

**RESOLUTION OF MEMBER STATES COMMENTS ON DS472 (V3) (STEP 8) "ORGANIZATION, MANAGEMENT AND STAFFING OF A REGULATORY BODY FOR SAFETY"
&IAEA COORDINATION COMMITTEE COMMENTS ON DS472 (V5) (STEP 10)**

COMMENTS MADE BY:

Member States comments on DS472 V3 (STEP8)

Armenia (2 comments)

EC (3 comments)

Finland (57 comments)

Germany (24 comments)

Russia (10 comments)

Spain (14 comments)

USA (6 comments)

Submitted after deadline:

India (6 comments)

Japan (12 comments)

Pakistan (2 comments)

SUB-TOTAL 1: 136 comments

IAEA internal review of DS472 V5 (STEP10)

NSNI (53 comments)

Coordination Committee (6 comments)

SUB-TOTAL 2: 59 comments

GRAND TOTAL: 195 comments

COMMENTS BY REVIEWER: MEMBER STATES				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
GENERAL COMMENTS							
Finland #1	Main	The whole document should be in line with new GSR Part 2 (DS456).	DS456 has been enhanced after the DS472 was submitted to member states comments. The results from NUSSC 40 meeting in December 2015 (submitting also comments from WASSC and RASSC) should be considered.	X			Maintain the IMS, functions part; Pending DS456 publication.
Finland #2	General	The terminology in the whole document should be checked.	Especially the terminology in chapter 5 Management System is not in line with DS456 as an example use of leadership differs.	X			Pending DS456 publication.
Finland #3	General	The balance between chapters should be improved. See further comments below (repetition, interfaces, structure, content).	Some parts of the document repeat same texts as given in other documents causing more text as needed.			X	The intention is that DS472 is a stand-alone document.
Finland #4	General	The name of the document Organization, Management and Staffing of a Regulatory Body for Safety	The addition 'for safety' should be removed to be consistent with GSR Part 1 which uses the term 'Regulatory Body'.			X	Suggestion of Security Review Committee.
Finland #5	General	Interface with DS460 need to be clarified	Much repetition regarding communication with interested parties	X			DS472 was checked for consistency with DS460. A minimum of information related to communication with interested parties will remain in DS472.
Finland #6	Chapter 3, General	The title should be changed: Management Leadership for safety	The guidance in chapter 3 is more related to leadership than to management.			X	There has already been extensive discussion on this and some of the items covered are management, not leadership. Management includes leadership.
Finland #7	General	Interface with DS473 need to be checked, especial Chapter 4 repeats “functions and processes”, which are in the scope of DS473	There is a lot of repetition in these two documents, please consider delete or condense			X	In DS472 the functions are just introduced, DS473 expands them.
Finland #8	General	Terminology; the document uses terms “process” and “function” for the same purpose, especial in Chapter 4. The approach to tackle these items should also be from bigger issues to smaller things.	According to ISO process is a set of interrelated or interacting activities which transforms inputs into outputs.	X			IAEA recognizes the general character of the document with regard to the correlation between functions and (number of) processes. IAEA agrees that both “function” and “process” are used. “Function” is used as described in GSR Part 1. “Process” is used to show how the functions are implemented.
Finland #9	General	Suggestion: each chapter /subchapter/title could start with presenting and referring the	This approach has been used in several IAEA safety guides and is useful for the reader to follow the original requirement.	X			An Appendix with a matrix mapping the applicable GSR Part 1 requirements (as per the approved DPP) to DS472 chapters

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		requirement it is given guidance (how to apply it) –if existing.					was introduced.
Finland #21	General	Chapter 4 need to clarify the use of terminology (function and process)	To be consistent with DS456 and DS473	X			See resolution to Finland comment no.8.
Germany #1	General	It would be helpful to provide a more detailed descriptions of the power of the regulatory body to apply enforcement actions, limit authorizations (content and duration), access facilities at any time etc.	Clarification.			X	The core functions (including enforcement) are described in detail in DS473 and this aspect is referenced in DS472 (4.1, 4.15). The powers of the regulatory body are appropriately addressed in 2.x
USA #1	General	The document did not appropriately address regulatory structures for countries with small or limited nuclear programs or activities, such as those dealing only with sealed sources and limited medical/industrial/academic sources. We suggest adding additional guidance and information about the size and structure of the regulatory body based on ongoing limited near-term activities and needs. Requiring an extensive regulatory structure (<i>i.e., one size fits all</i>) as described may be too extensive and too elaborate for practical implementation to establish a country-specific regulatory body based on actual needs.	Completeness and caution in addressing organization, management, and staffing of a regulatory body using the concept “ <i>one-size-fits all</i> .” The guidance should provide more elaboration and discussion regarding regulatory body functions and structure for countries with no nuclear power programs.		Added at the end of 1.9.: “See Safety Glossary [17] for definition of graded approach”. New paragraph after paragraph 1.12: <u>This Safety Guide has been developed for use by all regulatory bodies, regardless of the size and type of the facilities and activities they regulate. Accordingly, the regulatory body should use a graded approach based on the risks and consequences associated with the authorized facilities and activities.</u> Change in last sentence of paragraph 4.56 to read: “Depending on the national circumstances <u>and in accordance with a graded approach</u> , the organization of the regulatory body will vary widely from State to State, <u>and therefore depending on the following factors should be taken into account:...</u> ”		For clarity.
SPECIFIC COMMENTS							
CHAPTER 1							
Germany #2	1.3	Maybe it is possible to specify which part of GS-G-1.5 is superseded.	Clarification.				The text follows the DPP. Essentially most of the documents referred to are either directly carried over or paraphrased to make them more general, i.e. relate to all facilities and activities.
Japan #1	1.3/3-4	...2013 (GSG-4) and Management Systems for Regulatory Bodies (DS113) .	Superseded guide must be formally approved and used in IAEA activities. Therefore, DS113 must be deleted from the series of superseded guide in this sentence.	X			

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Japan #2	1.5./2	This is one of the lessons learned from the Fukushima-Daiichi accident.	Since the concept of IAEA safety standards are to provide universal and common specification, mentioning a specific event is inappropriate.	X			
Spain #1	1.14	Interested parties, also known as stakeholders or concerned parties, are those individuals or organization concerned with safety and the regulatory body's decisions. Interested parties include, among others, the general public, such as people residing in the vicinity of facilities and activities; elected officials and governmental authorities at the national regional and local level; national and local non-governmental organizations; regulated industry and its employees, trade unions, and suppliers; professional and academic organizations; news media; and <u>other countries, specially</u> neighbouring countries.	In a global world, not only neighbour countries are concerned with national safety.	X	1.14. becomes 1.15.		Clarification
CHAPTER 2							
Germany #3	2.1 3 th hyphen	– Acting in the public interest and being accountable for its <u>the</u> decisions <u>of the regulatory body</u> ;	To be clear that the decisions of the regulatory body are meant.	X			Clarification
Germany #4	2.1 5 th hyphen	– Openness and transparency with authorized parties, the public and other interested parties to promote confidence and trust in it's <u>the regulator's</u> judgements and decisions;	To be clear that the decisions of the regulatory body are meant.		... confidence and trust in the judgement and decisions of the regulatory body		Clarification
Pakistan #1	2.1.	Preparing a set of organizational values helps to guide the behaviors of all staff to create a strong safety culture which is in line with the regulatory body's mission. Regulatory values should incorporate, but not limited, to the following characteristics:	This will encourage the organization to incorporate more values which seems appropriate in addition to the values documented in the said Para, e.g., caring & compassionate attitude.	X	Preparing a set of organizational <u>regulatory</u> values helps to guide the behaviors of all staff to create a strong safety culture which is in line with the regulatory body's mission. Regulatory values should incorporate, <u>but not be limited to</u> , the following characteristics:		Comment was accepted. IAEA addition: Including “regulatory” in sentence 1 would provide a link to the use of “regulatory values” at the beginning of the second sentence.
Germany #5	2.3	1 st sentence: “The need for regulatory independence is affirmed in the Convention on Nuclear Safety [13], the Joint Convention on the Nuclear Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management [14], the Code of Conduct on the Safety of Research Reactors [15], the	Please note that the Joint Convention is incorrectly designated in this paragraph. For the sake of completeness, Ref. [13–16] to the related conventions and codes should be added.	X			Correction and completeness

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		<p>Code of Conduct on the Safety and Security of Radioactive Sources [16] and in the IAEA Safety Requirements GSR Part 1 [2] and focuses on the separation of the regulatory body from the promoters of nuclear technology.”</p> <p>Please add the related conventions and codes to the list of references: “[13] Convention on Nuclear Safety, INFCIRC/449, IAEA, Vienna (1994).” “[14] Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, IAEA International Law Series No. 1, IAEA, Vienna (2006).” “[15] Code of Conduct on the Safety of Research Reactors, IAEA, Vienna (2006).” “[16] Code of Conduct on the Safety and Security of Radioactive Sources, IAEA, Vienna (2004).”</p>					
Russian Federation #1	Item 2.3	<p>The text under revision: "The need for regulatory independence is affirmed in the Convention on Nuclear Safety, the Joint Convention on the Nuclear Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, the Code of Conduct on the Safety of Research Reactors, the Code of Conduct on the Safety and Security of Radioactive Sources and in the IAEA Safety Requirements GSR Part 1 [2] and focuses on the separation of the regulatory body from the promoters of nuclear technology. The primary reason for this separation is to ensure that regulatory judgements can be made, and enforcement actions taken, without any pressure from interests that may conflict with safety, Furthermore, the credibility of the regulatory body in the eyes of the general public depends in large part upon whether the regulatory body is regarded as being independent from the organizations it regulates, as well as independent from government agencies or industry groups that</p>	<p>General comment in respect to this Draft General Safety Guide:</p> <p>There is a lack of recommendations concerning the organization of resident inspectors activities and especially recommendations regarding their independence ensuring, taking into consideration their permanent work in direct contact with and under conditions which depend on the supervised organization.</p> <p>Item 2.3 presents the grounds and the general approach to the independence of the regulatory authority. But it is necessary to reformulate this Item to emphasize that separation of regulatory authority from other governmental structures and non-governmental entities, that are promoting the development and the use of atomic energy, must be organized not only <i>de jure</i>, but <i>de facto</i> as well. Such <i>de facto</i> separation is not always present, but is recognized as the determining factor. It is very important to introduce this provision into the Safety Standard to enable experts under the frames of the IAEA IRRS missions to monitor the regulatory body's independence aspect. Additionally, it is necessary to point out the "other interests"</p>		<p>(Accepted with modifications) Additional wording will be added to paragraph 6.5 to address this issue.</p> <p>New paragraph after 4.59: <u>Regardless of the selected structure, the regulatory body should ensure that its staff members are not subjected to any undue influence by any interested party, especially the authorized parties.</u></p> <p>Last phrase in paragraph 6.5: “The regulatory staff should be formal and open but not familiar in their interactions with authorized parties <u>and should, at all times, maintain its integrity so as not to be influenced by the authorized parties.</u>”</p> <p>New paragraph after paragraph 5.3 <u>The integrated management system should have arrangements in place to ensure that the regulatory body and its staff are not subject to undue influence by any interested party, especially the authorized parties.</u>”</p>		<p>Completeness and clarification</p> <p>The use of resident inspector is a particular practice, not a general one. However point is taken.</p>

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		promote nuclear technologies".	besides facilitating the development and the use of atomic energy, which actually exist. In prospect, when formulating in detail the issues of independence for regulatory authority, these two aspects are to be taken into consideration.				
Russian Federation #2	Item 2.7, the first sentence	New text: "The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority to fulfil its statutory obligation for the regulatory control of facilities and activities and provide it with the necessary competence and the resources".	The first sentence of Item 2.7: it is not clear if the last part of this sentence is applicable to the authorities of the regulatory body or to its competences and resources only. We propose to read this sentence as follows:		2.7. GSR Part 1 [2] states that The "the government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities".		Better wording and clarity, as this is a direct quote from GSR Part 1.
Spain #2	2.9	It is suggested to delete de whole paragraph: Although the regulatory responsibilities may be divided among several authorities for specific safety aspects, having a single authority with regulatory responsibilities for all aspects of safety offers advantages with regard to legally specifying and clearly allocating regulatory responsibilities and avoids gaps or overlaps.	Recommendation on paragraph 2.8 are enough to underline the importance of defining clear interfaces between different regulators. Assigning regulatory responsibilities is a government choice and a low level document, as a guide, should not make such recommendation			X	The recommendation for a single authority should be retained, due to the advantages outlined in the paragraph. However, switch the order of paragraphs 2.8 and 2.9 As a guide, the recommendation is not obligatory.
Russian Federation #3a	Item 2.10	The text under revision: "Adequate and stable financing for all regulatory activities is fundamental to independence. The financing mechanism should be clearly defined in the legal framework. The budget for the regulatory body should not depend on fines or penalties collected from licensees, nor should it be decided by or be subject to the approval of those parts of the government which are responsible for exploiting or promoting nuclear technologies".	As rightly pointed out in Item 2.10, the adequate and stable financing of regulatory activities is considered as fundamental to independence of regulatory body. In this respect the correlation between the compensation levels of the specialists from the regulatory body and the supervised organization staff of the same level of qualification is of particular importance. If compensation rate of the specialists from regulatory authority is significantly lower than the compensation rate of the same specialists from the supervised organization, it constitutes the grounds for loss of independence. First of all, it is difficult to complete the staff of regulatory authority with the specialists of necessary qualification level, which is equal to qualifications of the specialists from the supervised organization.			X	Para 6.4. adequately covers compensation of regulatory body staff
Russian Federation	Item 2.10	The text under revision: "Adequate and stable financing for all	Secondly, various types of satisfaction of the regulatory body and its' specialists demands			X	Para 6.4. adequately covers compensation of regulatory body staff

