

DS500 “Application of the Concept of Clearance”

Status: STEP 8, Comments by Member States

Please note that, after the resolution of the Member States’ comments (that is reflected in this table), an extensive review by an IAEA safety standards specialist happened, which resulted in additional significant changes to the draft. Those changes are not reflected in this table. That review led to corrections of the terminology used, improving consistency with DS499, deletion of repetitive text, movement of text inside the document and to Annexes, and shortening some parts.

All those changes could be tracked back, if required so.

Comments **highlighted in yellow** have been resolved. There are several comments on two points, which need additional discussion in the review Committees:

1. treatment of radionuclides of natural origin coming from practices;
2. Former Annex V (Annex IX in the final version) on conservatism in the clearance process.

		COMMENTS BY REVIEWER				RESOLUTION			
		Reviewer: Country/Organization: Germany		Page.... of.... Date:06.07.2021					
Com- ment No.	Rele- vance	Comment No. (by MS)	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
				General comments					
1.		1-AUS	Feedback on whether to merge both documents DS499 (exemption) and DS500 (clearance) or to continue with two separate guides as developed.	The documents require significant revision before they are ready to progress towards publication. One solution that could solve the inconsistencies between the two documents would be to merge them into a single document. Another solution is to follow the structure that has been agreed upon by Member States in the DPP of both DS499 and DS500. Australia has no preference for either option of a merger or the current concept of the two documents. Australia would like to see the application and concepts of exclusion, exemption and clearance clearly articulated and presented in a way that allows for easy implementation by Members States.	Currently, the two documents on exemption and clearance are not consistent with each other. Specifically: • The two documents have clear scope overlap with clearly evident repetition • The concepts of exemption, clearance and exclusion are explained in both documents however do not use the same terminology, which creates confusion for the reader • There are significant structural and styling differences between the two	X			DS499 and DS500 are two separate documents addressing two different concepts, and they do not have to have identical structures, but we fully agree on the need for consistency at the technical level and in using the terminology. Numerous revisions have been done to the draft to improve the aspects raised in the comment.

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					documents, as well as differing language/terminology used within the text • DS500 is extremely detailed in nature and at times it is confusing to follow the application of concepts being conveyed to the reader. Revision of the structure and level of detail in DS500 is needed and should follow similar rationale to the text in the current Safety Guide on Application of the Concepts Exclusion, Exemption and Clearance (IAEA RS-G-1.7). Much of the current text could be removed from DS500 and placed in a standalone Technical Document. The documents require significant revision before they are ready to progress towards publication. One solution that could solve the inconsistencies between the two documents would be to merge them into a single document. Another solution is to follow the structure that has been agreed upon by Member States in the DPP of both DS499 and DS500. Australia has no preference for either option of a merger or the current concept of the two documents. Australia would like to see the application and concepts of exclusion, exemption and clearance clearly articulated and presented in a way that				The comments received to the draft are conflicting with regard to the level of details – some asked for removal of details, while some other requested or proposed additional details, clarifications and examples, adding even more details to the text.
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					allows for easy implementation by Members States.				
2.		GC-CZE	Feedback on whether to merge both documents DS499 (exemption) and DS500 (clearance) or to continue with two separate guides as developed.	The Czech Republic recommends to merge both documents DS499 and DS500 into one. In our opinion will be better to have both concepts in one document with one general part. It will be better also in the situation when EES will be included – there is big difference now how this concept of screening levels is explained in DS 499 and DS500. DS 500 is more explanatory and has a better logistic to explain this new concept. The Czech Republic also recommend to address the concept of screening levels in EES (if this is really necessary) in specific guide which will be developed for Existing exposure situations as approved in last RASSC meeting (June 2021)	It should be noted that both DS 499 and DS 500 are after division of RS-G-1.7. weak in general and explanatory parts. Those who participated in discussions during the development of both drafts can understand some ideas or connotations however those who have not such deep information could be really confused from some newly introduced terms and approaches. Specifically exemption-like and clearance –like approach and screening levels in existing exposure situations. This is something going almost beyond IAEA BSS. There is one reference to ICRP 104 – which is important ICRP recommendation - not very often used, but it is very complex and addressing in details all problems related to the definition of regulatory scope and so also exclusion, exemption, clearance concepts. But it is only explaining in more details what is already stated in ICRP 103. We must have on mind that at the moment almost all MS have implemented ICRP103,IAEA BSS,EU BSS into their national legislative. ICRP 104 is using for existing exposure situations and in the context of exemption the term “non-action values”(para		X		Proposed merge rejected; Appendix I Concept of screening levels revised to explain better the relation with clearance.

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					113,116, for example) which can be established in relation to selected reference level in given situation. In para A 1.8. of this draft is stated that screening level should be smaller or equal to selected RL and it is deducted that the value of 1mSv/y or less is the appropriate value as dose criterion. It is not clear why this value cannot be higher then 1mSv/y ? What about the situations where RL is 10mSv for example? The coincidence of proposed 1mSv/y for screening level and for exemption level for low-probability scenarios used as a reason for selection of this value is weak and not very logical. It would be worthwhile to make more explanations of newly introduced screening levels and to relate them more clearly to ICRP104 ideas. In fact the choice of reference levels in certain EES is already a very complex process which finally ends after optimisation with some level of residual dose which can vary significantly case by case. Do we really need a kind of general lowest level for this purpose? We fully understand that we want to solve and address some long time outstanding issues and we would support this effort however we should				
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					make more benefit than harm and we must be consistent with already existing documents and approaches. ICRP104/para 28 <i>Emergency and existing exposure situations do not fit into the exemption concept. Radiological protection regulations may provide for reference levels for dealing with these situations. The Commission has indicated that in emergency or existing controllable exposure situations, the reference level represents the level of dose or risk above which it is judged to be inappropriate to plan to allow exposures to occur, and below which optimisation of protection should be implemented. The chosen value for a reference level will depend upon the prevailing circumstances of the exposure under consideration. Thus, the Commission's protection principles require assessment of whether protective actions are justified and, if so, what the optimum intervention procedure would be, taking into account the reference level and all relevant aspects and factors. Following this approach, the protective actions may end up with residual dose values far below possible reference levels depending on the particular</i>				
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					<i>circumstances (best achievable result under the given conditions). Conversely, actual emergency or existing situations may result in some actual exposures that are above reference levels, and under the prevailing circumstances, these would have to be accepted. These complex situations cannot be covered by fixed generic or universal exemption values</i>				
3.		1-JPN	General	In accordance with DPPs, DS500 and DS499 should be published separately.	To avoid further time period and resources for the merger of two drafts.	X			
4.		NOR-1	General	We would prefer DS500 to be combined with DS499 on exemption. If not, they should be fully consistent with each other.	The concepts are closely related and the dose criteria are the same. In our view it would be easier to ensure consistency in addressing common elements, and to clarify where there are differences, in a single document. If it is decided to retain two separate Guides, it is critical that they are consistent with each other and with GSR Part 3.	X			Numerous revisions have been done to the draft to improve the consistency.
5.		41-SWE	DS499 and DS500 merged or not.	General comment.	The IAEA has asked for specific comments on whether to merge the two draft documents DS499 (exemption) and DS500 (clearance) into a single Safety Guide or to continue the development and publication of two separate but consistent Safety Guides. Sweden's standpoint is that the two documents should not be merged. Such a decision needs to be taken at the planning	X			

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					stage, i.e., in the development of the DPP(s), and should not be part of the discussion, we believe, at this stage when the two documents are about to be finalised. We received the additional comment from a Swedish licensee, Cyclife Sweden, that the two documents apply to different business areas in their organisation, so from that perspective there is no rationale for merging them.				
6.		2-WNA	Should the DS499 and DS500 be merged?	On the specific question of whether or not the DS499 and DS500 should be merged into one document, WNA recommends <u>not</u> to do this.	One reason for this is that the two concepts applies to different business areas.	X			
7.		1-WNA	General	General set up of the document	Wordings about the large conservatism in several layers and the proposed management of uncertainties, requirements on nuclide vectors etc. do not align.	X			
8.		1-SWE	General	General comment	Wordings about the large conservatism in several layers and the proposed management of uncertainties, requirements on nuclide vectors etc. do not align.	X			
9.		1-FIN	General comment	.	In our opinion, in general the safety guide is well written and applicable from the practical point of view, and allows reasonable and flexible clearance of material at nuclear facilities.	X			
10.		2-FIN	General comment	Could you clarify the scope even further (clear statement whether really all object removal from the controlled area of a nuclear facility is to be considered	The scope of the safety guide: Typically clearance is associated to waste, and it remains a bit unclear, whether	X			

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				clearance and e.g. additional examples if relevant)?	all removal of material and separate objects from the controlled area is to be considered clearance, e.g. tools and equipment, which may often enter and exit the controlled area with workers and for which records are not always kept. Most of the applications mentioned in the draft relate to clearance of waste and typically large amounts of material.				
11.		2-JPN	General	This draft provides good practices that are recently being applied in some countries based not on legacy "measurement error-approach" but on recent "measurement uncertainty approach" in the metrology area. Especially, for the consideration of the uncertainty in measurement in the conformity assessment such descriptions which are based on "measurement uncertainty-approach" should be kept as is, although negative comments based on the "measurement error-approach" may be given.	General comment	X			
12.		WNTI-1	General	"must" should be replaced by another appropriate wording.	"must" should not be used in a Safety Guide and should be replaced by other appropriate wording, depending on the context. Requirements must be moved to the upper-level documents (i.e. regulations).	X			
13.		1-UK	General	Review the Safety Guide to check if the structure can be improved to aid accessibility	We find the document difficult to read. It also has similar content repeated in multiple locations. The document should be reviewed to remove unnecessary repetition and	X			Numerous revisions have been done to the draft to avoid repetitions.

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					consider alternative structures, e.g. all information on characterization in its own chapter.				
14.		2-UK	General	Review the safety guide to ensure that the level of detail is comparable to other safety guides, or if some of the detail would be more suited to a TECDOC or Safety Report	The level of detail provided in DS500 is much greater than would be expected from this type of IAEA document. Although this information is useful to individuals making measurements to demonstrate clearance, some of this information may be better provided in an IAEA technical document rather than a Safety Guide. If retained in the document consider restructuring.	X			Numerous revisions have been done to reduce level of details where appropriate.
15.		4-UK	General comment	Exclusion, exemption and clearance are used as part of the process to determine the nature and extent of regulatory control as it applies to all exposure situations, including planned exposure situations, as part of the optimisation process.	Exemption and clearance are not relevant to existing and emergency situations – see para 1.16 of ds499 “Although, the use of the concept of exemption is exclusively applicable in planned exposure situations....”	X			Para. 1.1 revised with better explanation on how clearance relates to existing exposure situations.
16.		6-UK	General: Specific vs case by case clearance	Provide guidance on relationship between case by case and specific clearance. E.g. para 1.13 suggests that these are two different concepts	The document does not explain the relationship between case-by-case and specific clearance. Case-by case is a subset of specific clearance.	X			
17.		GC-FRA	General comment	The Safety Guide discusses the application of “screening levels” for recycle/disposal of materials and waste after the early and intermediate phases of a nuclear emergency (§ 2.14 and Appendix I). An opportunity to take into account globally comments related to existing		X			

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				exposure situations could be to address the concept of “screening level” in another guide (including the specific cases of post-emergency situations and remediation activities). It would allow to avoid any confusion between planned and existing exposure situations and to withdraw the existing exposure situations from those addressed in DS 499. If this concept should remain in the present guide, it would be at least necessary to precise that potential actions resulting from an exceeding of screening levels have to be locally discussed according to the specific existing exposure situation. A consultation process should be systematically implemented.					
18.		7-MOR	General	-	In the same way it was done in the DS499, it would be preferable to add Flow charts to summarize the application of the clearance concept , clearance levels and/or conditions (Fig. 2, 3 and 4 of the DS499), and a table (table 1 of DS499) to summarize the applicability of the clearance levels.	X			Figure added after para 2.15.
19.		8-MOR	General	-	The references within the guide should be reviewed because they are not easily found in the guide (example: reference 4 SRS44, reference 16 SRS67).	X			
				Specific comments					
20.		1-CZE	Title	Application of the concept of Clearance and screening levels	Current title is not in line with the current content of DS which is not only about concept of clearance			X	Screening levels are discussed in the Appendix only, and the relation with the concept of clearance is explained.

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21.		3-JPN	CONTENTS	Management MANAGEMENT of the Clearance Process..... 35	Editorial.	X			
22.		4-JPN	CONTENTS	Clearance Levels in Terms of Activity Concentration CONCENTRATION or Total Activity 73	Editorial.	X			
23.		5-JPN	CONTENTS	Surface specific SPECIFIC criteria for clearance	Editorial Unify whether or not to capitalize the first letter of nouns (throughout the table of contents).	X			
24.		6-JPN	CONTENTS	Aspects of liquid Liquid-materials MAterials determining the Clearance Option	Editorial	X			
25.		3-UK	Introduction	Text should be revised in conjunction with DS499 to ensure identical concepts are referred to in identical wording.	Introduction of different wording could cause misunderstanding confusion and divergence on how the concepts of exclusion, exemption and clearance are treated. The UK considers that the wording in DS499 is clearer and more concise in a number of these paragraphs.	X			Terminology adjusted: unconditional → generic; conditional → specific; mass-specific → mass-based; surface-specific → surface-based, etc.
26.		9-UK	1.1	Exclusion, exemption and clearance are used as part of the process to determine the nature and extent of regulatory control as it applies to all exposure situations, including planned exposure situations, as part of the optimisation process.	Exemption and clearance are not relevant to existing and emergency situations – e.g. see para 1.16 of ds499 “Although, the use of the concept of exemption is exclusively applicable in planned exposure situations....”	X			
27.		7-JPN	1.1/1 (p.9)	As defined and explained in GSR Part 3[1] and ICRP publ. 103[*], exclusion, exemption and clearance are used as ...	Clarification. Add the references for the definition of exclusion, exemption, and clearance. For exclusion, refer ICRP since this term has not been defined in BSS. Use the definitions given	X			

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					in Safety Glossary to be consistent with DS499.				
28.		1-USA	1.1	Change to say, “Exclusion, exemption, and clearance <i>can be used</i> as part of the process ...	Change from “are used” to “can be used” as there are other options	X			
29.		8-JPN	1.1/ Figure 1 (p.9)	Add the relevant reference of ICRP Publ.104 to the caption of this figure. In addition, the detailed explanations of the concepts of clearance and exemption are provided in DS499, hence some texts regarding DS499 should be added to this paragraph.	Clarification. Figure 1 is almost identical to Figure 4.2 of ICRP Publ.104. Figure 1 in DS499 includes too much information, so it is not necessary to replace Figure 1 of DS500 with that of DS499. However cross-reference would be helpful.	X			
30.		2-USA	1.1 (Figure 1)	The inner circle of Figure 1 should include “ <i>approved action</i> ” or similar term	Paragraph 1.2 notes that the decision for granting clearance occurs after the planned cleanup action; this point is not noted in Figure 1.			X	Figure 1 copied from ICRP 104
31.		3-USA	1.1 (Figure 1)	Remove or clarify the small arrow	It is not clear what significance the small arrow has in explaining the process.			X	Figure 1 copied from ICRP 104
32.		1-MOR	1.1 (Figure 1)	For a source, to enter the regulatory control area, it is through application for authorization or notification. The notification should be added to the figure	Notification is also an instrument for regulatory control, alike authorization.			X	Figure 1 copied from ICRP 104
33.		9-JPN	1.1/6 (p9)	Clearance is the removal of radiological regulatory control from radioactive material or radioactive objects within notified or authorized practices. -> Clearance is the removal of radioactive materials or radioactive objects within notified or authorized practices from regulatory control .	The sentence in DS500 seems unnatural. Please check the sentence in RS-G-1.7 2.13.	X			
34.		1-FRA	1.2/4	Delete “planned” before “activities”.	The notion of planned activity is confusing (not defined).	X			

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35.		1-HUN	1.3, 2 nd row	Instead of “may (gradually) become” we suggest the phrase of “might have become”	An inactive item or machine does not absolutely require notification or authorization if it “may become” radioactive somewhere in the future, only if it presumably of de facto became radioactive.	X			
36.		2-SWE	1.3	Last sentence: <u>Examples of processes that give rise to radioactive or surface-contaminated objects</u> are the activation of materials (including building) and objects in accelerator facilities or in nuclear power plants, or the contamination of objects (e.g. at the surface) by handling or spillage of open sources.	Examples of what?	X			
37.		10-UK	1.6-1.10	Delete these paragraphs and incorporate any necessary text in subsequent objectives and scope section	The content of these paragraphs is more properly addressed in the objective and scope sub-sections. Inclusion here makes the document repetitive and potentially inconsistent.		X		Other MS proposed modification to paras 1.7-1.10.
38.		2-HUN	1.6, 4 th indent	Instead of “conditional (specific) clearance” we suggest the phrase of “conditional (specific) and unconditional clearance”	In this section the “conditional (specific) clearance” is mentioned, but the general (unconditional) clearance is missing.	X			Agree, but para deleted on the basis of the UK comment.
39.		3-HUN	1.7	Consider to note, that the approaches of exemption and clearance in the national legislation should be at the same safety level, to avoid that items which could be exempted out of a practice could not be cleared in they arisen in a practice and vice versa.	It was questioned in several forum, why the guide for exemption and clearance has been divided into two parts. It is maybe not a best solution, but the exemption and clearance must be harmonized.	X			
40.		3-AUS	Paras 1.9, 1.10	Reference 4 (Safety Report Series 44) suggests avoiding ‘over-conservatism’. Para 1.10 also refers to avoid ‘additional layers of conservatism’. These paragraphs should be revised to avoid confusion.	DS500 relies on GSR Part 3, which clearly states the values are derived from conservative model. Revision of these paragraphs will provide	X			Clarification provided in the revised text

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					justification of avoiding over-conservatism.				
41.		4-HUN	1.9	We do not agree with this: “The calculation scenarios and models described in the Ref. [4] are still valid and therefore there is no need to repeat this information in this guidance document.” We suggest: “The calculation scenarios and models described in the Ref. [4] are still valid and summarized in para”	The scenarios referred in para 1.10, 4.4, 4.5, 4.14 and 4.35 can be understood if the reader is aware of the scenarios described in the Ref. [4]. So we strongly suggest to shortly summarize the scenarios in this guide.			X	There are already many comments to reduce level of details and repetitions within the document and reproduction of information from other documents. We consider that providing a reference to SRS-44 is sufficient.
42.		1-ENISS	1.9	The calculation scenarios and models described in the Ref. [4] are still valid and therefore there is no need to repeat this information in this guidance document. <u>There is however a need to recognize the level of conservatism, see paragraph 1.10.</u>	Suggested addition. The models from this reference are not realistic which need to be acknowledged as the need of realism in other parts of this draft is emphasized. (see para 1.10. It is recognized that the general clearance levels for artificial radionuclides are based on exposure scenarios that are highly conservative compared with the exposure that generally can be expected after clearance. This Safety Guide provides guidance on the relevant steps of the clearance process, aiming to assist in preventing build-up of unnecessary additional layers of conservatism. It also reflects the use of the graded approach, in the light of the conservative nature of the values and para 2.7.).			X	Para 1.10 already covers this point.
43.		3-SWE	1.10	It is recognized that the general clearance levels for artificial radionuclides <u>were derived with a prudent approach and thus</u> are based on exposure scenarios that are highly conservative compared with the exposure that generally can be expected	The purpose of the guidance should be how to show compliance with established clearance levels, not to prevent conservatism.		X		Accepted with modification to accommodate comments to the same para from Australia and Norway.

