DS472 ORGANIZATION, MANAGEMENT AND STAFFING OF A REGULATORY BODY FOR SAFETY, STEP 11, Draft April 2017

COMMENTS BY REVIEWER Reviewer: M-L. Järvinen, R. Bly.. All Committees Page.... of.... Country/Organization: STUK Date: 10th May 2017				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1.	1.3	This Safety Guide has been developed in parallel with the Safety Guide on Functions and Processes of the Regulatory Body for Safety, IAEA Safety Standards Series No. DS473 [4], which covers the technical and human and organizational aspects of the core functions of the regulatory body and the processes by which they are discharged. It is strongly recommended that this Safety Guide and DS473 [4] be read in conjunction with one another. Additional feedback: Please add a footnote *) the technical aspects include technical and human and organizational aspects	Add: technical and human and organizational a Not only the technical aspect are covered.		Footnote to "technical" aspects: *) includes human, technical and organizational aspects		From the point of view of DS473, HTO is a technical area pertaining to regulatory oversight and any other program, therefore it is not needed to be specified separately. The IAEA uses the HTO terminology in a specific context (factors to be taken into account in the regulatory oversight of safety). We agree – please see footnote text in the central column.
2.	2.1.	… – A questioning attitude, whereby opportunities for safety enhancement is sought and as needed regulatory decisions are challenged and examined. Additional feedback:	Please rephrase: Open minded environment is important through the impression that all the regulatory decisions are challenged			X	The questioning attitude is distinctly mentioned in GSR Part 2, together with a learning attitude, to discourage

		The questioning attitude should not be focus to a specific issue. As mentioned in the IAEA comment a learning attitude, to discourage complacency with regard to safety is important. Our understanding is that our comment is in line with GSR Part 2. It is proposed that the end of the sentence is deleted. New proposal is - A questioning attitude, ~~whereby regulatory decisions are challenged and examined.~~	is misleading.	X			complacency with regard to safety; we do not believe this is misleading.
3.	2.2.	The regulatory body should apply a systemic approach[5] so that it can effectively perform its functions [10].	Please complete the sentence; Systematic approach to oversight or safety?			X	Not needed. GSR Part 2 also uses the same expression.
4.	2.25	Regulations and guides should be clear and unambiguous, and should be written in a manner that can be clearly understood by authorized parties.	There are two very different ideas in para. 2.25. Please divide the paragraph for two separate. This would be useful from the requirements management point of view.	X			
5.	2.25 a	Effective communication with interested parties will help ensure that the regulatory body takes account of different	There are two very different ideas in para. 2.25. Please divide the paragraph for two	X			

		perspectives when establishing or modifying the regulatory framework.	separate. This would be useful from the requirements management point of view.				
6.	2.26.	The regulatory body should ensure that regulations and requirements are applied in a consistent, predictable, transparent, balanced and in a manner graded to the risk raised by the facility or activity. The regulatory body should establish policies to promote ~~proportionality~~ graded approach, transparency and consistency, and the broad sharing of information and ideas, to help ensure the highest standards of protection and safety. Transparency and openness towards the general public also enhances confidence and trust in the regulatory body.	Please rephrase and use the terminology in SF-1 and safety requirements.		The regulatory body should ensure that regulations and requirements are applied in a consistent, predictable, transparent~~,~~ and balanced manner, commensurate with the radiation risks associated with the facilities and activities. The regulatory body should establish policies to promote ~~proportionality~~ use of a graded approach, transparency and consistency, and….		
7.	3.1.	Senior management, managers and leaders at all levels of the regulatory body should demonstrate by their own behaviour consistent adherence to the values of the regulatory body. This should typically include the following: – Promoting a systemic approach to safety that embraces interactions between all human, technological and organizational	Please rephrase suitable for the regulatory body. to ensure that decision making at all levels is driven by the safety requirements and safety goals stated in regulatory framework; Please clarify the content		Footnote: Depicts different types of crisis situations that might have an impact on the regulatory body's capability to perform its functions.		The proposed modification changes the meaning. The intention is to highlight that the regulatory decisions re guided by safety requirements and safety goals The term Crisis management has been