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ion #3b		regulatory activities is fundamental to independence. The financing mechanism should be clearly defined in the legal framework. The budget for the regulatory body should not depend on fines or penalties collected from licensees, nor should it be decided by or be subject to the approval of those parts of the government which are responsible for exploiting or promoting nuclear technologies".	which arise in business and worldly interests for the account of the supervised organization inevitably occur. This undermines the independence of the regulator. Thus it is necessary to specify explicitly such aspect of the financial independence.				
Russian Federation #3c	Item 2.10	The text under revision: "Adequate and stable financing for all regulatory activities is fundamental to independence. The financing mechanism should be clearly defined in the legal framework. The budget for the regulatory body should not depend on fines or penalties collected from licensees, nor should it be decided by or be subject to the approval of those parts of the government which are responsible for exploiting or promoting nuclear technologies".	Another aspect of financial independence is concerned with the expenditures for the safety review carried out by the regulatory authority under the licensing process. Such expenditures are to be compensated for by organizations, which submitted safety case subject to safety review. However, such compensation must be not performed directly to the regulatory authority or to the organization appointed by the regulator to carry out safety review. Such type of activity is to be financed from the budget or by the insurance organizations that are maintaining the nuclear damage insurance; such activity in some or other form must be compensated for by organizations, which documentation is being reviewed. This aspect is also to be introduced into provisions dealing with the financial independence.			X	Para 6.4 adequately covers compensation of regulatory body staff
Russian Federation #4	Item 2.16	New text: "The credibility of the regulatory body to the general public depends in large part upon whether the regulatory body can demonstrate it is independent of the organizations that it regulates as well as independent of governmental organizations and industry groups that promote nuclear technologies <u>or have other interest</u> ".	It is suggested that the words " <i>or have other interests</i> " are to be included at the end of this sentence, because the instances of dependence from industrial groups with other interests which may be in conflict with the interests of nuclear and radiation safety regulatory authority are possible.		2.16. The credibility of the regulatory body to the general public depends in large part upon whether the regulatory body can demonstrate it is independent of the organizations that it regulates as well as independent of governmental organizations and industry groups that promote nuclear technologies <u>all other interested parties.</u>		Completeness and clarity
Germany #6	2.19, 3.1, 4.30 and 4.59	In the Draft Safety Requirements DS456 "Leadership and Management for Safety" (future GSR Part 2; latest version dated 22 October 2015) the term 'Individual,	Ensuring consistency between current IAEA Safety Standards with regard to the terminology used therein.	X			Consistency

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		technology and organization' (ITO) is not part of the used terminology. Under Para 3.1 and 4.24 of DS456 reference is rather made to Human, technology and organization' HTO. In order to be consistent, ITO should be replaced by HTO.					
Russian Federation #5	Item 2.21	New text: "The prime responsibility for safety rests with the authorized parties. The regulatory body should ensure that its actions do not take the prime responsibility From the authorized parties. <i>It means that the regulatory authority should not take on the implementation of activities classified as the responsibilities of the operating organization, for example, licensing of organizations which are carrying out works and rendering services. The operating organization is responsible for the activities performed by such organizations, but the regulatory authority must perform monitoring in respect to these activities under the frames of control of compliance with conditions of license issued to the operating organization</i> ".	It is suggested that the sentence in Item 2.21 should be completed along with the following: " <i>It means that the regulatory authority should not take on the implementation of activities classified as the responsibilities of the operating organization, for example, licensing of organizations which are carrying out works and rendering services. The operating organization is responsible for the activities performed by such organizations, but the regulatory authority must perform monitoring in respect to these activities under the frames of control of compliance with conditions of license issued to the operating organization</i> ".		Replace the second sentence of paragraph 2.21 with: "Therefore, the regulatory body should not undertake activities classified as the responsibility of authorized parties. The regulatory body should focus on the regulatory functions identified in Chapter 4." 2.21. The prime responsibility for safety rests with the authorized parties. Therefore, the regulatory body should <u>not undertake activities classified as the responsibility of authorized parties. The regulatory body should focus on the regulatory functions identified in Chapter 4.</u> ensure that its actions do not take the prime responsibility from the authorized parties		Clarification
CHAPTER 3							
Finland #10	Para 3.1	- Supporting and encouraging employees to achieve safety in their work and seek their active involvement in improving regulatory safety performance including the consideration of staff's input in safety-related decisions regulatory decision making.	Clarification, it is not clear what 'safety performance' means in the context of a regulatory body-.		-Supporting and encouraging employees to achieve safety in their work and seek their active involvement in improving safety performance including the consideration of staff's input in safety related decisions <u>focus on safety and include them in the regulatory decision-making process.</u>		Clarification and simplification
Finland #11	Para 3.1	Addition - Encouraging employees to bring up their safety concerns.	Good leadership includes promoting safety culture and open discussing environment.	X			Already incorporated in bullet 10
Spain #3	3.1	Demonstrating commitment to the establishment, implementation, assessment and continuous improvement of the integrated management system by actively seeking <u>and assessing</u> information on performance within their area of responsibility, sharing this information	Assessment is part of continuous improvement		Replace entire bullet with: "-Demonstrating commitment to the continuous improvement of the integrated management system by actively seeking and assessing information on performance within their area of responsibility and sharing this information within the regulatory body in an open and transparent manner;"		

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		within the regulatory body in an open and transparent manner;					
Spain #4	3.1	It is suggested to include “change management” and “competence management” part of leadership.			Replace second sentence of bullet 6 with:“ - This should include capabilities for competence management, change management and crisis management.”		
Russian Federation #6	Subsection "SAFETY CULTURE", Items 3.2 - 3.8		It is suggested that that these Items are to be complemented with another one to establish the necessity of introduction of the fundamental values of safety culture (that are presented in this subsection) into the guiding documents for the staff of regulatory authority (procedures, methodological instructions, etc.)		3.5. These characteristics should permeate the entire regulatory body <u>and should be reflected in the integrated management system</u> , so that individuals show a questioning attitude, feel responsible and are supported in identifying safety concerns.		This is covered under para 4.56. However, for clarity, see addition to para 3.5.
Japan #3	3.2 , 3.3, 3.4, 3.5, 3.6, 3.7	Wording “Strong safety culture” and “Good safety culture” should be unified to either one of them.	Wording. Two different words describing the same thing could confuse the reader.	X			Agreed. “strong safety culture” was kept.
USA# 2	3.2, 3.6, 3.7 and 4.70	Replace “good” with “strong.”	To be consistent, remove “good” as an adjective in front of “safety culture” and replace with “strong” in Sections 3.2, 3.6, 3.7 and 4.70.	X			Agreed. See Japan comment no.3.
Japan #4	3.6	The structure should be in the order of priority. 3.2 3.3 <u>3.6</u> 3.4 3.5 3.7 3.8	The engagement and commitment of the senior management has priority over contribution of other staffs in the regulatory body for fostering safety culture.	X	3.6. becomes 3.4. 3.4. becomes 3.6.		
Japan #5	3.6	<u>A good safety culture needs the strong commitment and engagement of the senior management with the support of the integrated management system.</u> A good safety culture does not grow by itself, nor can it be controlled but it can be influenced. The role model of leaders, their behaviour and commitment to safety influence the attitudes and behaviours of individuals. Therefore, a good safety culture needs the strong commitment and engagement of the senior management with the support of the integrated management system.	In order to emphasis necessity of strong commitment and engagement of the senior management, the last sentence should be moved to the top of this paragraph.			X	This was addressed by the resolution to Japan comment no 4.
Finland #12	Para 3.7	Clarification / addition: -An awareness of the risks and hazards relating to the potential	There are two different aspects in the original sub-paragraph. The intention of the first		Separate into two bullets as proposed. Second bullet to say:		Clarification

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		consequences of regulatory activities including risks and hazards related to them. -All factors that might impact upon safety must be taken into account during the regulatory body's decision-making process and other activities.	sentence should be clarified.		<p>“-All factors that might impact upon safety are to be taken into account during the regulatory decision-making process and other regulatory activities.”</p> <p>-An awareness of the risks and hazards relating to the potential consequences of regulatory activities <u>including risks and hazards associated to them.</u></p> <p>-All factors that might impact upon safety must be taken into account during the regulatory body's decision-making process and other regulatory activities.</p>		
Finland #13	Para 3.8	The regulatory body should establish and maintain a programme to develop, to foster and to evaluate its safety culture. This may be facilitated by installing a permanent internal working group that oversees for the safety culture development. Such a development programme should include safety culture self-assessments, workshops and seminars for defining improvement programmes as well as training and support.	The term oversee is ambiguous and may cause confusion		3.8. The regulatory body should establish and maintain a programme to develop, to foster and to evaluate its safety culture. This may be facilitated by installing a permanent internal working group that oversees the safety culture development. Such a development <u>programme</u> should include safety culture self-assessments, workshops and seminars for defining improvement programmes as well as training and support.		A permanent working group may not be the best way to achieve a strong safety culture.
Japan #7	Safety culture chapter P16-17	Please consider of adding the below description under the “Safety culture” chapter as a new paragraph and its heading. <u>HARMONIZATION WITH NUCLEAR SECURITY</u> <u>3.8a (new para) It is necessary to recognize that nuclear safety and security activities do not exist independently, namely complement each other and interfere with each other. All the individuals involved in nuclear safety and security activities shall respect each other’s way of thinking and make efforts for harmonizing both activities. Senior management should take responsibility to select the most appropriate solution.</u>	Harmonization between safety and security is very important and should be described including the interface with security under the new heading.			X	Interface between safety and security is addressed in paragraph 1.15. The scope of DS472 does not extend to security.
Finland #14	Para 3.9	-Have regulations and guides in place for all types of facilities and activities that are included in the scope of the national framework for safety;	Need to be clarified, ‘the national framework’ may lead cause confusion.		-Have regulations in place for all types of facilities and activities that are included in the scope of the national framework for safety <u>its responsibilities.</u>		

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					-Ensure that the facilities and activities are in compliance with these national <u>regulatory</u> requirements and that the authorized parties are aware of their prime responsibility for safety.		
USA #3	3.9	“Have regulations and guides in place for all types of facilities and activities that are included in the scope of the national framework for safety, <u>for which the regulatory body is responsible.</u> ”	The regulatory body can only develop regulations and guidelines for facilities and activities that they regulate.		See Finland comment #14		See resolution.
Japan #6	3.9./1	The people <u>public</u> and the environment	Amendment to make the description in line with the principle of Safety Standards.	X			
Finland #15	Para 3.11	Delete or need for clarification	It is not clear what is the basis for this guidance.		3.11. <u>To maintain a check and balance over the regulatory body’s activities, the State should provide for independent oversight and governance of the regulatory body and its key decisions. This may be achieved in a number of different ways, for example by appearing before legislative committees, referral of decisions to courts of law, the appointment of an independent auditor, etc.</u> the establishment of a Commission or Management Board. Such arrangements could also provide independent oversight and governance of an appeals process for actions and decisions made by regulatory staff. A method of ensuring accountability in some States is the establishment of a direct reporting line from the regulatory body to the highest levels of government. Peer review systems, national or international, can provide a useful input into demonstrating accountability. The need for accountability should not compromise the regulatory body’s independence in making decisions relating to safety.		Clarification. The regulatory body should be subject to independent oversight.
Spain #5	3.15	It is suggested to delete the whole paragraph: “The regulatory body should be able to either develop its own budget or – in the case of strong dependency or national restrictions – to influence the	It is included on 3.13 and this is more comprehensive: “In order to be able to act independently, the regulatory body should be allocated with sufficient financial resources and should have the authority to decide how these resources		Reordered the paragraphs: 3.15, 3.13, 3.14 (Create a budget proposal, then allocate resources based on graded approach, then review funding periodically based on an assessment of the regulatory body’s needs).		For clarity.