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				after clearance. This Safety Guide provides guidance on the relevant steps of the clearance process, aiming to assist in preventing build up of unnecessary additional layers of conservatism. It also reflects the use of the graded approach, in the light of the conservative nature of the values.	It is true that general clearance levels are based on exposure scenarios that are highly conservative compared with the exposure that <i>generally</i> can be expected after clearance, but this does not mean that the values are always conservative. It is thus misleading to use the wording “conservative nature”.				
44.		NOR-2	1.10	At the end of the last sentence: “...in the light of the conservative nature of the values <u>general clearance levels</u> .”	Just “values” could be ambiguous: it is the conservatism in the derivation of the general clearance levels that is addressed in the Guide.	X			
45.		10-JPN	1.10/1 (p.11)	It is recognized that the general clearance levels for artificial radionuclides are based on derived using a dose of 10 µSv in a year and a series of limiting (bounding) exposure scenarios that are highly conservative compared with the exposure that generally can be expected after clearance.	Clarification. Criteria = Cleared material is of the order of 10 µSv or less in a year. Clearance levels are derived based on the value of 10 µSv in a year.	X			
46.		4-SWE	1.11	The objective of this Safety Guide is to provide detailed guidance on the application of the concept of clearance for materials, objects and buildings that are to be released from regulatory control in the framework of planned exposure situations, as specified in GSR Part 3 [1]. That requirements <u>The Safety Guide</u> address regulatory framework for clearance, clearance process, process of derivation of clearance levels, application of clearance to solid, liquid and gaseous materials, unconditional (general) clearance and conditional (specific) clearance for both mass specific and surface specific clearance criteria. It also provides guidance on involvement of interested parties. The Safety Guide discusses the	1. Typo (“That requirements”) 2. Avoid the use of “/”; “or” is clearer. This applies to the whole document.	X			

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				application of screening levels for recycle/ or disposal of materials and waste after the early and intermediate phases of a nuclear emergency.					
47.		11-UK	1.11	interested parties. The Safety Guide discusses the application of screening levels for recycle/disposal of materials and waste after the early and intermediate phases of a nuclear emergency.	We assume this refers to existing exposures rather than emergency exposures. Consideration of existing exposure should be removed from this document and addressed elsewhere. Note that Para 1.19 states that waste management in an emergency is outside the scope of this document		X		Text revised to improve clarity.
48.		1-UKR	1.11, line 2	The objective of this Safety Guide is to provide detailed guidance on the application of the concept of clearance for materials (<u>including radioactive waste associated with planned activities</u>), objects and buildings that are to be released from regulatory control ...	It is desirable to clarify that this Safety Guide is applied for clearance of radioactive waste at different steps of radwaste management (following decontamination, decay storage etc.) as well	X			
49.		2-MOR	1.12	This safety Guide is intended for authorized parties, technical service providers in charge of radioactive waste management, characterization, or other clearance measurements and regulatory bodies in Member States to assist them in the application of the requirements of GSR Part 3 on the clearance of materials, objects and buildings from regulatory control.	The authorized party can have a contract with a technical service provider (eventually approved by the regulatory body, depending on the national regulatory infrastructure) to carry out clearance measurements (sampling, characterization, monitoring of compliance, etc.). We believe that this is a general comment that needs to be considered in the whole document, because these actions can be carried out on behalf of the authorized party. Meaning that, whenever	X			

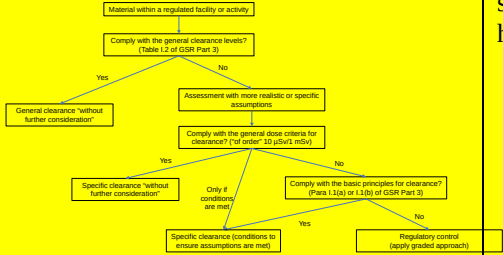
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					talking about the authorized party responsibilities, it might also be of interest to think of the requirements that the technical service providers may need to comply with.					
50.	2	2-GER	1.13 foot note 2 2.35	There are two different explanations of the term “radionuclide vector”. The authors should decide for one explanation only.	Improvement of understanding	X				
51.		12-UK	1.14	Re-draft this paragraph <i>The guidance provided in this Safety Guide is applicable during decommissioning of facilities, to assist in the minimization of waste that will require disposal as radioactive waste, and for removal of regulatory control by the regulatory body from other radioactive material or radioactive objects within other notified or authorized facilities and activities, such as releasing material for unconditional or conditional reuse/recycling or for disposal as non-radioactive waste at conventional disposal site during operation of a facility. The guidance is applicable to solid and liquid materials. For gaseous materials only a brief discussion of key aspects to be taken into consideration is provided in section 6. It is also applicable to clearance of sealed radioactive sources, if such practice is applied in a Member State.</i>	This paragraph is too long and contains many concepts. It also overlaps with the content of 1.13. Suggest the following points are addressed separately: • It applies to the whole life cycle of a facility including decommissioning. • that it facilitates minimizing classification of waste as radioactive • it facilitates application of waste hierarchy by enabling reuse and recycling (not the same as above point) • applicable to solids liquids and gases (stated in 1.13) Applicable to sealed sources					
52.		5-SWE	1.14	...this Safety Guide is applicable during <u>operational phase and</u> decommissioning of facilities,	Applicable during the entire operational phase, not least during maintenance and upgrade.	X				
53.		3-WNA	1.14	...this Safety Guide is applicable <u>during the operational phase and</u> decommissioning of facilities,	Applicable during the entire operational phase, not at least	X				

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					during maintenance and upgrades.				
54.	3	1-GER	1.14	... radioactive waste, and- for removal of ...	Period needs to be removed	X			
55.		1-INS	1.14/8	 to clearance of sealed radioactive sources, if such practice is applied in a Member State. Clearance of Sealed Radioactive Sources (SRS) can be applied only for a very low quantity level of radioactive waste.	In this case, how to determine the clearance level and unit should be determined, whether using Bq or Bq/g? Information from Radioactive Waste Management Installation in Indonesia showed that Ir-192 which has been stored for 10 – 20 years, is still emitting a large amount of radiation exposure due to its impurities. This fact means that the Sealed Radioactive Sources needs more evaluation before clearance.		X		We agree with your comment at a technical level. But adding the proposed text would require further explanations (what is a very low quantity level of RAW?), going into too prescriptive guidance, where we don't have a consensus view of Member States.
56.		6-SWE	1.18	Insert this paragraph after paragraph 1.13	Contrast what is NOT in scope to what is clarifies the understanding of scope.			X	Former paras 1.14 and 1.15 still describe what is in the scope, so 1.18 shouldn't be moved in front of them.
57.		2-ENISS	1.18	It should be noted that different concepts and criteria apply for clearance of buildings versus release of sites, <u>since there can be a different degree of certainty, which also depend on the case, about the potential uses of the land compared to the potential uses of the buildings, which could also include demolition and reuse of building materials for example.</u>	Suggested addition in order to address the main differences also here.	X			
58.		NOR-3	1.18	“Buildings on a nuclear site <u>that are to be demolished</u> can be cleared <u>by considering the demolition waste that will be produced</u> according to the guidance provided in this Safety Guide.”	If a building is left standing and remains on the nuclear site, then there is usually no issue of clearance. If a building is left standing but the nuclear site boundary is to be moved so that the building is no longer on the			X	Buildings can be cleared for reuse and not only for demolition.

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					nuclear site, then maybe WS-G-5.1 is more applicable (or this should be addressed when WS-G-5.1 is revised).				
59.		7-UK	General Structure (section 2)	Section 2 contains various statements which are too prescriptive and inconsistent with text elsewhere in document (e.g. section 3 and 4). The section on regulatory responsibilities actually describes elements of a clearance process, text on regulatory responsibilities similar to that in DS499 would seem more appropriate.	The document should give guidance and options rather than be prescriptive.		X		We tried to address this comment by doing numerous modifications to the draft. But at the same time there were many comments proposing further explanations and examples, adding even more details to the text.
60.		NOR-6	Somewhere in Section 2	Consider adding a diagram similar to that in DS499, for example:  *With detailed explanation in Norway table of comments	The text explains the flexibility provided in GSR Part 3, but some users may find a diagram helpful.	X			
61.		7-SWE	2.1, 2.4	In this Safety Guide term “clearance” is used in accordance with the definition from the IAEA Safety Glossary[8]:- “Removal of regulatory control by the regulatory body from radioactive material or radioactive objects within notified or authorized facilities and activities. GSR Part 3 [1], which defines the concept of clearance as “The removal of regulatory control by the regulatory body from radioactive material or radioactive objects within notified or authorized practices”, where a practice refers to “Any human activity that introduces additional sources	Only ONE definition of clearance should be used in the document. The definition should primarily be taken from a standard, not from the Glossary. Therefore we propose that text from 2.4 is moved to 2.1.	X			

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				<i>of exposure or additional exposure pathways, or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed.”.</i> Removal from regulatory control in this context refers to regulatory control applied for radiation protection purposes.					
62.		4-USA	2.1	Change to say, “The term “clearance” is used in relation to materials, waste and movable <i>objects</i> (e.g., <i>vehicles</i>), buildings or parts of buildings, ...”	Change from “... movable objects including vehicles, buildings, or parts of buildings ...” The sentence currently reads that buildings are movable objects.	X			
63.		2-UKR	2.1, last line	The terms “characterization” and “monitoring” are also used in accordance with the following definition from the IAEA Safety Glossary [8].	Typo. Definitions of terms are established in link [8] according to the list of References.	X			
64.	3	3-GER	2.2	Reference [9 SS 89] must be replaced with the correct Number (probably reference [9]).	Starting in paragraph 2.2, references are partly not defined (i.e. combination of letters and numbers instead of the numbers in the list of references). This requires correction throughout the document.	X			Short abbreviation is kept next to the number to make easier tracking the references. Will be removed in the final stage.
65.		5-HUN	2.2	To be deleted?	We do not know the reason to describe an outdated system.			X	The para provides information that the clearance is well established concept that exists in the international framework for several decades.
66.		5-UK	/2.4/ General (see para 2.4): terminology	Reconsider use of term “conditional clearance” and “unconditional clearance”	Use of the term “conditional clearance” risks introducing confusion as it inconsistent with terminology in GSR part 3 and proposed terminology in	X			

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					DS499. It would be more appropriate to find alternative phases for “mass specific” and “surface specific” It is also not necessarily the case that “conditional” and “specific clearance” are the same. We further note that “unconditional clearance” is frequently used in the document. It is unclear if this is intended to be synonymous with general clearance				
67.		6-HUN	2.4, last sentence	Instead of “The radiological basis for conditional clearance is the same as for clearance, namely those specified in...”, we suggest: “The radiological basis for clearance specified in...”.	We think, the “conditional clearance” is part of the clearance.	X			
68.		7-HUN	2.4, and the whole guide	It is suggested to uniform the term of specific/conditional clearance.	In the guide, there are used the terms of “conditional clearance”, “conditional (specific) clearance”, “specific (conditional) clearance”, etc, which is confusing.	X			
69.		8-HUN	2.4, and footnote no. 4 at page 16.	Revision of consistency with exemption is suggested.	In case of exemption the terms of “specific exemption” and “generic exemption” are used. So is footnote no. 4 valid also for exemption?	X			
70.		13-JPN	2.4/2 (p.16)	Change ‘in GSR Part 3, Schedule 1, section I.13’ to ‘in <u>paragraph</u> I.13, Schedule <u>I</u> of the GSR Part 3 [1]	I.13 is not section but paragraph. ‘Para’ used in 2.7 should be ‘paragraph’. Unify the description method with 2.7.	X			
71.		9-HUN	2.5	To be deleted?	It is not clear, what is the sense and function of this para.	X			

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72.		13-UK	2.5 and 2.6		The intent of these paragraphs is unclear. Is it attempting to state that clearance is only relevant to justified practices? In which case why introduce the concept of authorized parties proposing own clearance values? This should be addressed in a section (section7) on specific clearance.	X				
73.		3-ENISS	2.7	The general criteria for clearance should include the concept trivial dose, of the order of 10- 100 µSv in a year, <u>which has no safety concern</u>	In communication with laypeople as discussed several times in the draft it seems necessary to inform what is actually meant with a “trivial dose(risk?)”.	X				
74.		NOR-4	2.7	Keep all references to the dose criteria for clearance exactly consistent with the wording in GSR Part 3.	Some previous drafts included wording concerning the dose criteria for clearance that were different from that in GSR Part 3. Any differences in wording may cause confusion and may be interpreted to imply different dose criteria, which could undermine the concept of clearance (and exemption). There is flexibility in the GSR Part 3 criteria for those Member States that wish to use it. Other Member States may suggest changes to the text in their comments at this step of the process, and silence from other Member States might be taken to mean that there are no objections to such changes from other Member States. We wish to make clear that we would not agree with any	X				

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					changes that deviate from the criteria in GSR Part 3.				
75.		5-USA	2.7	Para 2.7 stated: “that the expected effective dose (e.g.; for clearance) incurred by any individual is of the order of 10 μSv or less in a year for a realistic exposure scenario and does not exceed 1 mSv in a year for scenarios that address bounding exposure situations (which are termed “low probability scenarios” in GSR Part 3). If clearance is allowed at such relatively high doses (e.g.; not to exceed 1 mSv/y) the safety standard should <i>include a cautionary remark for safety particularly if such material would go through transboundary shipment to another country to avoid shipment rejection and complex administrative controls for safety and security.</i> In addition, if release of such materials in large quantities at these high dose levels could impact another country, consultation and harmonization for reconciliation is recommended.	Clearance of materials at high dose levels, similar to maximum public dose limits may be allowed under certain low-probability impact situation for local country decision but should be coordinated with others if such materials to be shipped to, or to be disposed-off in large quantities at boundaries that could impact another country.	X			
76.		11-JPN	2.7/9-10 (p.16)	.. the concept trivial dose of the order of 10 μSv in a year. The value of 10 μSv in a year was used for the derivation of the generic clearance levels. → .. the concept trivial dose of the order of 10 μSv or less in a year. Taking into account any possible contribution arising from multiple cleared practices, 10 μSv in a year was used for the derivation of the generic clearance levels for each single clearance source.	The meanings of the values should be strictly described as: ● Trivial dose = the order of 10 μSv or less in a year. ● The upper boundary of the trivial dose = the order of 10 μSv in a year = somewhere in between 10 and 100 μSv in a year. The lowest boundary of the values of the upper boundary of the trivial dose = 10 μSv in a year.	X			
77.		12-JPN	2.7	Insert the following text after the last sentence on page 16:	Interpretation of the phrase “of the order of” should be more	X			

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				... the derivation of the generic clearance levels. The phrase “of the order of (10μSv in a year)” as the clearance level in this safety guide should be interpreted in a pragmatic way to allow flexibility for regulation of the clearance level.	elaborated in DS500 as well as in para 4.6., DS499. Moreover, concrete numerical range “of the order of 10 μSv in a year” would be strongly recommended to be explained and expressed in order for both of regulator and implementer to address regulation related to clearance in each Member State, especially in non-English states.				
78.		8-UK	/2.8/ General Application to NORM (2.8, 3.10 and 3.12)	Re consider these paragraphs 2.8These values also apply to radionuclides of natural origin used for their radioactive, fertile or fissile properties because these radionuclides arise from an authorised practice in a planned exposure situation, see para. 3.10.	This text is incorrect. Whilst some countries may apply the more stringent clearance criteria to natural radionuclides used for their radioactive, fissile or fertile properties this is not mandated by GSR part 3 Any NORM residue, not just those used for the radioactive, fissile fertile properties, can result from an authorized practice in a planned exposure situation. See para 3.4(a) of GSR part 3. We would advocate a specific section or sub-section on NORM with a reference to SSG-60	X			
79.	3	4-GER	2.8	Criterion (b) <u>in para. 3.11</u>	Clarify reference	X			
80.		10-HUN	2.8, 3 rd row	Instead of “These values also apply..” we suggest “Values listed in Table I.2 of GSR Part 3..”	Table I.3 of GSR Part 3 is not relevant for radionuclides of natural origin used for their radioactive, fissile or fertile properties,	X			

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81.		11-HUN	2.8, 5 th row	“Criterion(b) is applied “ should be specify.	It is not clear, what criterion (b) should be applied. Criterion (b) of para I.10 of GSR Part 3?	X			
82.		2-FRA	§2.9	The clearance levels in Tables I.2 and I.3 of GSR Part 3 are based on the dose criteria provided in para. I.11 of GSR Part 3, and are derived using generic models.	The clearance levels given in Table I.3 of GSR Part 3 were not based on a dose criterion. Instead, they were based on consideration of the worldwide distribution of concentrations of radionuclides of natural origin.	X			
83.		14-JPN	2.9/1 (p.17)	The clearance levels for artificial origin in Tables I.2 and I.3 of GSR Part 3 are based on the dose criteria provided in para. I.11 of GSR Part 3, and are derived using generic models. On the other hand, the clearance levels for natural origin in Table I.3 of GSR Part 3 are determined on the basis of consideration of the worldwide distribution of activity concentrations for radionuclides of natural origin. Compliance with these clearance levels may be taken without further consideration to indicate compliance with the dose criteria for clearance in para. I.11 of GSR Part 3. Where appropriate, different clearance levels corresponding to the dose criteria in para. I.11 of GSR Part 3 may be derived using more specific, e.g. less conservative, models, or specific materials may be cleared on consideration of specific circumstances and the qualitative criteria in para. I.10 of GSR Part 3.	The clearance levels for radionuclides of natural origin in Table I.3 of GSR Part 3 are not based on the dose criteria provided in para. I.11 of GSR Part 3, as shown in para. 4.2 and 4.3 in RS-G-1.7: <i>RADIONUCLIDES OF NATURAL ORIGIN</i> 4.2. The values of activity concentration for radionuclides of natural origin, derived using the exclusion concept (paras 3.2–3.3), are given in Table 1. 4.3. The values have been determined on the basis of consideration of the worldwide distribution of activity concentrations for these radionuclides.	X			
84.		6-USA	2.10	For clearance of artificial radionuclides during normal operations and decommissioning, an upper bound of 1 mSv per year (for low probability scenarios) is excessive and should be on the order of 0.1 mSv per year, as an	0.1 mSv per year is an appropriate fraction of the public dose limit and allows for public exposure from other licensed radiation sources.			X	This is an internationally accepted approach to both exemption and clearance, which is reflected in GSR Part 3, Schedule I, paragraphs I.2 and I.11.

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				appropriate fraction of the public dose limit.					
85.		3-FRA	2.10/1	For radionuclides of natural origin (<i>as described in the paragraph 3.10</i>) in residues that might be recycled into construction materials, or for which the disposal may present a risk of contamination of drinking water supplies, the activity concentration in the residues should not exceed specific values derived to meet a dose criterion of the order of 1 mSv in a year.”	In order to be consistent with the paragraph 3.10, it is necessary to specify that this point concerns radionuclides that do not arise from authorised practices.			X	In this para we don’t refer strictly to radionuclides coming from authorized practices, so the link with para 3.10 is not appropriate.
86.		NOR-5	2.11	Consider adding a footnote: “In some States, conditional (or specific) clearance may be considered as authorization with minimal conditions.”	As soon as any conditions apply, the distinction between clearance and authorization becomes less clear. The Guide should principally use the terminology of clearance, but some States may find that a concept of ‘authorization with reduced conditions’ fits better with their regulatory framework than ‘clearance with conditions’.	X			
87.		8-SWE	2.12	Clearance is, in principle, applicable to solid, liquid and gaseous materials. Once the clearance process has taken place, the waste or material that meets the clearance levels <u>is the material has been cleared, it no longer considered has to be handled as</u> radioactive material and can be used, recycled or disposed of without further regulatory consideration regarding the radiological aspects. ...	Proposed simplification of the text and to clarify that the material may still be radioactive but this is no concern.	X			
88.		4-ENISS	2.13	This means clearance regulations should be embedded into a regulatory framework specifying that cleared materials are no longer radioactive in a legal sense or, equivalently, that the residual activity of	Para 2.13 - – suggesting adding “as it will not be of safety concern”. (see also para.8.1) Clearance is a regulated process that is safe and in	X			

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				cleared materials may be disregarded <u>as it will not be of safety concern.</u>	accordance with GSR Part 3 [1]. It is defined as the release from radiological regulatory control of material that poses a trivial level of risk to people and the environment, irrespective of its future use. Hence, clearance involves the release of material arising within a radiation regulated activity, e.g. nuclear industry, medical or educational facility, to a destination that is not part of a radiation regulated industry. Cleared material will most likely be processed or used by people who are not familiar with radiation protection and who do not necessarily understand the concept of radiation risk, nor equate the dose criterion of the order of 10 µSv per year with a trivial level of risk to people and the environment. Also, people who use the cleared material without taking any particular radiation protection measures may not understand that they are implicitly protected by the application of the clearance levels (because the scenarios used to derive the clearance levels assume that the material is used by people who are unaware of the origin of the cleared material and therefore do not apply any particular radiation protection measures).				
89.		4-FRA	2.13/8	This means clearance regulations should be embedded into a regulatory framework	The second part of the sentence (“that the residual			X	This is an important message we want to

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				specifying that cleared materials are no longer radioactive in a legal sense or, equivalently, that the residual activity of cleared materials may be disregarded.	activity of the cleared materials may be disregarded”) is sufficient. To affirm that materials containing small quantities of radioactivity is legally no more radioactive may be provocative from the point of view of several stakeholders.				preserve, that we are not releasing radioactive materials.
90.		5-FRA	2.15-2.16		The presentation of the concept of exclusion should be harmonized in both DS 499 and DS 500. The way in DS 500 is better.	X			
91.		12-HUN	2.15 - 2.16	To be deleted? If so, than 1.16 should be revised as well,	Exclusion is out of scope of this guide. These paras do not contribute to the guide at all.			X	In 1.16 we say exclusion is described in Section 2, so there is no inconsistency between 1.16 and 2.15-2.16.
92.		3-MOR	2.15 – 2.16	-	These two paragraphs may be deleted from this safety guide, and the relevant paragraphs in the guide related to the concept of exemption (DS499) can be referred to. The information provided in these two paragraphs is the same given in the guide related to the concept of exemption (DS499).			X	This was done intentionally, following an agreement that identical short text on exclusion will be introduced in both DS499 and DS500.
93.		15-JPN	2.15/5 (p.19)	The text of “ <i>Therefore, sources leading to such exposures are, by their nature, excluded from regulatory control and are out of the scope of the requirements of the GSR Part 3 [1]</i> ” in paragraph 2.15 of DS499 is missing in DS500. Hence this text should be added to the end of paragraph 2.15 of DS500.	Consistency with DS499.	X			
94.		2-AUS	Para 2.17-2.33	This section is disproportionately lengthy.	The responsibility of the Regulatory Body is specified			X	Missing concrete proposal for revisions.

