DS499 Application of the Concept of Exemption - Step 9 Member State Comments Resolution

Please note that a one-to-one correspondence with the comments resolution given in this table may not be traceable in the revised draft at Step-11 due to further significant editing at Step-10 by the Standards Specialist.

COMMENTS BY REVIEWER Date: July2021/March 2022				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
AUS	Feedback on the retention of the text dealing with existing exposure situations, including trade, in the draft safety guide DS499. (Agree/Disagree)	Agreed with modifications to text	Australia supports the retention of the text with regard to existing exposure situations. Currently, the text on existing exposure situations is too detailed in nature for the level of document it is presented in. At times it can also be confusing to try and follow the application and concepts being conveyed to the reader. The existing exposure text needs to be more concise and should be revised to provide overarching guidance on situations such as exposures related to commodities, trade and bulk materials. A similar style to that used in the current Safety Guide on Application of the Concepts Exclusion, Exemption and Clearance (IAEA RS-G-1.7) would be appropriate.	X			The drat has been revised thoroughly addressing Member States' comments as well as Standards Specialist's review. This has resulted in some structural changes, consistency with terminologies and addressed the suggestions.
AUS	Feedback on whether to merge both documents DS499 (exemption) and DS500 (clearance	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.	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 documents, as	X			Significant revision made to address the comments.

	) or to continue with two separate guides as developed.	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.	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. Australia feels that 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.				
AUS	Section 4 and Section 5		Australia would like to take this opportunity to express our support of the Secretariat's efforts so far by providing content that is well organized and carefully considered in Section 4 and Section 5 of this draft Safety Guide.	X			
WNTI	General		The official symbol for "year" is "a" (and not "y"). Appropriate changes should be made throughout the document.	X			

CZ	<u>General comments to draft:</u> First answers to the specific questions as requested: 1. Feedback on the retention of the text dealing with existing exposure situations, including trade, in the draft safety guide DS499. (Agree/disagree) The Czech Republic doesn´t support the retention of the text dealing with existing exposure situations in DS 499. It is recommended better to include this issue (if really necessary) into new SG on regulation in EES which will be developed based on approval of RASSC in the last meeting (June 2021). The concept of screening levels as a specific tool for EES regulation is very artificially introduced into the text of both DS and in many parts makes the text not well understandable and consistent. Further arguments are given below. 2. 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. 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 113,116, for example) which can be established in relation to selected reference level in given situation. In para 6.3. 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.				The drat has been revised thoroughly addressing Member States’ comments as well as Standards Specialist’s review. This has resulted in some structural changes, consistency with terminologies and addressed the suggestions. The proposed merger is rejected and follows the approved DPP.

	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 make more benefit than harm and we must be consistent with already existing documents and approaches. ICRP104/para 28 *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 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***						
JAPAN	General Comment	DS499 and DS500 should be separate, not integrated.	The concept of "exemption" related to the entrance of "regulatory control" and "clearance" related to the exit of "regulatory control" are similar in terms of the management of low-dose radiation risk, however, the users of them are very different, so they should be defined separately as safety guidelines following the DPP approved by CSS.	X			
JAPAN	General Comment	A description of the existing exposure situation should be included in DS499 and DS500.	DS499 should provide descriptions on trade as RS-G-1.7 provides the descriptions related to trade, which is considered as existing exposure situations according to GSR Part 3. Otherwise, there would be no more valid	X			

			guidance on trade in Safety Guide level documents issued by the Agency. Also, the status of the draft of DS499 and DS500 was discussed at the Technical Meeting (EVT1804123) held on 19-22 March 2019, and treatment of the existing exposure situation was agreed upon. The results of the Technical Meeting were also reported to and discussed at the 47th RASSC meeting (November 2019), and the subsequent drafting has been proceeding according to that direction. The DPP approved by the CSS states that "There are some differences in terminology and approach between SS-115 and GSR Part 3 that necessitate revision of RS-G-1.7. Specifically, the requirements in SS-115 apply to practices and interventions while GSR Part 3 is structured around three different types of exposure situations (planned, emergency, and existing). The concept of exemption in planned exposure situations and application of reference levels for existing exposure situations are both included in GSR Part 3, but supporting guidance has not yet been developed. RS-G-1.7 needs to be updated to take account of these changes." The original agreement for DPP should be respected in this regard.				
UK	Over-arching comments	The UK considers that DS499 and DS500 should be merged back into one document as in RS-G 1.7. Clearance and exemption are inextricably linked and separation has led to different words being used to describe the same issue leading to potential confusion – examples are the use of generic and specific in DS499 and the use of unconditional and conditional in DS500.	This would ensure consistency in using the concepts that would aid understanding and remove confusion and complexity.				The drat has been revised thoroughly and resulted in some structural changes, consistency with terminologies and addressed the suggestions. The proposed merger is rejected and follows the approved DPP.

CZ	Title	Application of the concept of Exemption and screening levels	Current title is not in line with the current content of DS which is not only about concept of exemption – see also para 1.8., 1.16			X	Current title is as per the approved DPP and is appropriate. However, title will be reviewed by the publication's editor.
UK	Title	The Title the guide should be extended to include exclusion and the use of screening levels that are neither exclusion or exemption "Application of Concepts of exemption and exclusion, and in addition the use of screening levels.	This would more accurately reflect the contents of the guide, or screening level could be removed from DS499 and placed entirely in DS500. AS indicated previously the UK support the use of screen levels but do not consider that fit within this document whilst DS499 & DS500 remain separate			X	Current title is as per the approved DPP and is appropriate. However, title will be reviewed by the publication's editor.
Ukraine	Title	Application of the Concept of Exemption within the framework of planned exposure situations	For clarification and according to the objective of this Safety Guide as stated in Para 1.7			X	Current title is as per the approved DPP and is appropriate. However, title will be reviewed by the publication's editor.
UK	Introduction	Text should be revised in conjunction with DS500 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			
UK	Introduction	Text needs to be added to define what screening levels are - these are neither exclusion nor exemption	The use of screening levels and definition needs to be clearly articulated and needs to be completely consistent with the text within DS500.	X			Screening level is not intended to be a new concept. Revised relevant parts of the text.
UK	General Comment	The extension of this safety guide to cover existing exposures levels is not appropriate for a guide entitled "Application of Concepts of Exemption" – these aspects	By the IAEA definition "exemption" covers circumstances that are never by virtue of their hazard or risk - not existing exposure or emergency exposures situation is that are within regulatory control – by virtue of the fact that reference levels should be set they			X	The drat has been revised thoroughly addressing Member States' comments as well as Standards Specialist's review.

		should be removed and placed in a separate document.	are within regulatory control – screening levels are simply the expression of reference levels in terms of quantities of specific radionuclides. In addition, the extension to existing and emergency exposure situations using screening levels is out the scope of the DPP. The UK considers these are important concepts where a safety guide may be the appropriate vehicle, but they should not be within this particular safety guide. We also note that in paragraph 4.33 that the "concept of exemption is only related to planned exposure situations"				This has resulted in some structural changes, consistency with terminologies and addressed the suggestions.
Ukraine	General	Instead of the terms 'generic exemption" and "specific exemption","unconditional (general) exemption" and "conditional (specific) exemption"should be used.	It is proposed to use the terms·'unconditional(general) exemption" and "conditional (specific)exemption" to comply with DS500 and consider the meaning of two options for exemption			X	Generic and Specific is used in both guides and explained in the text.
ISRAEL	General comment	We are of the opinion that it would be preferable to merge both documents (DS499 and DS500) into one comprehensive document.	Both documents deal with closely related concepts and the separation into two documents is rather artificial. As a proof of artificial separation, one can mention the adoption of Table I.2 from GSR Part 3 as Table I.2 in DS499, while the caption was changed to exclude clearance.			X	Follows the approved DPP. Tables in GSR Part 3 will be reproduced as such.
ISRAEL	General comment	We do not favor the introduction of an exemption-like approach for existing exposure situations (as part of Section 6) in the document. If the subject is of importance (and it looks like it is), we propose to deal with it in a separate document (which could also be a Safety Report). As a less preferable alternative, the subject could be moved to an annex of the present document.	The text on the subject does not provide guidance on a subject dealt with in GSR Part 3. The text on the subject could provide the basis for a separate document, after it is more elaborated.				The drat has been revised thoroughly addressing Member States' comments as well as Standards Specialist's review. This has resulted in some structural changes, consistency with terminologies and addressed the suggestions