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		budgetary conditions of the regulatory body's funding.”	are to be used, respecting a graded approach.”		3.15. becomes 3.13. 3.13. becomes 3.14. 3.14. becomes 3.15		
Finland #16	Para 3.21	Addition: Examples of information and knowledge relevant for regulatory bodies include: - Records, decisions, regulations and guides,				X	This is not meant to be an exhaustive list.
India #1	3.21	One more bullet ' peer review outcome ' may be added.	Peer review gives important feedback/learning/knowledge			X	The indicated information is contained more generally in next-to-last bullet.
Finland #17	Para 3.22	Delete the whole para	Does not give any additional information or guidance.	X			Does not give any additional information or guidance.
India #2	3.23	One more bullet may added ' systems to get the environmental radiation data of various nuclear installations for emergency preparedness '	Important part of emergency arrangement and needs specific mention.		3.23. becomes 3.22.	X	Aspect already covered more generally under bullet ”Regulatory measuring and testing equipment, plus laboratories”
Spain #6	3.24	Regulatory bodies have a number of interested parties, including their own staff and other groups within government, the industry, the media and the public, as well as residents living close to facilities, and <u>other countries, specially neighbouring countries</u> . In some cases, there may be legal requirements which prescribe the provision of information and consultation. As part of a policy of openness and transparency and in order to secure the continued confidence and trust of all parties, regulatory bodies should establish effective working relationships with the interested parties.	International (multilateral and bilateral) regulatory interactions are more and more important.		3.24. becomes 3.23. 3.24. Regulatory bodies have a number of interested parties, including their own staff and other groups within government, the industry, the media and the public, as well as residents living close to facilities. As part of a policy of openness and transparency and in order to secure the continued confidence and trust of all parties, regulatory bodies should establish effective working relationships with the interested parties. <u>Regulatory bodies may have legal requirements which prescribe the provision of information to, and consultation with, interested parties (including multilateral and bilateral regulatory interactions).</u> As part of a policy of openness and transparency and in order to secure the continued confidence and trust of all parties, regulatory bodies		Clarification

COMMENTS BY REVIEWER: MEMBER STATES				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
					should establish effective working relationships with the interested parties.		
Finland #18	Para 3.25	Clarification: Regulations and guides represent a powerful mean to communicate the regulatory body's opinions requirements and guidance, modes of work and basis for decisions to interested parties. Therefore, in developing regulations and guides, the opinion and needs comments and expectations of interested parties should be considered.	Opinion is not explicit enough	X	3.25. becomes 3.24. 3.25. Regulations and guides represent a powerful mean to communicate the regulatory body's opinions <u>requirements and guidance</u> , modes of work and basis for decisions to interested parties. Therefore, in developing regulations and guides, the opinion and needs <u>comments and expectations</u> of interested parties should be considered.		Clarification
Finland #19	Para 3.26	Clarification: In order to understand and address these needs and expectations the regulatory body should have systematic means to secure establish a process securing effective interactions with all interested parties. A suitable process of 'interested party relations' would include: This would include: This would include:	In line with DS456		3.26. becomes 3.25. Interested parties may have differing... ... the regulatory body should have a process to establish effective interactions with all interested parties. This should include: 3.26. Each interested party parties <u>may</u> have differing expectations of the regulatory body according to their functions, roles and interests. In order to understand and address these needs and expectations the regulatory body should establish <u>have</u> a process securing to establish effective interactions with all interested parties. A suitable process of 'interested party relations' would This should include:		Clarification
Finland #20	Para 3.27	Clarification: The results of the analysis should provide an input to the continuous improvement process of the regulatory body's activities.			3.27. becomes 3.26. The measurement of interested party satisfaction essentially involves gathering information about interested parties?		Clarity.

COMMENTS BY REVIEWER: MEMBER STATES				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
					perceptions of the role and performance of the regulatory body should consider methods of gathering information regarding the effectiveness of its interactions with interested parties. The results of the analysis should provide an input to the continuous-improvement process of the regulatory body.		
CHAPTER 4							
Finland #22	Para 4.6	Clarification: Involve Are developed in consultation with the interested parties.	Clarity	X			Clarity
Finland #23	Para 4.7	The objective of granting authorizations is for the regulatory body to exercise effective regulatory control throughout the lifetime of a facility or duration of an activity in relation to safety	Need to be clarified, it is not clear what is the objective of this sentence. Facilities and activities with that may raise significant radiation risk must be authorized, however, other type of facilities and activities can be controlled effectively.		Change title to “Notification and authorization” 4.9 becomes 4.7 and 4.7 becomes 4.9. New 4.9. reads: 4.7 9 . The objective of granting authorizations is for the regulatory body to exercise effective regulatory control throughout the lifetime of a facility or duration of an activity in relation to safety. The authorization process should require assurance that by the applicant that it can fulfil its <u>comply with all safety obligations requirements; demonstration of staff competence, where appropriate; and demonstration of safety by the applicant.</u> These aspects should be subject to suitable review and assessment by the regulatory body before the authorization is issued. In the granting of an authorization for a facility or an activity, the regulatory body may have to impose limits, conditions and controls on the authorized party’s subsequent activities.		The regulatory body exercises its authority by issuing authorizations in accordance with national legislation and this authorization brings facilities and activities under the control of the regulatory body. Additional “to” added by IAEA for language clarity. For old 4.9 (new 4.7) see also Germany comment no.7 below.
Germany #7	4.9	“The regulatory body should have the power to accept and process notifications and applications for authorisation for any use and handling of radioactive material <u>radiation sources</u> .”	According to the IAEA Safety Glossary (2007 Edition), the term ‘radiation sources’ is more comprehensive since it includes radioactive materials and radiation generators. As mentioned in Para 1.2 and Footnote No. 1, this Safety Guide provides guidance on safety regulation applicable to all facilities and activities in which people may be exposed to radiation from naturally occurring or artificial sources.	X	4.9 becomes 4.7 and 4.7 becomes 4.9. New 4.7 now reads: 4.9 7 . The regulatory body should have the power to accept and <u>to</u> process notifications and applications for authorisation for any use and handling of radioactive material <u>radiation sources</u> .		Accepted. IAEA: For conciseness and correlation with DS473. For old 4.7 (new 4.9.) see Finland #23 above
Armenia #1	4.10-4.11	<i>The comment is general, no specific changes are proposed.</i>	According to IAEA document GSR Part 1 §4.45:		4.11. The review and assessment process is a critical appraisal, performed by the regulatory		Clarification and completeness

COMMENTS BY REVIEWER: MEMBER STATES				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
			<p><i>“In the process of its review and assessment of the facility or activity, the regulatory body shall take into account such considerations and factors as:</i></p> <p>.....</p> <p><i>(16) Feedback of operating experience nationally and internationally and especially of relevant operating experience from similar facilities and activities;”</i></p> <p>It seems that currently the feedback of operating experience is not included in the section on “Review and assessment of facilities and activities”.</p>		body, of information submitted by the authorized party or which comes from inspection, <u>feedback of operating experience nationally and internationally, and information on events or other specified reports (Periodic Safety Reviews, monthly and annual reports, etc.) to demonstrate the safety of the facility or activity....”</u>		The importance of OPEX feedback is recognized. A reference to NS-G-2.11 (A system for the feedback of Experience from Events in Nuclear Installations, IAEA, 2006) was added in DS473.
Finland #24	Para 4.14	Clarification: Provision shall be made for free access by regulatory inspectors to any facility or activity at any time, within the constraints of ensuring operational safety at all times and other constraints associated with the potential for harmful consequences.	This guidance should not be limited to operational safety only.	X			Clarification
Russian Federation #7	Item 4.14.	New text: “...Provision shall be made for free access by regulatory inspectors to any facility or activity at any time, <u>including organizations, which are exercising works and rendering services to the supervised organizations</u> , within the constraints of ensuring operational safety at all times and other constraints associated with the potential for harmful consequences...”	It is suggested to introduce into the second sentence of Item 4.14 after the words «at any time» <u>“including organizations, which are exercising works and rendering services to the supervised organizations”</u> .		4.13. GSR Part 1 [2] makes it clear <u>requires</u> that the...		Paragraph 4.14 is a direct quote from GSR Part 1.
Germany #8	4.17	“The principal objectives of enforcement (in conjunction with inspections) are to provide a high level of assurance that all activities performed by the authorized party at all stages of the authorization process and all stages during the lifetime of a facility or activity (i.e. siting, design, construction, commissioning, operation and decommissioning or closure) <u>or the duration of an activity</u> have been executed safely and meet the safety objectives and authorization conditions.”	Ensuring consistency with Paras 4.7 and 4.10 of DS472 as well as with the Safety Requirements publication GSR Part 1 (Rev. 1) which is referring to “the lifetime of a facility or the duration of an activity” in several paragraphs.		The principal objectives of enforcement <u>should be</u> (in conjunction with inspections) are to provide a high level of assurance that <u>the authorized party all activities performed by the authorized party</u> at all stages of the authorization process and all stages during the lifetime of a facility (i.e. siting, design, construction, commissioning, operation and decommissioning or closure) <u>or the duration of an activity complies with all safety requirements and meets the safety objectives and authorization conditions, and promptly identifies and corrects non-compliances with safety requirements.</u> have been executed safely and meet the safety objectives and authorization conditions.		Accepted and combined with IAEA proposal, for consistency with DS473, para 3.289.

COMMENTS BY REVIEWER: MEMBER STATES				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
Finland #25	Para 4.20	Clarification: Functions and processes that the regulatory body should perform are: Ensuring on-site emergency arrangements; Ensuring coordination with off-site response organizations; Establishing and maintaining internal arrangements; and Discharging its assigned responsibilities in emergency response. See DS473[9] for further details on the regulatory body's EPR functions and processes	On-site emergency arrangements are part of license holders responsibility, the role of regulatory body is to oversee these arrangements.		As a minimum, the regulatory body should: -verify that on site emergency arrangements are in place; -verify that coordination with off-site response organizations is in place; -establish and maintain its internal arrangements; -discharge its assigned responsibilities in emergency response.		Clarity
Germany #6	2.19, 3.1, 4.30 and 4.59	In the Draft Safety Requirements DS456 "Leadership and Management for Safety" (future GSR Part 2; latest version dated 22 October 2015) the term 'Individual, technology and organization' (ITO) is not part of the used terminology. Under Para 3.1 and 4.24 of DS456 reference is rather made to Human, technology and organization' HTO. In order to be consistent, ITO should be replaced by HTO.	Ensuring consistency between current IAEA Safety Standards with regard to the terminology used therein.	X			Consistency (Duplication; same comment appears also in chapter 2).
Finland #26	Para 4.21	Missing?		X			Will be addressed during quality check for publication.
Finland #27	Para 4.22	Clarification: The regulatory body should be as transparent as possible while complying with requirements of commercial confidentiality and information security. Public information should be managed by experts in the field so as to ensure that the information provided is clear and comprehensible. The establishment of a specialized public information unit should be considered.	Need to focus on EPR function and organization Interface with DS472 should be considered		4.22. becomes 4.21. 4.22. The regulatory body should provide information concerning its activities to the interested parties including the public, both on a regular basis and in relation to abnormal events. Information should be factual and as objective as possible, reflecting the regulatory body's independence. The regulatory body should be as transparent as possible while complying with requirements of commercial confidentiality and information security. Public information should be managed by experts in the field so as to ensure that the information provided is clear and comprehensible. The establishment of a specialized public information unit should be considered.		Clarity. In conjunction with comment Finland no.5
Finland	Para 4.24,	Most of these functions should also be	Move this to Chapter 5 (Management		4.24. becomes 4.23.	X	The regulatory body's integrated

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
#28	last sentence	represented in processes of the regulatory body's integrated management system.	Systems)				management system should establish processes that account for all of these functions.
Germany #9	4.24	2 nd bullet: "Technical functions directly related to the effective implementation and fulfilment of the core regulatory functions- (e.g. legal support, research and development, external expert support, advisory committees, international cooperation <u>and assistance</u>)."	See our related comment on Para 4.49.	X	4.24. becomes 4.23. -Technical functions directly related to the effective implementation and fulfilment of the core regulatory functions. (e.g. legal support, research and development, external expert support , <u>advisory committees, external expert support, liaison with other governmental organizations, international cooperation and assistance</u>)		Ensure consistency with latest revision of GSR Part 1. See also Spain #7
Spain #7	4.24	It is suggested to reconsider the whole paragraph: "There are two categories of supporting functions that enable the regulatory body to implement its core functions effectively: - Administrative functions supporting the routine operations of the regulatory body (e.g. finance, management of documents and records, equipment purchasing and control) and, - Technical functions directly related to the effective implementation and fulfilment of the core regulatory functions. (e.g. legal support, research and development, external expert support, advisory committees, international cooperation) Most of these functions should also be represented in processes of the regulatory body's integrated management system."	1. The proposed classification is arbitrary (for example, accounting can be considered one technique) 2. It is inconsistent with consecutive paragraphs.	X	4.24. becomes 4.23. -Technical functions directly related to the effective implementation and fulfilment of the core regulatory functions. (e.g. legal support, research and development, external expert support , <u>advisory committees, external expert support, liaison with other governmental organizations, international cooperation and assistance</u>)		For clarity. See also Germany #9
Finland #29	p. 26	Title "technical functions" is missing (addition)	Para 4.24 categorizes supportive functions into two main groups.		Technical Functions was added above Legal Support (above para 4.26)		Consistency in defining the sections of the document.
Spain #8	4.26	The regulatory body by its nature is engaged in activities that involve meeting legislative requirements and so may require professional legal	Supporting functions (for example contracting or accounting) can require legal support. See last sentence of 4.28	X	4.26. becomes 4.25.		Clarity See also Finland #30