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			Responsibilities of The Regulatory Body	This section should be presented in a concise form.	in GSR Part 3 and in GSR Part 1 though GSR Part 1 is not referred to in this document. It would be useful and easy to understand if all relevant requirements of GSR Part 3 and GSR Part 1 are summarized in one or two paras.				Not clear which part of the text is problematic.
95.		9-SWE	2.18	<u>Depending on the national framework</u> , the regulatory body should set the requirements for radiological characterisation and depending on the national framework , review the results of the characterisation programme implemented by the authorized party (described in para. 2.35) to define the radionuclide inventory subject to clearance.	The regulatory body should focus on setting the requirements. The way of review depends on the national framework.	X			
96.		4-WNA	2.18	Depending on the national framework, + The regulatory body should set the requirements for radiological characterization and depending on the national framework, review the results of the characterization programme implemented by the authorized party (described in para. 2.35) to define the radionuclide inventory subject to clearance.	The regulatory body should focus on setting the requirements. The way results will be review varies between national frameworks.	X			
97.		2-INS	2.18/1	Depending on the national framework, the regulatory body should review and validate the results of the characterisation programme implemented by the authorized party (described in para. 2.35) to define the radionuclide inventory subject to clearance	The authorized party has different standard to perform characterization, however to make sure that the result is true, the regulatory body need to validate the result. The regulatory body can hiring a standard laboratory to perform this validation process.	X			
98.		4-AUS	Para 2.19	In addition to regulatory guidance on bulk materials referring to GSR Part 3 (Table	Clear guidance on ‘moderate quantities’ of materials will be	X			

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				I.2 and Table I.3), there should also be clear guidance on ‘moderate quantities’ of material	useful for consistency and clarity.				
99.		1-ISR	2.21-2.22 and 5.10-5.12	These paragraphs address the role of the nuclear regulatory body regarding aspects of non-radiological requirements and limits when establishing or approving radiological clearance levels. We suggest to consider the need to harmonize the phrasing used in these paragraphs to avoid possible partial contradictions or unclarity. Presently, the phrasings include: <i>...the regulatory body should be <u>aware</u> and <u>to the best extent</u> in par. 2.21 ("mild")</i> <i>...should <u>require</u> ..and <u>should approve</u> in par. 2.22 ("strict")</i> Par. 5.10 uses <i>...should be <u>taken into account</u> when <u>deciding if...</u>("liberal")</i>.	Completeness and Clarity			X	It is not possible to do such kind of harmonization, as certain things are to be required and approved by the regulator, while some others don't need that level of control.
100.		16-JPN	2.23/3 (p.20)	 or to approve parameters information relevant to “the material (or material geometry)” proposed by an authorized party.	Clarification. The word of “parameters” is unclear in this sentence.	X			
101.	3	5-GER	2.26	... processing or reuse).	Surplus bracket	X			
102.	1	6-GER	2.26	3rd sentence should be as follows: If an approval by the regulatory body as to whether specific material is suitable for clearance after it has passed the monitoring process is deemed necessary according to the national framework, it should be based on the monitoring results and the regulatory body’s own verification programme according to paragraph 2.25.	The role of the regulatory body must be clarified because an additional approval of clearance by the regulatory body might be required.	X			
103.		6-FRA	2.26/3 and 2.28/11	2.26 In addition, in case of specific (conditional) clearance, <u>the regulatory body should be provided assurances for compliance with all the conditions attached to the clearance process</u>, such as destination for the material and its further processing or reuse).	Similar topic seems to be presented in paragraphs 2.26 and 2.28. Proposition: to put together in the same paragraph or give more indications to specify the subtle	X			

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				2.28 In the case of conditional clearance (specific clearance), the regulatory body should establish a mechanism to demonstrate compliance with the conditions attached to the process, e.g. that the metal will only go to a recycling facility and will be melted rather than reused directly.	distinction between these two paragraphs.				
104.		5-AUS	Para 2.26: 'statistically based methods'	Guidance on 'statistically based methods' would be useful including sample size, standard deviation etc. A 'footnote' can be considered.	This will help user to apply a consistent approach			X	Beyond the scope of the Safety Guide to explain statistically based methods.
105.		7-FRA	§2.26/8	In addition, in case of specific (conditional) clearance, the regulatory body should be provided assurances for compliance with all the conditions attached to the clearance process, such as destination for the material and its further processing or reuse).		X			
106.		4-MOR	2.28	In the case of conditional clearance (specific clearance) , the regulatory body should establish the mechanism to demonstrate to verify compliance with the conditions attached to the process, e.g. that the metal will only go to a recycling facility and will be melted rather than reused directly.	It is the responsibility of the authorized party to demonstrate compliance with the clearance conditions, while it is the responsibility of the regulatory body to verify whether these conditions have been respected.	X			
107.		17-JPN	2.28/4 (p.21)	In addition, the regulatory body should allocate be clarified responsibilities for the process and consequences in case of non-compliance.	It should be clarified that the word of "allocate".	X			
108.		13-HUN	2.30	Guidance for "documentation that demonstrates compliance of clearance" needed.	In para 5.5 of DS499 for exemption, the safety assessment is suggested for demonstration of compliance. So the role of safety assessment should be outlined in this guide as well.			X	The text says the regulatory body should define what that documentation is. This Safety Guide can't prescribe that.
109.		18-JPN	2.34/1 (p.22)	According to para. 3.38 2.35 of GSR Part 3 ...	Editorial.	X			

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110.		10-SWE	2.35	...determination of the radionuclide vector (fraction of the activity concentration contributed by the each present <u>radionuclides originating from the operations and of importance for the clearance</u>)...	Unreasonable to include each present nuclide. It should be enough to include the nuclides contributing to more than 1% of the total activity or more than 1% of the clearance quota at the time for the clearance.	X			
111.		5-WNA	2.35	...determination of the radionuclide vector (fraction of the activity concentration contributed by the each present <u>radionuclide originating from the operations and of importance for the clearance</u>)...	It is unreasonable to include each nuclide present in the medium. It should be enough to include the nuclides contributing to more than 1% of the total activity as discussed in para. 3.27 or more than 1% of the clearance quota at the time of the clearance.	X			
112.	2	7-GER	2.36	In the first sentence "making the measurements and verifying compliance with the clearance criteria" should be replaced by "perform all necessary steps of the compliance process such as radiological characterization, treatment like decontamination and especially carrying out the measurements to verify compliance with the clearance criteria"	It should be clarified that the authorized party is responsible for all steps necessary in the clearance process, not just for performing the measurements.	X			
113.		5-ENISS	2.36	The authorized party should set up the clearance process, making the measurements and verifying compliance with the clearance criteria, including selecting proper equipment and place for clearance measurements, calibration of equipment, establishment of organisation with clear responsibilities, hiring of competent people, training of staff, promotion of safety culture, development of procedures and documentation, and interfacing with the regulator and interested parties , according to the national framework	It is not necessary to mention interested parties at this point. The National regulation may or may not foresee interfacing with the interested parties.			X	It is already mentioned in the current text "according to the national framework".

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114.		6-ENISS	2.41	The authorized party should engage with interested parties to explain the application of the concept of clearance and seek acceptance from receivers of waste and materials. Interested parties may include professional associations (e.g., a national association of metal recyclers), non-governmental organizations, and the party that is requested to receive the cleared material.	Suggest to delete. Acceptance from the public and parties receiving cleared material is very important for the nuclear industry. The general responsibility described in this paragraph is however too general to be included in “Responsibilities of the authorized party”, where processes, characterization etc are described. The general responsibility is described in paragraph 8.2, and covers both the licensee and the regulator, and can therefore be deleted in “Responsibilities of the authorized party”.			X	We consider it is essential that the authorized party engages with receivers of their cleared waste / material.
115.		3-UKR	2.42	Add a new bullet after bullet (a): Establishing an appropriate procedure for verifying compliance with the clearance criteria	It is proposed to supplement this paragraph with the requirements for the need to establish a procedure for verifying compliance as a very important part of the clearance process	X			
116.		7-ENISS	2.42 c)	Organizing involvement of interested parties (receivers of waste and materials) prior to implementation of the process in accordance with existing national law on public involvement and with graded approach (paragraphs 2.45-2.52).	It is impossible to identify all interested parties of receivers of material. Cleared material on no longer a radioactive material and can be used everywhere and for every purpose.			X	The text refers to receivers taking the material from the authorized party.
117.		7-USA	2.43	<i>Justification</i> should be provided when the authorized party uses generic clearance values or a combination of generic clearance levels and derived clearance levels.	A basis for why individual clearance levels, including generic clearance values, can be applied by the authorized party should be provided to justify their use.	X			
118.		19-JPN	2.43/4 (p.24)	.. for the specific conditional clearance case.	Editorial		X		In this case the intended meaning of the term “specific” was “concrete case, particular case”, and

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									not “conditional clearance”.
119.		5-MOR	2.44	-	Since the authorization or licensing for clearance differs from the instruments adopted for the regulatory control of the practice, it would be of interest to define what is meant by “authorization or licensing for clearance”.			X	It has been explained in the guide (para 1.4) that clearance is a regulated activity that needs regulatory authorization. The authorization could be different, depending on the national regulatory framework. This guide is not prescribing the authorization process.
120.		11-SWE	2.45, 3.13	2.50, 3.13	Change the use of the word “monitoring” to what is really meant, for example, “control programme” (2.45), “measurement process/strategy” (2.50, 3.13), “measurement tools” (3.13)	There is an inconsistent use of the term “monitoring” in the report. In some sections the meaning seems to be “control or surveillance” and in other sections the meaning is “measurement of radioactivity”.	X		
121.		1-ITA	2.45	In order to verify compliance with clearance levels, the authorized party should put in place an appropriate monitoring programme, based on a reliable characterisation, selection of representative samples , and a good definition of the source term (list of radionuclides and their expected activities in the material). The monitoring programme should be submitted to the regulatory body for approval, according to the national framework, before the start of the clearance process	The term reliable characterisation seems to not include the sampling strategy. So a reference to the representative sampling has been proposed	X			
122.		12-SWE	2.46	Clearance occurs at the point at which <u>the operator or the regulatory body decides that</u> regulatory control due to radioactivity of the material is removed. This might involve independent verifications by the regulatory body. Additional considerations for the point at which clearance occurs in	Unclear sentence. It should be made clear that a decision by the operator or the regulator is needed for clearance.	X			

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				case of conditional clearance are addressed in section 7.					
123.		8-ENISS	2.49	The application of the graded approach to the clearance process should take into account aspects such as the size and complexity of the facility or project (e.g. nuclear power plant versus research laboratory, decommissioning versus operational activities), the amount of material to be cleared, operational history, the national regulatory framework and general social and economic factors.	The process of clearance should be based solely on national regulation. General social factors should be taken into account during the development of the regulation. Economic factors should not play any role. Clearance depends on radiological factors and is in itself a graded approach with respect to economic factors.			X	If clearance requires expensive and complicated decontamination or if a cheap disposal is available, the authorized party may decide not to go ahead with clearance on the basis of economic factors.
124.		13-SWE	2.49	The application of the graded approach to the clearance process should take into account aspects such as the size and complexity of the facility or project (e.g. nuclear power plant versus research laboratory, decommissioning versus operational activities), the amount of material to be cleared, the level of <u>knowledge of the</u> operational history, the national regulatory framework and general social and economic factors.	The amount of material should not be a factor, since also small amounts can cause problems if they are not measured properly (cf para 2.52). Instead, the level of knowledge of the operational history is an important factor when designing the clearance process.		X		The Secretariat disagrees that the amount of material is not a factor to be considered. For example, for small amounts it might be cheaper to manage the material as radioactive waste than to invest time, money and effort for establishing and implementing the clearance process.
125.		14-UK	2.49	Add in risk to individuals (workers and public)	Primarily clearance levels are set to protect individuals from risk of radiation exposure			X	Radiological risks in all cases of clearance should be trivial (of the order of 10 micro Sv in a year), so it is not a factor relevant for the application of the graded approach. Materials that could potentially contribute to significantly higher exposures should not come into a situation to be considered for clearance.

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126.	1	8-GER	2.50	The following sentence should be appended: The process of declaring material to be radiologically not impacted by a practice should be subject of regulatory approval.	Especially in the case of nuclear power plants, a considerable amount of material might be considered as not being impacted by the practice (e. g. part of the buildings). That fact alone might be difficult to comprehend for third parties. Therefore, the regulatory body should participate in the decision process to ensure that such decisions are part of a regulated activity according to paragraph 1.4.	X			
127.		15-UK	2.50 1 st sentence	Low levels of contamination – needs some qualification, replace agreement with commensurate	Lack of clarity on low level of contamination and “use of commensurate mor accurately reflects intent of the sentence	X			
128.		16-UK	2.50 2 nd sentence	Replace should with may not need to be applied.	This cannot be a should but a may	X			
129.		17-UK	2.50 3 rd sentence	Replace with “It may be sufficient to state that the material has not been radiologically impacted by the practice; it may however, be necessary that monitoring is required to confirm the absence of activation and contamination.	Improved clarity of intent	X			
130.		8-FRA	2.50/4	In the case where the history and provenance of the material is well known and shows no indications for activation or contamination, the clearance procedure should <u>may</u> not be applied, <u>after the approval of the regulatory body.</u>	To specify that the last point should be approved by the regulatory body.	X			
131.		9-FRA	2.50/7	If any doubt exists, a few confirming measurements should be made to confirm the non-existence of activation or contamination.	If doubt, the clearance process has to be applied.	X			
132.		18-UK	2.52	Replace adequate with proportionate. Suggest that sentence ends after body are met. Followed by “The level of effort	Improved clarity – adequate monitoring could be disproportionate to the circumstance.		X		Radiological risks in all cases of clearance should be trivial (of the order of 10 micro Sv in a year), so

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				should be commensurate with the radiological risk, scope and complexity					it is not a factor relevant for the application of the graded approach. Materials that could potentially contribute to significantly higher exposures should not come into a situation to be considered for clearance.
133.		14-SWE	2.53	<u>In the light of the graded approach</u> , further discussion on the management of the uncertainties in the clearance process is given in section 4.	There are no paragraphs on the graded approach for uncertainties in compliance with clearance levels in section 4. The relevant paragraphs in 4.73 and 4.86 should be revised appropriately, taking account of the graded approach (see comments for para. 4.73 and 4.86 below). The graded approach for uncertainties should be explained more specifically.	X			
134.		6-WNA	2.53	<u>In light of the graded approach</u> , further discussion on the management of uncertainties in the clearance process is given in section 4 <u>and Appendix 2</u> .	There are no paragraphs on the graded approach for uncertainties in compliance with clearance levels in section 4. The relevant paragraphs in 4.73 and 4.86 should be revised appropriately taking account of the graded approach (see comments for para. 4.73 and 4.86). The graded approach for uncertainties should be explained more specifically, e.g. Appendix 2* provided in a separate document * APPENDIX 2, GRADED APPROACH TO UNCERTAINTIES OF MEASUREMENT AND RADIONUCLIDE VECTORS.			X	Appendix 2 had been considered in the early versions of DS500 and was strongly opposed by Japan.

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135.		10-FRA	Chapter 3		Many provisions of this chapter could be moved to a Safety Report or a TECDOC.			X	Please provide a concrete proposal.
136.		10-ENISS	3.2	Only very Short lived radioactive waste [14-GSG-1] can be cleared after storage, when its activity falls below the clearance levels.	Waste that are not very short-lived according to GSG-1, can also be cleared if the storage time is sufficient. The clearance after decay should not be limited to only very short lived waste, as long as the activity criteria or 10 µSv/a limit is met.			X	There is no such class of radioactive waste defined in GSG-1.
137.		3-FIN	3.2	Only very Short lived radioactive waste [14-GSG-1] can be cleared after storage, when its activity falls below the clearance levels.	Waste that are not very short-lived according to GSG-1, can also be cleared if the storage time is sufficient. The clearance after decay should not be limited to only very short lived waste, as long as the activity criteria or 10 µSv /h limit is met.			X	There is no such class of radioactive waste defined in GSG-1.
138.		13-FRA	§3.2/2	The clearance process results in a decision as to whether the waste or material can be released from further regulatory control regarding its radiological properties. Only very short lived radioactive waste [14-GSG-1] can be cleared after storage, when its activity falls below the clearance levels. Storage cannot be used to take advantage of radioactive decay in order to meet the clearance levels, except for very short lived radioactive waste [14-GSG-1]. Other properties, e.g. the hazardous properties of the waste or material, will determine whether other controls remain or become appropriate.	The important idea to highlight is not to use radioactive decay to meet the clearance levels. Moreover, in France, the concept of clearance is not applied to very short-lived waste (i.e. only containing radionuclides with a half-life of less than 100 days). Very short-lived waste can only be sent to a conventional waste route after a period ten times longer than the half-life of the radionuclide. On the planned evacuation date of this waste to an elimination route, a measure must be carried out in order to estimate the residual radioactivity of this waste:	X			

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					- If the result of this measurement is greater than twice the background level, waste is kept in the place of storage. - If the result of this measurement is equal to or less than twice the background level, waste can then be directed to the appropriate route.				
139.		14-HUN	3.2	The first part of sentence of “only very short lived waste can be cleared after storage ...,” suggested to be reformulated, as e.g.: “Decay storage prior to clearance is applicable for materials containing short lived radionuclides, ...”	To be more exact, since any waste or materials can be cleared after storage. The question is, whether the storage is applicable or not.		X		Revised text takes into account multiple comments to this sentence.
140.		19-UK	3.2 sentence 2 nd	Suggest “Only waste that contains very short-lived radioactive species can be cleared after storage, when its radioactivity falls below clearance levels.”	Improved clarity		X		Revised text takes into account multiple comments to this sentence.
141.	2	10-GER	3.3	The first sentence should be changed: “As part of the clearance process, the radionuclide content composition of the material should must be determined ...”	The changes emphasize that here the nuclide vector (i.e. composition) is mentioned but not the overall activity content. In addition, it is emphasized that this is a mandatory part of the clearance process.	X			We are not allowed to use the word “must” in the Safety Guide. It is reserved for the Safety Fundamentals only.
142.	3	12-GER	3.6	... and <i>n</i> is the number of radionuclides present.”	The quotation mark is missing	X			
143.		6-AUS	Para 3.6	The equation given is for the clearance of a mixture of radioactive material of artificial origin for bulk materials. An equation for derivation of clearance of moderate quantities of a mixture of radioactive material of artificial origin would be useful.	No guidance is provided specifically related to the derivation of clearance of moderate quantities of a mixture of radioactive material of artificial origin in this section. It would be useful to have clear derivation equation for both bulk materials and moderate quantities of radioactive materials.			X	The equation is applicable to both moderate and bulk quantities of material. The text doesn’t say it is applicable to bulk amounts only.

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144.		20-JPN	3.6/12 (p.27)	Need a closing quote after "...present."	Editorial	X			
145.		21-JPN	3.6/17 (p.27)	<i>CLi</i> is its corresponding clearance level in the material and <i>n</i> is ... → <i>CLi</i> is its corresponding unconditional or conditional clearance level in the material derived from dose criteria and <i>n</i> is ...	To define <i>CLi</i> clearly in this Guide.	X			
146.		22-JPN	3.7/1 (p.28)	Change 'SRS-44 [3]' to 'SRS-44 [4]'	Editorial.	X			
147.	2	13-GER	3.10	The last sentence should be extended "... naturally-occurring radionuclides, as these clearance levels are not derived considering the 10 µSv per year criterion according to Sect. 2 of Ref. [4]."	It should be explained why the value of 1 Bq/g is not applicable.	X			
148.		7-WNA	3.10	The clearance levels from Table I.3 of GSR Part 3 for the control of radionuclides of natural origin should be applied irrespective from where materials are come from.	The existing text is not consistent with the graded approach and introduces additional practical confusion for no improvement in safety. It may also lead to the unnecessary imposition of clearance levels that are lower than those in Table I.3 of GSR Part3.				CONSENSUS IN WASSC / RASSC NEEDED !
149.		1-ARG	3.10	It is suggested to use the values stated in Table I.3 of GSR Part 3 for the control of radionuclides of natural origin irrespective from where materials come from.	Clearance process is aimed to contribute to optimize protection and safety applying graded approach to regulation of materials, waste and objects containing radionuclides with low activity concentrations, intended to establish which material under regulatory control can be removed from this control. Clearance is a clue process in the minimization of waste that will require disposal as radioactive waste. Bearing in mind the objective of clearance process is the minimization of radioactive				CONSENSUS IN WASSC / RASSC NEEDED !