SPAIN	General	Intentional dilution, activity heterogeneity in the mass involved, uncertainty of the activity, etc, should be also addressed in this document and almost in the same way than in the clearance process.	It is clear the concepts of exemption and clearance, but from the point of view of activity and dose to the person/worker/public, they are practically identical. By this reason something should be addressed in relation to activity distribution in the matter (mass) involved	**X** Reference to DS500 paragraphs added in new para II.2			
Morocco	I. I.		We suggest that this provision be recalled as it was presented in thegeneral safety requirements. The same was done with the exposuresituations whose definitions was recalled at this level. Such reminder will enable the readerto link the requirements of the general safety requirements with the importance of applying the concepts of exemption and exclusion.	X			Link to GSR Part 1 added.
Morocco	1.3		Examples to illustrate the concepts of exclusion, exemption and clearance may be of an added valueto this paragraph.			X	This is only an introduction. Relevant examples are given in subsequent paragraphs.
Morocco	1.3	Exemption refers to the determination by a regulatory body or government that a source or practice need not be subject to some or all aspects of regulatory control on the basis that: [...]; or that the regulatory control is not justified regarding the level of risk posed by the source or the practice.	We suggest that this phrase of the present version of the guide ("[...] or that exemption is the optimum option for protection irrespective of the actual level of the doses or risks.) be replaced, because when exempting a source or a practice from the regulatory control, there is no protection that can be considered and/or controlled.		X Modified.		
Ukraine	1.3	…; or that exemption is the optimum option for protection irrespective of the actual level of the doses or risks <u>provided that the level of acceptable risk is not exceeded</u>	It should be clarified that in any case the dose limit should not be exceeded			X	

CZ	1.5	The exemption values for natural and artificial radionuclides are derived from conservative exposure scenarios. As such, it is important that further conservativism in the application of these values in practice is avoided.	This sentence sounds strange – how far it is in fact recommended to go with conservatism? How to avoid further conservatism in practice?		X		The intention is to avoid further conservative approach in using the values. See also France comment. Revisions made to improve the text.
FRANCE	§1.5	The exemption values for natural and artificial radionuclides are derived from conservative exposure scenarios. As such, it is important that further conservativism in the application of these values in practice is ~~avoided~~limited.	The use of the value in practice can also bring uncertainties that have to be taken into account.		X		editorial
Hungary	1.5, first sentence	The exemption values for natural and artificial radionuclides are derived from conservative exposure scenarios, as described in Safety Reports Series 44 [11].	The reference literature is suggested to be referred also in this para, not only in Chapter 4.	X			
RUSSIA	para 1.5 Section 1 Introduction	The exemption values for natural and artificial radionuclides are derived from conservative exposure scenarios. As such, it is important that further conservativism in the application of these values in practice is avoided. It should be noted that scenario-based dose calculations underlying the derived exemption levels were intentionally performed with a high degree of caution to ensure a sufficient level of protection. Hence, additional conservatism, either with respect to the practical aspects of verification of compliance with the exemption levels. ~~or with the~~	The recommendation not to include in the legislation and regulations the exemption levels from Tables I. 1 and I. 2 of Annex I of the IAEA safety standards GSR Part 3 contradicts the requirement of paragraph 3.10 GSR Part 3, according to which the government or the regulatory body shall determine which practices or sources within practices are to be exempted from some or all of the requirements of these Standards, including the requirements for notification, registration or licensing, using as the basis for this determination the criteria for exemption specified in Schedule I or any exemption levels specified by the regulatory body on the basis of these criteria.		X		This is about applying additional conservatism while incorporating exemption values in national regulations. Relevant text edited.

		~~formal embedding of these exemption levels in national legislation and regulations~~ should be avoided.					
UK	1.5	The exemption values for ~~natural and~~ artificial radionuclides are derived from conservative exposure scenarios.	Most natural values are based on upper expected concentration of natural radionuclides in soil they are not derived on exposure scenarios. It is important that this point is understood when considering the concept of exemption and clearance for NORM. see para 2.9 of DS499	X Modified relevant paragraph			
Indonesia	1.7/1	The objective of this Safety Guide is toprovide recommendations, criterions,requirements and guidance …….	To clarify the intendedaspects of the scope			X	Requirements and criteria are already provided in Schedule I of GSR Part 3.
UK	1.7		Refers to “case by case” exemption and names it “specific exemption” note the inconsistency with DS500 that refers to conditional clearance. A common approach to case by case/specific/conditional exemption and clearance is required	X			
UK	1.7	footnote	Clarify if includes consumer products which are addressed in 1.15	X			
CZ	1.8	The Safety Guide also provides guidance on the concept of exclusion and on the application of screening levels for decision making in existing exposure situations including trade.	Here is a first use of term “screening levels” without any context, any explanation – it is necessary to introduce some explanation what it is, why it is proposed to introduce such levels into the system. Maybe to put together para 1.8., 1.12, 1.16. and 2.11. where is something like definition, but this is not still enough because this is something going beyond GSR Part3. In para 1.16. it is stated that exemptions levels are exclusively applicable for PES and suddenly some screening levels are appearing here. This is really confusing. See also general comments below		X Text modified.		

Morocco	1.8	We suggest that a definition of "screening levels" be included at this level (even though it was more detailed in paragraph 2.11 below).	In order to clarify what is the meaning that was given to the term in the safety glossary and in the GSR Part 3.		X No new concept of screening level is intended. Para modified.		
UK	1.8	Delete para	Application of screening levels to existing exposure should be removed from this document and addressed elsewhere			X	The removal will create a gap in the recommendations. Text has been edited significantly and a screening approach for international trade is included.
Morocco	1.9	[...] It will also be of interest to operating organizations and to (approved) technical service providers in radiation protection.	In fact, this guide may be used not only by operating organizations, but also by technical bodies that could be hired by operators to provide them with expertise and consultancy in radiation protection matters. Depending on the applicable system in the concerned country, these technical bodies may need to be approved by the regulatory body in order to provide the desired services.	X			
Indonesia	1.9/9	This Safety Guide is intended for Governments, Regulatory Bodies andUsers (Applicant) …….	The Users or Applicant isalso important entity to know this guide	X			Significant changes made in the revision.
Morocco	1.10	This Safety Guide addresses the exemption of practices or sources within practices from regulatory control, as described in Schedule I of GSR Part 3 [1]. It is applicable to any facility or activity that may be subject to the regulatory control.	In order to clarify the intended idea, and because of the potential users of this safety guide might not be able to decide whether it is relevant to apply the concept of exemption or not to a specific facility or activity, this suggestion was made.			X	To be more specific to exemption.
UK	1.12	Remove	This Safety Guide should focus on planned exposure situations – it is confusing and unhelpful to introduce screening levels of			X	Paragraph modified to remove the focus of post-accident

			post-accident situations into this document. Should be discussed in a separate document.				situations. Text modified significantly.
Hungary	1.12	This Safety Guide defines and explains the use of the screening levels for decision making in existing exposure situation […]	Neither GSR Part 3 nor IAEA Glossary do not define the term of "screening level". So this Safety Guide not only explains the use of that, but does define the concept as well.		X		Screening levels is not introduced as a new concept. It is suggested to use a screening-based approach to support decisions in existing exposure situations. Paragraph modified. To avoid confusion "screening level" is removed and changes made throughout the text.
UK	1.12	Delete para	Application of screening levels to existing exposure should be removed from this document and addressed elsewhere			X	See reply to Hungary comment.
AUS	1.12	This Safety Guide explains the use of screening levels for decision making in existing exposure situations, in particular, large scale post-accident remedial actions.	Another example should be given for screening levels for decision making in existing exposure situations, as "emergency exposure situations" are outside the scope of the Safety Guide as stated in para 1.16. The large scale post-accident remedial actions are considered part of the transition phase of the emergency exposure situation and have been include in Safety Guide GSG-11. Some suggestions for screening levels for decision making in existing exposure situations could be: - Construction materials - Trade of commodities	X Added additional example of constructio n materials.			
CZ	1.13	This Safety Guide provides guidance to a generic approach that should be followed relating to international trade of non-food commodities containing	This generic approach should be followed by whom?	X Para modified.			