COMMENTS BY REVIEWER: MEMBER STATES				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		support. The objective of legal support is to provide the regulatory body with legal advice on international obligations, national legislation and development of rules, regulations and guidance documents, for the implementation of the regulatory body's core functions.			The regulatory body by its nature is engaged in activities that involve meeting legislative requirements and so may require professional legal support <u>should have access to legal advice</u> . The objective of legal support is to provide the regulatory body with legal advice on international obligations, national legislation and development of rules, regulations and guidance documents, for the implementation of the regulatory body's core functions.		
Finland #30	Para 4.28	The legal support should review and advise the regulatory body regarding: -How the regulatory body performs its regulatory responsibilities and functions; -The adequacy of its regulations, implementing guidelines and procedures; -Authorization by the regulatory body for facilities and activities; -Enforcement actions; -Existing and proposed safety standards, and technical and policy issues related to the authorisation of facilities and activities; and, -Other matters deemed relevant by the regulatory body (e.g. Contracts, cooperative matters).	This guidance should be reconsidered as in many countries the responsibility of legal support vary a lot.		4.26. becomes 4.25. 4.26. The regulatory body by its nature is engaged in activities that involve meeting legislative requirements and so may require professional legal support <u>should have access to legal advice</u> . The objective of legal support is to provide the regulatory body with legal advice on international obligations, national legislation and development of rules, regulations and guidance documents, for the implementation of the regulatory body's core functions.		Clarity. See also Spain #8
Finland #31	Para 4.29	Since legal support is embedded in many activities of the regulatory body, the regulatory body should establish a subprocess <u>systematic means describing how</u> to document the results of a legal review, as well as the criteria for the acceptance or rejection of recommendations from legal support.	There is no need to require a specific sub process.		4.29. becomes 4.28.	X	The integrated management system is the systematic means.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
Finland #32	Para 4.30	Research and development provide supporting information in regard to the safety of <i>the design and</i> operation of a facility or the conduct of activities and should be performed under a systemic view, considering ITO aspects.	Add: design, not only the operation should be considered. The pointing out ITO is not needed in this paragraph which is quite general. An other alternative is to list several essential topics including ITO.		4.30. becomes 4.29. Research and development provide supporting information in regard to the safety of the <u>design and</u> operation of a facility or the conduct of activities and should be performed under a systemic view, considering ITO aspects.		This keeps the advice general.
Finland #33	Para 4.31	Research and development is intended to: -Confirm existing knowledge; -Identify any technical <i>safety</i> issues and resolutions; -Improve existing scientific and technical knowledge or <i>safety assessment methods</i> ; and, - Develop <i>technical and scientific</i> bases to support new regulations and/or operational procedures of <i>the regulatory body</i> .	Add: safety Add: safety assessment methods The use of the term operational procedures in this context is confusing. Both technical and scientific aspects should be considered. Add: and scientific ...of the regulatory body		4.31. becomes 4.30. Research and development is intended to: – Confirm existing knowledge; – Identify any technical <u>safety</u> issues and resolutions; – Improve existing scientific and technical knowledge <u>and safety assessment methods</u> ; and, – Develop technical <u>and scientific</u> bases to support new regulations and/or operational procedures <u>of the regulatory body</u> .		For clarity.
Finland #34	Para 4.34	The regulatory body should request authorized parties to carry out the research and development necessary to produce an adequate body of knowledge to demonstrate safety. In addition, the authorized party's research and development methodology and results should be assessed by the regulatory body for adequacy. The regulatory body may consult with an appropriate advisory committee for the evaluation of the research and development programme.	Delete the paragraph. The oversight of the authorized party should include the oversight of the research activities. This should be a topic covered by DS473.		4.34. becomes 4.33.	X	Although correct that authorized party R&D is part of the regulatory body oversight, it makes sense to leave it here with the remainder of the discussion on R&D.
Finland #35	Para 4.35	Advisory committees provide the regulatory body with independent expert opinion on the adequacy of the regulatory activities to maintain safety . Advisory committees are typically independent bodies of experts having the power or right to give advice and make suggestions about <i>safety issues requested by the</i>	Main safety is unnecessarily limiting the scope of the advice given by the advisory committees. The advisory body typically makes the independent opinion on the request by the regulatory body. It does not independently chose the topics.		4.35. becomes 4.34. Advisory committees provide the regulatory body with independent expert opinion on the adequacy of the regulatory activities to maintain safety . Advisory committees are typically independent ¹ bodies of experts having the power or right to <u>that give advice and make suggestions to the regulatory body</u>		Clarity

¹ "Independent" means that the members are not staff of the regulatory body.

COMMENTS BY REVIEWER: MEMBER STATES				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		<i>regulatory body.</i>			about what should be done to maintain safety issues for authorized facilities and activities.		
Spain #9	4.37	Typing mistake? “Advisory committees should be distinguished from other forms of external expert support as their role is not to deliver technical input, but is intended to <u>advise</u> on...”		X	4.37. becomes 4.36.		Typo
Finland #36	Para 4.39	Consider and addition here: “It may consist of representatives from government departments, other regulatory bodies, regulatory bodies of other States, scientific organizations, senior technical experts, academia, non-government organizations and authorised parties.” <i>Everyone, who may have a conflict of interest to any subject under discussion/assessment, should disqualify himself</i>	Clarification		4.39. becomes 4.38. The advisory committee should report to the highest level of authority within the regulatory body. It may consist of representatives from government departments, other regulatory bodies, regulatory bodies of other States, scientific organizations, senior technical experts, academia, non-government organizations and authorised parties. <u>Any advisory committee member, who might have a conflict of interest on any subject under discussion, should be disqualified from that discussion.</u> Membership of the advisory committee should represent a balance of interests across various sectors of interested parties. The regulatory body should clearly define terms of reference which specify the role and responsibility of the advisory committee, its constitution and the selection criteria for its membership. The advisory committee should solicit, where appropriate, views from the public, industry, regional and local governments, and other interested parties on regulatory matters.		Clarification and completeness. IAEA addition justification: this shouldn't permanently disqualify the member; adequate rotation according to conflicts of interests can be ensured.
Germany #10	4.40	“The regulatory body should have, at a minimum, adequate competence in every core and supporting function, so that it has the ability both to formulate and manage its requests for technical advice and to understand, evaluate and implement the advice (see 3.16, 3.18 and chapter 6).”	Refer to paragraphs where this topic is addressed.		4.40. becomes 4.39. The regulatory body should have, at a minimum, adequate competence in every core and supporting function, so that it has the ability both to formulate and manage its requests for technical advice and to understand, evaluate and implement the		Clarity

COMMENTS BY REVIEWER: MEMBER STATES				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
					advice (see Chapter 3, para.3.16 and 3.18 and Chapter 6).		
Germany #11	4.41	1 st sentence: “Should the regulatory body decide to establish a dedicated technical support organization (TSO), the regulatory body should set clear limits on the degree of control and direction ...”	The abbreviation ‘TSO’ is used in Paras 4.42 and 4.56, but is not introduced in the main text of the Safety Guide.	X	4.41. becomes 4.40.		
Finland #37	Para 4.42	Addition: "In the case of individual experts, the expert should conform to the regulatory body's integrated management system," <i>as appropriate.</i>	It is not necessary to conform the whole MS (may not be relevant).		4.42. becomes 4.41.	X	Individual experts must conform to the IMS to the same extent as any regulatory body staff member.
Finland #38	Para 4.47	All staff members of the regulatory body should be made aware of the reasons for and the implications of the overlapping responsibilities and of the fact that good working relationships at all levels are necessary.	Not necessary for all staff members.	X	4.47. becomes 4.46.		Clarification
Germany #12	after 4.48	Title of subsection (Paras 4.49–4.55): “ <i>International cooperation and assistance</i> ”	Ensuring consistency with Requirement 14 of GSR Part 1 Rev. 1 which is referred to in this subsection. See also our related comment on Para 4.49.	X			Ensure consistency with latest revision of GSR Part 1
Germany #13	4.49	“Requirement 14 of GSR Part 1 states that the government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation <u>and assistance</u> to enhance safety globally.”	Ensuring consistency with Requirement 14 of GSR Part 1 Rev. 1. The requirement is entitled “International obligations and arrangements for international cooperation <u>and assistance</u> ”. The underlined amendment was not contained in Requirement 14 of GSR Part 1 but was added in GSR Part 1 Rev. 1 (DS462) as it constitutes one of the lessons learned from the Fukushima Daiichi NPP accident. The same amendment has also been introduced in a number of recommendations in the related subsection “GLOBAL NUCLEAR SAFETY REGIME” of the Draft Safety Guide DS486 “Establishing the Safety Infrastructure for a Nuclear Power Programme” (revision of SSG-16; latest version dated 3 September 2015).		4.49. becomes 4.48.	X	Ensure consistency with latest revision of GSR Part 1
Germany #14	4.50	Last bullet: “Regular multilateral and bilateral cooperation with relevant national <u>and international</u> organizations that to enhance safety by means of harmonized approaches as well as to increase the quality and effectiveness of safety reviews and inspections	Ensuring consistency with Para 3.2 (e) of GSR Part 1 Rev. 1 (latest version dated 27 June 2015; final editing after the 39 th NUSSC meeting), see http://www-ns.iaea.org/committees/files/NUSSC/1578/DS463GovernmentalLegalandRegulatoryFrameworkforSafetyGSRPart12010Rev.115-06-27.pdf	X	4.50. becomes 4.49.		Clarity and completeness

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		through <u>by means of sharing of</u> knowledge and <u>feedback of</u> experience sharing (e.g. by developing networks).”	Multilateral and bilateral cooperation cannot be restricted to national organizations, but includes international organizations, too.				
Japan #8	4.50./1	The regulatory body should, under agreements made by the government <u>or its policies</u> , take part in a range of international cooperation activities. Such activities-agreements include:	There are some activities that aren't carried out under “agreements made by the government” in those items described in this paragraph.		4.50. becomes 4.49.	X	The international cooperation is carried out solely as part of governmental agreements.
Finland #39	Para 4.69	The role and responsibilities of managers of a regulatory body may not differ essentially from roles and responsibilities of managers in other companies <u>organizations</u>	Replace companies → organizations	X			Makes sense.
CHAPTER 5							
Finland #45	p.38	There is a lot of repetition in Chapter 8, special in the three phases of the MS. For clarity, it is suggested to combine: RESPONSIBILITY AND RESOURCES FOR THE INTEGRATED MANAGEMENT SYSTEM and DEVELOPMENT PHASE OF AN INTEGRATED MANAGEMENT SYSTEM MAINTENANCE PHASE OF THE INTEGRATED MANAGEMENT SYSTEM and MEASUREMENT, ASSESSMENT, EVALUATION AND CONTINUOUS IMPROVEMENT	Decreases repetition and clarifies the text.		5.4. The development, implementation, maintenance and improvement of the integrated management system need substantial resources — human, financial, information, others. Senior management should ensure that these resources are made available. Old 5.4. was replaced. New 5.4. <u>The integrated management system should have arrangements in place to ensure that the regulatory body and its staff are not subject to undue influence by any interested party, especially authorized parties.</u> 5.67. becomes 5.5. 5.5. becomes 5.6. 5.6. becomes 5.7. 5.7. becomes 5.8. New 5.8. The development phase <u>of the integrated management system</u> can be divided in two stages. The first stage includes the identification and definition of the processes necessary for the regulatory body to discharge its responsibilities. The second stage <u>and</u> details and documents the content of each individual process in the context of the overall structure. 5.8. becomes 5.9. New 5.9. The implementation phase of the integrated management system involves rolling out the processes in a planned and		The sections of Chapter 5 were not combined, but were be revised for repetitions and clarity. Old 5.4. was deleted as it was stating the obvious without adding any value. Replaced with new text, in correlation with Russian Federation #1 For new 5.8: Additional IAEA modification for consistency with the way the next paragraphs are introducing their respective phases. Revised for repetitions and clarity.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
					<p>systematic way across the regulatory body. This includes training for the whole staff, selective training of users of specific processes and distribution and kick off the use of the integrated management system. Considering the availability of resources for the implementation, it is advisable not to implement the system as a whole, but to start with certain pilot processes and later complement them with the rest of the system. Coaching for certain users may be advisable.</p> <p>5.9. becomes 5.10. 5.10. becomes 5.11. 5.11. becomes 5.12. New 5.12. From in the very early phase of the development of the integrated management system, the regulatory body should designate a member of the staff with professional knowledge of integrated management systems as a “<u>management system manager</u>” to manage all activities concerning the integrated management system and to report to the corresponding senior <u>management staff member</u>.</p> <p>5.12. becomes 5.13. New 5.13. The regulatory body should use a project management approach for the development and implementation of the integrated management system. The regulatory body should <u>consider</u> assigning a project manager to lead a team including staff with knowledge of regulatory responsibilities, supported by internal or – if necessary – external expertise in integrated management system design. The project manager should have sufficient authority and should have direct access to the <u>senior management system manager responsible for the integrated management system</u>.</p> <p>...etc.... 5.59 becomes 5.60 5.60 was deleted.</p>		<p>Revised for repetitions and clarity.</p> <p>Revised for repetitions and clarity. IAEA additional revisiting of new 5.12. and new 5.13. to clarify roles and responsibilities in the framework of a project management approach. Supposing the use of a project manager working under the leadership of the MS manager. It is a proposed approach (“should consider”)</p>
Finland	p. 40	Addition to the end of the	An important check-point before			X	This is implicitly covered by the “project