		factors; – Developing shared values for safety, establishing behavioural expectations so as to shape a strong safety culture, and encouraging acceptance of personal responsibility for safety among all individuals; – Establishing and communicating a clear vision for safety, which is elaborated through a safety policy, strategy, plans and objectives, whereby safety is paramount; – Ensuring that responsibilities and accountabilities are in line with policies, strategies and objectives, to ensure that decision making at all levels is driven by the safety requirements and safety goals stated in regulatory framework; – Effectively communicating the regulatory body's vision, strategy, plans and objectives; – Encouraging the involvement of all individuals in the regulatory body in the implementation and continuous improvement of the regulatory body's vision, strategy, plans and objectives; – Developing and maintaining leadership capabilities at all levels in the regulatory body, including capabilities for competence management, change management and crisis management; – Encouraging open communication and seeking feedback on how effective leadership in the regulatory	of crisis management! Is this referring to the Emergency preparedness or managing different types of crisis situations having impact of the regulators capability to perform its functions.				used to suggest/depict a process by which an organization deals with a sudden threatening situation. Not EPR. OK to insert footnote – see text proposed by Technical Editorial review.

		body is in ensuring and improving safety, and taking action as necessary; – Supporting and encouraging staff to focus on safety and including them in the regulatory decision making process; – Demonstrating a commitment to 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; – Fostering and encouraging the involvement of all individuals in the regulatory body in the implementation and continuous improvement of the integrated management system and encouraging a readiness to challenge acts or conditions that are inconsistent with the values of the regulatory body; Additional feedback: IAEA justification is fine and that should be used in the text. New proposal for the first to ensure that regulatory decisions are guided by safety requirements and goals Second comment on crisis management:					

		Please add a foot note to crisis management foot note crisis management has been used to suggest/depict a process by which an organization deals with a sudden threatening situation. This includes e.g. contingency planning, crisis communication, emergency preparedness etc.					
8.	3.4	A strong safety culture does not grow by itself and it needs to be fostered and sustained. The behaviour and commitment of leaders to safety influences the attitudes and behaviours of individuals. Therefore, a strong safety culture needs the strong commitment and engagement of senior management, with the support of the integrated management system. Additional feedback: IAEA justification is exactly what is proposed. The safety culture needs to be fostered and sustained. New proposal A strong safety culture does not grow by itself, but it needs to be fostered and sustained.	Replace but by needs to The "but" indicates a contrariness/discrepancy. What is the actual meaning of the phrase? Is it: A strong safety culture does not grow by itself, it needs to be fostered and sustained?		3.4. A strong safety culture does not grow by itself~~, but~~; it ~~can~~ should be fostered and sustained.		See Technical Editorial modification; safety standards language, avoids ambiguities.
9.	3.6.	A strong safety culture of a regulatory body has the following important attributes: – Safety is a clearly recognized value; – Leadership for safety is clear;	Licensee has the prime responsibility of safety. Please rephrase: The role of the regulator	X		X	The attributes or safety culture are applicable to both regulator and operator and are defined in GSR Part

