes are worthless and, thus, cannot be bought or sold, these are also included.	Clearance applies to worthless wastes that can be disposed in a landfill or incinerated.					

Reviewer: Co		.S. Member State Co.	mments	Resolution				
Pageof 3 Country/Orga		10 August 2002 VNRC, DOE, EPA, DC						
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection	
15	1.3/6	Add sentence to bullet on exclusion: "Unamenable to control through regulation" usually means that regulation cannot be justified, i.e., no net benefit.	Clarification of principle applied					
16	1.3/10	Add sentence: Exempted sources have such a low risk that regulation is unwarranted.	Clarification of rationale					
17	1.3/12	Add sentence: Continuation of regulation is unwarranted due to low risk.	Clarification of rationale.					

	nents by Revie			Resolution				
1		.S. Member State Cor	mments					
Pageof 31		·10 August 2002						
Country/Organizations: USA/NRC, DOE, EPA, DOL						, 		
Comment	Para/Line	Proposed New Text	Reason	Accepted	Accepted but	Rejected	Reason for	
No.	No.				modified as	ļ .	modification/	
					follows		rejection	
18	1.4/ALL	1.4. In addition, the	The changes to				1	
j		ICRP	paragraph. 1.4 are				1	
ĺ		recommendations	needed because 1) the					
		and a number of	word "mechanism" is					
		international	incorrect in the text (no			ļ		
\		conventions have	mechanisms are					
		considerations that	addressed), and 2) the			}		
		outline their scope	1 st bullet may be	,		l		
-		of application:. A	misinterpreted to indicate that the		i]		
1		summary of these considerations are:				}		
}	!	•The exemption	avertable dose target level of 10 mSv/a is				1	
1	 	from intervention,	applicable to materials	·		ŀ		
1		which involves the	not requiring regulatory	;		.		
1		use of the ICRP	control. The reference		•			
		concept of	needs to be qualified to	,				
1		intervention	avoid misapplication of			\	1	
		exemption levels	large accident cleanup			1		
	ļ	[6], is "	strategies to low			Ì		
		[[0], .0	activity commercial			}	}	
			products.			1		

Reviewer: C		.S. Member State Cor	nments		Reso	lution	
Pageof 3 Country/Orga		10 August 2002 VNRC, DOE, EPA, DO	L_				
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
18 (continued)	1.4/ALL (continued)	recommended specifically in the context of international trade in essential "commodities" such as food, in areas affected by significant incidents and 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					

	nents by Revie			Resolution				
Reviewer: C Pageof 3		J.S. Member State Co.: 10 August 2002	mments					
		AVNRC, DOE, EPA, DC)L					
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection	
19	1.5/3	Delete: "for the purposes of radiation protection in accordance with the BSS"	Specification of activity concentrations in commodities to determine whether authorization is required is contrary to the BSS, because it circumvents justification, optimization, and dose limitation. Additionally, clearance of concentrations of Ra-226 or other radionuclides at concentrations 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.					

Reviewer: Co	Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Pageof 31 Date: 10 August 2002			Resolution				
		VNRC, DOE, EPA, DO	L					
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection	
20	1.6/2	Delete: "but, rather, they clarify their scopes of application in relation to commodities."	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 concentration of radioactivity due to processing. In contrast, scope defining levels would allow the same level of radioactivity at any stage of industrial processing or consumer use. Doses to individuals,					
			especially consumers, could be much greater than 10 µSv in a year.					

Reviewer: C	Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Pageof 31				Resolution				
Country/Orga	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		
21	1.7/3	ADD SENTENCE: 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.	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.						