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
#47		Development Phase: <i>When the development phase is ready, a gap-analysis should be done to compare the MS against the standard it was created. After that, a development programme should be launched to correspond the findings of the gap-analysis.</i>	implementing the MS.				management approach” mentioned in para 5.12. Section “Implementation phase” specifically addresses the progressive roll-out of the IMS (para 5.30-5.31)
Finland #50	Sub title page 43	Measurement and evaluation of integrated management system processes and behaviours	It would be good to organize the document in line with the chanced DS456 so that assessment of the management system and its improvement as well as the assessment of the safety culture of the regulatory body is presented as own topics.	X			Clarification.
Finland #40	Para 5.1	The requirements for establishing, implementing, assessing and continually improving an integrated management system, integrating safety, health, environmental, security, quality, societal and economic elements, are in the IAEA Safety Requirements no. GS-R-3 “The Management System for Facilities and Activities” DS456 “Leadership and management for Safety” [5]	The reference should be made to the new requirements document. The document is to be finished quite soon well before publishing this safety guide. Ref. 5 should be changed into DS456.		The requirements for establishing, implementing, assessing and continually improving an integrated management system, <u>which integrating integrates</u> safety, health, environmental, security, quality, societal and economic elements, are <u>established</u> in the IAEA Safety Requirements no. GS-R-3 “The Management System for Facilities and Activities” [5].		Correlation with DS456 will be pursued. Pending DS456 publication. Modifications made for clarity of text.
Finland #43	Para 5.1	Add reference to GSR Part 1 req. 19 and DS456	Addition		Matrix of GSR Part 1 requirements was added as a new appendix.		Pending publication of DS456.
Finland #41	Para 5.2	"The integrated management system of the regulatory body is a set of coherent processes and procedures to that control the fulfilment of the regulatory functions in an effective and efficient manner, considering all internal and external conditions. The processes of an integrated management system should coherently reflect all internal and external requirements, such as:"	Clarification.		"The integrated management system of the regulatory body <u>should integrate its organizational structure, resources and processes.</u> is a <u>A</u> set of coherent processes and procedures <u>should be used to help that control the fulfilment of the regulatory functions</u> in an effective and efficient manner, considering all internal and external conditions. The processes of an integrated management system should coherently reflect all internal and external requirements, such as:"		Clarification. Rewording to introduce a recommendation.
Finland #44	Para 5.2 and 5.9	These paras should be in line with DS456	Clarification		Add Human performance to the list @5.2. 5.9 remains unchanged.		Clarification.
Finland #42	Para 5.3	Senior management has the ultimate responsibility for the integrated management system, since this system is an essential tool to ensure: -Regulatory functions are carried out	Open and questioning attitude is includes in the strong safety culture.		Senior management <u>should</u> <u>have</u> the ultimate responsibility for the integrated management system, since this system is an essential tool to ensure: -Regulatory functions are carried out in an		Agreed, but we propose to merge last two lines in order to highlight the importance of the questioning attitude. Rewording in first sentence to introduce a

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		in an effective and efficient manner; -Regulatory responsibilities are adequately discharged; -Consistency and predictability of regulatory actions; -Continuous improvement; -Fostering a strong safety culture; -Promotion of an open and questioning attitude.			effective and efficient manner; -Regulatory responsibilities are adequately discharged; -Consistency and predictability of regulatory actions; - Continuous improvement; -Fostering a strong safety culture; <u>including</u> P promotion of an open and questioning attitude.		recommendation.
Finland #46	p. 39 Development phase	Addition: Therefore, the regulatory body should ensure that those people are <i>communicated</i> , consulted and involved in the development of the processes.	Communication about the development work is essential to inform people (and all staff may not be consulted during the process). If communication is done only as described in 5.31, it is a bit too late.		5.28. becomes 5.29. An integrated management system lives through requires the commitment of the people that fulfil tasks and responsibilities. Therefore, the regulatory body should ensure that those people <u>staff concerned</u> are consulted and involved		The first part of the phrase was changed for clarity. Editorial change only. It is implied that consultations cover information. Identification of staff concerned is an essential part of the development phase.
Finland #48	5.40	For consideration to combine this paragraph with the next paragraphs.	Measuring and performance indicators go hand-by-hand.		5.40. becomes 5.41.	X	5.39 and 5.40 address the means by which management can measure how the regulatory body performs and should stay under the same sub-section. 5.41 to 5.47 address the means by which the health of the IMS/processes is evaluated.
Germany #15	5.43	“Methods of self-assessment can include: ... – Comparison with international standards, such as those of the International Standards Organization (ISO 9001 [17], ISO 14001 [18]) or the IAEA safety standards.” Please add the ISO standards 9001:2008 and 14001:2004 to the list of references: “ [17] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Quality Management Systems: Requirements, ISO 9001:2008, ISO, Geneva (2008). ” “ [18] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Environmental Management Systems: Requirements with Guidance for Use, ISO 14001:2004, ISO, Geneva (2004). ”	Many standards according to which organizations and institutions let themselves be certified are ISO standards. Although they are not binding for the IAEA, comparison with ISO standards is a usual method of self-assessment. With regard to Ref. [17, 18], see Footnote No. 6 to Para 1.7 of the Draft Safety Requirements DS456 “Leadership and Management for Safety” (future GSR Part 2; latest version dated 16 June 2015).		5.43. becomes 5.44. Accepted in principle.		Placeholder pending publication of DS456. For the moment it is preferred not to insert specific examples.
Finland #49	5.45	Addition: -audit results	Very important for improvement actions.		5.45 becomes 5.46. : <u>Process owners should conduct periodic structured evaluations of integrated</u>		Clarification.

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					<u>management system processes in accordance with a graded approach</u> Periodic structured measurement and evaluation of integrated management system processes in a graded approach by process owners can be used to confirm that they are meeting operating as expected and delivering to expectations expected standards of efficiency and effectiveness. Mechanisms of measurement <u>Inputs to the evaluation should include, but are not limited to:</u> -Reviews of reported non-conformances to establish trends and any common problems...		
Finland #51	Para 5.46	Periodic surveys of staff attitudes and behaviours may be a valuable source of feedback on the state of the culture of the regulatory body.	This paragraph should be in context of the assessment of the safety culture. The structure of the guide should be in line with the revised DS456.		5.46. becomes 5.47. Modification of 5.46 was accepted, however the paragraph stays here.		It is part of the measurement and evaluation.
Finland #52	Para 5.51	Independent assessments should be conducted regularly on behalf of senior management in order to evaluate the efficiency and effectiveness of the regulatory body. Such independent assessments could assess: - The fulfilment of the regulatory mandate and the vision, mission policies, strategies, plans and objectives; - Governance, leadership, management and culture of the regulatory body; - The adequacy of resources provided to meet requirements, policies, strategies, plans and objectives ; and, - The effectiveness of regulatory activity in securing safe operation by authorized parties.	This is much more than independent assessment of the management system of the regulatory body. It should be considered whether the paragraph is suitable to this safety guide.		5.51. becomes 5.52. -“The effectiveness of regulatory activity in securing safe operation <u>of facilities and conduct of activities</u> by authorized parties”		To be consistent with terminology proposed in Chapter 1 (1.14).
Germany #16	5.53	1 st sentence: “External organizations may be used to review and evaluate the regulatory body’s leadership and integrated management system using services such as the IAEA Integrated Regulatory Review Service (IRRS) , peer review by other regulatory	Please introduce abbreviations before using them for the first time in the document.	X	5.53. becomes 5.54.		

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		bodies or by independent consultants, and international quality standards.”					
Self-identified issue	Para 5.60	Move this paragraph to a bullet (after current bullet 11)in paragraph 3.1: “-involvement in the resolution of difficult issues, including differences in professional opinions;	Better location for guidance	X	New bullet (after current bullet 11)in paragraph 3.1: “-involvement in the resolution of difficult issues, including differences in professional opinions; Paragraph 5.60 (old) was deleted.		Clarity. In conjunction with Finland #45
Finland #53	Para 5.64	"The documentation should be clear, understandable, <i>available</i> and flexible enough to accommodate changes..."	Documentation does not help if it is not available (thus, even in difficult circumstances arrangements should be considered).		For consistency, in 5.68 the second phrase begins as: "...This documentation <u>management system</u> should allow for storing and retrieving...."		Availability of documentation is addressed in paragraph 5.69.
Self-identified issue	Para 5.67	Move to after paragraph 5.3 and change to read: “Suitable checks and balances, challenge and redundancy within the system should ensure appropriate ‘defence in depth’ for processes with significant impact on regulatory effectiveness and safety. Independent review of important decisions may be appropriate in some cases.”	Clarity and better location for guidance	X	5.67. becomes 5.5. Suitable checks and balances, <u>as well as</u> challenge and redundancy within the integrated management system should ensure appropriate ‘defence in depth ² ’ for processes with significant impact on regulatory effectiveness and safety. Independent review of important decisions may be appropriate in some cases.		clarity
India #3	5.70	One more section may be added after 5.70 to mention, ' Proper handover of the records/documents from one process owner to other e.g. transfer of project stage to operation stage of the plant'	Important function of authorization		5.70. becomes 5.69.	X	Paragraphs 5.68 and 5.69 already address the integration of documents, processes and the responsible process owners.
CHAPTER 6							
Russian Federation #8	Item 6.4.	New text: "In addition to working in an appropriate legal framework and employing sufficient staff with suitable qualifications and expertise, the effectiveness of the regulatory body will also depend on the status of its staff in comparison with that of the staffs of both the authorized parties and the other organizations involved. Staff members of the regulatory body should be appointed at such grades and with such salaries and conditions	It is suggested that the Item 6.4 is to be completed with the following sentence: " <i>The compensation for the specialists of the regulatory authority must be commensurable with the compensation for the employees from the supervised organizations that are of the equal level of qualifications</i> ".			X	Appropriate salaries are already covered in the document – e.g. see last phrase of 6.4

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		of service as would facilitate their regulatory relationships and reinforce their authority. <i>The compensation for the specialists of the regulatory authority must be commensurable with the compensation for the employees from the supervised organizations that are of the equal level of qualifications</i> ".					
Finland #54	Para 6.5	"Regulatory staff should not engage in, or hold a financial <i>or any kind of</i> interest in, activities that may be the cause of a conflict of interest with the performance of regulatory functions."	There are also means for getting profit than just financial.		Regulatory staff should not engage in, or hold a financial <u>any kind of</u> interest in; activities that may be the cause of a conflict of interest with the performance of regulatory functions.		
Germany #17	6.8	1 st sentence: "The staffing needs are assessed based on the regulatory body's main <u>core</u> functions as listed in Chapter 4."	To be in line with the terminology used in Chapter 1 and Chapter 4 of this document, 'main functions' should be replaced by 'core functions'.	X	Also, for simplicity, "other" was removed from the second phrase (first part).		
Germany #18	6.9 Line 6	Staff assignments should be regularly reviewed to ensure that regulatory independence and objectivity is maintained in dealings with the authorized bodies <u>parties</u> .	Wording The term "authorized parties" is used throughout the document.	X			
Germany #19	6.13	2 nd sentence: "Useful guidance can be found in the Safety Reports Series 79 "Managing the Regulatory Body <u>Competence of the Regulatory body</u> " [11]."	This is the correct title of IAEA Safety Reports Series No. 79.	X			
Germany #20	6.15 hyphen 1 - 6	=Competence needs analysis; -o Task analysis leading to required competence; -o Gap analysis; -o Prioritization and choosing ways of filling gaps; = Human resources management; o Succession planning and recruitment; -o Management of organizational change (reallocation of duties within the organisation or replacement of staff members); -o Personal development plan; -o Personal performance review and assessment; = Training and development; o Establishment of training and development plans; -o Delivery of training and development activities; -o Evaluation of training and development activities.	Adapt the structure of paragraph 6.15 to the structure of paragraph 2.2 in SRS 79. Prioritization and choosing ways of filling gaps is not a part of the gap analysis, but the step coming after the gap analysis. Competence gaps can be filled by recruitment, training of the staff or by using external expert support (outsourcing of competence).		6.15. The competence management process may include the following typical sub-processes [11]: -Competence needs analysis; o Task analysis leading to required competence; o Analysis of existing competence o Gap analysis (Personal performance review and assessment); -Prioritization and choosing ways of filling gaps o Recruitment and Human resources planning; o Training and development; o Management of outsourcing (external expert support); -Knowledge capture and management; -Reviews and audits of competence management	An editorial change was made in the first sentence, for keeping only the number of the reference to SRS79. The proposed change was accepted with only the first two levels of detail (for the details, SRS79 is to be consulted).	

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		<p>= Management of outsourcing (external expert support); = Knowledge capture and management; = Reviews and audits of competence management and feedback.</p> <p>I. <u>Competence needs analysis;</u> 1) <u>Task analysis leading to required competence;</u> 2) <u>Analysis of existing competence</u> 3) <u>Gap analysis (Personal performance review and assessment);</u></p> <p>II. <u>Prioritization and choosing ways of filling gaps</u> 1) <u>Recruitment and Human resources planning;</u> a) <u>Succession planning and recruitment;</u> b) <u>Management of organizational change (reallocation of duties within the organisation or replacement of staff members);</u> c) <u>Personal development plan;</u> 2) <u>Training and development;</u> a) <u>Establishment of training and development plans;</u> b) <u>Delivery of training and development activities;</u> c) <u>Evaluation of training and development activities</u> 3) <u>Management of outsourcing (external expert support);</u></p> <p>III. <u>Knowledge capture and management;</u> IV. <u>Reviews and audits of competence management and feedback.</u></p>			and feedback.		
EC #2/1	6.21	6.21: “As the regulatory body matures, it should build its knowledge base so it can become more self-sufficient <i>if intended.</i> ”	6.21 states “As the regulatory body matures, it should build its knowledge base so it can become more self-sufficient.” and continues in 6.75 “A small and newly established regulatory body will need external expert support, whereas a large and experienced regulatory body may be self-sufficient.” This implies that all RBs should aim for self-sufficiency. This is very ambitious and apparently not policy of all MS (self-sufficiency vs intelligent customer in 6.13, A1.4). In particular, European countries have		6.21. A new The regulatory body should adopt or define a strategy to build the competence of its staff. In the early stages, the initial organizational structure could necessitate In particular a new regulatory body may need considerable reliance on other bodies external support for building its competence to provide technical expertise and advice. As the regulatory body matures, it should build its knowledge base so it can become more self-sufficient.		As part of the competence management, the strategy of building competence aims at a continuous improvement process.