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					waste, that a sustainable approach for the management of waste has to be applied whenever possible, moving from a linear to a circular economy, that the values of Table I.3 were determined on the basis of consideration of the upper values of the worldwide distribution of activity concentrations in soils, which is related with the exclusion concept and implies recognition of the cost of exercising regulatory control and the net benefit to be gained by doing so, and finally the great confusion that could be caused to Stakeholders by creating different set of values for the same radionuclides, it is suggested to analyze the convenience to derivate new and more restrictive values from 10 µSv/y, that are clearly against the objectives mentioned.				
150.		23-JPN	3.10/1 (p.28)	Contamination with radionuclides of natural origin, where these result from authorised practices in which natural radionuclides are processed for their radioactive, fissile or fertile properties, such as uranium extraction, conversion, enrichment, fuel fabrication and fuel reprocessing, are is treated in ...	Editorial	X			
151.		2-ITA	3.13.	3.13. The objective of radiological characterisation of the material to be cleared is to provide a reliable database of information on quantity and type of radionuclides, their spatial distribution and their physical states and chemical properties.	Physical states and chemical properties are more appropriate definition of the properties of materials to be cleared	X			

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152.		3-ITA	3.14	3.14. Characterisation requires a logical and systematic approach. A comprehensive characterisation programme comprises the following steps [15 TRS389]: (a) review of historical information including process knowledge of the material; (b) activation and decay calculations; (c) preparation of the sampling and analysis plan based on an appropriate statistical approach and on the review of the historical information (step a);	Step c) should take into consideration step a) in a logical approach, as also recalled in para 3.20	X			
153.		11-FRA	3.15/7	3.15 [...] homogeneity distribution of contamination (identification of hotspots on the surface or within the volume) [...]	When a material is contaminated, in particular concrete structures, radionuclides have not the same behavior and don't migrate uniformly.	X			
154.		4-UKR	3.18.	This detailed history should include information on:; location of <u>free access area</u> , controlled and supervised areas; ...	It is proposed to mention a <u>free access area as</u> material and waste will be radiologically clean due to their origin from the free access ("clean") area of the facilities. This could avoid unintentional mixing of clean and potentially radioactive materials.	X			
155.		12-FRA	3.18/5	This detailed history should include information on: the processes or activities during the operation of the facility; location of controlled and supervised areas; ... whether the material has been potentially activated by neutron exposure <u>or by photonuclear reactions</u> ; ...	Photonuclear reactions have to be added as a way of activation (situation that can occur for example in medical accelerators)	X			
156.		5-UKR	3.20, line 4	Initial measurements (<u>e.g. dose rate, radiation type, surface contamination</u>) provide useful information that can be used to guide the sampling plan, e.g. by defining zones	It is desirable to clarify what types of initial measurements can be carried out to provide useful information to guide the sampling plan	X			
157.	3	9-GER	3.21	Steps (e) and (f) <u>described in para 3.14</u>	Add reference	X			
158.		15-HUN	3.21	"Steps () and (f) <i>of para 3.14.</i> "	Missing reference to paragraph.	X			

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159.		20-UK	3.24	Include reference to NW-T-1.18, “Determination and Use of Scaling Factors for Waste Characterization in Nuclear Power Plants” and also ISO21238:2007.	These document comprehensively address the topic of scaling factors.	X			
160.		24-JPN	/3.24/ Footnote6 (p.32)	Factors or parameters determined from sampling and analysis data and used in calculating the radioactivity of difficult-to-measure radionuclides on the basis of measured radioactivity of easy-to-measure radionuclides. To determine the value, it is necessary to consider the practical condition about the sample such as the effect of the averaging mass and the change in the range of radioactivity by the decontamination. It is not intended that the term “scaling factor” is bounded by the other special requirements defined in the other document for the specific application (e.g. NW-T-1.18) outside this definition.	More explanation about scaling factor is necessary. NW-T-1.18 focuses low level radioactive waste. However, in case of the clearance, it is necessary to consider not only the difference of the radioactive concentration within the object and investigation sample but also the effect by the decontamination. In addition, there were some confusions about the term “scaling factor” during the discussion of this draft in our country by the experts who are familiar with NW-T-1.18. To avoid such confusion, it is necessary to clarify that it is not intended that the special requirements for the term defined in other documents are applicable to the term used in this document.		X		See the resolution of the previous comment. A reference to NW-T-1.18 has been added, so we consider it is not necessary to provide additional explanations of the terms and their meaning in NW-T-1.18.
161.		21-UK	3.25 1 st sentence	Suggest replaced with “Scaling factors for DTM radionuclides should be used with caution and reviewed at an appropriate frequency. “	Clarity	X			
162.		25-JPN	Fig.3.1 3.27 (p.33)	Fig 3.1 does not match to the sentences.	In Fig 3.1, these points are lacked. ● Selection of the key nuclide.	X			Selection of the key radionuclide added, conditions for selection of the significant radionuclides and explanation for the third

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					- Condition for the selection of the “significant nuclides” - The smallest number of the “significant nuclides” is acceptable when the ratio over 90%. In SRS-67, the condition is described as “less than 10%” as same Fig 3.1. However, the sentence 3.27 is “>90%”. Why are they different?				bullet are provided in the text. The condition “less than 10%” related to the difference between the sums of C/CL for all RNs and for the significant ones. In the text the sum of C/CL refers to significant RNs, and not the difference, so these two conditions are equivalent.
163.		26-JPN	3.28/11 (p.34)	C _j is the activity concentration (Bq/g) of <i>i</i> th radionuclide for evaluation CL _j is the clearance level (Bq/g) of <i>j</i> th radionuclide for evaluation	Correspondence with C _j (CL _j)	X			
164.		27-JPN	3.31/7 (p.35)	Change (2) to (3) Change (3) to (4)	Editorial.	X			
165.		22-UK	3.34	Remove first sentence	Where the responsibility lies within an organization is not relevant here.	X			
166.		23-UK	3.36 – 3.44	These would be better in an appendix rather than in the body of the standard				X	The Secretariat consider the text fits into the section on management of the clearance process.
167.		16-HUN	3.36	The subtitle “prerequisites for the clearance process” should be changed for “conditions of the clearance process”	Paras 3.36 - 3.42 does not restricted only to prerequisites, since those cover the clearance process itself. For example characterization mentioned in para 3.37 is part of the clearance process not a prerequisite, and para 3.41 describes an idealized clearance process.	X			Subtitles in the section MANAGEMENT OF THE CLEARANCE PROCESS have been removed.
168.		1-RUS	3.36	1. The implementation of the clearance process will require sufficient and adequate equipment to perform the radiation	Clarification of conditions of the clearance process	X			

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				monitoring and equipment to handle the material. The implementation of the clearance process will include the characteristic of material, for example, availability of free liquid and dusting. The area where clearance measurements are being performed should be cleaned previously and should have a low radiation background to the extent practically possible.					
169.	1	14-GER	3.37	The following should be added: “Sometimes, it is not possible to finalize the characterization prior to production of material to be released (e. g. when larger components are not accessible prior to dismantling). In that case, the characterization must be finalized at a later stage of the clearance process. When doing so, the results of the radiological characterization must be available latest prior to the decision measurements.”	It is a common problem that radiological characterization cannot be finalized prior to production of material. This should be addressed.	X			
170.	3	11-GER	3.40 (h)	... according to <u>para</u> 2.25.	Clarify reference	X			
171.		17-HUN	3.41	Suggested to be shortened, emphasizing the key points.	The details of para 3.41 are not too exact, so keeping the key steps, but the very details should be erased. For example the surface specific contamination should be measure on spot if feasible (see para 4.3 (a)), not after wrapping of item and moving it to buffer storage. So para 3.41 (c) is an option, but not idealized one. Also para 3.41 (d) says “... if not, additional decontamination may be necessary and the material is sent of a controlled area for further treatment ...”, This		X		In this paragraph we are addressing the final set of measurements for demonstrating compliance with clearance levels. It is not about the preliminary characterization to determine relevant radionuclides, scaling factors, etc., which can be done in situ (at the place of generation).

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					implies that the characterization does not carried out in a controlled area!				
172.		1-ESP	3.41 (a)	We suggest, as an additional good practice option in a dismantling process, to have a dedicated workshop to classify (clearable, VLLW, LLW), cut, decontaminate (wipe, blasting, scrubbing...), to produce radiological homogeneous (by activity classification) boxes (releasable/clearable, VLLW....) and then to measure the releasable box in a place with a very low background and very precise device.	The proposed ways suggest several on site places for clearance in a dismantling project, and it is not a feasible way		X		We agree with the proposal, and para 3.40 is already talking about that. New text added to the point (b).
173.	1	15-GER	3.41 (b)	The following should be added: "Preferably, sorting has already been performed at an early stage when the material is produced (e.g. during dismantling). This is important to avoid cross-contamination and dilution (i.e. mixing possibly clearable with non-clearable material). In that regard, early sorting avoids unnecessary additional later handling and sorting."	For practical reasons, it is highly recommended to perform sorting as early as possible. This is reflected here.	X			
174.		15-SWE	3.41.c	...measurement of surface specific contamination, including contamination of inner surfaces <u>which could be exposed in the further use of the material and could have been contaminated of significance for the clearance and may have an impact such measurements are required and possible.</u>	Very vague text. Open for interpretations of the words <i>required</i> and <i>possible</i> .	X			
175.		8-WNA	3.41. c	...measurement of surface specific contamination, including contamination of inner surfaces <u>which could have been exposed during their use, and could have been significantly contaminated before the clearance process, and may have an impact such measurements are required and possible.</u>	Very vague text. Open for interpretations of the words required and possible.	X			
176.		16-SWE	3.41.f	...gamma spectrometric measurements are used for this step (in such devices, the mass of material per measurement is usually in	Remove text within the brackets. Wrong location.	X			

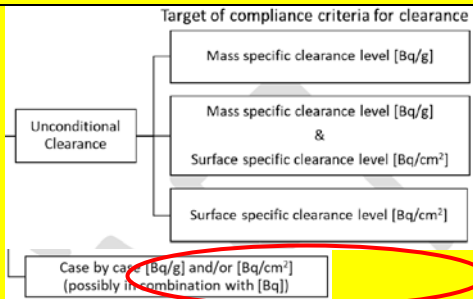
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				the range between a few 10 kg and a few 100 kg).					
177.		9-WNA	3.41. f	...gamma spectrometric measurements are used for this step (in such devices, the mass of material per measurement is usually in the range between a few 10 kg and a few 100 kg).	Remove text within the brackets. Wrong location.	X			
178.		2-ESP	3.41 (f)	Omit the following “in such devices, the mass of material per measurement is usually in the range between a few 10 kg and a few 100 kg)”	This is not an industrial way to proceed, if so, it would take ‘hundreds of years’ the clearance process in a NPP. The measurement process should include a ton or some few tonnes at each time in the final decision.	X			
179.		4-ITA	3.41.	Add: (j) check the buffer storage for any contamination before proceeding to a new batch dislocation	The buffer storage should also be monitored in order to exclude cross contamination due to its sequential use	X			
180.		24-UK	3.44 1 st sentence	.. it may be advisable to construct an appropriately designed separate building where the process deleting lightweight construction	To prescriptive - Lightweight construction may not be appropriate for a facility that could be needed for many decades even if shielding is not required	X			
181.	2	16-GER	3.44	“in lightweight construction” should be omitted	In the framework of a high level guidance document, it seems overly detailed to prescribe construction details which are in any case dependent on the requirement of each particular case.	X			
182.		28-JPN	3.44/3 (p.39)	..., it may be advisable to construct a separate building (in lightweight construction) where the process can be implemented.	There may be no need for “lightweight”.	X			
183.	2	17-GER	3.44	The following sentence should be added after “ ... without extensive demands for shielding or ventilation.” “It requires adequate prior characterization to ensure that only material with	A separate building with reduced protection is only adequate as long as only material with sufficient low activities is allowed to enter.	X			

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				sufficiently low residual activity enters such separate building.”	This, in turn, especially requires adequate prior characterization.				
184.		29-JPN	Section 4 (p.40-68)	Some description in section 4, it is common item not only the solid one but also the liquid and gas. Therefore, some description (for example 4.59-4.86) are possible to move to section 3 (General information about clearance).	Clarification			X	We considered the same idea during drafting, but found it more difficult, as then the flow of information is broken.
185.		14-FRA	Chapter 4		Many provisions of this chapter could be moved to a Safety Report or a TECDOC.	X			In the final round of revision the text of Chapter 4 was shortened significantly.
186.		7-INS	Section 4	For unconditional clearance, the object with economic value can be reuse directly after clearance. For conditional clearance, recycle should be conducted for economic benefit object before reuse it.	This section needs to be added with an explanation regarding the clearance scenario of object that still has economic value.			X	This statement is not valid generally. There are many examples contradicting the statement – unconditionally cleared metallic segments from vessel or pipe cutting need recycling before the metal can be reused; conditionally cleaned building rubble can be reused directly for backfilling of cavities, etc.
187.		11-INS	Section 4	This section needs to give good practice example about clearance of liquid material. Before the liquid effluent is released into the environment, it needs to be collected in an integrated disposal tank for final monitoring and deposition of remaining particles or dirt as implemented in the Serpong Nuclear Area-Indonesia	It is easy to control collected liquid effluent before release into the environment.			X	Section 4 deals with clearance of solid material.
188.		3-INS	4.1/2	 coming from practices, which are addressed in this document. Definition of nomenclature are as follows:	This document needs to explain the definition and example of object for each criteria of	X			

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				Mass specific clearance level (Bq/g) is criteria of clearance for object that contaminated almost at all parts of the object, such as soil, building waste. Mass specific clearance level (Bq/g) and Surface specific clearance level (Bq/cm ²) are criteria of clearance for object that contaminated only at a certain depth, such as metal plate, metal pipe, and tank. Surface specific clearance level (Bq/cm ²) are criteria of clearance for object that contaminated only on surface, such as contamination on impermeable material.	clearance Clear guidelines are needed for each clearance criteria.				
189.	1	18-GER	/4.1/ Fig. 4.1	In case of unconditional clearance, the clearance option with surface specific clearance levels only should be omitted.	According to Paragraph 3.41 (d), compliance with mass-specific clearance levels should be demonstrated in any case. Demonstration of compliance with surface specific clearance levels is thus not sufficient (see also discussion regarding paragraph 4.19 below).	X			
190.		30-JPN	4.1, Fig. 4.1 (p.40)		Option for case-by-case approach should be also addressed under the unconditional clearance. Para. 4.32 and 4.33 in the section of CASE-BY-CASE APPROACH, states “If the derived clearance levels include conditions on the <u>type</u> of material, the <u>amount</u> of material or the <u>destination</u> of the material, then they are a type of conditional clearance level” and “If the decision contains conditions on the <u>type</u> of material, <u>the amount</u> of material or <u>the destination</u> of the material, then this is an example of conditional	X			

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					<i>clearance, see Section 7 for further details.</i> ”, respectively.				
191.		18-HUN	4.3	Instead of term of “clearance strategy” the “monitoring strategy” (see para 4.54.) suggested to be applied.	The term of “clearance strategy” (relevant for radiological characterization) is not used anywhere else in the document. The term of monitoring strategy is used later.		X		“Clearance strategy” replaced with “approach”
192.		4-INS	4.4/6	... material intended for use in food or animal feed. In the determination of mass specific criteria for clearance, the scenario of clearance should be considered, especially for clearance scenarios that allow concentration to occur”	In the case of incineration for contaminated vegetation, there is an increase in the concentration of activity when burning it	X			
193.		6-UKR	4.4, line 8	 is not applicable to large quantities when dilution is not possible or permissible (<u>for instance.....</u>).	It is desirable to give examples of such cases			X	The text already provides an example of excavated soil in the first part of the same sentence
194.	1	19-GER	4.5	The fourth sentence should be as follows: “The parameter values applied in “realistic” and “low probability” scenarios were chosen on the conservative side, with parameter values in “realistic” scenarios “chosen carefully to avoid overconservatism” according to Ref. [4].”	It is stated that “parameter values in “realistic” scenarios” would be “generally lower or equal to those in “low probability” scenarios.” This is not generally true as higher parameter values might not lead to more conservatism (trivially, e.g., a larger distance to a source would reduce the degree conservatism). It is, however, clear that parameters in realistic scenarios are chosen in a less conservative way. This must be clarified.	X			
195.		7-UKR	4.5	... of a set of exposure scenarios encompassing external irradiation, dust inhalation and ingestion (direct and indirect, <u>including ingestion of radionuclides via drinking water and water for agricultural purposes</u>)	It should be clearly defined that all exposure pathways including groundwater pathway have to be adequately considered	X			

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196.		5-INS	4.5	The parameter values applied in “realistic” and “low probability” scenarios were chosen on the conservative side, with parameter values in “realistic” scenarios generally higher in term of radiation protection or equal to those in “low-probability” scenarios.	Parameter value in “realistic” scenarios are not always to those in “low-probability” scenarios. Distance in “realistic” scenarios must be higher than in “low-probability” scenarios.		X		We agree with the comment. Similar formulation proposed by Germany was included in the revised text.
197.		18-FRA	§4.6	Values for other radionuclides of artificial origin should be derived using the models and approach for radionuclides of artificial origin described in Ref. [4 SRS44]. Examples of values for other radionuclides can be found in regulations of some Member States [24,25]. (regulations of Germany, Switzerland)	In the EU BSS directive (annex VII), there is only a dose criterion of 10 µSv / year in the general clearance criteria for radionuclides of artificial origin, for all feasible circumstances. There is no distinction between realistic and low probability scenarios. Furthermore, it would be preferable not to provide examples of values used in certain countries, without the values having been validated at an international level.			X	We consider there is no harm from providing country specific examples in a Safety Guide level publication.
198.		2-ARG	4.7	A scenario-based approach was not used in the case of material that contains radionuclides of natural origin not arising from practices . Instead, the mass specific clearance levels given in Table I.3 of the GSR Part 3 [1] were derived using a pragmatic approach that involved consideration of the worldwide distribution of the concentration of radionuclides of natural origin present in material that is found in the environment	It is suggested to remove “ <i>not arising from practices</i> ”. The documents that present these values do not state they applied only for materials not coming for practices. Besides clearance apply only for practices. <i>RS-G 1.7 states, regarding the application of these values:</i> <i>p. 5.1. It is usually unnecessary to regulate radioactive material in activity concentrations below the values given in Table 1.</i> <i>5.2. If the activity concentration of the radionuclide exceeds the value of activity concentration given</i>				Similarly to comments 148 and 149, CONSENSUS IN WASSC / RASSC NEEDED !

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					in Table 1, the regulatory body should decide on the extent to which the regulatory requirements set out in the BSS [1] should be applied. A graded approach as described in paras 5.11–5.13 may be applied. 5.3. In addition, the values of activity concentration in Table 1 may be used to determine whether material within a practice can be released from regulatory control. 5.4. The way in which these values should be incorporated into national regulatory requirements will depend on the particular regulatory approach adopted. One approach may be to use these levels in the definition of the scope of the regulations. Another approach may be to use the levels to define radioactive material for the purposes of the regulations.				
199.		10-WNA	4.7	Remove the following words from the clause: “not arising from practices”	The original documents (RSG1.7 for example) do <u>not</u> state that the clearance levels only apply to materials coming from practices.				Similarly to comments 148 and 149, CONSENSUS IN WASSC / RASSC NEEDED !
200.		19-FRA	§4.7/6	The same pragmatic approach should be used to determine the mass specific clearance levels for other radionuclides of natural origin, e.g. primordial radionuclides. A mass specific clearance level of 1 Bq/g should be used for these primordial radionuclides pending establishment of specific values for these radionuclides on the basis of worldwide distribution.	It is not obvious that the worldwide distribution of concentrations for other radionuclides of natural origin lead to the establishment of a clearance level of 1 Bq/g.	X			

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201.		3-ARG	4.8	It is suggested to use the values stated in Table I.3 of GSR Part 3 for the control of radionuclides of natural origin irrespective from where materials come from.	Same reason established in Comment No. 1. Besides the doses to individuals as a consequence of Table I.3 of GSR Part 3 would be unlikely to exceed about 1 mSv in a year, excluding the contribution from the emanation of radon, which is dealt with separately in the BSS.				CONSENSUS IN WASSC / RASSC NEEDED !
202.		13-WNA	4.8	(Same comment as in section 3.10) The clearance levels from Table I.3 of GSR Part 3 for the control of radionuclides of natural origin should be applied irrespective from where materials come from.	(Same comment as in section 3.10) The existing text is not consistent with the graded approach and introduces additional practical confusion for no improvement in safety. It may also lead to the unnecessary imposition of clearance levels that are lower than those in Table I.3 of GSR Part3.				CONSENSUS IN WASSC / RASSC NEEDED !
203.		20-FRA	§4.9	GSR Part 3 [1] also specifies that the mass specific clearance levels given in Schedule I, Table I.3 in [1] may also be applied for the clearance of materials arising from practices subject to the clearance criteria given in para. I.11, pending establishment of radionuclide specific values for the radionuclides of natural origin given in Table I.3. The member state should develop a programme for establishing these radionuclide specific values.	Defining these levels is not necessarily the member state's responsibility. These values could be established by the applicant, with a complete demonstration of the compliance with the dose criterion of 10 µSv per year, and a validation on a case-by-case basis by the regulatory body, as explained in §2.22.	X			
204.		31-JPN	4.10(b)/5 (p.45)	The explanation of the term "safe enclosure" in a footnote is helpful. SSG-47 refers to "safe enclosure" in footnote 3 as follows;	Clarification. There is no definition of "safe enclosure" in IAEA Safety Glossary 2018 ed.	X			

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				<i>the term ‘safe enclosure’ means the period during the implementation of the deferred dismantling strategy in which the facility is placed and maintained in a safe, long term storage condition until decontamination and dismantling actions are performed.</i>					
205.		11-ENISS	4.11	An alternative approach is described in para 4.12. If direct handling without significant decay time could be avoided and a decay storage for several days or weeks a sufficient time arranged before clearance of materials with very short-lived radionuclides, that may eliminate the need for such considerations	Should be applicable to all radionuclides. The storage time depends on the half-life, but may even years. Cf. GSG-1, definition for very short-lived waste: “Waste that can be stored for decay over a limited period of up to a few years and subsequently cleared from regulatory control...”			X	Decay storage is possible for all radionuclides, but during the decay storage the material is kept under regulatory control, so can’t be released. This guide aims to provide guidance on how to release material from regulatory control (immediately or after a relatively short decay storage).
206.		1-BEL	4.12/line 1	“When direct handling after clearance of moderate quantities of material is considered as specified by the regulatory body, the exemption levels given in Table I.1 of GSR Part 3...”	“moderate quantities” not defined except in a footnote in appendix (page 124). Better to define in main document, earlier.	X			Definition inserted in para 2.20, when the “moderate quantities” are mentioned for the first time.
207.		32-JPN	4.13(a)/2,3 (p.46)	Two sets of scenarios have been used in parallel, one applying so-called “realistic scenarios” for an individual effective dose limit criterion of the order of 10 µSv per year, and one applying so-called “low probability scenarios” for an individual effective dose limit criterion of 1 mSv per year.	Consistency with BSS	X			
208.	3	20-GER	4.13 (b)	... in the model.	Sentence point missing	X			
209.		17-SWE	4.13	Text to be added: (c) Calculated clearance levels have been rounded to the nearest potential of 10.	This introduces conservatism in some cases and non-conservatism in other cases.	X			
210.		8-USA	4.14	Change to say, “A less conservative, but impractical approach would be to sum the	Change “...and evaluate then the activity value leading ...”	X			

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				contributions of the radionuclides in the radionuclide mixture for each scenario and each exposure pathway first and <i>then evaluate</i> the activity value leading to full utilisation of the dose criterion of the order of 10 µSv per year.”	to “... and then evaluate the activity value leading ...” to make the sentence easier to understand				
211.	1	21-GER	4.16	Second sentence should be: “It is recognized that the derived clearance levels have been derived on a sufficiently conservative basis while avoiding to be overly conservative [4]. Their implementation in practice could take into account this model-intrinsic conservatism to avoid the imposition of further conservatisms commensurate with the degree of conservatism in the model as well as considering the particular case and the requirements of the national regulatory framework.”	It is not justified to omit any conservatism by just stating that the clearance levels are derived in a conservative way. It is clear that additional conservatism is not generally required, however, care must be taken that such omission is commensurate with the level of conservatism in the model and does not lead to a situation, which is not compatible with the 10 µSv per year concept. In practice, it must thus be ensured, that such omission is compatible with the particular case and with the requirements of the national framework.	X			
212.	1	22-GER	4.17	... using larger averaging areas or averaging masses etc. <u>The usage of less conservative calibrations should be documented taking into account the conservatism of the clearance levels and should be approved by the regulatory body.</u> Further aspects ...	Clarification of the requirements to use less conservative calibrations and the role of the regulatory body within this procedure	X			
213.	1	23-GER	4.17	An explanation should be added after sentence one ending with “... using larger averaging areas or averaging masses etc.” “This must consider the particular circumstances and must be in accordance with the national regulatory framework while such implementation is subject to regulatory oversight. Care should be taken to avoid the impression to interested third	Similar arguments apply as above for paragraph 4.16. Practical implementation of the clearance process requires consideration of the particular circumstances and of the regulatory framework. Moreover, care is required that interested third parties do not get the impression that		X		The new text combines proposals from comments 212 and 213.