		radionuclides. Additional detailed technical information on radiation safety in the trade of commodities will be provided in a supporting Safety Report [3].		Section-3 provides responsibilities			
UK	1.16	This Safety Guide ~~primarily~~ addresses exemption from regulatory control in planned exposure situations. ~~Although,~~ as the use of the concept of exemption is exclusively applicable in planned exposure situations. Guidance on the application of screening levels for decision making in managing particular cases of existing exposure situations will be provided in a separate document ~~is also provided.~~ Emergency exposure situations are also outside the scope of the Safety Guide, although the relationship between different exposure situations is explained.	Consideration of existing exposure should be removed from this document and addressed elsewhere			X	
UK	1.18	Following this introductory section, Section 2 gives an overview of the basic definitions and concepts of exclusion, exemption and clearance, ~~with focus on a detailed explanation of the exemption concepts~~ in planned exposure situations, ~~and the application of screening levels for decision making in existing exposure situations~~.	Consideration of existing exposure should be removed from this document and addressed elsewhere			X	Numerous changes made in the revised draft to address overall comments.
AUS	1.20	Annex II should be removed.	Annex II, the example of a practical use of screening levels for decision making applied in the management of residual waste material			X	The example is intended to focus existing exposure situations after the

			in Japan after Fukushima Daiichi nuclear accident, should be removed. Another example should be given for screening levels for decision making in existing exposure situations, as “emergency exposure situations” are outside the scope of the Safety Guide as stated in para 1.16. The large scale post-accident remedial actions are considered part of the transition phase of the emergency exposure situation and have been include in Safety Guide GSG-11.				emergency and transition phase has ended. Additional example given as suggested.
UK		Remove Annex II	See comment above – the case study information is very helpful and gives useful insight into the use of screening levels for dealing with radioactive waste, but the UK considers this information is not suitable for this document.				Appreciate the comment, but the Annex is only one of the examples. Additional example added (see comment from Australia).
Morocco	2. THE CONCEPTS EXPOSURE SITUATIONS	(ii) An emergency exposure situation is a situation of exposure that arises as a result of an accident, a malicious act, or any other unexpected event, and requires prompt action in order to avoid or lo reduce adverse consequences. Preventive measures and mitigatory actions have to be considered in order to prevent the occurrence of an emergency exposure situation, or its dissemination in case it arises.	This is because the way it is stated in this version of the paragraph, one can believe that there is no way to prevent the occurence of an emergency situation, and this is not actually the point of considering preventive measures.			X	The text is directly from GSR Part 3.
Mexico	2.2	The ***Safety*** Standards ***Series No. GSR Part 3*** [I] have evolved from the previous process-based protection approach using practices and interventions by moving to an approach based on exposure	Editorial	X			

		situation.					
FRANCE	2.2(i)/1, 2	A planned exposure situation is a situation of exposure that arises from the ~~planned~~ *deliberate* operation of a source or from a ~~planned~~ *deliberate* activity that results in an exposure due to a source.	The definition of a planned exposure situation (PES) is ambiguous. Literally, it means that the implementation of an emergency plan, which is an activity planned for some circumstances, is a PES. The term "deliberate", used in 1.1 is better.			X	The text is directly from GSR Part 3.
Hungary	2.3	Suggested to be deleted	It is a general information, and it does not seem to have any contribution to the guide.	X			
Indonesia	2.6/ 3	. ……. These include production, extraction, storage, utilization and transport of such material. …..	To complete intendedaspects of the scope	X			Draft has been modified significantly
UK	2.6	If radionuclides of natural origin are intentionally used for their functional4 properties, they should comply with the requirements for planned exposure situations, regardless of their total activity or activity concentration in the material or source. These include production, extraction, storage, and transport of such material. Typical examples of such situations are consumer products (deliberate incorporation) and uranium and thorium mining and processing.	This is inconsistent with GSR part 3 (see para 3.4) which makes no reference to natural radionuclides being used for their functional properties. The criteria is strictly by reference to activity concentrations irrespective of intended use. We accept that this is a positon adopted in many countries but may not be universally adopted.		X Removed. Clarified better in footnote 4 in Section 4. (see revised draft)		
FRANCE	2.6/1	If radionuclides of natural origin are intentionally used for their ~~functional~~ *radioactive* properties	The notion of "functional" properties is vague despite the foot-note. Any case of intentional use of material containing natural radionuclides could be included. Another option is to replace "used" by "added".		X modified		See reply to UK comment.
FRANCE	2.6 vs 2.8		The link between §2.6 (as it is) and §2.8 is unclear. For example, fertilizer contains radionuclides of natural origin intentionally used for their radioactive properties.	X Paragraphs modified			

ISRAEL	2.7/2	Replace "the requirements for planned exposure situation do not always apply" by "**the requirements for planned exposure situations generally do not apply**"	Clarification		X		Will be fixed in the final editing.
ISRAEL	2.8/1	Replace "An exception to paragraph 2.7" by "**An exception to the situations referred to in paragraph 2.7**"	Clarification	X			
FRANCE	2.10/1	All aforementioned ~~planned~~ exposure situations *for which the requirements for planned exposure situations should apply* within the regulatory framework should be subjected to a graded approach.	Some of them still are existing exposure situations.	X			
ISRAEL	2.10/3-6	The sentence beginning with "Once not exempt,…" is too long.	It would be preferable to separate the sentence into 2 sentences.		X		Will be fixed in the final editing. Numerous revisions made in the draft.
UK	2.10	~~Once not exempt~~Above the emption level~~,~~ the practice	Editorial change for clarity in second sentence, as noted in previous comments In addition, as previous comments the UK considers that "removing sources of exposure from regulatory control" by whatever method is not exemption but clearance. (Exempt sources of exposure are those never within regulatory control) This clearly stated in GSR Part 3.	X			
Hungary	2.11	Screening level is defined in this Safety Guide as a derived (operational) quantity applied for exemption like approaches in particular existing exposure situations. It is used for decision making above which additional actions from the viewpoint of radiation protection should be	It seems, the screening level is always used in the Safety Guide, as a derived (operational) quantity, and nowhere is mentioned as a dose criterion. Hence the original text of "Screening level is defined in this Safety Guide as a certain level (either a dose criterion or a derived (operational) quantity)" is confusing. Even in para 6.3 the dose criterion does not named as a screening		X This paragraph and all other relevant paras modified.		

		considered and below which no further actions are necessary. In this way, the screening level is a radiation-protection tool in existing exposure situations aiding in the decision-making processes in a similar way that exemption level in planned exposure situations.	level: “If an exemption-like process in such situations is necessary, any derived screening level should be based on an underlying, case specific effective dose criterion…”.				
ISRAEL	2.11		Paragraph difficult to understand. Needs editing.	X			Paragraph edited. See revised draft.
ISRAEL	2.12/3	Replace "para. 2.10" by "**para. 2.11**"	Clarification	X			Numerous revisions made in the draft to address comments.
ISRAEL	FIG. 1		The intention to have all information provided in para. 2.1-2.11 in one figure is positive. However, the result is difficult to understand and we recommend to simplify the figure.	X			GSR part 3 requirements marked and fig is simplified.
ISRAEL	2.13/4	Delete "an instrument of".	Clarification				This editorial suggestion will be fixed in the final editing.
ISRAEL	2.14/7	Delete "(pre-1960s)".	The moratorium started in 1963, but further atmospheric testing was conducted until 1980.	X			
ISRAEL	2.19/3	Add examples to criterion (b)	We would like to suggest to add some kind of "real life" examples to criterion **(b)** of para. 2.18, as it is done in paras 2.13 and 2.14. The text in para. 2.19 related to criterion (b) may sound not completely "intuitive", thus "real life" examples could help.			X	Numerous revisions made in the draft. These are qualitative criteria and guidance in subsequent sections address the comment.
UK	2.12 & Fig. 1	This figure should be simplified by removing the existing exposure system as this is not relevant to exemptions the diagram included in DS500 introduction is more useful as it explains the	Regulatory controls relevant regulatory controls is useful information but not relevant to this document.		X		Fig.1 is simplified by adding relevant GSR Part 3 requirements.

		relationship between exclusion, exemption and clearance. .					
CZ	FIG I		We are not sure if this figure is really helpful. Specially for EES it is not clear –additional and separate decision making process based on screening levels is really confusing. Should be clarified what does it mean in fact. Exemption, clearance as such are part of graded approach what is graded approach for exemption purposes?		X		Fig.1 is simplified by adding relevant GSR Part 3 requirements. Graded approach is better explained.
Morocco	2.20	[...] .This means that regulatory control on the basis of additional, non-radiological (e.g.: environmental) requirements(and related legislation) may still apply.	We suggest clarifying that environmental requirement are just an example of non-radiological requirements. In fact, other legislation related to non- radiological risks (included in labor or health related legislation for instance) may also apply to the practice or the source.	X			
ISRAEL	2.20/3	Cross-reference non-radiological requirements in paras 2.20 and 3.5.	Para. 2.20 presents the issue of **non-radiological** requirements that may still apply when exemption from regulatory control is given on radiological aspects. Para. 3.5 points out that (radiological) exemption levels should not be in contradiction with other regulatory requirements of both radiological and **non-radiological** nature. We suggest to consider cross-referencing the messages presented in both paras. In such manner, it will be easier for the intended users to get the "full picture" of essence, responsibilities and interrelations between radiological exemptions and non-radiological requirements.	X			
Hungary	2.21 – 2.22	To be deleted?	These paras seem to be out of scope of the Safety Guide.			X	For completion's sake it was agreed to write short texts on exclusion, exemption and clearance in both Safety Guides.