		– Accountability for safety is clear; The prime responsibility of safety is on the licensee; The role for the regulator in ensuring safety is clear; – Safety is integrated into all activities; – Safety is learning driven.	should be understood.				2. There is no need to alter the attributes.
10.	3.7.	Attitudes and behaviors that support a strong safety culture in the regulatory body include the following: – Individual and collective commitment to safety; – Understanding the personal contribution // regulatory impact to safety; – An open attitude that encourages trust, collaboration and free communication, and that values the reporting of problems; – The prompt acknowledgement of and feedback regarding identified problems and suggestions for improvement; – Continuously seeking to develop and improve safety and safety culture by regulations – Encouraging a questioning and learning attitude and discouraging complacency at all levels in the regulatory body with regard to safety; – A common understanding of the key aspects of safety and safety culture within the regulatory body; – An awareness of the potential	Replace. understanding the personal contribution // regulatory impact to safety or Acceptance of personal responsibility for behaving in a manner that promotes safety; The licensee has the prime responsibility for safety and the regulator has different role that should be presented Continuous seeking to develop and improve safety is for the licensee. or is it meant to be ? : Continuously seeking to develop and improve safety and safety culture by regulations		Acceptance by individuals of personal ~~responsibility~~ accountability for their attitudes and conduct with regard to safety	X X	We agree with the concept, but understanding is not an attitude or behavior. Propose to use GSR Part 2 para 5.2. (b) The bullet refers to developing and improving safety and safety culture "in the regulatory body", as suggested by the beginning of the umbrella-phrase. Where directed at authorized parties, statements clearly indicate this. Improvement of SC should be done by various means, including regulatory body staff attitudes, behavior and

		consequences of regulatory activities, including risks and hazards associated with them; – Ensuring that all factors that might impact upon safety are taken into account in the regulatory decision making process and other regulatory activities. Additional feedback: Please use the alternative given Acceptance of personal responsibility for behaving in a manner that promotes safety;					actions and the relevant regulatory framework.
11.	3.11	The State should provide for independent oversight 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 and the appointment of an independent auditor. Such arrangements could also provide independent oversight and governance of the appeals process against regulatory decisions and actions. Further accountability can be achieved by establishing a direct reporting line from the regulatory body to the highest levels of government. Peer review systems, at national and international levels, can also provide a useful input into	This should be in line with Table A-4 Please clarify and structure. The version 2015 was better. The State should provide for independent oversight of the regulatory body and its key decisions. This is a clear guidance. However the elemnt below at 3.11. are a mixture of different types of activities. There arerequirements for good governance that are generally written in nationalconstitutional and governance laws and every public authority is expected		The State should provide for independent oversight of the regulatory body and its key decisions, depending on the national legal framework. This may be achieved in a number of different ways, for example …		Please see proposed modification that we believe addresses the concern.

		demonstrating accountability. The need for accountability should not compromise the regulatory body's independence in making decisions relating to safety. Additional feedback: Restructuring the paragraph is recommended. The State should provide for independent oversight of the regulatory body and its key decisions. The need for accountability should not compromise the regulatory body's independence in making decisions relating to safety. <u>The national practices may wary depending of the national legislation and practices.</u> This may be achieved in a number of different ways, such as - by appearing before legislative committees, - referral of decisions to courts of law and - the appointment of an independent auditor - the appeals process against regulatory decisions and actions. - establishing a direct - reporting line from the regulatory body to the highest levels of government. - peer review systems, at national and international levels, can also provide a useful input into demonstrating accountability.	to follow these regulations. 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 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….				

12.	3.19.	Information and knowledge are part of the corporate memory of the regulatory body and should be managed as a key resource that is embedded in the regulatory body's processes, activities and functions (see Table A-19 in the Annex). Effective management for safety will take into account the knowledge and information resulting from both positive and negative experiences (e.g. good practices and bad practices). Examples of information and knowledge relevant for regulatory bodies include the following: – The collective experience of the staff of the regulatory body <u>such as decisions, memorandums, regulations etc.;</u> – Technical expertise; – Lessons learned from regulatory practices, e.g. techniques of assessment and inspection; – Feedback from interested parties; – Feedback of experience from other authorities and national and international bodies; – Operating experience in authorized facilities and activities in the State and in other States.	clarity please add such as decisions, memorandums, regulations etc.			X	The addition proposed are elements of the collective experience but we intend to keep the information at high level in order not to miss relevant aspects.
13.	4.3.	In addition, ~~management~~ <u>support</u> functions are necessary to enable the regulatory body to sustain an efficient and effective organization with sufficient competent staff.	terminology in line with 4.2.			X	The functions are: core, support and management. This terminology is used throughout the document.