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				parties that the clearance process is not sufficiently safe.”	practical implementation of clearance lacks sufficient care.				
214.		18-SWE	4.17	The fact that the clearance levels have been derived on the basis of a certain degree of conservatism may, however, also be used with benefit <u>considered</u> in the implementation of the clearance process by reducing the conservatism <u>making simplifications</u> in the calibration of instruments (e.g. assuming homogeneous activity distribution rather than hotspot configuration), using larger averaging areas or averaging masses etc. Such assumptions should be based on arguments or scanning measurements. Further aspects of conservatism in relation to the derivation of clearance levels and the implementation of the clearance process are provided in Annex V, which discusses quantitative estimates of typical levels of conservatism.	To assume homogeneous activity distribution could be a NON-CONSERVATIVE but acceptable simplification, provided other measurements show that “hotspots” can be excluded. Annex V should be taken out of the document since it virtually disqualifies the clearance levels in GSR Part 3. A process to change the clearance levels should not start in an annex to a safety standard. Moreover, Annex V is clearly biased since no consideration is made to the unphysical simplifications made in the scenarios in SR 44, or to the rounding procedure, which actually brings non-conservatisms to the derivation process.	X			The part of the comment related to removal of Annex V needs to be discussed in WASSC/RASSC.
215.	2	24-GER	4.18	The following sentence should be added after sentence two ending with “...authorized by the regulatory body.” “Alternatively, surface specific clearance levels could be introduced by the regulatory body as part of the regulatory framework.”	In a number of member states, surface specific clearance levels are part of the legislation. This should be recognized here.	X			
216.		15-FRA	§4.18	For surface contaminated items where radioactivity may be concentrated on surfaces, compliance with the mass specific clearance level (activity concentration per unit mass) may not be sufficient in all cases because there are additional considerations relating to the handling of the material. In these cases, surface specific clearance levels	As surface-specific clearance levels are not defined in guidance issued by the IAEA, it could be difficult to consider these types of levels as the reference solution to apply.	X			

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				should could be derived by the authorized party and reviewed and authorized by the regulatory body. The authorized party should then comply with these surface-specific clearance levels, in addition to complying with the general (unconditional) clearance levels expressed as activity concentration per unit mass. Note: in many cases, compliance with mass specific clearance levels can be inferred from measurements of the surface specific activity through conversion, taking the measured are, the thickness of the density of the material into account (see example below).						
217.	1	25-GER	4.19	The paragraph should be changed as follows: Examples (a) and (b) should be omitted or put into a context which allows the implementation of this recommendations.	The examples given for clearance using only surface specific clearance levels are not comprehensive and contradictory to statements in the document that mass specific clearance levels must always be met. In example (a) it is not understandable why one should use only surface clearance levels when meeting mass specific levels would be problematic. The logical consequence would rather be that such material is not suitable for clearance. Therefore, it is suggested to change paragraph 4.19 accordingly. We recommend amending in example (a) that the exclusive use of surface specific clearance values shall comply with the national	X				

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					legislative framework. Furthermore, it should be referred to examples for the derivation of surface specific clearance for the reuse of materials (e. g. RP 101). In the case of example (b) it should be pointed out, that the use of surface specific clearance values requires a case by case study in which the surface contamination is accounted for. The derivation of surface specific clearance values from mass specific values is not sufficient and will yield surface contamination values, which do not comply with good radiation practice. Example (b) implicitly describes the situation which is encountered during the clearance of building structures. We recommend putting the RP 113/RP 114 as an example in which surface specific values are derived and the exclusive application of this values is justified given that penetrated activity is adequately taken into account.				
218.		6-INS	4.19	(c) regulatory body should determine the limit of surface area to volume ratio and also mass to surface area ratio	This ratio is important to make decision whether the surface specific criteria for clearance compliance with the mass specific clearance level		X		Examples removed to address the comment 217.
219.		33-JPN	4.19 (p.49)	Add "See 3rd category of Table1" after (a). Add "See 1st category of Table1" after (b). Add "See 2nd category of Table1" after the last sentence of 4.19.	Clarification It is necessary to show the relationship with the sentence and Table 1.		X		Examples removed to address the comment 217.

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220.		16-FRA	§4.19/6	However, when mass-specific clearance levels cannot be applied or are not sufficient as the sole criterion, the surface-specific activity concentration should could be appropriately limited. Examples are : (a) surface contaminated items with a large ratio of surface area to volume, such as paper, card, plastic sheeting and clothing, and glass and thin metal sheeting of low to moderate density, where meeting the mass specific limit is problematic, For this category of items, clearance should could be granted solely on compliance with surface specific clearance levels; (b) surface contaminated items with a large ratio of mass to surface area, where the mass of uncontaminated internal material would effectively dilute the Bq/g. If it can be demonstrated that no contamination has penetrated in the bulk of the material, clearance should could be granted solely on compliance with surface specific clearance levels since compliance with mass specific levels will not be sufficient to restrict the surface contamination.	As surface-specific clearance levels are not defined in guidance issued by the IAEA, it could be difficult to consider these types of levels as the reference solution to apply.		X		Examples removed to address the comment 217.
221.		19-SWE	4.21	Text missing [explanation of how direct reuse scenarios are independent of material is needed]	The rationale is not stated.	X			Sentence deleted.
222.		20-SWE	4.22	The numerical values for some radionuclides differ among different international studies and recommendations. The differences are due to different conditions and parameters assumed in derivation of surface-specific clearance levels (material, size of the item, geometry, exposure scenarios, and other aspects). Hence, it is to be expected that various studies will determine different surface specific clearance levels that comply with the same dose criteria. Therefore, application of a set of existing	The last sentence is unclear and does not add any guidance. Also, clearance values are generally independent of the size of the object.	X			

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				values (derived for a particular situation) to a different situation should be done with care, taking into account adequacy of assumptions, characteristics of the material, exposure scenarios used, and other aspects. For example, applying surface contamination levels derived for clearance of large objects would be too strict and conservative for small objects.					
223.		2-RUS	4.24	To delete para. 4.24.	Current para. and references to Transport Regulations SSR-6 (Rev.1) para 402-407 concern more the specific exemption than clearance matters and are considered (should be considered) in draft standard “Application of the Concept of Exemption” (DS499). Besides the references to para. 107 of SSR-6 (Rev.1) are not justified because this para does not relate to clearance or exemption aspects but relates to applying the different regulating tools (documents) for transport (moving) of dangerous radioactive objects.			X	This paragraph was a subject to a detailed discussion in a dedicated Working Group formed by WASSC. The current text represents a consensus reached in that WG and supported by WASSC, RASSC and TRANSSC.
224.		3-RUS	4.24 new instead of current para 4.24.	4.24 Contamination values in para 214 (0,4 Bq/cm ² for beta and gamma emitters and low toxicity alpha emitters and 0,4 Bq/cm ² for other alpha emitters) of IAEA Transport Regulations SSR-6 (Rev.1) [XX] may be considered like clearance taking into account that such activity can give rise only to insignificant exposure through any of these pathways. For instance, packages and vehicles that have been used for radioactive transport may be used for transport of other non-radioactive goods (materials) if surface contamination is lower than these values.	It is reasonable to make information for specific clearance cases for transport of radioactive material. Although these values may be as well considered as exemption at least for transport of radioactive material cases (specific exemption). It is reasonable to consider this matter (exemption or clearance) additionally in frame of developing DS499 and DS500 in common.			X	This paragraph was a subject to a detailed discussion in a dedicated Working Group formed by WASSC. The current text represents a consensus reached in that WG and supported by WASSC, RASSC and TRANSSC.

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				Also for instance, a non-radioactive solid object with levels of surface contamination lower than the above levels is beyond the scope of the Transport Regulations and no requirement is applicable to its transport [XX SSG-26, paras.214.2, 214.3]					
225.	2	26-GER	4.26	The following sentence should be added after the example: “It should be noted that the mass specific clearance level is not met if both sides of the metal sheet would be contaminated.”	While mathematically correct, the example is somewhat misleading, as usually contamination will be expected on both sides of a metal sheet coming from a contaminated area. This should be mentioned.	X			
226.		4-FIN	4.27	If the contamination has penetrated through the surface and into the volume, a prudent approach is to estimate the total activity using the sum of the contamination present directly on the surface and the contamination inside the volume beneath the same surface area. For comparison with mass specific clearance levels, this activity should be divided by the total mass below the surface. This approach also applies to materials with activation inside the volume of the material.-	Remove, as surface contamination measurement is hardly feasible for cases in which contamination has penetrated through the surface or activation has happened into the depth.	X			
227.		9-USA	4.31	Change to say, “This means that all <i>scenario-specific</i> exposure pathways (external irradiation, inhalation of contaminated aerosols, direct ingestion of small quantities, secondary ingestion of radionuclides via the food chain and skin contamination) should be adequately included in the scenarios.”	Add scenario-specific ... By definition the case-by-case approach is intended to only incorporate the applicable exposure pathways and not all of them (e.g., if there is no water then there is no water ingestion pathway considered)	X			
228.	3	27-GER	4.33	... Schedule I of GSR Part 3 ... Table I.2 of GSR Part 3	Misspelling	X			
229.		17-FRA	§4.33/3	GSP GSR Part 3		X			
230.		21-SWE	4.35	The general clearance levels specified in Schedule 1 of GSR Part 3 [1] for artificial	It is not obvious that averaging can be done based on	X			

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				radionuclides are calculated using a set of scenarios, and these scenarios consider exposure to a large quantity of homogenous material. For example, the transport scenario considers a truck containing 10 tons of material and the landfill scenario considers even larger quantities [4 SRS44]. When applying the clearance levels, the regulatory body should recognise that they were derived for bulk amounts and that the averaging should <u>could</u> be done accordingly, <u>with due consideration of the exposure scenarios</u> . Hence, very small averaging masses are not appropriate, and the exposure scenarios are consistent with some inhomogeneity within the averaging mass as long as the averaging mass is below 10 tons.	assumptions in the scenarios. For example, in the case of transport, the material closest to the driver gives the main contribution to the dose. This should be considered when deriving averaging masses. The last sentence is unclear and does not add any guidance. Also, it cannot generally be stated that 10 tons is an appropriate upper limit for the averaging mass. Other guidance propose a few 100 tons (eg RP89), as is also stated in 4.36.				
231.	3	28-GER	4.35	... Schedule 4 I ...	Misspelling	X			
232.	2	29-GER	4.36	The following sentence should be added before the last sentence starting with “In case...”. “It must be ensured that this is not used to partition larger objects into smaller ones to achieve clearance.”	Care must be taken that partitioning into smaller objects is not used to achieve clearance, which would otherwise be unattainable.	X			
233.		22-SWE	4.39	In deciding on a measurement strategy, the authorized party should batch the material so that it is as homogenous as possible in relation to both material and origin, and thus radionuclide vector and activity level. Variations of activity level within the averaging unit of mass or area for decision making should be allowed. For example, variations of up to a factor of 10 with respect to the average value for the decision unit are generally considered to be acceptable, whereas a greater variation would be acceptable if the overall average	Does the last sentence add any guidance compared with the second last sentence? As it is written, it can be impossible to show compliance, since “any measurement unit” could be interpreted as every infinitesimal part of the decision unit.	X			

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				concentration was a very small fraction of the clearance level. Also, it is recommended that the maximum concentration in any measurement unit does not exceed ten times the clearance level, while the average value over the decision unit does not exceed the clearance level (Appendix A of Ref. [30 TECDOC-1000]).					
234.		5-ITA	4.42	The authorized party should select measurement units and should propose decision units that are sufficiently representative of the material, with appropriate adjustments to satisfy homogeneity limitations and confidence level requirements for the clearance measurements. The measurement and decision units should therefore usually be related to the same origin of material for clearance, or one of several origins of a very similar nature. In general, larger measurement and decision units are acceptable where the contamination in the material is reasonably uniform homogeneous and smaller measurement units should be used where inhomogeneity is significant. The decision units should be agreed with the regulatory body and formally recorded by the authorized party as part of the clearance measurement process. The regulatory body should also provide some guidance and quantitative criteria related to uniformity or inhomogeneity of the contamination.	The terms uniform and homogenous have not the same meaning and it would be better to use only one of them in the sentence. (see also in 4.45 where again the term non-uniformity is used) Non-homogeneity could be used in that para. In the draft DS499 only the term non-homogeneity is used.	X			
235.		8-UKR	4.43 in general	The regulatory body should define a maximum value for a hotspot that should be kept in mind in defining the size of a decision unit.	It would be useful to include some recommendations regarding determination of the maximum value for a hotspot based on para. 4.39			X	No specific text proposed.

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236.		6-ITA	4.44	If the results of samples taken from the bulk waste or material are subject to considerable variability, as defined in Appendix A of Ref. [30 TECDOC-1000], then averaging over the whole waste or material mass (as a single decision unit) is unlikely to be acceptable without proper (documented) consideration of: (a) The practicability of segregation and separation; (b) Suitable revision of monitoring, sampling plan including numbers of samples;	Sampling plan and number of samples are different aspect of the sampling process design. In case of variability of the measurments	X			
237.		2-BEL	/4.45/ page 57/145	Suggestion to add a section on characterization by sampling with respect to measurement unit and decision unit on case of heterogeneity.	The part about “presences of hotspots and distribution of activity with depth and area” does not speak about characterisation with the use of sampling. But precisely, cases where sampling is used are the ones where heterogeneity makes it harder to extrapolate from the “sampled measurement units” to the “decision units”			X	No specific text proposed.
238.		3-ESP	4.48	Example of the last part of the paragraph: This is not a very good example to verify volumes lower than 200 litres,	Bulk mass is considered lower than 10 tonnes. A drum for sure have masses in the range of 200 kg, therefore no additional subdivision should be done. For a box containing e.g. 1- 2 tonnes, it could be a good example trying to derive volumes equivalents to a drum inside the box. But not volume lower than 200 litres. It wouldn't be a feasible process.			X	Not clear what is the proposed revision.
239.	2	30-GER	4.49	... where isotopic radionuclide vector or key nuclides have been identified...	The terms “isotopic vector” and “radionuclide vector” are used as synonyms. However, these terms should be harmonized.	X			

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240.		7-ITA	4.49	The monitoring programme to support clearance process should be based on the results of the characterization, where isotopic radionuclide vector or key nuclides	Check the use of the same term for the vector, i.e radionuclide vector in the whole text	X			
241.		23-SWE	4.55	The involvement of personnel with suitable qualifications, experience and knowledge in the selection <u>and establishment</u> of monitoring techniques is beneficial <u>important</u> .	It is crucial to involve knowledgeable people when selecting and establishing technical systems for clearance.	X			
242.		8-INS	4.55/10	The involvement of personnel with suitable qualifications, experience and knowledge in the selection of monitoring techniques is highly recommended	Competent and experienced personnel greatly affect the measurement results		X		Revised text includes similar proposal from Sweden (comment 241).
243.		9-INS	4.61/4	The procedure can be greatly simplified by performing the calibration for a single radionuclide and deriving the calibration factors for other nuclides through calculations or through scaling factors as defined in the radionuclide vector, and also by considering the type of detector which will be used	Each type of detector has different response in the different energy of radiation	X			
244.	1	31-GER	4.66	The second sentence should be: "In order for an instrument to be suitable for compliance verification with the clearance level for a specific radionuclide, this threshold should must be sufficiently below the clearance level."	The statement reflect that it is mandatory that the detection threshold is below the clearance level. Moreover, it is usually not sufficient to reach this threshold just barely.	X			We can't use the word MUST in a Safety Guide, so instead we used HAS TO.
245.	1	32-GER	4.69	The following sentence should be introduced after the first sentence: "The regulatory body should approve the process for determination of the background activity."	Omission of background is usually a far-reaching decision; therefore, the regulatory authority should be involved.	X			
246.		12-ENISS	4.69	When determining what background needs to be subtracted during clearance measurements, variations in the background activity level should be considered. Especially with total gamma	For example with handheld detectors the determination of the 5th percentile is not practical. Also when it is possible, it may add excessive	X			

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				measurements, the contribution from the activity that can be disregarded needs to be carefully established in order not to misinterpret the measurement signal from the activity undergoing clearance. The activity to be disregarded needs to be established using a suitable low percentile (e.g. 5 %) from the distribution of measured background values, thus preventing overestimating <u>so that the signal to be subtracted is not overestimated</u>. The distinction between these various contributions to the total activity can be significantly improved by using spectrometric information.	conservatism – the background should be assessed as realistically as practicable.				
247.		5-FIN	4.69	When determining what background needs to be subtracted during clearance measurements, variations in the background activity level should be considered. Especially with total gamma measurements, the contribution from the activity that can be disregarded needs to be carefully established in order not to misinterpret the measurement signal from the activity undergoing clearance. The activity to be disregarded needs to be established using a suitable low percentile (e.g. 5 %) from the distribution of measured background values, thus preventing overestimating <u>so that the signal to be subtracted is not overestimated</u>. The distinction between these various contributions to the total activity can be significantly improved by using spectrometric information.	For example with handheld detectors the determination of the 5th percentile is not practical. Also when it is possible, it may add excessive conservatism – the background should be assessed as realistically as practicable.	X			
248.		7-AUS	Para 4.71-4.97: Uncertainty consideration	This section is too detailed. The key information should be summarized in a few paragraphs. For details a TECDOC should be referred to as suggested under general comment.	This is specific safety guide not a TECDOC. Details should be captured in a TECDOC.	X			Text shortened.

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249.		19-HUN	4.71 – 4.91	Suggested to be moved to an annex, or to delete and refer to a literature.	These para are not clearance specific ones but part of general measurement theory.	X			Text shortened.
250.		4-ESP	4.71	in addition to type A and B, something should be said in advance in relation to measure the whole material or to sample a part of it for inferring the total activity.	In the first case, measuring the whole material, the uncertainty is the measurement uncertainty, in the second, sampling, the uncertainty due to sampling is linked to the standard deviation of data and therefore it has to be added to the measured uncertainty. This is a crucial difference, in the first case, data variability in the material is not uncertainty because we have measured the whole material, in the second case, the Standard Deviation of data or something like that, has to be added to the measurement uncertainty data.			X	There are multiple comments that the text of this section is too detailed, so adding even more details is not the preferred approach.
251.		5-ESP	4.71	Explicitly indicate that the uncertainty to evaluate is the uncertainty on the decision criteria, namely the uncertainty of the sum of fraction (or the derived concentration) applying the rules of uncertainty following the guide of expression of uncertainty	Just to provide our approach, we try to infer the uncertainty of the decision criteria, namely the sum of fractions, and apply on that relationship the guide of expression of uncertainty. The final goal is that the Sum of Fractions plus $2 \times \text{Uncertainty of Sum of Fractions} < 1$. ISO-IEC .GUIDE 98-1 Guide to the expression of uncertainty in measurement	X			
252.		34-JPN	4.71/1 (p.62)	The clearance process, in particular the measurements and evaluated of relation to the specified fraction in the nuclide vector process , involve a number of uncertainties that have to be properly taken into account, depending on the measurement techniques.	Next pages (f) involve evaluation. And added the red words to section 4.71.			X	The proposal is unclear, we don't understand the proposed sentence.

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253.	2	33-GER	4.73	Ref. 23 should be replaced with reference to correct DIN 25457 part 1. DIN 25457 part 1 should be include into the references section with the following text: “GERMAN INSTITUTE FOR STANDARDISATION, DIN 25457-1 Activity measurement methods for the clearance of radioactive substances and nuclear facility components – Part 1: Fundamentals, DIN Deutsches Institut für Normung, Berlin, (2014).”	Ref. [23] deals exclusively with metal scrap. Treatment of measurement uncertainties is considered in part 1 of the DIN 25457 series. This should be added as a separate reference.	X			
254.		8-AUS	4.73	4.73. When performing actual clearance measurements, due account must be taken of measurement uncertainties. Appropriately selected upper confidence level of the measurement result has to be below the clearance level (expressed in the same unit), taking all relevant uncertainties should be appropriately taken into account considering the graded approach in compliance with clearance level according to the IAEA GSR Part 3 Requirement 6[1]. Examples for this are provided in Refs [19] (MARSSIM), [23] (DIN25457), [34] (ISO 11929), etc. Examples of linking the measurement uncertainty to the detection limit are provided in sections 5.1 5.3 of the Ref. [16 SRS67]. However, Noting the overall conservatisms built in the clearance levels, it is not appropriate to introduce significant additional conservatisms for consideration of the uncertainties through this mechanism. For example, if one of the uncertainties is biased to a very high level, then fluctuations relating from the other uncertainties are less important.	The requirements for using the upper confidence levels (UL) in paras 4.73 and 4.86 should be removed for the following reasons: 1. If the UCL is to be applied to clearance level monitoring, then, logically, it should also be applied to <u>all</u> radiological protection criteria, where there are uncertainties in measurements and methods. Applying the UCL to clearance levels for potential trivial doses is not justified. 2. In practice, the requirement to comply with an UCL means that there is a stricter level of control being applied to clearance, compared to other protection criteria, which is not justified for potential trivial doses of 10uSv/y. 3. A stricter level of control for such low doses is not consistent with the IAEA graded approach.			X	There was a Working Group created by WASSC to discuss this issue in December 2020 – January 2021. The WG supported the approach presented in the current draft. It is not clear how the uncertainties are taken into account in the decision making if only mean value of the result is used for comparison with the clearance level.