ISRAEL	2.21/4	Add "were conducted" after "a source within a practice"	Clarification	X			Will be fixed in final editing.
AUS	Concept of Clearance 2.21-2.22	Concept of clearance should be directed to DS500 and GSR Part 3.	Although the concepts of clearance are very well written and explained in para 2.21-2.22 and could be useful in the drafting of DS500. The following text should be the only remaining information available to the reader. “As the concept of clearance is out of the scope of this Safety Guide, detailed recommendations on clearance of materials and objects from a practice are described separately in the Safety Guide DS500 [2] and will not be discussed further in this guidance.”	X			For completion’s sake it was agreed to write short texts on exclusion, exemption and clearance in both Safety Guides. Relevant references are cited in the paragraphs.
ISRAEL	2.22/3	Delete "the operations of"	Clarification	X			
ISRAEL	2.22/4	Delete "the execution of"	Clarification	X			
ISRAEL	2.22/6	Add "materials" after (including building"	Clarification	X			
ISRAEL	2.22/7	Replace "open" by "unsealed"	Clarification	X			
Serbia	2.23	The application of the concept of exemption is always carried out after the application of the principle of justification (because only justified practices can be exempted).	Here the practical application of the concept of exemption is compared with the principle of justification that is more general by its nature			X	It is not comparison but underlines the principle of justification to apply first.
CZ	2.28	Last sentence…The graded approach for exemption purposes should be consistent with the optimization principle	And what is the role of optimization here? It is aimed to say that exemption is under given circumstances an optimal option? Should be explained in more details		X Deleted last sentence.		
WNTI	2.29	2.29. (…). These conditions can refer to a specific type of practice, to specific requirements under which the activities can take place without further regulatory control, or to a combination of both (more guidance is included in paras. 2.2930–2.3435).	Typo. The reference to more guidance in paras. 2.29 – 2.34 does not seem to be correct, because the actual paragraph is already 2.29. The numbers of the paragraphs should be shifted up of one unit.	X			

ISRAEL	2.29	Move Fig. 2 in para. 6.21 to 2.29.	The flowchart greatly helps to understand the process of granting generic and specific exemption and should be moved to para 2.29.	X			Shifting to introductory paragraph may not be helpful. Fig.2 and Fig.3 are now moved to Section 5 which is more appropriate.
ISRAEL	2.31/1-2	The two first sentences are somehow a repetition of text in para. 2.29		X			Repetitions will be checked throughout the text.
Morocco	2.31	Exemptions of sources, including materials and objects, may also be granted subject to certain conditions established by the regulatory body	This is because conditions for specific exemption of practices or activities have been introduced in paragraph 2.29 above (*"[...] or by the 19 imposition of specific conditions pre-approved by the regulatory body (specific exemption).* *These conditions can refer to a specific type of practice, to specific requirements under which the activities can take place without further regulatory control, or to a combination of both [...]."*)		X		
Mexico	2.32	...The conditions for a justified practice to be subject to notification are to be specified by the government or regulatory body. More guidance on the process of notification is given in IAEA Safety Standard Series No.GSG-13, Functions and Processes of the Regulatory Body for Safety [8].	Editorial	X			
UK	2.32- 35	Should be removed	How practices are dealt within the regulatory regime, i.e. those not excluded or exempt, is not required in this guide.			X	Exemption is also a form of regulatory control, and the paragraphs indicate if not excluded or exempted then what next.

Ukraine	2.32-2.35	·'low to moderate radiation risks" and " relatively high radiation risks" are mentioned In order to decide about exemption	It is desirable to provide the recommended risk values to be considered as low, moderate or high			X	These are qualitative statements not intended to be with fixed numbers.
Hungary	2.33 – 2.35	To be deleted?	These paras seem to be out of scope of the Safety Guide.			X	See the reply to UK comment.
AUS	Figure 1	Figure 1 is very complex and hard to understand.	Figure needs to be re-draw in a flow process with clear information for stakeholders to understand.	X			Fig.1 simplified by adding relevant GSR Part 3 requirements.
Belgium	§3.5 / Line 4	"Transport of Radioactive	"Transport of Radioactive" (textual)	X			
WNTI	3.5	(…). Examples are the requirements laid down in the IAEA Safety Standards Series No. SSR-6 (Rev.1), Regulations for the Safe Transport of Radioactive Material, 2018 Edition [10] or in other environmental regulations with corresponding exemption levels.	Editorial. Two commas are missing.	X			
Morocco	3.6	The person or organization responsible for facilities and/or activities that (may) give rise to radiation risks should verify if the practice or source within the practice is automatically exempted 22 from regulations or requirements of GSR Part 3 [I], or ask the regulatory body to confirm whether the intended practice or source is automatically exempted. If not, the concerned person or organization apply to the regulatory body for possible specific exemption or[...].	This is because depending on the maturity of the radiation protection system of the country and the safety culture of applicants/operators, the latter may need to ask the regulatory body for clarifications on the generic exemption instead of verifying the requirements of GSR Part 3, or the ones of relevant regulations, by themselves.	X			
UK	3.6-3.8 Section 5	The text does not explain the relationship between notification and specific exemption. Include	A person should not apply for exemption but should notify the regulatory body in accordance with national requirements. A	X			

		text to explain that exemption is a possible outcome of notification	possible outcome of that notification is specific exemption for the notifier, or specific exemption for widely applicably to the practice in question	Paragraph modified.			
UK	3.7 bullet points	- to comply with the specific conditions attached to the relevant exemption, and to periodically verify this compliance. - to conduct an adequate safety assessment commensurate with the potential radiation risk from a future practice where a generic exemption does not apply. - to ensure that no modifications or changes to the practices would invalidate the exemption or any conditions attached. -to inform the regulatory body if any changes to the practice do invalidate the exemption and seek to notify, register or license the practice as appropriate.	Bullet points reworded to improve clarity	X			
UK	3.8	The regulatory body should provide the criteria for generic exemption and additional information relevant to specific exemption (case by case exemption). While generic exemption is fulfilled automatically, in a specific exemption, interaction between the ~~applicant~~ person responsible for the source or practice and regulatory body may be required for the decision-making process. There may be exemptions where specific exemptions are granted to product types (see paragraphs 5.6 and 5.15).	The term applicant is not appropriate for exemption since exemption is to be considered prior to registration or authorisation. See 5.6 which makes this clear.		X Para modified.		