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			strong dedicated TSOs and networks such as ETSO and well defined long lasting relations to (mandate) the respective RBs.				
Finland #55	Para 6.21	A new regulatory body should adopt or define a strategy to build the competence of its staff. In the early stages, the initial organizational structure could necessitate considerable reliance on other bodies to provide technical expertise and advice. As the regulatory body matures, it should build its knowledge base so it can become more self-sufficient. The regulatory body should define a strategy to build the competence of its staff. The strategy should include also the consideration of the competences acquired from external organizations and their ability to supply the needed independent support to the regulatory body.	The RBs use TSOs regardless the maturity of the RB stage. It is important that the RB defines what competences are needed in own organization and what competences or services are contracted.		6.21. [also in EC#2] A new The regulatory body should adopt or define a strategy to build the competence of its staff. In the early stages, the initial organizational structure could necessitate <u>In particular a new regulatory body may need considerable reliance on other bodies external support for building its competence to provide technical expertise and advice.</u> As the regulatory body matures, it should build its knowledge base so it can become more self-sufficient. Also, for clarity, in para 6.19 “for competence and staffing” was added at the end of the first phrase.		Agreed. Para 6.21 was revisited for clarity.
Armenia #2	6.39	6.39... They should possess a good working knowledge of the various regulations and guides applicable in their area of work, should have a strong understanding of the design and operation of the authorized facility or activity they are assessing and basic knowledge/experience in the field of safety assessment techniques (assumptions, modeling techniques, codes, etc.)....	Review and safety assessment function often requires from RB staff to deal with the safety submittals developed using specific codes and modeling techniques. It is important to assure that corresponding staff of RB has enough experience to cover specific nuances of safety analysis.		6.39... They should possess a good working knowledge of the various regulations and guides applicable in their area of work, and should have a strong understanding of the design and operation of the authorized facility or activity they are assessing <u>and basic knowledge/experience in the field of safety assessment techniques and tools.</u> Deleted last phrase.		Clarification.
Spain #10	6.40	Reference should be made to “independent judgment”				X	Independent judgement by the inspectors is appropriately covered in 6.40 (last phrase).
Finland #56	Para 6.42	Regulatory personnel should be able to review, assess and make independent judgements on the adequacy of on-site emergency arrangements and to evaluate emergency exercises. Regulatory personnel should also be able, directly in cooperation with relevant off-site authorities or indirectly through the coordinating mechanism, to assess the coordination and integration of on-	The first sentence is the oversight of the authorized party and it should be presented in DS473.		6.42. Regulatory personnel <u>working in this area should have the competence</u> be able to review, assess and make independent judgements in line with the appropriate regulations and independent of the authorized party on the adequacy of on-site emergency arrangements., and to evaluate the emergency exercises. and to evaluate some of its emergency exercises. Regulatory personnel should also be able, directly in cooperation with relevant off-site authorities or indirectly		Para was revisited for clarity regarding necessary competences of the RB in EPR. In line with DS473. Comment is also impacted by minor additions by the CC.

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		site emergency arrangements with those off- site. The regulatory body should have necessary arrangements (such as plan, procedures, exercise and training programmes, tools, communication means, equipment) to fulfil its assigned functions in emergency response including, where applicable, those for assessing the emergency situation and its potential development. The staff having duties in emergency response should have necessary qualifications, skills and training to perform their duties.			through the coordinating mechanism, to assess the coordination and integration of on-site emergency arrangements with those off-site. <u>The staff having duties in emergency preparedness and response should have necessary qualifications, skills and training to install establish and maintain</u> The regulatory body should have necessary arrangements (such as plan, procedures, exercise and training programmes, tools, communication means, equipment) to fulfil its <u>the functions assigned functions to the regulatory body</u> in emergency response including, where applicable, those for assessing the emergency situation and its potential development. The staff having duties in in emergency response should have necessary qualifications, skills and training to perform their duties.		
India #4	6.43	The sentence may be modified to read as "Among other things they should be able to talk effectively preferably in local language in small groups and with large audiences, to respond appropriately to questions..."	For better communication			X	The proposal reflects a particular national aspect and cannot be included in IAEA safety standards.
Japan #9	6.43/3-4 understanding potential sources of bias of people <u>the differences in risk perception among people</u> and delivering meaningful messages.	Better wording. This expression "potential sources of bias of people" has a negative impression. Such expression is not appropriate to be used in the field of (risk) communication. It is important to understand the differences and factors in risk perception, for better communication.			X	The specific expression "sources of bias" is relevant in the context and intention of the paragraph. The aim is to convey the message of effective, meaningful communication, unaffected by prejudice (unbiased).
Pakistan #2	6.46.	The regulatory body should be able to follow and conduct the research and development activities and to evaluate the quality and suitability of the results.	Some Research capability should be maintained as well within the regulatory body for ongoing activities considering experience feedback for resolving outstanding safety issues etc.			X	Research is not a core regulatory function, which would be required of the regulatory body to conduct. The scope of this safety guide covers only core regulatory functions, as described in GSR Part 1.
Germany #21	6.48 Line 1- 3	The regulatory body should have competence to decide which of its activities need support from external organizations (consultants, research institutes, dedicated support organizations, etc.) and to be able to set criteria for the service needed and to evaluate the outcome <u>being what is called "an intelligent customer"</u> which is described in Appendix 1.	Clarification Add a reference to Appendix 1		6.48. The regulatory body should have competence to decide which of its activities need support from external organizations (consultants, research institutes, dedicated support organizations, etc.) and to be able to set criteria for the service needed and <u>as well as</u> to evaluate the outcome, <u>being an "intelligent customer"</u> as described in <u>Appendix I.</u>		Minor editorial changes to the proposal, for phrase clarity and flow.
EC #1	6.50	Review proposed	DS472 refers to the need or use of experts (expertise in general) in all chapters of the document. Such expertise is generally			X	Covered under section "Competence Management".

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			understood as intrinsic part of the RB. In some places reference is also made to external expert support (6.48, 6.82 or appendix I). The similarities and links in the management and activities of <i>internal and external</i> expert support are not reflected. But this is a major aspect because expert groups in RBs can be small and therefore limited in scope and need collaboration and exchange. 6.50 describes collaboration of the RB with national and international organizations only in a general context.				
USA #4	Page 60, paragraph 6.61, line 2	Change “instil” to “instill”	editorial	X			
EC #2/2	6.75	6.21: “As the regulatory body matures, it should build its knowledge base so it can become more self-sufficient <i>if intended.</i> ” 6.75: “A small and newly established regulatory body will need external expert support, whereas a large and experienced regulatory body may be self-sufficient <i>if intended.</i> ”	6.21 states “As the regulatory body matures, it should build its knowledge base so it can become more self-sufficient.” and continues in 6.75 “A small and newly established regulatory body will need external expert support, whereas a large and experienced regulatory body may be self-sufficient.” This implies that all RBs should aim for self-sufficiency. This is very ambitious and apparently not policy of all MS (self-sufficiency vs intelligent customer in 6.13, A1.4). In particular, European countries have strong dedicated TSOs and networks such as ETSON and well defined long lasting relations to (mandate) the respective RBs.		6.75. <u>External support for training may be needed in particular by A small and newly established regulatory bodies.</u> y will need external expert support, whereas a large and experienced regulatory body may be self-sufficient.		There will always be a component of continuous improvement (especially in the area of training). However it is important to have in mind and explicitly mention the challenges of the newly formed regulatory bodies in this area.
Finland #57	Para. 6.82	If the regulatory body is not entirely self-sufficient in all the technical or functional areas necessary To discharge its responsibilities, it regulatory body should seek advice or expert opinion, as appropriate, from external experts as described in Appendix I.	TSOs and advisory bodies have a specific role independent of the self-sufficiency of the regulatory body.			X	The proposed change suggests that all regulatory bodies should implicitly seek external expert support to discharge their responsibilities, which is not in line with GSR Part 1.
Germany #22	6.82 Line 3	... external experts as described in Appendix I. <u>In this case the regulatory body should have the competence to evaluate the work of the external expert (Intelligent customer).</u>	If the regulatory body uses external expert support, it is essential for the regulatory body to have sufficient competence to evaluate the work delivered by the external expert. Consistency with GSG-4, Para 4.8	X			
APPENDIXES/ANNEXES							
Spain #11	A1.3	Please check paragraph. “Advisory bodies: many governments and regulatory bodies appoint external experts in the form of an advisory	Possible inconsistency with 4.36: Advisory committees should be distinguished from other forms of external expert support as <u>their role is not to deliver technical input</u> , but		Change first subtitle to: “PURPOSE AND RESPONSIBILITY FOR USING EXTERNAL EXPERT SUPPORT”		

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		committee. In some cases, the advisory body with provide technical advice to the regulatory body, while in other cases, the advisory body provides policy advice.”	is intended...		Replace first bullet with: “-Advisory committees: many governments and regulatory bodies appoint external experts in the form of an advisory committee to give advice on overall regulatory approaches and policies. -Expert panels: a regulatory body may appoint external experts to a panel to give advice on technical and/or policy issues.”		
Russian Federation #9	Item A1.7.	<u>New text:</u> <i>"The regulatory authority is fully responsible for the decisions made upon recommendations submitted by external expert organizations; that is why the selection of such organizations should be based solely on their competence and confidence placed by the regulatory authority".</i>	Item A1.7: it is suggested to amend this Item to read as follows: It is impermissible to select the safety experts on the grounds of market economy approaches.		Switch order of paragraphs A1.7 and A1.8 New paragraph after A1.16: “The regulatory authority should be fully responsible for the decisions made upon recommendations submitted by external expert organizations.”		Clarity and completeness
India #5	A1.10	There should be no conflicts of interest. In case of a potential or perceived conflict of interest, the situation should be discussed with all involved parties and managed; In addition, the regulatory body should take undertaking from the external expert	Prescribed forms are to be filled in by the experts as an undertaking to avoid conflict of interest.			X	The proposal is too detailed, but the general idea is already expressed in A1.9 and supplemented by section “Requirements to an external expert support organization” – Independence – in particular A1.21. Furthermore, DS472 is directly supporting GSR Part 1, and does not address recommendations to regulatory bodies to use external expert support.
India #6	A1.10	External experts support providers should be able to conduct their work within the time frame specified by the regulatory body. The time allowed for the work to be performed should be commensurate with the scope of the work and consistent with the time frame set by the regulatory body; on completion of the assigned work, a report should be submitted to the regulatory body.	The external experts should a report on completion of the assigned work.			X	Paragraphs A1.7 to A1.10 address the selection of external expert support. A task completion report is not the sole method of closing a task/contract.
Russian Federation #10	Item A1.18. para. 3	<u>New text:</u> "Verifying that the organizational structure of the provider of external expert support and its internal procedures <i>make it impossible to carry</i>	Item A1.18, para. 3: The words “provide functional and personal separation to ensure effective independence between units carrying out work for the regulatory body and units carrying out similar work for a licensee or other organization. The links between such			X	Proposal changes the meaning of the guidance.

