

— OIP
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 Trotter'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

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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 entire document		SDLs for artificial radionuclides are based on clearance analyses. However, implementation of SDLs is more complex. Clearance analyses limit the concentrations of radioactivity that enter commerce from the practice. Limits are based on assessments of the doses from all subsequent diluting and concentrating processes and uses. In contrast, implementation of SDLs would allow the same concentrations to be present in any or all commodities. Generic dose assessments of SDLs have not been				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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 (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 year.				
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.				

Comments by Reviewer				Resolution			
Reviewer: Consolidated U.S. Member State Comments							
Page ___ of 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
4	General--Applies to entire document		Clearance levels in units of Bq/cm ² 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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
7	1.2	Delete reference to human activities in this sentence. Change to read. ...radionuclides 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/footnote 3	add H-3, and C-14 to list	Significant quantities of these radionuclides naturally occur on earth				
11	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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 30 Date: 17 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 30 Date: 17 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 30 Date: 17 August 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
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 μ Sv in a year.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 30 Date: 17 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 30 Date: 17 August 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
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."				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
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.	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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
28	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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 30 Date: 17 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
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 $\mu\text{Sv/a}$ to 100 $\mu\text{Sv/a}$	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 Page __ of 30 Date: 17 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
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 $<10 \mu\text{Sv}$ in a year. See reason above for paragraphs 1.6/2 and 2.1/1 (comment 20).				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
38	4.1/3	Delete sentence beginning, "Where commodities have an activity concentration above the scope-defining 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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
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 from normal operations and processes and dilution for the purpose of meeting a specified concentration level.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 30 Date: 17 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 30 Date: 17 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 30 Date: 17 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
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.				

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 30 Date: 17 August 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 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 based on assessments of the doses from all subsequent diluting and concentrating processes and uses. In contrast, implementation of SDLs would allow the same concentrations to be present in any or all commodities. Generic dose assessments of SDLs have not been				

Deleted: analyses

Deleted: Limits

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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 (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 year.				
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.				

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer				Resolution			
Reviewer: Consolidated U.S. Member State Comments Page ___ of 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
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.				

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer				Resolution			
Reviewer: Consolidated U.S. Member State Comments Page __ of 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
4	General-- Applies to entire document		Clearance levels in units of Bq/cm ² 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.				

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
7	1.2	Delete reference to human activities in this sentence. Change to read. ...radionuclides 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/footnote 3	add H-3, and C-14 to list	Significant quantities of these radionuclides naturally occur on earth				
11	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.				

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer				Resolution			
Reviewer: Consolidated U.S. Member State Comments Page __ of 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
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.				

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer				Resolution			
Reviewer: Consolidated U.S. Member State Comments Page __ of 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
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 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.				
		•The exemption from intervention, which involves the use of the ICRP concept of intervention exemption levels [6], is "					

Deleted: are

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
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.				

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer				Resolution			
Reviewer: Consolidated U.S. Member State Comments Page ___ of 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
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.				

Deleted: .
Deleted: F

Deleted: 30
Inserted: 30
Deleted: 30

Comments by Reviewer				Resolution			
Reviewer: Consolidated U.S. Member State Comments Page __ of 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
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 μ Sv in a year.				

Deleted: 30
 Inserted: 30
 Deleted: 30

Comments by Reviewer				Resolution			
Reviewer: Consolidated U.S. Member State Comments Page ___ of 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
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.				

Deleted: 30
 Inserted: 30
 Deleted: 30

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 30 Date: 17 August 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
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.				

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
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., 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."				

Deleted: above

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer				Resolution			
Reviewer: Consolidated U.S. Member State Comments Page __ of 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
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.				

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
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.	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.				

Deleted: 30
 Inserted: 30
 Deleted: 30

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 30 Date: 17 August 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
28	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.	Provide sound guidance established by the BSS.				

Deleted: and

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer				Resolution			
Reviewer: Consolidated U.S. Member State Comments Page ___ of 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
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.				

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 30 Date: 17 August 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
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.				

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 30 Date: 17 August 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
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 μ Sv/a to 100 μ Sv/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				

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 30 Date: 17 August 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
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.				

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 30 Date: 17 August 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
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 μ Sv in a year. See reason above for paragraphs 1.6/2 and 2.1/1 (comment 20).				

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 30 Date: 17 August 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
38	4.1/3	Delete sentence beginning, "Where commodities have an activity concentration above the scope-defining levels but below the exemption levels," OR specify additional safety criteria applied only to clearance that would be required to be equivalent to 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.				

Deleted: or

Deleted: and

Deleted: applied to

Deleted: equalize

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer				Resolution			
Reviewer: Consolidated U.S. Member State Comments Page __ of 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
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.				

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 30 Date: 17 August 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
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.				

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
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.				

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 30 Date: 17 August 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
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

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer				Resolution			
Reviewer: Consolidated U.S. Member State Comments Page __ of 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
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.				