UK	3.9	Such interaction could vary from simple information provided by the person responsible for the source or practice ~~applicant~~ to a complete safety assessment depending on the characteristics of the practice and the requirements of the regulatory body.	The term applicant is not appropriate for exemption since exemption is to be considered prior to registration or authorisation. See 5.6 which makes this clear.	X			
Indonesia	3.10	In some cases, the regulatory body may identify certain activities that need to be reviewed in order to makethe decision regarding their exemption. Review of certain activities principle.	Justification goes beyondthe consideration of protection and safety, and involves the consideration of economic, societal and environmental factors also.			X	Suggestion not clear.
Ukraine	4.3 line 20	Conclusion: As one of the two criteria (ie, total activity, activity concentration) is fulfilled. The materials can be generically exempted.	Needs to be explained. Total activity and activity concentration could be involved in differentexposure scenarios (e.g.total activity in situations where disposal of material could cause contamination of water supplies that could be used for supply of drinking water and activity concentration in case of ingestion of small fragments of contaminated soil); i.e. it seems that two criteria must be fulfilled simultaneously to exempt radioactive material	X			Revisions made in the text.
Morocco	4.4		We suggest that "**exemption without further consideration**"is defined in this guide so that its comprehension would be clear for its readers/users.		X modified		
Ukraine	4.4	To provide quantitative guidance on exemption without further consideration, the values of total activity (Bq) and/or activity	It should be explainedwhether the values of total activity and activityconcentrations should beapplied simultaneously for exemption and in which cases either one or		X		Already explained in subsequent paragraphs.

		concentrations (Bq/g) for a wide range of radionuclides have therefore been derived (see Tables T.1, I.2 and para. I.2 of GSR Part 3 [1], …	other values should be applied. According to para 4.16, 'Materiäl in a moderate amount for which either the total activity of an individual radionuclide present on the premises at any one time or the activity concentration ration as used in the practice does not exceed the applicable exemption level				Table I.1 is for moderate amounts and Table I.2 is for bulk amounts.
UK	4.5	Here, the term "moderate amount" refers to masses that "are at the most of the order of a tonne", and the term "bulk amounts of materials" can be taken as masses that are greater than of the order of 10 tonnes	The current text leaves a gap in the advice between 1 and 10 tonnes. It would be simpler to just define moderate amounts with bulk amounts being anything greater.	X			
UK	4.12	Table 1	This table is an over- simplification for natural radionuclides. For moderate amounts reference is provided to table I.1 but the values in this table are derived from a 10 microSv criterion rather than the 1 mSv criterion referred to in para 4,10		X		Table 1 is modified as well as relevant discussion paragraphs.
Ukraine	4.12	Delete	Outside the scope of this Safety Guide			X	It is well within the scope.
Hungary	4.14	Comment or footnote: Take note, that the derived generic exemption levels are rounded values, hence the 10 µSv/y lowest boundary of trivial dose cannot restore from the generic exemption levels.	The rounding rule described in footnote no. 9 of in Safety Reports Series 44 is: "If the calculated values lie between 3 × 10x and 3 × 10x+1, the rounded value is 10x+1." It means, that application of generic exemption level could result 3-30 µSv/y, instead of 10 µSv/y. It may be useful to interpret the phrase "of the order of 10 µSv or less in a year" as well,	X Paragraph modified.			
CZ	4.14	…..for that reason , in some cases " of the order of 10 uSv/y can be up to 100USv/y. Detailed explanation of the basis of the	Para 4.13. is a citation of GSR Part3 saying that for exemption purposes we use a effective dose 10uSv/y. it is not useful to say in next para that this dose could be up to 100uSv/y . the reference to ICRP104 is		X Paragraph modified.		

		trivial dose concept can be found in ICRP Pu.104	correct but there is a lot of explanatory text about this issue (see paras 69, 70, etc..). it is not so easy to explain, and this simplification could be dangerous. We used 10uSv/for derivation of generic EL and we use in regulations 10uSv/y also for specific exemption. This must be clearly stated.		In addition, see comment from Hungary and Israel.		
ISRAEL	4.14/1	We praise the inclusion of "the range of 10–100 mSv/y" as definition of trivial dose and support reinforcing the sentence.	The phrase "of the order of 10 mSv or less in a year" in GSR Part 3 allows unnecessary conservatism.	X			
ISRAEL	4.15/5	Replace "exponents" by "**powers**"	Clarification	X			
Hungary	4.16 lines 8-10	Instead of “For instance, if there are several workplaces in a single authorized facility, one should consider the premise as the facility itself and should not consider each workplace as one premise.” we suggests: “For instance, if there are several premises in a single authorized facility, one should consider all premises inside the controlled area (the facility itself) and should not consider premises separately.”	The workplace could be a synonym of functionally connected premises and the facility both. That is why we suggest to avoid the term of workplace in this para.		X Workplace is replaced with location.		
ISRAEL	4.16/10-12	The text beginning with "At the same time …" needs further editing.	Clarity.	X			
UK	4.16	~~At the same time~~ Where a single owner has multiple facilities operating at geographically separate sites below the exemption levels but taken together, they may exceed exemption levels, these should be treated separately where the exposed populations are distinct.	Wording revised to aid clarity	X			

UK	4.16	According to para. I.3(a) of GSR Part 3 [1], generic exemption ~~applies~~ may be applied to:	The Schedule is not a definition of exemption, but rather an application of it. It does not preclude other applications.	X			
FRANCE	§4.18	In cases where the generic exemption levels in Tables I.1 and I.2 cannot be met or cannot be applied, the practice or source could still be eligible for exemption on a case by case basis (see Section 5 for Specific Exemption).	It is not only a matter of compliance with levels but also a matter of applicability (e.g. for consumer products)	X			
UK	4.19	According to Paragraph I.3(b) of GSR Part 3 [1], generic exemption ~~applies~~ may be applied to	As 4.16	X			
UK	4.22 sentence 2 & 3	The worded "granted" should be replaced with applied.	Granted implies that the circumstance is "given" something via a regulatory body – such as a clearance as referred to correctly in paragraph 4.24 - when in fact the situation where an exemption is applied is a more clear and accurate representation of the situation.	X			
UK	4.23	For mixtures of radionuclides, the approach on how to use the values in Table I.2 is described in para 4.28, following the weighted summation rule.	editorial	X			
UK	4.26 and throughout	person responsible for the source or practice~~applicant~~	It is better not to use the term applicant with exemption	X			Will be checked in the final editing.
Mexico	4.28	... is that the sum of the individual radionuclide activities or activity concentrations, as appropriate, is less than the derived exemption level for the mixture (Xm), determined asfollows: $X_m = \frac{1}{}$	Editorial. Missing numbering ofequation 1.	X			

		,r $f(i)$ **XO)** (Eq. 1)					
FRANCE	§4.31	~~In Eq. 2, from a practical point of view, a radionuclide whose contribution to the weighted summation is marginal can be neglected [15] in determining exemption level of the material containing mixture of radionuclides. For example, radionuclides that together contribute to the weighted summation by less than 0.1 could be excluded.~~	All radionuclides should be taken into account in the weighted summation.			X	considering the principle of optimization.
Mexico	4.32	... 1) A moderate amount (10 kg) ofa liquid material containing Sx10• Bq *of* 241Pu at an activity concentration of 5 Bq/g and 9xl 0^3 Bq ***of*** wAm at an activity concentration of 0.9 Bq/g.	Editorial			X	Will be fixed in the final editing.
RUSSIA	4.33	4.33. The values in Tables I.1 and I.2 cannot be automatically applied to **all** existing situations because the concept of **generic** exemption is only related to planned exposure situations. ~~Furthermore~~ **For example**, these values do not apply to the following case: - ~~Material in transportation in accordance with the IAEA Transport Regulations SSR-6 (Rev.1) [10]~~ - Control of radioactive discharges of liquid and airborne effluents (GSR Part 3 [1], para/ I9). **Furthermore, as it is pointed out in SSG-26 [XX] (para. 401.4)**	Exemption levels (values) in SSR-6 (Rev.1) (Table 2) completely correspond to the Tables I.1 of GSR Part 3 based on explanations of para. 401.4 SSG-26. It is reasonable to make such example of using general exemptions for specific case (transport of radioactive material)		X Paragraph modified. (see new para 4.30)		

		exemption values (in BSS [5]) were derived by using a variety of exposure scenarios and pathways that did not explicitly address the transport of radioactive material. Additional calculations were performed for transport specific scenarios [7]. These transport specific exemption values were then compared with the values in the BSS [5]. It was concluded that the relatively small differences between both sets did not justify the incorporation into the Transport Regulations of a set of exemption values different from that in the BSS, given that the use of different exemption values in various practices may give rise to problems at interfaces and may cause legal and procedural complications. To add in DS499 under the appropriate number ref [7] FRANCOIS, P., et al., "The application of exemption values to the transport of radioactive materials", IRPA 9 (Proc. Ninth IRPA Int. Congr. Vienna, 1996), Vol. 4, IRPA, Vienna (1996)					
UK	4.33		The values in table I.1 are the same as those used in SSR6 and the values in table I.2 are all lower or equal to the values in I.1 meaning that they do apply to transport.	X			
CZ	4.33	The values in tab 1.1. and 1.2. cannot be automatically applied to EES because the concept of exemption is only related to PES.	Does it mean that under some circumstances we can use these values? Here it is stressed that exemption concept is related only to PES whilst parallely is introduced something like	X Para 4.33 modified.			