14.	4.25.	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, purchasing and control of equipment); – Technical, human and organizational functions directly relating to the effective implementation and fulfilment of the core regulatory functions (e.g. legal support, research and development, the functions of advisory committees, external expert support, liaison with other governmental organizations, international cooperation and assistance). Additional feedback: foot note 1, see comment 1.	Please add: the human and organizational aspect			X	HTO is a technical area pertaining to regulatory oversight and any other program, therefore it is not needed to be specified separately. The IAEA uses the HTO terminology in a specific context (factors to be taken into account in the regulatory oversight of safety), while the current context relates to the technical aspects of the regulatory core functions. Footnotes are placed once.
15.	**Technical functions**	**Technical, human and organizational functions** Additional feedback: **see comment 1.**	Add. **human and organizational functions**			X	There is no regulatory function related to HTO.
16.	4.30.	Since legal support is embedded in many activities of the regulatory body, the regulatory body should- ~~establish processes describing how to~~ ensure that the results of a legal review are documented, as well as the criteria for the acceptance or rejection of recommendations from experts providing legal support.	As the legal support is embedded in many activities there is no need to establish a separate process.			X	Legal support is a separate process with many interfaces, as suggested by the text. The focus should be of establishing the

		Additional feedback: IAEA should not define what kind of processes the RB has. This could be a function as well. Please add foot note foot note legal support may be a separate processes depending on the national approach					process and documenting its criteria and results. Keep original text.
17.	4.37.	Advisory committees should advise the regulatory body on: – How effectively the regulatory body performs its regulatory responsibilities and functions; – The adequacy of its regulations and guides, and procedures for such regulations and guides; – Existing and proposed safety standards, and technical, human and organizational as well as policy issues relating to the authorization of facilities and activities; – Other matters referred to the committee by the regulatory body. Additional feedback: see comment 1.	Please add human and organizational issues			X	HTO is a technical area pertaining to regulatory oversight and any other program, therefore it is not needed to be specified separately. The IAEA uses the HTO terminology in a specific context (factors to be taken into account in the regulatory oversight of safety). See footnote in comment 1.
18.	4.55.	In order for the regulatory body to discharge its responsibilities and perform its functions effectively, it may be appropriate to establish an organizational structure that is flexible and adaptable to different circumstances and demands. Depending on the national circumstances and in accordance	Please add: Other organizations such as inspection organizations			X	Covered by “other existing regulatory authorities” in IAEA terminology.

		32 with a graded approach, the organization of the regulatory body will vary widely from State to State, and therefore the following factors should be taken into account: – The size, number, type, nature and stage in the lifetime of existing facilities and activities; – Future plans (e.g. for new installations and/or facilities, new technology and activities relating to new stages in the lifetime of facilities, such as decommissioning); – The national legal framework; – Other existing regulatory authorities; – <u>Other existing national infrastructure/organizations involved such as inspection organizations ;</u> – Expectations of interested parties; – The availability of competences at a national level (e.g. educational institutions and technical support organizations, as applicable); – The availability of funding. Additional feedback: Is it clear that inspection organizations are covered by existing regulatory authorities?					It is clear because, for example, the inspection authority for pressure boundaries equipment is a regulatory organization for this area.
19.	6.3	In order to achieve the necessary capability within the ~~technical~~ staff of the regulatory body, most <u>experts</u> should have an appropriate academic degree. This should be supplemented with specialized training	clarity, the expertise is not only technical that is needed			X	Technical expertise is the only subject of the paragraph. The terminology “experts” cannot be