Reviewer: C Pageof 3	1 Date:	wer I.S. Member State Co 10 August 2002 VNRC, DOE, EPA, DC		Resolution				
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection	
22	1.8	This document only addresses volumetric contamination in commodities. Surficially- contaminated materials eligible for release from regulatory control are not addressed	This is a significant omission from the safety series publications list. There are significant inventories of metals and other materials that should be included in the "commodities" heading, but are excluded from the SDLs listing.					
23	Table 1	New text is needed to explain the Pb- 210 and Po-210 values of 5 Bq/g	There is no explanation given for the Pb-210 and Po-210 values of 5 Bq/g					
24	3.1-3.4/all	Explicit ranges of doses from realistic clearance scenarios need to be presented for NORM radionuclides.	A full disclosure of the doses from NORM is required for an informed comparison of risk consequences with the levels for artificial radionuclides.					

	Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments				Resol	lution	
Pageof 3		10 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
25	3.1-3.4/all	Explicit ranges of doses from realistic clearance scenarios need to be presented for NORM radionuclides.	It is not true that "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." Table I-IV for low probability scenarios in the Safety Report gives annual doses for K-40, 17.5 mSv; Pb-210, 170 mSv; Po-210, 1 mSv; Ra-226, 37.5 mSv; Ra- 228, 16 mSv; Th-231, 3.35 mSv; Pa-231, 5 mSv. Even for some realistic scenarios, doses exceed 1 mSv.				

Reviewer: C Pageof 3	Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Pageof 31				Resolution					
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection			
26	3.2/8	Provide criteria and methods for determining "amenable to control."	The authority is left without guidance on how to determine amenability to control of exposures from materials containing radionuclides of natural origin.							
27	3.1/5, 3.5/4, 3.6I(B).	judged to be unlikely	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.							

	nents by Revie	ewer J.S. Member State Co	Resolution				
Pageof 3 ⁻	1 Date:	: 10 August 2002		ļ :			
Country/Orga	<u>inizations: US/</u>	AVNRC, DOE, EPA, DC					
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
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.	There may be little point to remediation of naturally poisonous areas that may 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.				

Reviewer: C Pageof 3	ments by Revie onsolidated U 1 Date: anizations: US		Reso	ution			
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
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, and dose limitation.	Provide sound guidance established by the BSS.				

Reviewer: Con Pageof 3	nents by Revie onsolidated U 1 Date: anizations: US/		Reso	lution			
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
30	3.3/13	Delete sentence, "Decisions on which materials should be within the system of regulatory control should be based on an analysis of the worldwide distribution of the activity concentrations of naturally occurring radionuclides."	This assertion is contrary to the principles of radiation protection, is not accompanied by cogent rationale, and is illogical. For example, concentrations of non-radiological environmental toxins, such as arsenic, are regulated on the basis of health risk.				

	nents by Revie		Resolution				
Reviewer: C		I.S. Member State Co					
Pageof 3		10 August 2002					
		VNRC, DOE, EPA, DC		ļ			
Comment	Para/Line	Proposed New Text	Reason	Accepted	Accepted but	Rejected	Reason for
No.	No.				modified as follows		modification/ rejection
31	3.3/14	of regulatory control and the degree of such control should be based on an analysis of the worldwide distribution of the activity concentrations of naturally occurring radionuclides and on the specific national circumstances (e.g., availability of resources).	Control can be institutional as in restriction of access or translocation of affected populations. The implications of the original language are too suggestive that remediation is the sole course of action.				
32	3.5/3-4	with modeling considering a low	The indefinite article "a" is unnecessary.				
33	3.6/6	Change to read	Exposure pathways				
		"selected set of	were evaluated on a				
		exposure pathway	nuclide-by-nuclide	[
		scenarios"	basis. All pathways for				
			a scenario were not				
			added to get a total				
		<u> </u>	exposure dose.	<u></u>	l <u> </u>	<u> </u>	<u> </u>

	nents by Revie		Resolution				
Reviewer: Consolidated U.S. Member State Comments Pageof 31							_
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
34	Section 3.6, page 8	This section should state that certain scenarios encompassed skin contamination also.	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)				
35	Section 3.6, page 8	This section should state that the dose basis ranged from 10 µSv/a to 100 µSv/a	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			,	

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Pageof 31					Reso	ution	
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
36	3.8/all	Revise section to state that the calculations apply to solids cleared from a practice. Similar analyses for liquids and gases have not be performed.	There is no rationale or 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.				