		…However the values of tables I.1 and I.2. can be used as screening levels in particular situations of trade as described in Section 6.	exemption also for EES. See also general comments.	In addition, see comments from Russia, UK.			
FRANCE	§4.34	Deliberate dilution of material, as opposed to the dilution that takes place in normal operations when radioactivity is not a consideration, to meet the generic exemption levels given in Tables I.1 and I.2 (GSR Part 3 [1]) should not be permitted ~~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			
UK	5.1	As above use of word applicant should be replaced with person responsible for the material	It is better not to use the term applicant with exemption	X			Will be checked in the final editing.
Hungary	5.2	Instead of "(2) complies with the criteria for general exemption" we suggest to use "(2) complies with the general criteria for exemption" (para. I.1, GSR Part 3 [1]).	According to GSR Part 3 Para I.1, there are general criteria for exemption. Terms of "criteria for general exemption" or "criteria for specific exemption" are not mentioned. There are general exemption (levels) and specific exemption (cases) but no criteria defined to those.	X			
ISRAEL	5.2/2	Replace "the criteria for general exemption" by "**the general criteria for exemption**"	Clarification	X			
ISRAEL	5.4/1	Replace "for generic nor" by **"for generic exemption nor"**	Clarification	X			
ISRAEL	5.5/2	Replace "the general exemption criteria" by **"the general criteria for exemption"**	Clarification	X			
ISRAEL	5.7/8	Replace "various aspects and criteria that should be covered in an appropriate safety assessment" by **"various aspects and criteria that should be covered in a**	Not all the aspects and criteria listed in para 3.29-3.36 of GSR Part 3 should be covered in all safety assessments for granting specific exemption. The aspects and criteria should be adapted to each specific case.	X			

		safety assessment, as appropriate"					
ISRAEL	5.9/9	Delete the word "also"	Clarification	X			Will be fixed in final editing
ISRAEL	5.10/3-4	Delete the sentence in parentheses (from their interpretation of the assessment)	The safety assessment should not be subject to different interpretations	X			
ISRAEL	5.10/7	Replace "to refuse exemption" by **"not to grant exemption"**	Clarification	X			Will be fixed in final editing
ISRAEL	5.16	Move Fig.3 in para 6.21 to 5.16.	The flowchart greatly helps to understand the process of granting specific exemption for bulk materials and should be moved to para 5.16.	X			Fig.2 and Fig.3 moved to the end of section 5, which is more appropriate.
Morocco	5.4		This paragraph is trivial, there's no need to keep it because the introduction of the guide and the reference document (GSR Part 3) already makes the difference between the different regimes.	X			
Morocco	5.7	Assessment of radiation risks in terms of expected likelihood and magnitude of exposure should not only cover 'normal operation' but should also include foreseeable, abnormal potential exposures.	Because there's a confusion between the operation conditions and the exposure situations.		X		Relevant text revised.
Morocco	5.9	(...] The scope of the safety assessment should cover the full life cycle of the consumer products including their production, storage, transport, and use, as well astheir disposal. **Even though exemption of the products is granted for their actual use – in as much as the general criteria for exemption are met - this does not necessarily imply that the entire chain is exempted automatically. The**	The general information given in this paragraph (specific case scenario) shouldn't be included in the safety assessment section. It should have been given earlier either in introduction or in the concepts, to explain the different case scenarios to which exception could not easily be applicable.			X	This paragraph points to SSG-36 (safety assessment in case of consumer products).

		manufacturing of the products could still be under regulatory control, or regulatory control may still be required if the number of consumer products exceeds a certain amount (for instance for storage, transport, or disposal). There may thus be several limitations or conditions also to the exemption of consumer products. These limitations and conditions will be based on the underlying safetyassessment l...].					
WNTI	5.9	Even though exemption of the products is granted for their actual use – inasmuch as much as the general criteria for exemption are met – this does not necessarily imply that the entire chain is exempted automatically.	Editorial.	X			Will be fixed in the final editing.
UK	5.9 3rd sentence	Replace “chain “with lifecycle	Editorial change for clarity and consistency	X			
ISRAEL	5.20/4	Replace "in deciding exemption of bulk amounts" by **"in granting exemption to bulk amounts"**	Clarification	X			See UK comment on para 4.22. Will be fixed in final editing
ISRAEL	5.21/6-7	See comment No. 25	Clarification	X			Will be fixed in the final editing
ISRAEL	5.22/3	Delete the word "planned"	Clarification	X			Will be fixed in the final editing
ISRAEL	5.22/4	Replace "intended" by "**planned**"	Clarification	X			Will be fixed in the final editing
ISRAEL	5.22/5	See comment No. 25	Clarification	X			Will be fixed in the final editing

ISRAEL	5.22/15	Replace "radiological dose" by "**radiation dose**"	Clarification	X			
FRANCE	5.24/6	The last sentence should be deleted. ~~For many radionuclides and exposure scenarios, most of the existing dosimetric models (see Annex I) support that these surface-contamination values comply with the general exemption criteria (para. I.2 of Schedule I, GSR Part 3 [1]).~~	The use of surface-contamination values from transport regulation as exemption levels should not be encouraged.			X	This is from pragmatic considerations.
UK	5.24	Surface-contamination values from the IAEA Transport Regulations SSR-6 (Rev.1) [10] para 214 (i.e., 0.4 Bq/cm2 for beta and gamma emitters and low-toxicity alpha emitters and 0.04 Bq/cm2 for all other alpha emitters, for removable surface contamination) were developed based on a simplified dosimetric model that was ~~not~~ constructed for exemption purposes specific to transport.	The wrong reference is used here – the exemption for surface contamination in transport is defined in para 214. The levels of 4 and 0.4 are actually operational controls, not exemption values.			X	Para 214 of SSR-6 Rev.1 is definition for surface contaminated objects below which it is not considered as contaminated for transport purpose. Added reference to para 508 of SSR-6 (Rev.1) and relevant para modified.
RUSSIA	5.24	Surface-contamination values **in para 508 of** IAEA Transport Regulations SSR-6 (Rev.1) [10] ……for exemption purposes **and properly speaking cannot be considered as specific exemption values for radioactive material transport itself. Respectively,** an appropriate safety assessment (see para/22) is needed on applicability of these surface-contamination values **and** for specific exemption **in other cases** ~~other than for radioactive material transport~~**.**	It is reasonable to emphasize more clearly that said transport surface-contamination values 4 Bq/cm^2 and 0,4 Bq/cm^2 are not specific exemptions for transport cases itself. These values and less are regulated and shall be taken into account at transport operations especially at loading and unloading of transport packages.		X It is clearly stated in the revised paragraph.		

		However, it should be noted that for many radionuclide and exposure scenarios ……					
RUSSIA	5.24 bis	**5.24 bis. 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) [10] may be considered as specific exemption taking into account that such activity can give rise only to insignificant exposure through any of these pathways and 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].**	It is reasonable to make information for specific exemption cases for transport of radioactive material. Although these values may be as well considered as clearance at least for transport of radioactive material cases (so named specific clearance). It is reasonable to consider this matter (exemption or clearance) additionally in frame of developing DS499 and DS500 in common.		X		This is the regulatory definition value of surface contaminated objects for transport and below these values it is not considered as even contaminated. The draft guidance is not providing a generic exemption for surface contaminated items. Such items are considered as specific exemption. (See modified para 5.21 in the revised draft).
ISRAEL	5.24/8	See comment No. 25	Clarification	X			
Belgium	§5.25 (c) / Line 2	"At a distance of 0.1 m from	"At a distance of 0.1 m from" (textual)	X			
Belgium	§5.25 (d)	"Necessary conditions for disposal of the equipment have bee, specified by the regulatory body"	Review space between words	X			
Morocco	5.25	[...](*a) The equipment containing radioactive material is of a type approved by the regulatory body.* [...]	We suggest that an explanation of the approval by the regulatory body is made. Which kind of approval is it? What process could be applicable and what type of requirements could be made?			X	Direct quote from GSR Part 3. The requirement itself is in detail.
ISRAEL	5.26/1	Add the word "equipment" after "categorize", reading as "**categorize equipment**"	Clarification	X			