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					4. The use of UCL for compliance <u>does not improve</u> the level of safety. 5. The compliance criteria have been developed with rounded values to the nearest power of 10 using a near logarithmic rounding approach and compliance does not require the level of precision implied by using the UCL. In addition, an effective dose criterion of 1 mSv/y for low probability scenarios has been used in derivation of clearance levels, and 10uSv/y for realistic scenarios. 6. For the public, the use of UCL may imply that the very low levels are not safe since they require a higher level of scrutiny. 7. The UCL requirement unnecessarily increases complexity and burden for practitioners and regulators for no increase in protection or safety.				
255.		24-SWE	4.73	When performing actual clearance measurements, due account must be taken of measurement uncertainties. Appropriately selected upper confidence level of the measurement result has to be below the clearance level (expressed in the same unit), taking all relevant <u>which may have a significant impact on the clearance</u> uncertainties into account. Examples for this are provided in Refs [19]	The phrase "all relevant uncertainties" is hard to interpret. Only uncertainties that could significantly impact the clearance decision should be considered. The last sentence does not improve the readability of the text as a whole and is not a good example.	X			

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				(MARSSIM), [23] (DIN25457), [34] (ISO-11929), etc. Examples of linking the measurement uncertainty to the detection limit are provided in sections 5.1-5.3 of the Ref. [16 SRS67]. However, noting the overall conservatisms built in the clearance levels, it is not appropriate to introduce significant additional conservatisms through this mechanism. For example, if one of the uncertainties is biased to a very high level, then fluctuations relating from the other uncertainties are less important.					
256.		25-SWE	4.73	When performing actual clearance measurements, due account must be taken of measurement uncertainties. Appropriately selected upper confidence level of the measurement result has to be below the clearance level (expressed in the same unit), taking all relevant uncertainties <u>should be appropriately taken into account considering the graded approach in compliance with clearance level according to the IAEA GSR Part 3 Requirement 6 [1].</u> Examples for this are provided in Refs [19] (MARSSIM), [23] (DIN25457), [34] (ISO-11929), etc. Examples of linking the measurement uncertainty to the detection limit are provided in sections 5.1-5.3 of the Ref. [16 SRS67]. However, Noting the overall conservatisms built in the clearance levels, it is not appropriate to introduce significant additional conservatisms <u>for consideration of the uncertainties through this mechanism.</u> For example, if one of the uncertainties is biased to a very high level, then fluctuations relating from the other uncertainties are less important.	Requirement for uncertainty using the upper confidence level should be deleted in the text and moved in Appendix. The uncertainty should be appropriately taken into account considering the graded approach, as given in para. 1.10: <i>1.10 This Safety Guide provides guidance on the relevant steps of the clearance process, aiming to assist in preventing build-up of unnecessary additional layers of conservatism. It also reflects the use of the graded approach, in the light of the conservative nature of the values.</i> Reasonable graded approaches for uncertainty are given in Appendix 2* that is separately provided document.			X	This comment contradicts the previous comment from Sweden to the same paragraph. There was a Working Group created by WASSC to discuss this issue in December 2020 – January 2021. The WG supported the approach presented in the current draft. It is not clear how the uncertainties are taken into account in the decision making if only mean value of the result is used for comparison with the clearance level.

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					The deletion of the above requirement for uncertainty is also justified by methodology in derivation of clearance levels as shown in para. 4.5: <i>4.5 The clearance levels were derived as the lower of the values obtained from:</i> <i>(a) The use of so-called realistic scenarios applying an effective dose criterion of the order of 10 μSv per year;</i> <i>(b) The use of so-called low probability scenarios applying an effective dose criterion of 1 mSv per year and a skin equivalent dose limit of 50 mSv per year.</i> <i>The parameter values applied in “realistic” and “low probability” scenarios were chosen on the conservative side, with parameter values in “realistic” scenarios generally lower or equal to those in “low probability” scenarios.</i> <i>The derived results from the scenario calculations were then rounded to the nearest power of 10 using a near logarithmic rounding approach [4 SRS44]. This implies that the radiological models do not possess such a level of accuracy that a higher</i>				
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					<i>precision of the result would be justified. In turn, consideration of the uncertainty in demonstrating that the resulting dose will be of the order of 10 μSv per year or less requires compliance only to the extent of the accuracy of the logarithmically rounded values of the clearance level.</i> Whether the requirement for uncertainty using the upper confidence level is justified for compliance with clearance levels is not only an issue in clearance levels but also in other radiological protection criteria. This is because if we need strict treatment for uncertainty, even in the case of compliance with a trivial dose criterion for clearance, the same or a stricter treatment for conformity assessment may have to be applied to other radiological protection criteria for doses exceeding 10 μSv/year (e.g. dose limit for workers, national regulatory levels for radon concentration, surface contamination criteria for daily radiation control using survey meters, ambient dose equivalent rates on an external surface and at 2m					
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					distance from the surface of transport packages, and derived discharge limits for liquid and gaseous materials, amount or concentration of radionuclides in waste packages monitored using scaling factor and direct measurement from the outside of the waste packages by non-destructive assay, and so on). On the other hand, IAEA Nuclear Energy Series No. NW-T-1.18* states in section 3.2: <i>3.2 Most Member States use some form of mean value to calculate the scaling factors, either an arithmetical mean (such as Japan, Slovenia and the UK) or a geometric (logarithmic) mean (such as Brazil, Canada, France, Republic of Korea, Italy, Spain, Sweden, Ukraine and the USA). The ‘mean value’ SF is based on the assumption that the relationship between a key nuclide and a DTM nuclide is linear over the range of activities of interest. The arithmetical mean will tend to produce a conservative (i.e. high) value, while the geometric mean will tend to produce a more representative average value when the data</i>				
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					<i>points are spread over several orders of magnitude.</i> As mentioned above, many member states are actually using an arithmetic mean or a geometric (logarithmic) mean for determining the scaling factors in waste management. The scaling factors shown in NW-T-1.18 is equivalent to that used in DS500 (para. 3.24, 3.25 4.84, 4.85, 4.86 and so on). Upper confidence level is considerably conservative and higher than the values of arithmetic and geometric means, which means that member states actually using arithmetic or geometric mean would lose the use of the mean values. This is just an example, but adoption of the requirement for uncertainty using upper confidence level to DS500 would lead to a lot of serious problems in the other radiological protection criteria. Such a conservative way using upper confidence levels should not be adopted as a compulsive requirement in DS500 without any options to select reasonable approaches. In para. 4.73, examples for the conformity assessment				
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					using upper confidence level are provided referring to a few documents, e.g., MARSSIM [19], DIN25457 [23], and ISO-11929 [34]. However, MARSSIM and ISO-11929 don't deal with conformity assessment. For example, ISO-11929 Part 4 guidelines to applications (2020) obviously states in chapter 11 counting clearance measurement, <i>"NOTE 1 Since this document does not deal with the problem of conformity with requirements, as e.g. with the clearance level for unconditional clearance, the question whether or not the material measured can be unconditionally cleared is not answered."</i> On the other hand, DIN25457 has an annex including the same approach to the conformity assessment using the upper confidence level, but DIN25457 is not an international standard but a national standard in one country. Hence, these references are inappropriate for the examples for IAEA safety guides DS500. In previous web-consultation on DS500, IAEA secretariats showed an example for the conformity assessment taking into				
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					consideration measurement uncertainty referring to section 5.2 in IAEA safety report 67 (SRS67). However, it should also be noted that SRS67 has another example for uncertainty of measurement and radionuclide vector in section 5.3. Details of section 5.3 are incorporated in Appendix 2* that is a separately provided document. Appendix 2 recommends using reasonable graded approach to uncertainty, and also allows to use a conservative approach including the conformity assessment using upper confidence level. DS500 should have multiple options for various situations in clearance process * APPENDIX 2, GRADED APPROACH TO UNCERTAINTIES OF MEASUREMENT AND RADIONUCLIDE VECTORS. ** INTERNATIONAL ATOMIC ENERGY AGENCY, Determination and Use of Scaling Factors for Waste Characterization in Nuclear Power Plants, IAEA Nuclear Energy Series No.				
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					NW-T-1.18, IAEA, Vienna (2009). https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1363_web.pdf				
257.		11-WNA	4.73	4.73. When performing actual clearance measurements, due account must be taken of measurement uncertainties. Appropriately selected upper confidence level of the measurement result has to be below the clearance level (expressed in the same unit), taking all relevant uncertainties should be appropriately taken into account <u>considering the graded approach in compliance with clearance level according to the IAEA GSR Part 3 Requirement 6[1]. Details of this graded approach for consideration of the uncertainties are given in Appendix 2. Examples for this are provided in Refs [19] (MARSSIM), [23] (DIN25457), [34] (ISO 11929), etc. Examples of linking the measurement uncertainty to the detection limit are provided in sections 5.1-5.3 of the Ref. [16 SRS67]. However,</u> Noting the overall conservatisms built in the clearance levels, it is not appropriate to introduce significant additional conservatisms <u>for consideration of the uncertainties through this mechanism.</u> For example, if one of the uncertainties is biased to a very high level, then fluctuations relating from the other uncertainties are less important.	Requirement for uncertainty using the upper confidence level should be deleted in the text and moved in Appendix. The uncertainty should be appropriately taken into account considering the graded approach, as given in para. 1.10: <i>1.10 This Safety Guide provides guidance on the relevant steps of the clearance process, aiming to assist in preventing build-up of unnecessary additional layers of conservatism. It also reflects the use of the graded approach, in the light of the conservative nature of the values.</i> Reasonable graded approaches for uncertainty are given in Appendix 2* that is separately provided document. The deletion of the above requirement for uncertainty is also justified by methodology in derivation of clearance levels as shown in para. 4.5: <i>4.5 The clearance levels were derived as the lower of the values obtained from:</i> <i>(a) The use of so-called realistic scenarios applying an effective dose criterion of the order of 10 µSv per year;</i>			X	There was a Working Group created by WASSC to discuss this issue in December 2020 – January 2021. The WG supported the approach presented in the current draft. It is not clear how the uncertainties are taken into account in the decision making if only mean value of the result is used for comparison with the clearance level.

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					<i>(b) The use of so-called low probability scenarios applying an effective dose criterion of 1 mSv per year and a skin equivalent dose limit of 50 mSv per year.</i> <i>The parameter values applied in “realistic” and “low probability” scenarios were chosen on the conservative side, with parameter values in “realistic” scenarios generally lower or equal to those in “low probability” scenarios.</i> <i>The derived results from the scenario calculations were then rounded to the nearest power of 10 using a near logarithmic rounding approach [4 SRS44]. This implies that the radiological models do not possess such a level of accuracy that a higher precision of the result would be justified. In turn, consideration of the uncertainty in demonstrating that the resulting dose will be of the order of 10 µSv per year or less requires compliance only to the extent of the accuracy of the logarithmically rounded values of the clearance level.</i> <i>Whether the requirement for uncertainty using the upper confidence level is justified for compliance with clearance levels is not only an issue in clearance levels but also in other radiological protection criteria.</i>				
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					This is because if we need strict treatment for uncertainty, even in the case of compliance with a trivial dose criterion for clearance, the same or a stricter treatment for conformity assessment may have to be applied to other radiological protection criteria for doses exceeding 10 mSv/year (e.g. dose limit for workers, national regulatory levels for radon concentration, surface contamination criteria for daily radiation control using survey meters, ambient dose equivalent rates on an external surface and at 2m distance from the surface of transport packages, and derived discharge limits for liquid and gaseous materials, amount or concentration of radionuclides in waste packages monitored using scaling factor and direct measurement from the outside of the waste packages by non-destructive assay, and so on). On the other hand, IAEA Nuclear Energy Series No. NW-T-1.18* states in section 3.2: <i>3.2 Most Member States use some form of mean value to calculate the scaling factors, either an arithmetical mean (such as Japan, Slovenia and the UK) or a geometric (logarithmic) mean (such as Brazil, Canada, France, Republic of Korea, Italy,</i>				
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					<i>Spain, Sweden, Ukraine and the USA). The ‘mean value’ SF is based on the assumption that the relationship between a key nuclide and a DTM nuclide is linear over the range of activities of interest. The arithmetical mean will tend to produce a conservative (i.e. high) value, while the geometric mean will tend to produce a more representative average value when the data points are spread over several orders of magnitude.</i> As mentioned above, many member states are actually using an arithmetic mean or a geometric (logarithmic) mean for determining the scaling factors in waste management. The scaling factors shown in NW-T-1.18 is equivalent to that used in DS500 (para. 3.24, 3.25 4.84, 4.85, 4.86 and so on). Upper confidence level is considerably conservative and higher than the values of arithmetic and geometric means, which means that member states actually using arithmetic or geometric mean would lose the use of the mean values. This is just an example, but adoption of the requirement for uncertainty using upper confidence level to DS500 would lead to a lot of serious problems in the other radiological protection				
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					criteria. Such a conservative way using upper confidence levels should not be adopted as a compulsive requirement in DS500 without any options to select reasonable approaches. In para. 4.73, examples for the conformity assessment using upper confidence level are provided referring to a few documents, e.g., MARSSIM [19], DIN25457 [23], and ISO-11929 [34]. However, MARSSIM and ISO-11929 don't deal with conformity assessment. For example, ISO-11929 Part 4 guidelines to applications (2020) obviously states in chapter 11 counting clearance measurement, <i>"NOTE 1 Since this document does not deal with the problem of conformity with requirements, as e.g. with the clearance level for unconditional clearance, the question whether or not the material measured can be unconditionally cleared is not answered."</i> On the other hand, DIN25457 has an annex including the same approach to the conformity assessment using the upper confidence level, but DIN25457 is not an international standard but a national standard in one country. Hence, these references are inappropriate for the examples for IAEA safety guides DS500.				
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					In previous web-consultation on DS500, IAEA secretariats showed an example for the conformity assessment taking into consideration measurement uncertainty referring to section 5.2 in IAEA safety report 67 (SRS67). However, it should also be noted that SRS67 has another example for uncertainty of measurement and radionuclide vector in section 5.3. Details of section 5.3 are incorporated in Appendix 2* that is separately provided document. Appendix 2 recommends using reasonable graded approach to uncertainty, and also allows to use a conservative approach including the conformity assessment using upper confidence level. DS500 should have multiple options for various situations in clearance process. * APPENDIX 2, GRADED APPROACH TO UNCERTAINTIES OF MEASUREMENT AND RADIONUCLIDE VECTORS. ** INTERNATIONAL ATOMIC ENERGY AGENCY, Determination and Use of Scaling Factors for Waste Characterization in Nuclear Power Plants, IAEA				
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					Nuclear Energy Series No. NW-T-1.18, IAEA, Vienna (2009). https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1363_web.pdf				
258.		WNTI-2	4.73	4.73. When performing actual clearance measurements, <u>appropriate detectors and measurement procedures should be used.</u> due account must be taken of measurement uncertainties. Appropriately selected upper confidence level of the measurement result has to be below the clearance level (expressed in the same unit), taking a <u>All relevant uncertainties should be taken</u> into account <u>appropriately</u> . Examples for this are provided in Refs [19] (MARSSIM), [23] (DIN25457), [34] (ISO 11929), etc. Examples of linking the measurement uncertainty to the detection limit are provided in sections 5.1-5.3 of the Ref. [16 SRS67]. (...).	Since the criteria of the clearance are derived based on conservative scenarios and already include large conservatism, it seems unnecessary to consider further conservatism including the upper confidence level for each measurement result as shown in paragraph 1.10 “ <i>This Safety Guide provides guidance on the relevant steps of the clearance process, aiming to assist in preventing build-up of unnecessary additional layers of conservatism.</i> ”. From practical point of view, complicated and burdensome procedures should be avoided in measurement operations on site.			X	There was a Working Group created by WASSC to discuss this issue in December 2020 – January 2021. The WG supported the approach presented in the current draft.
259.		3-BEL	4.73 & 3.6	3.6, formula (1) : $P \left[\sum_j \frac{C_j}{C_{j,L}} < 1 \right] \geq 1 - \beta$	The sum rule is a theoretical formula that is not directly applicable since it uses actual activity concentrations and in practice these values are not known and only approximated by measurement. Therefore, I suggest taking advantage of this section to rewrite a "practical" and general expression for using this sum rule, with an expression of the type:, $P \left[\sum_j \frac{C_j}{C_{j,L}} < 1 \right] \geq$			X	The summation rule uses activity concentrations estimated / calculated on the basis of measurements. What are C _j in the formula you propose, if not the activity concentrations?

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					$1 - \beta$ which de facto forces the operator to use detection limits and upper bounds of the confidence intervals, while remaining sufficiently general and allowing to efficiently address multi-isotope cases.				
260.	3	34-GER	4.74	... as discussed in para 4.74 (4.71?)	Clarify reference	X			
261.		26-SWE	4.74	Ref to 4.73	Typo.	X			
262.		12-WNA	4.74	ref to 4.73	Typo	X			
263.		35-JPN	4.74/1 (p.63)	in para. 4.74, => in para. 4.34,	Clarification. Editorial (mistype?)	X			
264.		27-SWE	4.75-4.91	The titles of the paragraphs: “Treatment of uncertainty related to...”	No information is given on how to treat the uncertainties when comparing with clearance levels.	X			
265.		4-BEL	4.77 / Last line	4.77 : “if the thickness layer does not respect criterion fixed by the regulator, no meaningful...”	“if the layer becomes too thick...”. the term “too thick’ is very large and depends of the situation. It’s should be easier to refer to a standard or international norm as describes in ISO 7503 for exemple		X		Text simplified.
266.		9-AUS	4.86	The uncertainty in the determination of scaling factors or radionuclide vectors need to be taken into account in the analysis of type B uncertainties. However, the way in which uncertainties in the derivation of scaling factors and the (equivalent) radionuclide vector are treated can give rise to high conservatism in the whole clearance process. For example, if a scaling factor is to be derived from an ensemble of activity measurements of difficult-to-measure radionuclides and key nuclides, it may be a prudent approach not to use to highest activity ratio as the scaling factor, but arithmetic mean ratio to calculate the scaling factors appropriately selected upper confidence level. A more representative	The same reason as shown in para. 4.73			X	The same reason as for the comment to para 4.73.

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				average value may be the geometric mean ratio. However, if the geometric mean is used for the scaling factor, it should be previously verified that uncertainty of the scaling factor is not too large according to a probabilistic approach.					
267.		28-SWE	4.86	The uncertainty in the determination of scaling factors or radionuclide vectors need to be taken into account in the analysis of type B uncertainties, <u>if a non-conservative vectorization approach is deployed.</u>	If the nuclide vectors have been constructed conservatively (UCL 95 or similar) the variation of the relation to the key nuclide is already included in the scaling factor itself.	X			
268.		29-SWE	4.86	The uncertainty in the determination of scaling factors or radionuclide vectors need to be taken into account in the analysis of type B uncertainties. However, the way in which uncertainties in the derivation of scaling factors and the (equivalent) radionuclide vector are treated can give rise to high conservatism in the whole clearance process. For example, if a scaling factor is to be derived from an ensemble of activity measurements of difficult-to-measure radionuclides and key nuclides, it may be a prudent approach not to use to highest activity ratio as the scaling factor, but <u>arithmetic mean ratio to calculate the scaling factors</u> appropriately selected upper confidence level.	The same reason as for para. 4.73 above.			X	The same reason as for the comment to para 4.73.
269.		14-WNA	4.86	4.86. The uncertainty in the determination of scaling factors or radionuclide vectors need to be taken into account in the analysis of type B uncertainties. However, the way in which uncertainties in the derivation of scaling factors and the (equivalent) radionuclide vector are treated can give rise to high conservatism in the whole clearance process. <u>Probabilistic approach to analysis of the fluctuations of the activity ratios of difficult-to-measure radionuclides and key nuclides can appropriately help reducing</u>	The same reason as shown in para. 4.73. In addition, use of probabilistic approach should be obviously recommended in this paragraph because the probabilistic approach can make both uses of mean value and upper confidence level justified, although this new text was used in previous version of DS500 (Date: 26 August 2020) but			X	The same reason as for the comment to para 4.73.