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		<i>out the similar works for the regulatory authority and the licensee or for other organizations. This must be carefully monitored".</i>	units should be carefully monitored" are to be replaced with the following: "make it impossible to carry out the similar works for the regulatory authority and the licensee or for other organizations. This must be carefully monitored".				
EC #3	A1.28	Where the regulatory body uses a technical support organization or consulting company, the regulatory body should establish the requirements for the integrated management system <i>including arrangements for quality management</i> to be used.	External expert organizations (TSOs) have their own quality management system including self-assessment and peer reviews. In contrast to this a RB undergoes complex review and audit processes detailed in 2.6, 2.18, 4.37, 4.49, 5.16, 5.34, 5.38 and others. To avoid different "quality standards" for the same activity either carried out by experts from a RB or by external support groups A 1.28 establishes the requirements for the integrated management system to be used at the external support organization. A 1.28 might be the right place to point out explicitly additional requirements for the quality management system to be applied.		Replace second sentence with: "...while in other cases, the regulatory body should, through the contract, establish the requirements for the management system to be used."		Clarity
Spain #12	A2.3	It is suggested to delete the whole paragraph: "Records are generated when written instructions in procedures are followed. In other words, after data, information, or results are recorded onto a form, it becomes a record, in paper or electronic form."	<ol style="list-style-type: none"> 1. This description is incomplete and can be confusing. 2. A more accurate description of "record" is on A2.11. 3. There is no need to describe "record" on "DOCUMENT CONTROL" section 		Move paragraph A2.3 to just before A2.11 (Under the heading of Control of Records)		A2.3 provides clarity, but was in the wrong place.
Spain #13	A.2.11	Regulatory bodies need to keep extensive records of their work and their interactions with authorised and interested parties. This includes all the documents incoming documents as well as	Repetition	X			typo
Spain #14	CONTROL OF RECORDS A2.11 to A2.17	It is suggested to include a reference to digital records		X			By moving A2.3, this is addressed.
Japan #10	A2.20	The regulatory body should adopt a communication policy <i>strategy/plan</i> in order to promote effective sharing of information with all interested parties.	Making the description consistent with terminology or description of other relevant IAEA documents such as DS460.			X	The policy precedes the strategy/plan.
Japan #11	A2.21	The internal communications policy <i>plan</i> should promote sharing of relevant up-to-date information,	Making the description consistent with terminology or description of other relevant IAEA documents such as DS460.			X	The policy precedes the strategy/plan.
Germany #23	App. III, A3.1	Penultimate bullet: "Radioactive Waste management and	According to the IAEA Safety Glossary (2007 Edition), the term 'radioactive waste	X			Valid comment

COMMENTS BY REVIEWER: MEMBER STATES				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		<u>including</u> disposal”	management’ covers all administrative and operational activities involved in the handling, processing (i.e. pretreatment, treatment and conditioning), transport, storage and disposal of radioactive waste. This implies that disposal is included in the definition of this term.				
Japan #12	A3.1	Waste management and disposal	Unification of terminology to make it consistent with IAEA Glossary. According to the IAEA Radioactive Waste Management Glossary, "Waste management" includes "disposal."		Waste management and <u>including</u> disposal		See Germany comment #23

REFERENCES

USA #5	Page 106, reference [1]	EUROPEAN ATOMIC ENERGY COMMUNITY, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, INTERNATIONAL MARITIME ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Fundamental Safety Principles, IAEA Safety Standards Series No. SF-1, IAEA, Vienna (2006).	Recognize all of the sponsors; and provide consistency with bibliography references for other safety guides.	X			
USA #6	Page 106, reference [3]	EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).	Recognize all of the sponsors; and provide consistency with bibliography references for other safety guides.	X			

COMMENTS BY REVIEWER: MEMBER STATES				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
Germany #24	Ref. [9]	“INTERNATIONAL ATOMIC ENERGY AGENCY, Regulatory Body Functions and Processes <u>of the Regulatory Body for Safety</u> , DS473”	This is the current working title of the Draft Safety Guide DS473 (version dated 7 July 2015).	X			

The Secretariat has made an additional review of the DS472 draft, for language and text flow purposes.

For transparency, the 53 modifications are reflected in the table below. It is noted that the modifications do not affect the technical quality of the document.

Where paragraphs already addressed by Member State comment resolutions were impacted, the resolutions have been merged and marked accordingly in both tables.

COMMENTS BY REVIEWER: IAEA				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
IAEA# 1	1.10.	1.10. The core functions are those described in GSR Part1 [2] and GSR Part 7 [4]: <ul style="list-style-type: none"> – Development <u>and/or provision</u> of regulations and guides; – Notification and authorization, including licensing procedures; – Regulatory review and assessment; – Regulatory inspection; – Enforcement; – Emergency preparedness and response; – Communication and consultation with interested parties. 	Due to comments resolved, DS473 now uses the phrase “development and/or provision of regulations and guides”.	X			For increase of consistency with DS473; the new text is in line with GSR Part 1.
IAEA# 2	1.16.	1.16. The scope of this Safety Guide is limited to the regulation of radiation	No need to use this term as it was defined in the para above as “safety”.	X			

COMMENTS BY REVIEWER: IAEA				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		and nuclear safety and does not extend to nuclear security. ...					
IAEA# 3	1.17.	... Appendices I, II and III give more detailed guidance on the use of external expert support, examples of generic management processes and basic elements of a regulatory body training programme, <u>respectively</u> , while Annexes I and II provide an overview of the structure of an integrated management system and generic process descriptions <u>respectively</u> .	Language flow.	X			
IAEA# 4	2.1.	Preparing a set of organizational <u>regulatory</u> values helps to guide the behaviors of all staff to create a strong safety culture which is in line with the regulatory body's mission. ...	Including "regulatory" here would provide a link to the use of "regulatory values" at the beginning of the next sentence.	X			Implemented.
IAEA# 5	2.3.	Second sentence: The primary reason for this separation is to ensure that regulatory judgements can be made, and enforcement actions taken, without any <u>unwarranted</u> pressure from interests that may conflict with safety. Furthermore,	These "interests" have legitimate types of interaction with the regulatory body. This legitimate interaction with the regulatory body is explained and the word "unwarranted" is used in para 10 of INSAG-17 "Independence in regulatory decision making."	X			Implemented.
IAEA# 6	2.5.	GSR Part 1 [2] states that, in order "to be effectively independent from undue influences on its decision making, the regulatory body shall be free from any pressures associated with political circumstances or economic conditions, or pressures from government departments, authorized parties or	The quotation marks imply that this is a quote from GSR Part 1.	X			Implemented. Not a direct quotation.

COMMENTS BY REVIEWER: IAEA				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		other organizations ²² .					
IAEA# 7	2.8.	Where <u>several authorities have regulatory responsibilities for safety</u> are divided , the legislation should establish clear lines of authority and responsibility so as to avoid gaps or overlaps.	Reworded, as it was not clear what “are divided” means.	X			Implemented. Improves clarity.
IAEA# 8	2.15.	The regulatory body may decide to obtain technical or other expert professional advice or services, as necessary, in support of its regulatory functions on a temporary or permanent basis. It is essential to underline that advice obtained <u>should be</u> is independent, <u>free from conflicts of interest</u> and <u>should</u> it does not relieve the regulatory body of its assigned responsibilities. As further detailed in section “Provision of resources”, the regulatory body should acquire, manage, maintain and preserve knowledge and information for building and maintaining adequate core competencies. This should be performed in the frame of a coherent process within the regulatory body’s integrated management system; <u>this is</u> further addressed in Chapter 5 Integrated m Management s System, with the . <u>The objective should be</u> is to <u>be able to</u> make informed decisions as well as to obtain the necessary <u>competence</u> means to assess advice	Consider rewording to introduce a recommendation. This section is dealing with competence, was not sure what the reference to “means” meant?	X			

COMMENTS BY REVIEWER: IAEA				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		provided by advisory bodies and information submitted by authorized parties and applicants. The external expert support may be provided in several ways, as described in further details in Appendix I External support.					
IAEA# 9	2.17.	Add at the end: Communication and consultation with interested parties is addressed in detail in DS460 [12].	Address DS460 [Ref12]	X			Implemented.
IAEA# 10	2.18.	First sentence: A systematic program for professional reviews and audits of regulatory performance should be used is a useful tool to promote independence in decision making by the regulatory body.	Reword to introduce a recommendation.	X			Implemented.
IAEA# 11	2.20.	Every member of the regulatory body should exhibit a strong commitment to safety. This commitment can be achieved by developing and fostering a strong safety culture within the regulatory body as further described in section 3.2 Safety culture.	Reword to introduce a recommendation.	X			Implemented.
IAEA# 12	2.22.	While this responsibility of the regulatory body is defined by legislation, expectations of the public may go beyond legal requirements. In order to maintain its authority and credibility the regulatory body should establish and maintain arrangements for effective communication <u>and consultation</u> with the public.	Reference to consultation is missing	X			Implemented.
IAEA# 13	2.24.	Second sentence: A strong communication with all interested parties <u>should</u> enables the regulatory body to take into account all the different perspectives and	Reword to introduce a recommendation.	X			Implemented.

COMMENTS BY REVIEWER: IAEA				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		expectations and to consider them in the basis for establishing or modifying the regulatory framework.					
IAEA# 14	2.25.	The regulatory body should <u>ensure</u> assure that regulations and requirements are applied in a consistent, transparent, balanced and predictable manner.	Language.	X			Implemented.
IAEA# 15	2.28.	Last sentence: This process is covered <u>in Chapter 5</u> , in section Measurement, assessment, evaluation and continuous improvement.	Make it easier to find the section referred to.	X			Implemented.
IAEA# 16	3.1.	Third bullet: -Establishing and communicating a clear safety policy, vision, strategy, plans and objectives, whereby safety is paramount, overriding all other <u>priorities</u> ;	If true, how would the regulatory body apply the ALARA principle which requires economic and social factors to be taken into account (see GSR Part 4).	X			Implemented.
IAEA# 17	3.4.	Everyone in the regulatory body, from senior management down, should contribute to promoting and maintaining a strong safety culture, by adopting <u>specific</u> those behaviors as routine ways of working.	This appears to come from the shifting of paragraphs and no longer makes sense.	X	3.4. becomes 3.5.		Implemented.
IAEA# 18	3.15.	The regulatory body should be able to either develop its own budget or – in the case of strong dependency or national restrictions – to influence the budgetary conditions of the regulatory body's funding.	Delete, creates confusion (what dependencies?).	X	3.15. becomes 3.13.		Implemented.
IAEA# 19	3.18.	Where external expert support is used, <u>the regulatory body should ensure</u> special attention should be made that sufficient internal staff is available, having the capability to determine the need and extent for using external	Clarity or recommendation and rewording to introduce a recommendation.	X			Implemented.

COMMENTS BY REVIEWER: IAEA				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		expert support, as well as being able to evaluate the adequacy of information received from external expert support. Responsibilities for <u>fulfilling</u> core regulatory functions <u>should not</u> cannot be delegated. Details on staffing and the competence management of the Regulatory Body are described in Chapter 6 Staffing and Competence of Staff.					
IAEA# 20	3.20.	First bullet: -Capture and transfer: questionnaires, interview, informal discussions, reports (special attention <u>to the need for</u> the transfer of tacit knowledge in the case of retirements and leaves);	Language.	X			
IAEA# 21	3.21.	First phrase: An effective management for safety should take into account the knowledge and information <u>resulted</u> from both positive and negative experiences (e.g. good practices and less effective practices).	Language.	X			
IAEA# 22	4.1.	To meet its regulatory responsibilities, there are several core functions that a regulatory body should fulfil. These core functions are described in detail in DS 473 [9] and only a brief description is provided below for completeness.	Add reference number for DS473.	X			
IAEA# 23	4.7.	The objective of granting authorizations is for the regulatory body to exercise effective regulatory control throughout the lifetime of a facility or duration of an activity in relation to safety. The authorization process should require assurance that <u>by the applicant that it can fulfil its</u> comply with all safety requirements	For consistency with the modifications made to DS473, para 3.87.	X	4.7. becomes 4.9.		Implemented, for conciseness and correlation with DS473. Impacts Finland #23 Merged

COMMENTS BY REVIEWER: IAEA				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		obligations; demonstration of staff competence, where appropriate; and demonstration of safety by the applicant. These aspects should be subject to suitable review and assessment by the regulatory body before the authorization is issued. In the granting of an authorization for a facility or an activity, the regulatory body may have to impose limits, conditions and controls on the authorized party's subsequent activities.					
IAEA# 24	4.10.	Requirement 25 of GSR Part 1 [2] <u>requires that</u> “The regulatory body <u>shall</u> reviews and assesses relevant information - whether submitted by the authorized party or the vendor, compiled by the regulatory body, or obtained from elsewhere - to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization. This review and assessment of information shall <u>ould</u> be performed prior to authorization and <u>again over</u> during the lifetime of the facility or the duration of the activity, as specified in regulations promulgated by the regulatory body or in the authorization.”	For consistency with DS473, para 3.145 and also for consistency with DS472 para 4.12 when introducing inspection.	X			
IAEA# 25	4.11.	The review and assessment process is a critical appraisal, performed by the regulatory body, of information submitted by the authorized party or which comes from inspection, feedback of operating experience nationally and internationally, and information on events, <u>feedback of operational experience at national and international level</u> or other specified reports (e.g. records, comprehensive Periodic Safety Reviews , <u>dose records</u> monthly and annual reports, etc.) to demonstrate the safety of the facility or activity. Review and assessment are undertaken in order to enable the regulatory body to make a	Rephrasing, to ensure consistency with DS473, para 3.146.	X			

COMMENTS BY REVIEWER: IAEA				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		decision or series of decisions on the acceptability of the facility or activity in terms of safety. The process consists of examining the authorized party's submissions on all aspects relating to the safety of the facility or activity.- The review and assessment process should include checks on the site and elsewhere to validate the claims made in the submissions.					
IAEA# 26	4.14.	Last phrase: These inspections may include, within reason , unannounced inspections.	For consistency with modified DS473, para 3.206.	X			
IAEA# 27	4.17.	The principal objectives of enforcement <u>should be (in conjunction with inspections)</u> are to provide a high level of assurance that <u>the authorized party all activities performed by the authorized party</u> at all stages of the authorization process and all stages during the lifetime of a facility (i.e. siting, design, construction, commissioning, operation and decommissioning or closure) or the duration of an activity <u>complies with all safety requirements and meets the safety objectives and authorization conditions, and promptly identifies and corrects non-compliances with safety requirements, have been executed safely and meet the safety objectives and authorization conditions.</u>	For consistency with DS473, par 3.289.	X			Merged with Germany #8
IAEA# 28	4.23.	Add at the end: Further details on communication and consultation with interested parties can be found in DS460[12].	Address DS460 [Ref12]	X	4.23. becomes 4.22.		
IAEA# 29	4.39.	Third phrase: Any advisory committee member, who might have a conflict of interest on any subject under discussion, should be disqualified <u>from that discussion</u> .	This shouldn't suggest permanent disqualification, it is not needed; adequate rotation according to conflicts of interests can be ensured.	X	4.39. becomes 4.38.		Merged with Finland #36
IAEA# 30	4.46.	First phrase: Where the responsibilities of the regulatory body and other organizations interact or have an interface, liaison between these bodies should be established by means of a	For consistency with use earlier in the sentence.	X	4.46. becomes 4.45.		