ISRAEL	5.26/2	Replace "need to be performed in subsequent" by "**need to perform a safety assessment in subsequent**"	Clarification	X			
ISRAEL	5.26/5	Replace "radioimmunoassay equipment" by "**radioimmunoassay unsealed sources**"	Clarification			X	
ISRAEL	5.26/6	Add word "equipment" after "fluorescence", reading as "**fluorescence equipment**"	Clarification	X			
ISRAEL	5.28/2	See comment No. 25	Clarification	X			
AUS	Section 6	RESTRUCTURE THIS SECTION – Perhaps divide into 3 sections – one for each topic such as: • Approaches in existing exposure situations; • Verification of compliance; and • The summary of steps in granting an exemption.	The title of this section is confusing. It can be read as being just about existing exposure situations. The contents of the section also are mixed up. This section contains information related to: • approaches in existing exposure situations; • verification of compliance; and • the summary of steps in granting an exemption. The Introduction (6.1 to 6.3) is about existing exposure situations. 6.4 to 6.7 – It is not clear if this applies to planned exposures, existing exposures, or both. 6.8 to 6.9 appear to be about planned exposures. 6.10 to 6.20 appears to be about existing exposure situations. 6.21 to 6.22 is about planned and existing exposures.		X		Restructured by shifting approaches in existing exposure situations in to a new section 7.
AUS	Section 6	Modifications to text	The text on existing exposure situations is too detailed in nature for the level of document it is presented in. At times, it can also be confusing to try and follow the application and concepts being conveyed to the reader. The existing exposure text needs		X		Revised the section.

			to be more concise and should be revised to provide overarching guidance on situations such as exposures related to commodities, trade and bulk materials. A similar style to that used in the current Safety Guide on Application of the Concepts Exclusion, Exemption and Clearance (IAEA RS-G-1.7) would be appropriate.				
CZ	Chapter 6	Verification of compliance and approaches in EES	The title of this section is confusing. It is not clear why verification of compliance with exemption levels (planned exposure situations) is put together with approaches in EES ?	X			Revised.
ISRAEL	6	Replace "VERIFICATION OF COMPLIANCE AND APPROACHES IN EXISTING EXPOSURE SITUATIONS" by "**OTHER ISSUES RELEVANT TO THE CONCEPT OF EXEMPTION**"	Change title to reflect more accurately the content of Section 6 in line with our proposal in General Comment 2 above of sending text related to exemption-like approach to a Safety Report or to an Annex.		X		Revised.
ISRAEL	6.1/2	Replace "with exemption levels, revoking" by "**with exemption levels and revoking**"	In line with proposal of sending text related to exemption-like approach to a Safety Report or to an Annex.	X			Will be fixed in final editing.
ISRAEL	6.1/2-3	Delete "and application of an exemption-like approach in existing exposure situations"	In line with proposal of sending text related to exemption-like approach to a Safety Report or to an Annex.			X	
ISRAEL	6.2	Move para. 6.2 to a Safety Report or to an Annex on Exemption-like approach.	In line with proposal of sending text related to exemption-like approach to a Safety Report or to an Annex.			X	
ISRAEL	6.2/7	Delete "in an existing exposure situation"	Clarification			X	
ISRAEL	6.2/8	Replace "c) construction materials within the framework of existing exposure situation etc." by "**c) use of construction materials**"		X			
Indonesia	6.2/9	... of existing exposure situation; d) decision making on decontaminationof former waste storage locations; etc	the location of former waste storage areas usually exposes radiationwhich requires a certain decision to determine the limit value when			X	Suggested text is under the clearance topic and not exemption.

			decontamination iscarried out				
CZ	6.3	In existing exposure situations …….	This para is trying to explain the use of screening levels and values – it is non understandable guidance without logical relation to the current regulatory approach to EES as recommended by ICRP and IAEA BSS as well – see also general comments			X	Revised version of DS499 brings further clarity to this aspect.
Morocco	6.3		The explanation given in this paragraph should be given earlier, or at least a hint on it should be given in the introduction or in the section relating to the concept of exemption (see remark n. 5).		X		See revised draft.
ISRAEL	6.3	Move para. 6.3 to a Safety Report or to an Annex on Exemption-like approach.	In line with proposal of sending text related to exemption-like approach to a Safety Report or to an Annex.			X	
ISRAEL	6.3/17	Replace "based on the existing exposure situation of application" by "**for each of the existing exposure situations of interest**"	Clarification		X		See revised draft.
UK	6.6	Verification should also be ~~done on~~conducted on ~~any~~ other conditions and circumstances ~~environment specified in which~~where the exemption applies.	Editorial change to aid clarity	X			
ISRAEL	6.9/5	Replace "complying to a change" by "**applying a change**"	Clarification			X	
ISRAEL	6.10–6.20	Move paras 6.10-6.20 to a Safety Report or to an Annex on Exemption-like approach.	In line with proposal of sending text related to exemption-like approach to a Safety Report or to an Annex.			X	
AUS	6.11	This text should be removed “Annex−II provides details of the application of the screening levels for supporting decision making with regard to the management of residual waste generated in Japan after the Fukushima Daiichi accident.” from paragraph.	Not in scope of document. Paragraph should refer to Safety Guide GSG-11 for additional information or TECDOC1826. If this Annex II has updated information then a revision of TECDOC1826 should be consider with the addition of the text from Annex II.			X	See revised draft

Morocco	6.12		This paragraph should be included in the section 'trade of commodities·, because it's included further, in paragraph 6.13 (definition of commodities).		X		See revised draft
Morocco	6.15		The paragraph states only what's given in paragraph 5.22 of GSR part 3, it would be better to rephrase the paragraph 5.22 and add something new, or explain further its application.			X	Para 5.22 is intended here.
Belgium	§6.15 / Line 3		Review the spacement between all the words	X			
UK	6.18 (c)		See comments on 5.24	X			
CZ	6.19	….In general, it should not be necessary…..	This last sentence is speculative and should be deleted.			X	This is from RSG 1.7
ISRAEL	6.21/Fig. 2	Move Fig. 2 to para 2.29	The flowchart greatly helps to understand the process of granting generic and specific exemption and should be moved to para 2.29.		X		Fig.2 and Fig.3 are provided as summary flow charts and is moved to end of Section 5.
ISRAEL	6.21/Fig. 3	Move Fig. 3 to para 5.16	The flowchart greatly helps to understand the process of granting specific exemption for bulk materials and should be moved to para 5.16.		X		Fig.2 and Fig.3 are provided as summary flow charts and is moved to end of Section 5.
ISRAEL	6.22/Fig. 4	Move to a Safety Report or to an Annex on Exemption-like approach for decision-making of non-food commodities.	In line with proposal of sending text related to exemption-like approach to a Safety Report or to an Annex.			X	Intended as recommendations.
UK	II-5 and II-6	According to para. 5.1 of GSR Part 3 [1], exposures to commodities with presence of artificial radionuclides and radionuclides of natural origin should be managed as existing exposure situations.	Based on the text in the report, a screening level should be applied when deciding whether an area of land contaminated with radioactivity should be remediated under regulatory control whilst an exemption level is applied when deciding whether disposal of waste created, in the case of the Annex by remedial action, needs to be regulated. What is described in this Annex, specifically in Para II-5 and II-6, are screening levels			X	This is due to relevant GSR Part 3 requirements. Annex is explaining a screening method proposed to deal with similar issues of exemption in existing exposure situations. See revised draft.

			being used to decide whether waste should be regulated for disposal purposes while exemption levels are not mentioned at all. This annex is therefore not consistent with the rest of the report.				
UK	11.14 or 15	Addition of a sentence on representative sampling arrangements to a quality system should be included in addition to the to the quality system for the laboratory.	The validity of the laboratory results is often dependent on the robustness of the sampling regime.	X			Representative sampling is already mentioned in II.4
Belgium	§ II.14	"... direct measurement ... monitoring techniques"	"... direct measurement... monitoring techniques" (textual)	X			Will be checked in the final editing.
Belgium	Annex I, §I-10 / Line 6-7-8	"Further development of the RIVM-SUDOQU model allowed for detailed parameter-sensitivity analyses and probabilistic dose evaluations."	Described the situation in 2018, since then more work has been done and probabilistic results are available	X			
RUSSIA	Appendix II para II.9	Use of statistically based methods that consider carefully defined parameters regarding the homogeneity of the contamination and the instrument-measurement characteristics can significantly reduce monitoring costs. Material with radionuclides that is unlikely to exceed the exemption levels could be subjected to a simplified monitoring scheme, whereas those at levels that may approach or exceed these levels usually require further extended monitoring. **(new)** **The decision to apply a simplified monitoring scheme should be based on reliable estimates of the content of radionuclides in the materials.**	The assessment of the possibility of exceeding or not exceeding the established exemption levels should be based on the results of the assessment or direct determination of activities (only for moderate amounts) and activity concentrations of radionuclides in the materials.	X			