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				<u>this degree of conservatism, as provided in sections 5.3 of the Ref. [16 SRS67] and Appendix 2. For example, if a scaling factor is to be derived from an ensemble of activity measurements of difficult to measure radionuclides and key nuclides, it may be a prudent approach not to use to highest activity ratio as the scaling factor, but appropriately selected upper confidence level.</u>	deleted without appropriate reasons.				
270.		30-SWE	4.87	Assumptions on the variation of the deviation between idealised and real wiping efficiency have to <u>should</u> be made and included in the analysis of type B uncertainties of measurements with wipe tests only, <u>if it is concluded that the used wiping efficiency is not conservative.</u>	The paragraph states that the wiping efficiency is often conservative and that the real wiping efficiency is next to impossible to assess. The uncertainty should only be accounted for if it is proven that the assumed wiping efficiency is not conservative.	X			
271.		15-WNA	4.87	Assumptions on the variation of the deviation between idealized and real wiping efficiency have to <u>should</u> be made and included in the analysis of type B uncertainties of measurements with wipe tests only, <u>if it is concluded that the used wiping efficiency is not conservative.</u>	The paragraph states that the wiping efficiency is often conservative and that the real wiping efficiency is next to impossible to assess. The uncertainty should only be accounted for if it is proven that the assumed wiping efficiency is not conservative.	X			
272.		13-ENISS	4.91	<u>... and other applicable standards.</u> (at the end of the para)	A reference is made to a US standard. It should be possible to use also other standards.	X			
273.		10-INS	4.92 – 4.97	Need clearer definitions and boundaries for mixing and dilution with examples. Activity that can be used as examples, <u>technical engineering for processing waste evaporated concentrate or used resin waste using the cementation method which is intentionally designed to meet the clearance level criteria, without going through a process of delay and decay.</u>	Mixing and dilution are debatable topic. IAEA must select some examples that can be used so member states can implement it as well.			X	An example is provided in para 4.93 (excavation). Please note the paragraph number might change during the final revisions.

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274.		21-FRA	§4.92	Deliberate dilution of material to meet the clearance levels, as opposed to the dilution that takes place in normal operations when radioactivity is not a consideration, should not be performed without the prior approval of the regulatory body.	Deliberate dilution should not be an authorized practice in any case. This practice is inconsistent with the hierarchy of management modes of waste in France, which gives priority to the reduction of the quantity of waste.		X		Sometimes that could be the best solution. The text has been modified to address your comment, but to keep the option open.
275.		31-SWE	4.93	Move the first sentence ("The regulatory body should ensure that dilution is not used to clear materials with relatively high activity concentrations by deliberately diluting them in order to meet clearance levels.") to 4.92.	Belongs better to the previous item.	X			
276.		16-WNA	4.93	Move first sentence ("The regulatory body should ensure that dilution is not used to clear materials with relatively high activity concentrations by deliberately diluting them in order to meet clearance levels.") to 4.92	Fits better with the previous item.	X			
277.		32-SWE	4.93	<u>Characterisation</u> for clearance should be carried out while the history of the material is still well known.	Rewording needed for practical reasons. What is important is characterisation, traceability and record keeping.	X			
278.		17-WNA	4.93	<u>Characterization</u> for clearance should be carried out while the history of the material is still well known.	Need rewording for practical reasons. What is important is characterization, traceability and record keeping.	X			
279.		33-SWE	4.93	Storage of material for decay of Decay storage of short lived radionuclides prior to clearance is acceptable for materials containing short lived radionuclides.	To make it clear that decay storage is OK also if the material contain long lived nuclides such as Ni-59 or Ni-63.		X		Text modified to accommodate your proposal.
280.		18-WNA	4.93	Storage of material for decay of Decay storage of short lived radionuclides prior to clearance is acceptable for materials containing short lived radionuclides.	To make it clear that decay storage is OK also if the material contains long lived nuclides such as Ni-59/63.		X		Text modified to accommodate your proposal.

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281.		22-FRA	§4.93/3	Decay storage prior to clearance is acceptable for materials containing very short lived radionuclides.	As mentioned in §3.2, decay storage prior to clearance is only acceptable for VSL waste.		X		Compromise text proposed, taken into account the other comments to this paragraph.
282.		34-SWE	4.94	Unavoidable Certain mixing of materials may occur, and is acceptable <u>as long as the purpose not is to dilute</u> , where the extent of mixing is consequent on the operation or decommissioning technique employed. For example, the use of an excavator to dig out a volume of contaminated soil may result in some unavoidable mixing of soil with differing levels of contamination. In this case this is considered to be mixing as part of the material management process.	If the target is increase the clearance and recycling, the practioners must have the possibility to optimise the processes. The word "unavoidable" may give the wrong signal. The target should be safe clearance, not micro management of the processes.	X			
283.		19-WNA	4.94	Unavoidable Certain mixing of materials may occur, and is acceptable <u>as long as the purpose is not to dilute</u> , where the extent of mixing is consequent on the operation or decommissioning technique employed. For example, the use of an excavator to dig out a volume of contaminated soil may result in some unavoidable mixing of soil with differing levels of contamination. In this case this is considered to be mixing as part of the material management process.	If the target is increased in the clearance and recycling, the practitioners must have the possibility to optimize the processes. The word "unavoidable" may give the wrong signal. The target should be safe clearance, not micro-management of the processes.	X			
284.		23-FRA	4.94	Unavoidable mixing may occur, and is acceptable, where the extent of mixing is consequent on the operation or decommissioning technique employed. For example, the use of an excavator to dig out a volume of contaminated soil may result in some unavoidable mixing of soil with differing levels of contamination. In this case this is considered to be mixing as part of the material management process. <u>However, the volumes of excavated soil must be consistent with those contaminated so as to avoid deliberate dilution.</u>	To add a sentence, so as to stress that deliberate dilution is not a consideration.			X	Sentence not clear.

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285.		6-ESP	4.94	Establish a Heterogeneity Criterium of 10 times de limit to the tenth of the material.	By this reason a heterogeneity criterium should be established to avoid intentional dilution or at least lo limit it. the criterium of 10 times de limit to the tenth of the material could be a good limitation, flexible but at least a limit. The contractor should verify that with measurements.			X	Missing a concrete proposal of a text to be added.
286.		35-SWE	4.97	In this case, The destination of the <u>conditionally cleared</u> contaminated materials should be restricted to non-nuclear facilities, providing for the average mixing ratio with clean materials, as considered in the radiological model.	To increase readability.	X			
287.		20-WNA	4.97	In this case, The destination of the <u>conditionally cleared</u> contaminated materials should be restricted to non-nuclear facilities, providing for the average mixing ratio with clean materials, as considered in the radiological model.	To increase readability.	X			
288.		36-SWE	4.97	The regulatory body should set the conditions for the clearance. The destination of cleared materials should be documented by the authorized party and approved by the regulatory body prior to implementation in the clearance process, as part of the traceability of the clearance process for this material.	The regulatory bodies should set the conditions, not intervene in the commercial trading activities.	X			“The regulatory body should set the conditions for the clearance” is a general statement written several times in the previous sections, so nothing specific to mixing and dilution.
289.		21-WNA	4.97	<u>The regulatory body should set the conditions for the clearance.</u> The destination of cleared materials should be documented by the authorized party and approved by the regulatory body prior to implementation in the clearance process, as part of the traceability of the clearance process for this material.	The regulatory bodies should set the conditions, not intervene in the commercial trading activities.	X			“The regulatory body should set the conditions for the clearance” is a general statement written several times in the previous sections, so nothing specific to mixing and dilution.
290.		10-AUS	Chapter 5- Clearance of liquid material	This chapter is inordinately lengthy. The guidance information of this chapter could be summarized in 3-4 paras. Considering that the document is a specific safety guide,	Any liquid discharges (effluent) from a nuclear facility is subject to licence conditions and/or conditions of			X	This is not guidance on discharges, but on clearance. We tried to explain the difference

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				consideration of dose basis, activity concentration with reference to cited documents in this chapter would suffice. Further, discharge of liquid waste to the sewage is subject to specific limits and conditions and in compliance with WHO drinking water guideline.	authorization. It is a standard regulatory practice to specify the volume of discharges in terms of activity per unit volume taking into account the dose implication.				between the two concepts.
291.		5-BEL	5.1 and 5.2	5.2 : The dose criterion mentioned in §5.1 (...)	After mentioning it in 5.1, dose constraint value are repeated again in 5.2.	X			
292.		20-HUN	5.2	Uniform use of “mSv per year” or “mSv/a” should be applied.		X			
293.		36-JPN	5.2/1 (p.69)	A dose criterion in the range between 0.1 mSv per year and 0.3 mSv/a mSv per year for any ...	Editorial	X			
294.		25-UK	5.3	There are situations where discharge of liquids contaminated with radionuclides is not a relevant concept and therefore these liquids have to be released from radiological regulatory control in a different way. Examples are situations where the facility in which the liquids arise does not possess a licence or authorisation for discharging liquids or where the liquids are not suitable for discharge into the environment. Clearance of liquids can also be used in cases where small amounts are produced, for which the management of a discharge regime (including its safety requirements) is not justified. There may also be cases where liquids constitute an asset and where there is commercial interest in reuse or recycling, e.g. in the case of lubrication oils used in pumps, cooling liquids in transformers in nuclear	Not having a licence is not an adequate reason in itself. The usual course of action would be to apply for a licence. The text below explains where a discharge regime is not justified.	X			
295.	3	35-GER	5.4	...increased (e.g. by filtration, evaporation, distillation or fractionation).	The closing bracket is missing	X			
296.		37-JPN	5.4/1 (p.70)	In most cases, once released to the environment, discharges remain dispersed in air or water media except in sediments or food products , (i.e. the activity in air or	Nuclides in discharged effluents are mainly diluted by diffusion or dispersion but may be concentrated again by		X		We cover the concentration in sediments in other paras of Chapter 5.

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				water are cannot be concentrated again by any process).	deposition, sorption, inhalation and digestion into sediments or food products.				
297.		24-FRA	§5.4/4	Cleared liquids may remain together, so that after clearance the activity concentration may be increased (e.g. by filtration, evaporation, distillation or fractionation).		X			
298.		38-JPN	5.4/5-7 (p.70)	Clearance of ³ H tritium (³ H) is a special case because the concentration of this radionuclide is highly unlikely to be significantly increased by natural processes in liquids, sediments, plants or animals (the ³ H tritiated water behaves in the same way as water).	(Editorial) There may be organically bound tritium in liquid materials. Confusion in the behavior of a nuclide and the behavior of a chemical substance.	X			
299.		6-BEL	5.4 / last line	(...) Clearance of ³ H in the form of tritiated water is a special case because the concentration of this radionuclide is highly unlikely to be significantly increased by natural processes in liquids, sediments, plants or animals (the ³ H behaves in the same way as water).	only true for H3 in the form of tritiated water	X			
300.		14-ENISS	5.6	radionuclides in the dust <u>incineration residues such as ash or slag</u>	To clarify, if all the residues are meant.	X			
301.		39-JPN	5.9/2 (p.71)	.. specific clearance → .. <u>conditional clearance</u>	Editorial.	X			We take this and all similar comments into account. In the finalization of the draft we will consistently use one of the terms. There are comments proposing use of 'specific clearance' instead of 'conditional clearance', so a final decision on the terminology will be made and applied throughout the document.

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302.		40-JPN	5.10/6 (p.71)	types of specific (conditional) clearance →types of conditional clearance	Editorial.	X			
303.		41-JPN	5.11/1 (p.71)	.. specific (conditional) clearance → conditional clearance	Editorial.	X			
304.		25-FRA	§5.12	Where the concept of clearance is applied to non-aqueous liquids, cleared aqueous liquids can also be discharged into a receiving water (lake, river, sea). As the liquid has been cleared, no authorization for the discharge from the nuclear regulatory body would be needed (while the approval of the water authorities would still be necessary). In such a case, the model used for describing the radiological consequences of this type of clearance needs to take into account all relevant pathways in the environment, i.e. migration of radionuclides in the water body, sedimentation or use of water for radioecological pathways, as described in Ref. [38 SRS19]. Special consideration should be given to 3H, as mentioned in para. 5.4. An environmental monitoring program could be implemented in order to verify the quality of the receiving water after the discharge of cleared aqueous liquid.	Although the respect of clearance levels should guarantee protection, it could be necessary for this specific case to add an environmental monitoring program as an additional barrier of protection.	X			
305.		42-JPN	5.13/8 (p.72)	cleared practice will not exceed 10 µSv. → cleared practice will not exceed the dose of the order of 10 µSv.	Clarification	X			
306.		6-MOR	5.19	[...] However, there is a possibility of concentration in sediment downstream and in some industrial uses, these situations-need consideration. or, dilution of radioactively contaminated liquids may be required to manage non-radiological properties, such as pH or salt content, prior to discharge. These situations need consideration.	There's no link between this case, the previous one and if its before or after clearance. Conditions applied to the process should be clarified.	X			
307.		26-FRA	§5.19/2	As for solid materials, deliberate dilution of the liquid material with clean material	Deliberate dilution should not be an authorized practice in		X		Text modified allowing such possibility in

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				(e.g. uncontaminated water) to reach the clearance levels prior to release of material from regulatory control is not an acceptable practice, unless a permission is obtained from the regulatory body for such an action.	any case. This practice is inconsistent with the hierarchy of management modes of waste in France, which gives priority to the reduction of the quantity of waste.				exceptional cases, to keep flexibility.
308.		11-AUS	Chapter 6- Clearance of gaseous material	In general, gaseous discharges from a nuclear facility is subject to regulatory authorization and limits of discharges are radionuclide-specific based on the dose implications. Some guidance on use of computer codes for gaseous discharges from routine operation of a nuclear facility would be useful.	For example, computer code PC-CREAM is commonly used for modelling the dose implications of gaseous discharges from a nuclear facility.			X	This is not guidance on discharges, but on clearance. We tried to explain the difference between the two concepts.
309.		27-FRA	§6		It is unacceptable to use the concept of clearance for gaseous materials originating from nuclear facilities. The discharges are part of the overall authorized process.			X	Example: helium gas used in a nuclear facility during operation (to provide for an inert atmosphere in the fuel channels) can be found stored in bottles/vessels during decommissioning. Clearance is the concept to make possible its reuse in another place. Why should it be discharged?
310.	3	36-GER	6.3	... are given in IAEA Tecdoc1000 [30]	Add reference	X			
311.		28-FRA	6.3/5	Exposure scenarios relevant to a compressed gas in a container may be fundamentally different to those for a gas under standard conditions. <u>Regulatory body has to define the physical state (pressure and temperature) of the gas taken into account in scenarios.</u>				X	This proposal seems to be too prescriptive
312.		43-JPN	6.3/ the last line(p.75)	...given in IAEA tecdoc TECOC-1000 [30].	Editorial.	X			

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313.		7-BEL	6.3 / Last line	“... a vent at the side of a building are given in Ref. [30 TECDOC-1000]	“... a vent at the side of a building are given in IAEA Tecdoc 1000”	X			
314.		44-JPN	6.5/4 (p.75)	will not exceed 10 µSv. → will not exceed the dose of the order of 10 µSv.	Clarification	X			
315.	3	37-GER	7.1	The radiological basis for conditional clearance is the same as for clearance, as described in §2.7 and §4.4, namely those specified in Schedule ± I, sections I.10 and I.11.	Clarify and add reference	X			
316.		9-UKR	7.3	After the phrase “In this way, the conditionally cleared material will be below the mass-specific exemption level for moderate quantities and therefore can be exempt from the requirement for notification”, add: <u>It may be necessary to limit quantities of conditionally cleared material over time (e.g. in kg/a).</u>	It is necessary to ensure that the total activity of radionuclides is below the activity exemption level	X			
317.		45-JPN	7.4/5 (p.76)	expected to be higher or the same as → expected to be higher than	Clarification	X			
318.	3	39-GER	7.4	... material is handled as non- radioactive material would be handled ,	Duplication?	X			
319.		37-SWE	7.4	Last sentence: The derivation of the conditional clearance levels should consider that the cleared material is handled <u>in the same way</u> as <u>similar</u> non-radioactive material would be handled, i.e., conditional clearance levels should not rely on special precautions to be taken by the receiving party to meet the dose criteria. <u>Since the fate of the material is better known, the derivation of conditional clearance levels could use other, less conservative approaches than those that have been used for general clearance levels, and, depending on the regulatory framework, be based on considerations of uncertainties in scenarios as well as in measurements.</u>	1. Proposed clarification. Information should be given on alternative methods to consider uncertainties in the clearance process, to focus on the main objective (trivial dose). An example is given in Meck and Jiselmark, Improved clearance verification, Journal of radiological protection, 2021.	X			

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320.		38-SWE	7.5	If the specified destination is an authorised practice, e.g. a licensed smelter, then these considerations are not relevant, conditional clearance may not be an appropriate concept to be applied <u>for the material delivered to this facility.</u>	Important to secure clarity.	X			
321.		22-WNA	7.5	If the specified destination is an authorized practice, e.g. a licensed smelter, then these considerations are not relevant, conditional clearance may not be an appropriate concept to be applied <u>for the material delivered to this facility.</u>	Important to secure clarity.	X			
322.		2-CZE	7.5./77	Conditional clearance levels	We have a problem with this statement in para 7.5. which is saying that conditional clearance levels should be lower than exemption levels for moderate amount material. This is strange and conditional clearance process was never constrained like this. Derivation of conditional clearance level includes specification of necessary conditions to ensure that clearance process will end successfully as it is designed. There is no need of license but still there is a kind of control. Moreover it is not consistent with para 2.11. We think that this condition is going beyond mandate of safety guide.	X			This is one possible approach to avoid a situation that conditionally cleared material requires notification. We don't use "should" statement for this. Formulation further revised to say "one approach could be".
323.	3	40-GER	7.7	(footnote 14) expressed in Bq/cm ²	Misspelling	X			
324.	3	41-GER	7.7 footnote 14	... clearance levels expressed in Bq/m ² 2 that...	The number "two" has to be superscripted.	X			
325.	2	38-GER	7.12, 7.13	Paragraphs 7.12 and 7.13 should be moved to section 4 (inserted after paragraph 4.18).	The criteria mentioned here apply generally to surface-specific clearance levels, not just to conditional clearance. It is therefore recommended to			X	We consider it is important to underline that the same general dose criteria are used for

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					move those into Section 4 after paragraph 4.18				derivation of surface-specific clearance levels.
326.		WNTI-3	7.15	7.15. (...). In case mixing is required with non-radiological metal as part of the condition, the mixing ratio used in the derivation of the conditional clearance levels should be respected. Likewise, a building that was cleared on the condition that it would be demolished must <u>should</u> not be used in the meantime for new workplaces (e.g. as an office building or a workshop) but must <u>should</u> be demolished without prior reuse.	As in the previous sentence, “should” should be used instead of “must” in this Safety Guide.	X			
327.	3	42-GER	7.20	... in a legal sense (compare ...	Blank missing	X			
328.	3	43-GER	7.20	... (if so, it would be necessary that the transport is performed by a licensed shipping company).-	Two periods	X			
329.		WNTI-4	7.20	7.20. (...). In such cases the question often arises whether transport of the material to its destination, which is necessary to complete the clearance process, will require a license <u>an approval</u> in accordance with SSR-6 (Rev. 1) [29], and whether handling the material during this time will require an authorisation, permit or license <u>by the competent authorities</u> (if so, it would <u>may</u> be necessary that the transport is performed by a licensed shipping company).-	“approval” is the common wording used in SSR-6. “authorisation, permit or license” are granted by the competent authority in each state. “licensed shipping company” is not used in SSR-6 and can only be an example. Therefore, “may” is more appropriate than “would”. Editorial – One stop at the end of the sentence is enough.	X			
330.		29	§7.20/11	(if so, it would be necessary that the transport is performed by a licensed shipping company).-		X			
331.		21-HUN	7.21 last sentence	Last sentence of para 7.21 (“There may be situations...”) should be moved into para 7.22.	Last sentence of para 7.21 is a special case, which belongs to para 7.22.	X			

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332.		WNTI-5	7.21	7.21. (...). There may be situations where conditionally cleared material would exceed the transport exemption levels (including surface contamination) defined in SSR-6 (Rev. 1) [29] at the time of transportation.	Editorial – “Transport” is the word that is usually used in this document, and more generally in IAEA publications.	X			
333.		22-HUN	7.22, first sentence	Instead of “not suitable for that particular material” the phrase of “not applicable for the transport of that particular material” should be used.	Presently 7.22 (prohibit clearance) and first sentence of 7.23 (allows clearance) is contradictory, hence reformulation of 7.22 is necessary.			X	We are referring to conditional clearance not being suitable for the material described in 7.22. A sentence that “conditional clearance is not applicable for the transport...” would sound strange.
334.		12-AUS	Chapter 8- Involvement of Interested Parties and Enhancing Public Understanding	This chapter should be deleted and key information related to interested parties and public consultation should be captured in Chapter 2: Regulatory Framework for Clearance.	Involvement of interested parties and public consultation are requirements for the regulatory body as specified in GSR Part 3 (Requirement 4, Requirement 29) and GSR Part 1 (Requirement 36)			X	Chapter on involvement of interested parties was foreseen in the approved DPP for DS500. There is a clear role for the authorized parties related to involvement of interested parties, which is described in the Chapter 8.
335.		3-CZE	Chapter 8		We don’t see this chapter as very appropriate to include in this more technical guide. We understand the importance of right communication and also difficulties of some countries in this sense however it is not easy to give a general advice how to deal with – it depends more or less on the specific situation in each country. Para 8.8. – mainly last sentence is too specific and intentional – it must be deleted.	X			Last sentence of para 8.8 modified to be less specific.

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336.		30-FRA	Chapter 8		The way dealing with the issue of stakeholders fits for planned exposure situations but not well for existing situations, notably contaminated sites and post-emergencies where people have many concerns and expectations and where trust may be lost. For example, the use of the term “safe”, which is related to the clearance, is controversial. There is no word about self-measurements, self-help protection, RP culture development, empowerment of people or co-expertise process.			X	The meaning of “self-measurements” and “self-help protection” not clear.
337.		31-FRA	§8.2	Therefore, <u>before a clearance process is authorized and executed</u> , authorized parties and regulatory bodies should engage with interested parties to explain the concept of clearance, the rationale(s) for it and how it is regulated and performed in practice.	This dialogue should be implemented before any practice of clearance.	X			
338.		15-ENISS	8.3	The aim of the engagement is not only to understand the concerns of the interested parties and to address them with respect and in a proportionate manner, but also to share the social, economic and environmental benefit obtained from the cleared materials through recycling and a more sustainable use of resources. Communication should be maintained in order to develop a common understanding, based on trust, of the concept of clearance with interested parties. <u>There is no need for regulators to require the authorized party to apply an excessively conservative clearance process simply in order to gain public acceptance.</u> Both the regulators and the authorized parties should be involved in pursuing the social, economic and environmental benefits of clearance.	Keep the deleted text. This in in accordance with the new appendix 2.	X			The new proposed text added in the end of para 8.4, as it doesn't fit well in para 8.3.