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer				Resolution			
Reviewer: Consolidated U.S. Member State Comments Page __ of 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
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.				

Deleted: 30

Inserted: 30

Deleted: 30

Comments by Reviewer				Resolution			
Reviewer: Consolidated U.S. Member State Comments Page __ of 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
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.				

Deleted: 30
 Inserted: 30
 Deleted: 30

Comments by Reviewer				Resolution			
Reviewer: Consolidated U.S. Member State Comments							
Page ___ of 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
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.				

Deleted: 30

Inserted: 30

Deleted: 30

Title:

Comments by Reviewer				Resolution			
Reviewer: Page 1 of 3 Country/Organization: USA/Nuclear Regulatory Commission				Date:			
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)				

Comments by Reviewer				Resolution			
Reviewer: Page 3 of 3 Country/Organization: USA/Nuclear Regulatory Commission							
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/rejection

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

Comments by Reviewer				Resolution			
Reviewer: G. Gnugnoli Page 1 of 6 Country/Organization: USA/Nuclear Regulatory Commission				Date: August 9, 2002			
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 document.	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 document.	SDLs should specify total concentration or concentrations above background levels, specifically for naturally-occurring radionuclides.	See above reason.				

Comments by Reviewer				Resolution			
Reviewer: G. Gnugnoli Page 2 of 6 Country/Organization: USA/Nuclear Regulatory Commission				Date: August 9, 2002			
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/rejection
	1.4/ALL	<p>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:</p> <ul style="list-style-type: none"> •The exemption from intervention, which involves the use of the ICRP concept of <i>intervention exemption levels</i> [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 	<p>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 1st 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.</p>				

Comments by Reviewer				Resolution			
Reviewer: G. Gnugnoli Page 3 of 6 Country/Organization: USA/Nuclear Regulatory Commission				Date: August 9, 2002			
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/rejection
	1.7/3	ADD SENTENCE: It is acknowledged that this may result in noncomparable 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.				
	1.8	This document only addresses volumetric contamination in commodities. Surfactually-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 which should be included in the "commodities" heading, 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, 3.5/4, 3.6I(B).there is little chance that an individual...	If the term "low probability" is used, then an estimate should be provided. 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.				

Comments by Reviewer				Resolution			
Reviewer: G. Gnugnoli Page 4 of 6 Country/Organization: USA/Nuclear Regulatory Commission				Date: August 9, 2002			
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. Gnugnoli Page 5 of 6 Country/Organization: USA/Nuclear Regulatory Commission				Date: August 9, 2002			
Comment No.	Para/Line No.	Proposed New Text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/rejection
	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. The IAEA and other international nuclear material safety organizations should be used to harmonize the control of such commodities and the attendant transboundary interactions.	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.				
	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 SDLs. That is clearly counterproductive and constitutes poor guidance.				
	4.6/5residues 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.				

Comments by Reviewer				Resolution			
Reviewer: G. Gnugnoli Page 6 of 6 Country/Organization: USA/Nuclear Regulatory Commission				Date: August 9, 2002			
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.				

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 31 Date: 10 August 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 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 Reviewer: Consolidated U.S. Member State Comments Page ___ of 31 Date: 10 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 31 Date: 10 August 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
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/cm ² that implement the radiological criteria for clearance are missing.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 31 Date: 10 August 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
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				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 31 Date: 10 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 31 Date: 10 August 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
10	1.2	Delete reference to human activities in this sentence. Change to read. ...radionuclides 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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 31 Date: 10 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 31 Date: 10 August 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
18	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 <i>intervention exemption levels</i> [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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 31 Date: 10 August 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
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					

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 31 Date: 10 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 31 Date: 10 August 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
20	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 μ Sv in a year.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 31 Date: 10 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 31 Date: 10 August 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
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 Page __ of 31 Date: 10 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 31 Date: 10 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 31 Date: 10 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 31 Date: 10 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 31 Date: 10 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 31 Date: 10 August 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
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 "...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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 31 Date: 10 August 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
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 μ Sv/a to 100 μ Sv/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 Page ___ of 31 Date: 10 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 31 Date: 10 August 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
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 $<10 \mu\text{Sv}$ in a year. See reason above for paragraphs 1.6/2 and 2.1/1 (comment 20).				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 31 Date: 10 August 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
38	4.1/3	Delete sentence beginning, "Where commodities have an activity concentration above the scope-defining 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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 31 Date: 10 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 31 Date: 10 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 31 Date: 10 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 31 Date: 10 August 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
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 from normal operations and processes and dilution for the purpose of meeting a specified concentration level.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 31 Date: 10 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page __ of 31 Date: 10 August 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
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 result in nontrivial impacts.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 31 Date: 10 August 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
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.				

Comments by Reviewer Reviewer: Consolidated U.S. Member State Comments Page ___ of 31 Date: 10 August 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
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.				