Reviewer: Co Pageof 31	Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Pageof 31					lution	
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
37	4.1/1	Change to read: "Materials and equipment [alternatively: Commodities and waste] cleared from an authorized practice with activity concentrations below the clearance levels should not be subject to regulatory controls from radiological protection considerations."	If the levels in DS161 were applied to all commodities, they would not necessarily meet the dose criterion of <10 µSv in a year. See reason above for paragraphs 1.6/2 and 2.1/1 (comment 20).				

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		J.S. Member State Co	mments	ľ			
Pageof 31		: 10 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
38	4.1/3	Delete sentence beginning, "Where commodities have an activity concentration above the scopedefining levels but below the exemption levels," or specify additional safety criteria and applied only to applied to clearance that would be required to equalize the prerequisite conditions of exemption.	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.		CHOIG		

	nents by Revie	Resolution					
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39	4.2/3-4	In general, countries should coordinate their regulatory strategy and implementation with their neighboring States, including their monitoring programmes for commodities, in order to avoid unnecessary nuisance alarms at boundary transfer points.	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.				

Reviewer: C Pageof 3	1 Date:	ewer I.S. Member State Co. 10 August 2002 VNRC, DOE, EPA, DO	Resolution				
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
39 (continued)	4.2/3-4 (continued)	The IAEA and other international nuclear material safety organizations should be used to harmonize the control of such commodities and the attendant transboundary interactions.					
40	4.2/8-9	appropriate techniques and equipment to ensure that detection levels are calibrated to detect materials having contamination at or above scope defining levels.	Original wording implies that detection equipment and techniques would result in nuisance alarms, because calibration would pick up levels below the scope defining levels. That is clearly counterproductive and constitutes poor guidance.				

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Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection
41	4.5/all	This section appears to contradict some possible scenarios with NORM at the levels in Table I	An individual dose from the realistic scenario with the level of Ra-226 at 0.5 Bq/g yields 1.85 mSv/a. This is above the public dose limit. So, would limitation and control of occupational exposure be required just below this scope defining level? If so it would be a contradiction with the concept of scope defining level.				
42	4.6/5	residues in the environment or vice versa. (Guidance	This underscores the guidance that intervention exemption or exclusion levels are not routinely appropriate for clearance of commodities.				

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No.	No.				modified as follows		modification/ rejection
43	4.7/1	Change to read: Deliberate dilution, as opposed to dilution that takes place in normal operations when radioactivity is not a consideration, in order to meet clearance levels	Distinction should be make from normal operations and processes and dilution for the purpose of meeting a specified concentration level.				

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	anizations: US	A/NRC, DOE, EPA, DO)L						
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/ rejection		
	4.7/3	Change to read: "the processing of commodities containing either artificial or natural radionuclides"	While 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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Comment	Comment Para/Line Proposed New Text Reason				Accepted but	Rejected	Reason for
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45	4.7/5	defining levels.	The text was unclear				
ļ		This may occur in	as to circumstances	į			
		cases where water	where SDL-compliant				
		recycle from	releases could results	ļ .		ļ	
		sanitation systems	in nontrivial impacts.	<u> </u>		ļ	
		results in re-				i	
		concentration of					
Į į		diluted agents. In				1	1
		such cases]	

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46	4.7/7	ADD SENTENCE: 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.	The risk that a neighboring country rejecting commodities, when the two regulatory implementations are inconsistent, should be explicitly recognized in the guidance.					

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47	References	Reference 13 is EC's RP-122, but the supporting Draft Safety Report references EC RP- 89. Which reference is correct?	The Safety Guide and Safety Report should have similar references.						