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339.		16-ENISS	8.5	One approach that is useful in enhancing public understanding of the trivial radiation risk from cleared materials is to compare the radiation risk from the cleared material with the average lifetime background cancer risks in the member state, and with the variation in these average lifetime background cancer risks in the different regions in the member state.—This comparison of risks should use the LNT (Linear Non Threshold) model and the radiation risk coefficient of 5% per Sv, as defined by Ref. [45 ICRP103/2007]. Comparisons of the trivial risk from cleared material with commonly accepted radiation risks, e.g., intercontinental flights, natural radionuclides in foodstuffs, are also useful communication tools. Relevant information for these comparisons can be found in IAEA posters and leaflets about radiation protection [46].	In the risk communication with individuals outside radiation protection area the use of LNT and the radiation detriment (as presently defined by the ICRP) should be avoided. There are clear deficiencies in the present calculation methodology of radiation detriment as recently identified by the ICRP and concurrently that discloses some carefullness in using these two concepts (LNT with DDREF and the detriment). These concepts are used in optimization which is OK but in communication with the public one has to strive for more realism and facts. Otherwise the fear of radiation at doses of very low or negligible risks will continue to increase in society. The advice could be to also compare with criteria/situations for genotoxic chemicals in general and not only focus on the radiological situation. Delete the LNT sentence.	X				
340.		6-FIN	8.5	One approach that is useful in enhancing public understanding of the trivial radiation risk from cleared materials is to compare the radiation risk from the cleared material with the average lifetime background cancer risks in the member state, and with the variation in these average lifetime background cancer risks in the different regions in the member state. This comparison of risks should use the LNT (Linear Non Threshold) model and the radiation risk coefficient of 5% per Sv, as defined by Ref. [45 ICRP103/2007].	Remove the sentence referring to the LNT model, as it is not feasible for risk assessment especially for very low doses, such as in the level of 10 µSv. For example ICRP 103 points out the high degree of uncertainty of the risk factors in the low dose range and e.g. advices to avoid the calculation of the number of cancer deaths based on collective effective	X				

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				Comparisons of the trivial risk from cleared material with commonly accepted radiation risks, e.g., intercontinental flights, natural radionuclides in foodstuffs, are also useful communication tools. Relevant information for these comparisons can be found in IAEA posters and leaflets about radiation protection [46].	doses from trivial individual doses.				
341.		7-ESP	8.5	Two aspects that should be added and addressed: - Dose from cleared material that a person/worker could receive in a year is as much 100 times lower than the natural dose coming from background by nature. - The economic savings by clearance is very important in comparison with treatment, conditioning and final disposal of that material.	From our point of view, these are the most important reason to justify clearance	X			
342.		32-FRA	8.7/5	Examples of different forms of communication are a formal consultation or communication on the national framework; discussions between regulators, authorized parties and waste management organisations; seminars and workshops with interested parties; <u>public hearings</u> ; printed material including leaflets; and the use of electronic media such as web pages and social media.	The chapter 8 concerns involvement of interested parties and enhancing public understanding. In fact, the topic of this chapter concerns essentially the communication to interested parties and not their real involvement (only mentioned in the paragraph 8.7 for conditional clearance).	X			
343.		48-JPN ⁽¹⁾	8.9/1 (p.83)	The last decade has seen → The last decades have seen	Clarification	X			
344.		4-CZE	Appendix 1		The introduction of screening levels and clearance –like process is very strange here , although it is better explained then in DS499. However this way again confusing. It is also not clear why waste treatment after Fukushima is described as	X			In DS500 we are neither referring to clearance nor to exemption. In the Appendix 1 we describe a process to decide how certain waste from remediation should be managed (waste already

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					exemption in DS499 and as clearance in DS500. See also general comments below				collected and stored, effectively under regulatory control), applying similar process to clearance, but using a different dose criterion that is adequate for the situation. So, some part of the waste would need to remain as radioactive, while the part that complies with the criteria (screening levels) can be managed otherwise.
345.		33-FRA	Appendix 1		The clearance concept cannot be fully applied to the post-emergency situations. It should be better to remove this appendix from this guide to avoid confusion.			X	We agree with the point you raise, but we consider the explanation is provided in para A1.7.
346.		39-SWE	Appendix 1, the title	Change "after an emergency" to "in a post-emergency situation"	Make it clearer that this is not handling of waste after an emergency (as is stated in 1.19), instead this is handling of waste in planned activities during the post-emergency period.	X			
347.		34-FRA	AI.8	Replace "If a clearance-like process..." by "If recycling of material or disposal of waste on landfills..."	The concept of clearance-like is too confusing, especially when the current well-established clearance levels cannot be used.	X			
348.		35-FRA	AI.8		Mentioning 1 mSv/y as a possible criterion below which no further optimisation may be necessary in a long-term post-emergency situation may pose a problem of consistency. 1 mSv/y is already recognized as a reference level for the			X	We understand and accept the reasoning for the comment. However, this para mentions a criterion "of the order of 1 mSv per year or less" only as an example and

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					long-term post-emergency situation. Below a reference level, optimisation is still relevant.				not as a generally recommended value.
349.		WNTI-6	A1.8	A1.8. An example of such a dose criterion, for the later stage of recovery after an emergency, could be of the order of 1 mSv per year or less for reasonably expected scenarios (e.g. the dose to operators and the public under normal operations, doses during normal transportation, doses associated with recycling, and doses from groundwater migration following disposal in a landfill).	Editorial – “Transport” is the word that is usually used in this document, and more generally in IAEA publications.	X			
350.		36-FRA	AI.9 to AI.24		These paragraphs are mainly related to the Japanese experience after the Fukushima accident. It is very ambiguous because clearance was not used for the management of the corresponding waste, neither conceptually nor in terms of numerical levels.	X			Yes, that part focuses on experiences from Japan. Appendix 1 was proposed by Japan. There we describe a process to decide how certain waste from remediation should be managed (waste already collected and stored, effectively under regulatory control), applying similar process to clearance, but using a different dose criterion that is adequate for the situation. So, some part of the waste would need to remain as radioactive, while the part that complies with the criteria (screening levels) can be managed otherwise.
351.		46-JPN	A1.13/3 (p.87)	...the Nuclear Regulation Authority (NRA) of Japan	Editorial.	X			
352.		47-JPN	A1.19/3 (p.88)	. safety assessment → dose calculation	Clarification	X			

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353.	3	45-GER	A1.21	... with less than 5_μSv/h of surface dose rate...	Space is missing	X			
354.	3	46-GER	A1.23	... to meet the criteria of 1_μSv/h of additional exposure due to the recycling. The 1 μSv/h corresponds to the minimal value of the dose rates in the air at the 1_m height from...	Spaces are missing	X			
355.	3	47-GER	Figure A1.1	Below 2_mSv/y, 10% of dose limit for worker Below 1_mSv/y at the site boundary evaluated	Spaces are missing	X			
356.	3	48-GER	Table A1.1	Floor slab thickness 20_cm *Restricted use in the building based on an effective dose rate of 0.1_μSv/h in the building (scaled from a value of 160,000 Bq/kg corresponding to 1_μSv/h that was calculated by JAEA).	Spaces are missing	X			
357.	3	49-GER	References	Ref. 23 should be: “GERMAN INSTITUTE FOR STANDARDISATION, DIN 25457-4 Activity measurement methods in the clearance of radioactive substances and components of nuclear facilities –Part 4: Contaminated and activated metal scrap, DIN Deutsches Institut für Normung, Berlin, (2013).”	Title was not correct	X			
358.	3	44-GER	Annex I	(footnote 16) ... Figure I-1_refer...	Blank missing	X			
359.		11-USA	I-19	Add to end of paragraph ... The NRC only uses NUREG-1640 to assist with evaluating specific exposure scenarios and their relevant exposure pathways. The NRC does not use the values provided in NUREG-1640 to make regulatory decisions.	The NRC only uses NUREG-1640 to assist with evaluating scenarios. The specific values included in the document are not used to make regulatory decisions.	X			The new text added as a separate paragraph, for better flow of the information.
360.		WNTI-7	I.28 Table I-1 Second line	Order of 10 μSv/ya or less	The official symbol for “year” is “a” (and not “y”). -	X			
361.		11-BEL	Annex I- I.35/line 1	“A model for “SURface DOse QUantification” or SUDOQU [I-10]” has been developed.	- [I-9] is the wrong reference, it should be [I-10]	X			

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					- The development has been finalized since 2018				
362.		12-BEL	Annex I-I.38	It was concluded in [I-11] that the suitability of the SUDOQU model for dose assessments related to clearance of objects from nuclear facilities could be demonstrated. “Further development of the model allowed for detailed parameter-sensitivity analyses and probabilistic dose evaluations. Derived surface clearance levels have been accepted by the Belgian Federal Agency for Nuclear Control (FANC) as regulatory surface specific clearance values.”	In the meantime (original text written in 2018-2019) probabilistic dose calculations have been performed and derived surface clearance levels have been accepted by FANC as Belgian regulatory surface specific clearance values.	X			
363.		10-USA	Annex I, References Page 106, Reference I-05	Suggest adding the following reference website: http://resrad.evs.anl.gov/docs/surface Clearance Criteria for workers.pdf		X			
364.		WNTI-8	II-2	II-2. (...). In addition, the IAEA Transport Regulations [II-9] are addressed, which do not contain clearance levels, but from which surface-related activity values have been frequently misused as clearance levels, in order to point the fundamental differences in the radiological models underlying calculation of exposure from surface contaminations in the case of clearance and in the case of transport.	The reference number should be added.	X			
365.	3	50-GER	Annex II, II-6	... presented in section 0 Annex I, so that ...	Clarify and add reference	X			
366.		WNTI-9	II-11	II-11. The IAEA Safety Standards Series No SSR-6 (Rev. 1), Regulations for the Safe Transport of Radioactive Material 2018 Edition [II-9] contain surface-related values of 0.4 Bq/cm² for beta and gamma	Para. II-11 is in Annex II, which is about “Examples of surface specific values for unconditional clearance”. SCO-I is a category of material			X	The idea with this part was to explain why the transport values are not applicable to clearance as surface specific clearance

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				emitters and low toxicity alpha emitters and 0.04 Bq/cm ² for all other alpha emitters in the definition of contamination (for fixed and non-fixed contamination) as well as values of 4 Bq/cm ² and 0.4 Bq/cm ² , respectively, for the limit of surface contaminated objects (SCO-I) and surface contamination on packages and conveyances, relating to the non-fixed contamination only. These limits are applicable when averaged over any area of 300 cm ² of any part of the surface.	that is subject (i) to additional requirements regarding the fixed contamination on the accessible surface and the non-fixed contamination plus the fixed contamination on the inaccessible surface, and (ii) to all the requirements of the IAEA Regulations for the Safe Transport of Radioactive Material (2018 Edition) (SSR-6 (Rev. 1)). Therefore, it does seem appropriate to include this (partial) requirement about SCO-I in the examples of this Annex about “Examples of surface specific values for unconditional clearance”.				levels (this is relatively frequent misunderstanding).
367.		WNTI-10	II-12	II-12. (...) A review of this model together with proposal of new modelling approaches for limiting the surface contamination on packages and conveyances in transport has been given in [II-11] and [II-13] ¹² . The following assessment of the Fairbairn model was provided in [II-12] ¹³ : (...).	[II-11] is mentioned in the previous sentence and can be deleted. It seems more appropriate to exchange the references [II-12] and [II-13] (the text that is quoted after this sentence is from para. 4.4.1 in [II-13]).	X			
368.	3	51-GER	III-6	... a level of 1_Bq/g for U _{tot} ...	Space is missing	X			
369.	3	52-GER	III-8	1_Bq/g to 10 Bq/g	Space is missing	X			
370.		WNTI-11	III-27	III-27. (...). They take into consideration exposure of workers that may arise from transport ation of the material to the site, the handling of the material at the landfill and releases of radionuclides to the atmosphere in case of a landfill fire. (...).	Editorial – “Transport” is the word that is usually used in this document, and more generally in IAEA publications.	X			
371.	3	53-GER	III-41	... ranging from 10 ⁻⁴ Bq/l to 10 ³ Bq, 80% of them laying between 0.01 Bq/l and 1_Bq/l.	Spaces are missing				
372.		37-FRA	Annex IV		This annex is focused on a case study in the medical case. It is	X			This Annex is an example provided by FORO (as

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					very interesting and could be extended to other fields than the medical ones, e.g. the management of contaminated solids in non-nuclear industries such as those using irradiators (particle accelerators)				mentioned in the footnote 21) on the basis of their Practical Guide. So the IAEA can't extend the example beyond the scope of the provided example.
373.	1	54-GER	Annex IV, IV-12	... feasible [IV-1]. <u>However, it must be taken into account that in addition to the radionuclide used, the preparations usually also contain other radionuclides as a result of production, either as impurities or through decay processes.</u>	This aspect can be of importance. It should be explicitly referred to.	X			
374.	1	55-GER	Annex IV, IV-19	... is known with precision. Hence, the remnant activity in the waste could be estimated by mean of a simple balance of activity and the corrections for decay, in correspondence with the characteristics of the practice and the time frame involved. <u>However, if present, the impurities or decay products contained in addition to the radionuclides used must also be taken into account. Their relative importance can increase significantly over time.</u>	This aspect can be of importance. It should be explicitly referred to.	X			
375.		8-BEL	IV-21	For solids wastes generated as a consequence of patients' treatment (papers, cottons, chiffon gloves), the method to estimate the activity on the waste bags could be done by simple measuring the dose rate or counts rate at a certain distance.	<i>"the method to estimate the activity on the waste bags could be done by simply measuring the dose rate (...)"</i> . The devices measuring the dose rate are generally not sensitive or suitable for clearance. Given the importance of this guidance, we would advise against carrying out sub-optimal practices. This leads to an over-reliance on decay, with the risk of allowing sorting errors (Cr51 with Tc99m waste for example).	X			Comment well noted. This Annex is an example provided by FORO (as mentioned in the footnote 21) on the basis of their Practical Guide ... We can't change the description of their approach. If the prevailing feeling is that the example is not appropriate, the entire Annex needs to be removed. This will be discussed in the next review of the draft by the

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									Safety Standard Committees.
376.		9-BEL	/IV-26/ formula IV1		Is it a good thing that an IAEA guidance of this importance recommends in practice the use of a surface measurement probe for the measurement of a mass activity? Even if one were to recommend a best practice and live with the "source point" approximation, there are probes where the manufacturer provides cps Bq factors.	X			Comment well noted. This Annex is an example provided by FORO (as mentioned in the footnote 21) on the basis of their Practical Guide ... We can't change the description of their approach. If the prevailing feeling is that the example is not appropriate, the entire Annex needs to be removed. This will be discussed in the next review of the draft by the Safety Standard Committees.
377.	1	56-GER	Annex IV, IV-41	... Such quick check could be performed by gamma dose rate measurements, <u>if no radionuclides are contained as significant impurities, the control of which requires a higher measurement effort.</u> Normally, ...	This aspect can be of importance. It should be explicitly referred to.	X			
378.		10-BEL	IV-41		IV-41: it is recommended to carry out a measurement before clearance, i.e. after decay, to detect sorting errors of long half-lives in short ones. It should be remembered that these facilities almost never have access to spectrometry measurements!	X			
379.	3	57-GER	IV-50	Harmonize page numbers	The page numbers switch from 137 to 1.	X			This will be fixed during the final editing.
380.		NOR-7	Annex V	Should remain an Annex.	This was an Appendix in earlier drafts, but the content and provenance of this text are appropriate to an Annex.	X			

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					We wish to make clear that we would not agree to its inclusion as an Appendix.				
381.	1	58-GER	V	ANNEX V should be omitted or modified according to the comment.	Annex V provides an overview about typical conservatism and their impact on the clearance process. Clearly, the reduction of conservatism and the resulting impact on the respective clearance process have to be considered. The source of the mentioned factors of conservatism is not clear and would be highly dependent on the specific details of a clearance process. Moreover, some conservatism stated is not evident. If one considers, e.g., Co-60, the conversion to activity concentration is affected by non-conservative rounding (i.e. from 3,09e-2 to 1 e-1 according to Ref. [4]). Thus, the assumption of a factor of conservatism of 15 is not justified. A factor of 15 also would contradict the statement in Ref. [4] that overconservatism has been avoided. Also, there was a very low probability demanded in 1988 for a few tens of microsieverts while this is not the case for the current 10-µSv-criterion. Hence, the criterions cannot be directly compared and the factor of 3 should be omitted. Furthermore, Annex V as it stands could be seen as guideline for a generic and				NEEDS TO BE DISCUSSED AND DECIDED BY WASSC/RASSC

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					quantitative reduction of clearance standards (e.g. increase of clearance levels). It is therefore suggested to omit the mentioned factors of conservatism as they are not helpful in the framework of a general Safety Standard which should serve as a clear guideline. Instead, Annex V should serve only as qualitative guideline that shows which conservatism could be reduced depending on the particular circumstances. Either these aspects are clearly pointed out in Annex V or the ANNEX is omitted completely. Given that a qualitative discussion is already provided in Paragraphs 4.13 - 4.17, omission seems to be the prudent option.				
382.		40-SWE	Annex V	Annex V should be taken out of the document.	See comment No 11 above.				NEEDS TO BE DISCUSSED AND DECIDED BY WASSC/RASSC
383.		48-JPN(2)	V.4/4 (p.4)	2. Conversion from the dose rate criterion → 2. Conversion from the dose criterion.	dose rate = dose per unit time is not the same as committed effective dose in a year	X			
384.		49-JPN	V.8/title (p.5)	2)...dose rate criterion → ...dose criterion	Editorial	X			
385.		NOR-8	V.8 (should be V-8, since this is now an Annex)	Reword to make clear that these remarks relate to the models used to derive the tabulated activity concentrations in GSR Part 3, which were intentionally designed to be conservative 'screening' type models.	As written, this section could be understood to apply to (and implicitly to criticize) all assessment modelling. Different approaches to addressing uncertainty are rightly adopted in different assessments for different purposes, and it is misleading			X	The Annex V doesn't describe how the clearance levels presented in the GSR Part 3 were derived, but discusses the overall conservatism in a typical clearance process.

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					(and irrelevant to this Safety Guide) to suggest that an approach of extreme conservatism is always applied.				
386.		WNTI-12	V-11	V-11. The activity concentration values derived as in (2) above are usually established as legally binding values in national legislation – in effect they become limits. It is then an offence in law to release material exceeding these values, and it is seen as an extremely sensitive offence in terms of public perception. Operators working with clearance— must <u>should</u> therefore allow margins of confidence within their clearance measurement regime. (...).	Methods to handle the safety margins depend on the national legislation and then “should” seems better than “must” in an annex of a safety guide.	X			
387.	3	59-GER	entire document	Constant British or American English throughout the document	Improvement of fluent reading	X			This will be fixed during the editing of the final version.
388.	3	60-GER	entire document	The terms “nuclide” and “radionuclide” are used as synonyms. However, these terms should be harmonized.	Improvement of fluent reading and understanding	X			
389.		-SWE	Appendix 2	Separate file provided with Appendix 2				X	Basically the same material, that had been included in an early version of DS500 (2018) as Annex IV, was strongly opposed by Japan during the TM in March 2019.
390.		-WNA	Appendix 2	Separate file provided with Appendix 2				X	Basically the same material, that had been included in an early version of DS500 (2018) as Annex IV, was strongly opposed by Japan during the TM in March 2019.
391.	1	61-GER	Comment on building of competence in the field of clearance			X			New para 2.35 added

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		According to the requirement 2 of GSR Part 3, requirements shall be established for education, training, qualification and competence of all persons engaged in activities relevant to protection and safety, the formal recognition of qualified experts as well as the competence of organizations that have responsibilities relating to protection and safety. The requirement 4 of GSR Part 3, among others, introduces qualified experts and radiation protection officers, organizations or persons, who shall have responsibilities in specific areas related to protection and safety. Especially in the nuclear field or in other radiologically relevant sectors, it is international common practice to rely on the expertise of qualified experts and radiation protection officers, who, depending on the respective national framework, give advice and bear responsibility as an external consultant (organizations and/or individual persons) and/or in the framework of the authorized party. IAEA SSG-44 (Specific Safety Guide No. SSG-44: Establishing the Infrastructure for Radiation Safety) specifies in action 53, among other provisions concerning building of competence, that the regulatory body and other authorities should establish requirements for competence in safety for all persons engaged in activities relevant to protection and safety, including radiation protection officers and qualified experts. The Draft Safety Guide DS 500 contains no specific requirements on the training and qualification of responsible persons in the field of clearance. Based on the high-level provisions of GSR Part 3 and SSG-44, IAEA SRS No. 20 (Safety Report Series No. 20: Training in Radiation Protection and the Safe Use of Radiation Sources) gives detailed recommendations on the education and training of responsible persons in the field of protection and safety encompassing qualified experts, radiation protection officers, occupationally exposed workers, qualified operators and regulator. However, SRS No. 20 provides no advice or guideline for the training content of persons bearing responsibility in the field of clearance. We recommend adding recommendations to the Draft Safety Guide DS 500 on the role of both the qualified expert and the radiation protection officer according to GSR Part 3. Furthermore, we consider it as valuable and helpful to define the basic requirements concerning the qualification and the training content of persons bearing responsibility in the field of clearance (e.g. qualified experts, radiation protection officers).				
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