		and/or professional work experience in their specific area of work, especially relating to the facilities and activities to be regulated.					used here, as it produces confusion with the TSO spectrum.
20.	6.5.	In order to maintain the necessary independence, the staff of the regulatory body should be as objective as possible in discharging their responsibilities. <u>The following features should be maintained:</u> a) They should be open to receiving information and opinions from others, and regulatory positions and decisions should demonstrate transparency and clarity. b) Staff of the regulatory body should not engage in, or hold any kind of interest in, activities that may represent a conflict of interest with the performance of regulatory functions. c) The staff of the regulatory body should be open but also formal and professional in their interactions with authorized parties and should, at all times, maintain their integrity and independence. Additional feedback: The proposed use of the list would clarify the paragraph and make it more readable.	clarity, The paragraph contains several different topics.		6.5. In order to maintain the necessary independence, the staff of the regulatory body <u>should maintain the following characteristics</u>: – Should be as objective as possible in discharging their responsibilities. – Should be open to receiving informatio		The paragraph contains only one topic: characteristics of the regulatory body staff (all four sentences). However, listing does improve readability - see proposed modification.

					n and opinions from others, and regulatory positions and decisions should demonstrate transparency and clarity. – ~~Staff of the regulatory body~~ Should not engage in, or hold any kind of interest in, activities that may represent a conflict of		

					interest with the performance of regulatory functions. – ~~The staff of the regulatory body~~ Should be open but also formal and professional in their interactions with authorized parties and should, at all times, maintain their integrity and		

					independence.		
21.	6.16.	The competence management process may include the following sub-processes [16]: – Analysis of competence needs: o Task analysis leading to determination of the necessary competences; o Analysis of existing competences within the regulatory body; o Gap analysis (personal performance review and assessment); – Prioritization of competence needs and filling competence gaps: o Recruitment and human resources planning; o Staff training and development; o Management of external expert support. – Knowledge capture and management. – Reviews and audits of competence management and feedback. Additional feedback: Which one IAEA is going to follow?	Please use 6.16 from SRS-79 or the orld version 6.15 sub-processes: -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			X	The observation is correct, as the intention is not to have the 1:1 correspondence with SRS-79. Para. 6.16. is aligned with SRS 79 and presents a possible structure of the sub-processes for the competence management process (from an integrated management system point of view).

			and development activities. − Management of outsourcing (external expert support); − Knowledge capture and management; − Reviews and audits of competence management and feedback.				
22.	6.39	Graded approach should be implemented in the qualifications of the staff carrying out authorizations so that most demanding ones are performed by senior and experienced staff. Additional feedback: Yes, graded approach is used for the qualification of the staff and when requirements are set for different positions.	Authorization of very simple practices on routine basis can be performed by junior staff.		6.39. Staff of the regulatory body … if applicable. ~~Authorization is normally performed by senior and experienced staff.~~		Last sentence deleted.
23.	6.41	~~Regulatory inspection differs somewhat from other regulatory functions in that the principal activity takes place at the authorized facility or where the authorized activity occurs.~~ Additional feedback: Regulatory inspection is here defined as an inspection at license holders premises. This limitation should not be maid. Also other type of inspections should be possible in modern oversight environment. The regulatory body may send control tests samples and use questionnaires	There are also pre-authorization inspections when appropriate. Regular inspections are carried out a the authorized facility or where the authorized activity occurs.			X	All inspections are carried out in the frame of an authorization process. Keep current text.