COMMENTS BY REVIEWER: IAEA				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		formal agreement specifying each body's organization's responsibilities, the areas of interface and the means of resolving any conflicts between different requirements.					
IAEA# 31	4.58.	The regulatory body should ensure that the different parts of its organisation have a clear delineation of their specific responsibilities. The organisational structure of the regulatory body may be based e.g. according to regulatory functions (<u>e.g.</u> a process-based organization), according the technical areas to be covered (<u>e.g. in a line-organization</u>), according the facilities and activities to be oversight or a mixture of these (e.g. in a matrix organization or project organization). Nevertheless, <u>whichever organizational structure is employed</u> , it should allow for the integration and interaction of among the various technical and administrative units <u>involved in the implementing ation of the activities associated with the core and supporting functions.</u>	Rephrasing. For clarity.	X	4.58. becomes 4.57.		
IAEA# 32	4.59.	Regardless of the selected structure, attention should be paid to the distribution of expertise and required competences in organisational units. However, it should be emphasized that the regulatory body <u>should</u> uses an interdisciplinary approach to the oversight concept, enabling the regulatory body to implement a systemic approach and adequately consider all aspects relevant to safety with an integrated view to HTO and their interactions.	Is this a recommendation or an observation? It is not clear. If it is to be a recommendation, it should be reworded.	X	4.59. becomes 4.58.		
IAEA# 33	4.61.	In accordance with the organizational structure, The roles, responsibilities, interfaces and communication <u>between ways of</u> organizational units, managers and staff should be clearly defined and assigned, <u>in accordance with the organizational structure</u> , to allow for the effective and efficient implementation of the core and	For clarification, what aspect of “managers and staff should be clearly defined”? Their position in the structure? Their role? Their responsibilities?	X			Clarity was improved by moving first part of phrase to the middle.

COMMENTS BY REVIEWER: IAEA				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		supporting functions.					
IAEA# 34	4.66.	Senior management should be is responsible for the establishment, maintenance and change of an appropriately structured and staffed regulatory body with sufficient competence to fulfil the regulatory functions as well as for the development, implementation, maintenance and review of an effective integrated management system.	Reword to introduce a recommendation.	X			
IAEA# 35	4.67.	Second bullet: All m Managers communicate effectively...	For consistency with bullets 1 and 3.	X			
IAEA# 36	4.68.	In supporting to the implementation of the plans for the achievement of the regulatory body's objectives, senior management should ensure that the essential resources are identified and made available.	Language.	X			
IAEA# 37	5.1.	The requirements for establishing, implementing, assessing and continually improving an integrated management system which ; integrates ing safety, health, environmental, security, quality, societal and economic elements, are <u>established</u> in the IAEA Safety Requirements no. GS-R-3 "The Management System for Facilities and Activities" [5].	For clarity of text.	X			Merged with Finland #40
IAEA# 38	5.2.	The integrated management system of the regulatory body <u>should</u> integrates its organizational structure, resources and processes. A set of coherent processes and procedures <u>should be</u> is used to help fulfil the regulatory functions in an effective and efficient manner, considering all internal and external conditions.	Reword to introduce a recommendation.	X			Merged with Finland #41
IAEA# 39	5.3.	Senior management <u>should have</u> has the ultimate responsibility for the integrated management system, since this system is an essential tool to ensure:	Reword to introduce a recommendation.	X			Merged with Finland #42
IAEA# 40	5.5.	Suitable checks and balances, <u>as well</u> as challenge and redundancy within the integrated management system should ensure appropriate 'defence in depth'	Language flow. The use of the inverted commas implies some	X			

COMMENTS BY REVIEWER: IAEA				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		for processes with significant impact on regulatory effectiveness and safety. Independent review of important decisions may be appropriate in some cases.	other understanding of the term “defence in depth”. It might be better for understanding to explain rather than imply.				
IAEA# 41	5.5.	The development, implementation, maintenance and improvement of the integrated management system need substantial resources – human, financial, information, others.	Consider deleting as it is stating the obvious and adds no value.	X			
IAEA# 42	5.6.	For the continuous improvement of the integrated management system, the effectiveness of the processes should be regularly evaluated against preset criteria. Processes that do not meet these criteria should be corrected (e.g. plan, do, check, <u>and</u> act).	Language.	X	5.5. becomes 5.6.		
IAEA# 43	5.7.	The development phase <u>of the integrated management system</u> includes the identification and definition of the processes necessary for the regulatory body to discharge its responsibilities and details and documents the content of each individual process in the context of the overall structure.	For consistency with the way the paras below introduce their respective phases.	X	5.7. becomes 5.8.		Merged with Finland #45
IAEA# 44	5.11.	From the very early phase of the development of the integrated management system, the regulatory body should designate a member of the staff with professional knowledge of integrated management systems as a “management system manager” to manage all activities concerning the integrated management system and to report to the corresponding senior <u>management</u> .	Senior who/what?	X	5.11. becomes 5.12.		Merged with Finland #45
IAEA# 45	5.12.	The regulatory body should use a project management approach for the development and implementation of the integrated management system. The regulatory body should assign a <u>project manager</u> the management-system manager to lead a team including staff with knowledge of regulatory responsibilities, supported by internal or – if necessary – external expertise in integrated management	First time that this person has been mentioned. It appears to be a different role to the “management system manager” It is also noted that this person reports to a senior manager, and not the “management system manager”? Is this bypass intended?	X	5.12. becomes 5.13.		Revisiting of 5.13 and 5.14 together, to clarify roles and responsibilities, in the framework of a project management approach. Supposing the use of a project manager working under the leadership of the MS manager. It is a proposed approach (should consider...) Merged with Finland #45

COMMENTS BY REVIEWER: IAEA				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		system design. The project manager should have sufficient authority and should have direct access to the senior management system manager-responsible for the integrated-management system.					
IAEA# 46	5.15.	Third phrase: It is therefore essential that senior management <u>should</u> retain oversight of process development, maintenance and implementation and <u>should</u> take action to ensure that processes are fit for purpose (e.g. it is compatible with current priorities and resources) and effectively implemented.	Reword to introduce a recommendation.	X	5.15. becomes 5.16.		
IAEA# 47	5.17.	To support this <u>organizational</u> responsible audit entity, the regulatory body should appoint and train a group of suitable individuals from different parts of the regulatory body to form a pool of auditors from which audit teams can be assembled for specific audits.	For consistency, using the term that identified this entity from the previous para.	X	5.17. becomes 5.18.		
IAEA# 48	5.26.	Second bullet: -Core processes - derived from the core functions, which relate directly to the discharge of the regulatory responsibilities such as authorization, review and assessment of facilities and activities, inspection and enforcement, emergency preparedness and response (for more details on the core functions see DS 473 [409]); and,	Correction of reference number.	X	5.26. becomes 5.27.		
IAEA# 49	5.32.	First phrase: During the rollout, the process owner <u>should</u> play a central role.	Reword to introduce a recommendation.	X	5.32. becomes 5.33.		
IAEA# 50	5.34.	Opportunities for improvements in the integrated management system, as well as improvements to the efficient and effective discharge of the regulatory body's work, should be identified and actions to improve processes and the regulator's effectiveness and efficiency should be selected, planned, <u>implemented, adequately</u> resourced and recorded. This phase includes audit, evaluation, process review and update, including system	First proposal is for completion of information. Reword to introduce a recommendation.	X	5.34. becomes 5.35.		

COMMENTS BY REVIEWER: IAEA				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		documentation and procedures. In this phase again, the process owner <u>should</u> play a central role.					
IAEA# 51	5.36.	To achieve sustained success, managers at all levels should monitor, measure, <u>and</u> review performance as a basis of:	Flow of text.	X	5.36. becomes 5.37.		
IAEA# 52	5.59.	The regulatory body should take necessary preventive actions to identify and eliminate potential non-conformances that <u>could</u> negatively could affect the regulatory work.	Flow of text.	X	5.59. becomes 5.60.		
IAEA# 53	6.11.	Second phrase: In any event, the regulatory body should have sufficient numbers of staff with the basic <u>knowledge, skills and attributes</u> necessary to operate the regulatory system without depending on the immediate availability of external expert support.	For consistency with SRS-79	X			

Under Step 10 – Second internal review of the draft publication, the Coordination Committee has made an additional review of the DS472 draft, for language and text flow purposes. For transparency, the 6 modifications are reflected in the table below. It is noted that the modifications do not affect the technical quality of the document, but provide further details and clarity in certain aspects addressed by the draft, and update references. Where paragraphs already addressed by Member State comment resolutions were impacted, the resolutions have been merged and marked accordingly in both tables.

COMMENTS BY REVIEWER: COORDINATION COMMITTEE (CC)				RESOLUTION			
Comment No.	Para/Line no.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
CC#1	4.19.	The roles and responsibilities in emergency preparedness and response (EPR) are to be allocated among authorized party, response organization and the regulatory body. While certain roles and responsibilities in emergency preparedness and response are valid for any regulatory body (<u>for example, those addressed in paras. 4.10-4.15 and 6.30 of GSR Part 7</u>), the government may assign the regulatory body additional roles and responsibilities in emergency preparedness and response but their precise nature will depend on	Modification originating from CC				

		the specific legal and organisational arrangements in the Member State. In the following text, therefore, it is only possible to identify the necessary functions and processes that the regulatory body should perform, in relation to these roles and responsibilities, in a generic manner.					
CC#2	Para 6.42	Regulatory personnel should be able to review, assess and make independent judgements on the adequacy of on-site emergency arrangements and to evaluate emergency exercises. Regulatory personnel should also be able, directly in cooperation with relevant off-site authorities or indirectly through the coordinating mechanism, to assess the coordination and integration of on-site emergency arrangements with those off-site. The regulatory body should have necessary arrangements (such as plan, procedures, exercise and training programmes, tools, communication means, equipment) to fulfil its assigned functions in emergency response including, where applicable, those for assessing the emergency situation and its potential development. The staff having duties in emergency response should have necessary qualifications, skills and training to perform their duties.	The first sentence is the oversight of the authorized party and it should be presented in DS473.		6.42. Regulatory personnel <u>working in this area should have the competence</u> be able to review, assess and make independent judgements in line with the appropriate regulations and independent of the authorized party on the adequacy of on-site emergency arrangements., and to evaluate the emergency exercises. <u>and to evaluate some of its emergency exercises.</u> Regulatory personnel should also be able, directly in cooperation with relevant off-site authorities or indirectly through the coordinating mechanism, to assess the coordination and integration of on-site emergency arrangements with those off-site. <u>The staff having duties in emergency preparedness and response should have necessary qualifications, skills and training to</u> install establish and maintain <u>The</u> regulatory body should have necessary arrangements (such as plan, procedures, exercise and training programmes, tools, communication means, equipment) to fulfil its <u>the functions</u> assigned functions to the regulatory body in emergency response including, where applicable, those for assessing the emergency situation and its potential development. The staff having duties in in emergency response should have necessary qualifications, skills and training to perform their duties.		Para was revisited for clarity regarding necessary competences of the RB in EPR. In line with DS473. CC comment impacts Finland#56.
CC#3	A1.30.	The organization providing external expert support may have to address two <u>several</u> types of confidential information: nuclear security related <u>sensitive information</u> , or protected information, and proprietary information.	Modification originating from CC				
CC#4	Section sub-title	Nuclear security related <u>sensitive information</u> or protected information	Modification originating from CC				
CC#5	A1.31.	In most States, the management of nuclear security related confidential <u>sensitive</u> information is controlled at	Modification originating from CC				

		the government level, and the verification of the trustworthiness of every organization and individual requiring access to this information is required. Such information can only be transmitted to any provider of external expert support (or its subcontractors) in accordance with relevant government requirements.					
CC#6	Reference 4	<u>FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL CIVIL AVIATION ORGANIZATION, INTERNATIONAL LABOUR ORGANIZATION, INTERNATIONAL MARITIME ORGANIZATION, INTERPOL, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, PREPARATORY COMMISSION FOR THE COMPREHENSIVE NUCLEAR-TEST-BAN TREATY ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, UNITED NATIONS OFFICE FOR THE CO-ORDINATION OF HUMANITARIAN AFFAIRS, WORLD HEALTH ORGANIZATION, WORLD METEOROLOGICAL ORGANIZATION, Preparedness and Response for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GSR Part 7, IAEA, Vienna (2015)-INTERNATIONAL ATOMIC ENERGY AGENCY, Preparedness and Response for a Nuclear or Radiological Emergency, GSR Part 7 (approved by BoG 2015)</u>	Modification originating from CC				