RUSSIA	Appendix II para II.17	For some materials there could be information on the ratios of radionuclides in the corresponding mixture, the so-called correlation factors. Correlation factors can allow the estimation of activity concentrations of radionuclides that cannot be easily detected. These include low-energy beta emitters that neither emit energetic beta particles nor photons in their nuclear transformations (e.g., 3H, 63Ni, 14C). Monitoring of such radionuclides normally requires laboratory measurements and/or radiochemistry. **(new)** **Examples of the implementation of this approach is presented in ISO 21238 []**	The international standard ISO 21238:2007 «Scaling factor method to determine the radioactivity of low - and intermediate-level radioactive waste packages generated at nuclear power plans» contains a general methodology for determining the scaling (correlation) coefficients between easily measurable gamma emitting nuclides and difficult-to-measure nuclides, such as alpha and beta-emitting radionuclides.		X		References checked and retained the relevant ones in the revised draft.
RUSSIA	Appendix II para II.27	Information on proper calibration of various types of instrumentation can be found in SRS-16 [24], ISO 7503~~-2~~**,** [25], ~~DOE guide [26], and~~ ISO-17025 [27] **(new)** **and ISO-19017 []**	1. The ISO 7503 series of standards was revised in 2016. Information on instrument calibration is provided in all the standards of the ISO 7503 series. 2. DOE guide [26] was canceled due to approval of DOE guide G 441.1-1B. 3. According to section II.16 of DS 499, typical radioanalytic laboratories are usually equipped with HPGe gamma-ray spectrometers for the qualitative and quantitative analysis of gamma-emitting radionuclides. Section 5 of ISO 19017: 2015 «Guidance for gamma spectrometry measurement of radioactive waste» contain information on proper calibration of gamma spectrometry equipment.		X		References checked and retained the relevant ones in the revised draft.
RUSSIA	Appendix II	INTERNATIONAL ORGANIZATION FOR	The ISO 7503 series of standards was revised in 2016. Information on instrument	X			

	REFERENCES [25]	STANDARDIZATION, Evaluation of Surface Contamination — Part 1: Beta-Emitters (Maximum Beta Energy Greater than 0.15 MeV) and Alpha-Emitters, ISO 7503-1, ISO, Geneva (1988), Evaluation of Surface Contamination — Part 2: Tritium Surface Contamination, ISO 7503-2, ISO, Geneva (1988), Evaluation of Surface Contamination — Part 3: Isomeric Transition and Electron Capture Emitters, Low Energy Beta-Emitters (E Bêtamax Less Than 0.15 Mev), ISO 7503-3, ISO, Geneva (1996).	calibration is provided in all the standards of the 7503 series.				
Serbia	Appendix II.26	(temperature, pressure, humidity)	Humidity usually takes an important role in sample measurements	X			
Serbia	Appendix II.29	the involvement of all relevant regulatory bodies, institutions and organizations	There are not only regulatory bodies	X			
WNTI	REFERENCES [10]	[10] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, 2018 Edition, IAEA Safety Standards Series No. SSR-6 (Rev.1), IAEA, Vienna (2018).	Editorial. One comma is missing.	X			
WNTI	Annex I I-6	After its publication, the basic IAEA-CRP model has been modified and extended for further use outside the domain of transport~~ation~~ [I−7], [I−8], [I−9].	“Transport” is the word that is usually used in this document, and more generally in IAEA publications.	X			
WNTI	REFERENCES TO ANNEX I [I-3]	[I–3]. INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the safe transport of radioactive materials, IAEA	Editorial. One comma is missing and there is no need for “a” after the year of publication.	X			

		Safety Series No. 6, IAEA, Vienna (1961~~a~~).					
WNTI	REFERENCES TO ANNEX I [I-4]	[I–4]. INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the safe transport of radioactive materials; Notes on certain aspects of the regulations, IAEA Safety Series No. 7, IAEA, Vienna (1961~~b~~).	Editorial. There is no need for “b” after the year of publication.	X			Ref deleted in the revision.
FRANCE	Annex II	To be deleted.	The management of waste is more a matter of clearance than of exemption.		X		Only existing exposure situations are covered in the example. Additional new examples added.
Mexico	Annex II, II-7	Fig. J---l. *II-1* shows the flow diagram for treatment of decontaminationwaste and soil and Specified Waste based on the Act on Special Measures [IJ- 3] in Fukushima Prefecture.	Editorial	X			
Italy	II.10	For verification of compliance, it is neededthat: , a) the samples are collected properly they are representative and traceable, b)	Concept of representativeness and traceability should be included in the verification process of compliance, also in agreement with the following para II.15	X			
WNTI	Annex II II-12	Therefore, the aforementioned screening level for the transportation vehicle in the Temporary Storage Sites satisfies the guideline (i.e., 13,000 cpm < 21,000 cpm), which implies that the additional dose to a member of the public and the worker remains below 1 mSv/y.	“Transport” is the word that is usually used in this document, and more generally in IAEA publications.	X			
ISRAEL	II.13/2	Replace "sample collection" by "**collection of representative sample**"	Clarification	X			

ISRAEL	II.22/2	MDA well below the corresponding exemption value(s)	Consider adding a quantitative figure to specify "well below" meaning, i.e. order of magnitude.			X	Such quantitative statements will result in limiting use of many equipment perhaps unnecessarily.
Italy	II.24	If the presence of radionuclides is non- homogeneous within the averaging mass, volume or area, averageactivity concentrations determined from any single measurement canlead to (large) uncertainties as the outcome may strongly depend on how the measurement was performed. These 54 uncertainties can be reduced by homogenizing by physical mixing of the material prior to monitoring; performing a larger number of measurements to partially account for non-homogeneity of thematerial; and using longer counting times. The choice of one or more of the above listedprocedures, should be documented	The choice of the strategy in order to overcome the uncertainty due to non-homogeneity should bedescribed and documented in the quality management process	X			
ISRAEL	II.29/1	Material with the presence of both radioactive and other hazardous substances.	It is proposed to harmonize requirements for other hazardous materials with concepts related to non-radiological limits developed in DS500 "Application of the concept of Clearance" (i.e. para. 2.21)	X			
Italy	II.29.	Materials with the presence of both radioactive and other hazardous substances, e.g. radioactively contaminated asbestos,require special attention. Consequently, verification of compliance	Not only personnel health should be take into consideration whenthere is some hazardous materials, but also the impact on the environment.	X			

		with the radiological exemption criteria then may not be sufficient to grant exemption (without further consideration)of the practice. This requires the involvement of all relevant regulatory bodies, not just those associated with the radioactive aspects. Monitoring of such materials, including the corresponding strategy to protect personnel and the environment, should recognize and take account of all involved health and environmental hazards, which imposes conditions on training, education and equipment to work safely with these materials. In general, the radiological aspects ~~of the protection strategy~~ may be integrated in the overall protection strategy.					
Indonesia	13a (new)	The location of the former waste storage area which is then decontaminated will remain radiation exposure. Presence of artificial radionuclides and radionuclides in the location shouldbe managed as existing exposure situations.	The location of the former waste storage area which is then decontaminated needs to be considered			X	Not clear
Serbia	Answers to the questions requested in Explanatory Note: <u>Answers to the comments in relation to:</u> • Relevance and usefulness: Are the stated objectives appropriate, and are they met by the draft text? *Stated objectives are appropriate and met by the draft text.*			X			

	yes • Scope and completeness: Is the scope appropriate, and is it adequately covered by the draft text? *Scope is appropriate and is it adequately covered by the draft text.* ***yes*** • Quality and clarity: Does the guidance in the draft text represent the current consensus among specialists in the field, and is this guidance expressed clearly and coherently? *Guidance in the draft text represent the current consensus among specialists in the field, and expressed clearly and coherently.* ***yes*** <u>Answers to the specific comments:</u> 1. Feedback on the retention of the text dealing with existing exposure situations, including trade, in the draft safety guide DS499. (***<u>Agree</u>***/disagree) ***<u>Agree</u>*** 2. Feedback on whether to merge both documents DS499 (exemption) and DS500 (clearance) or to continue with two separate guides as developed. *Continue with two separate guides as developed.* ***<u>Continue with two separate guides as developed.</u>*** Several comments are in the Form for Comments.	X X X X			