		as a example an inspection to dentists. Please rewrite the sentence.					
24.	6.42.	Staff who are assigned to inspect major facilities and activities (e.g. the manufacture of components and the commissioning and initial operation of facilities) should have sufficient relevant work experience, preferably in facilities and activities of a type similar to those they will be assigned to inspect. <u>As part of the function they are performing, inspectors are routinely involved in compliance assurance activities.</u> Additional feedback: Please clarify the need for the last sentence. Inspection is a compliance assurance function. Is it need to emphasize the need for the experience?	Please clarify: Old version was better. The meaning is different. Compline assurance is used in IAEA documents for program containing two aspects: review and assessment, and inspection. The term is specially used in context of transport. IAEA glossary **compliance assurance** A systematic programme of measures applied by a *regulatory body* that is aimed at ensuring that the provisions of regulations are met in practice. ⓘ *Compliance assurance* is a systematic programme of measures applied by a *competent authority* that is aimed at ensuring that the provisions of the [Transport] Regulations are met in practice. (From Ref. [2].)	X			This terminology is not used only in transport. Agreed to delete last sentence.
25.	6.53.	The staff of the regulatory body should be able to coordinate and manage the activities of the	Please clarify; Is this needed for the			X	Yes, it refers to one of the extremes of the spectrum, as the

		regulatory programme that are performed with the assistance of consultants or dedicated support organizations. Some staff should have experience in technical programme management or project management. Furthermore, some staff of the regulatory body should have appropriate management experience and technical experience to be able to assess and judge the effective coordination and management of large engineering companies and quality assurance programmes.	supervision of the TSO support?				variety in the support offered may be indeed large. The text states this for "some" staff, depending on the different potential cases.
26.	**APPENDIX I EXTERNAL EXPERT SUPPORT**	This is overlabing with GSG-4. There is not one to one coverage of the text. What is intention of IAEA with regard to GSG-4? Additional feedback: Should be discussed at NUSSC meeting!				X	The observation is pertinent. As per the DS472 DPP, the relevant content of GSG-4 should be included in this guide and this was the process followed for drafting of the text.
27.	**APPENDIX III ELEMENTS OF A TRAINING PROGRAMME FOR THE REGULATORY BODY**	Depending on the tasks to be performed, it may be necessary additionally to impart knowledge of: – Physics; – Nuclear engineering; – Systems engineering; – I&C and Electrical engineering; – Mechanical engineering; – Civil engineering; – Radiation protection; – Chemistry;	Add. I&C and		We may add it in the brackets of III.1. - Facilities and systems (design, operation and maintenance, including instrumentation and control and surveillance		I&C is an technical area of expertise, the rest of the bullets are basic technical specializations.

	III.2.	– Biology; – Behavioural sciences; – Ergonomics; – Medicine; – Geology; – Law; – Communication; – Administration;			methods);		
28.	**REFERENCES**	If there is updating of the safety standard the DS number should be indicated in the reference.			This is part of a future step in the publication process.		
29.	TABLE A-16. EXTERNAL EXPERT SUPPORT	Table A-16 describes the process for individual expert purchasing. The prosecco should consider how the RB manages the overall TSO process. The assurance of the continuity of the TSO support available, audited organizations etc.				X	Table A-16 does not describe the individual expert purchasing, but the generic steps exemplified for the purchase of external expert support in general. Please refer to purchasing process (Table A-24) to confirm.
30.	TABLE A-17. INTERNATIONAL COOPERATION	Table A-17 describes an individual activity only. It would be fruitful to describe the overall process.				X	Table A-17 exemplifies generic steps in an International cooperation process.
31.	TABLE A-19. KNOWLEDGE MANAGEMENT	1. Periodically identify the regulatory body's information needs; 2. Periodically review the existing knowledge base; 3. Identify needs for update of information; 4. Compare with existing knowledge	Please clarify.			X	Can range from using an exit interview as a source for training of specific staff to converting a

		base and identify gaps; 5. Identify and access internal and external sources of information and capture the necessary information to fill the gaps (essential for retirements and departures); 6. Convert information to knowledge of use to the regulatory body: 7. Store the information adequately and safely; 8. Ensure easy retrieval; 9. Inform the concerned individuals about changes and updates.					meeting report into a presentation for the information of all staff. The diversity of possibilities makes it impossible to be captured in a generic document such a safety guide.
32.	TABLE A-25. MEASURING AND TEST EQUIPMENT[10]	Add interface to Inspection process and Emergency preparedness process.	X				
33.	**ANNEX PROCESS DESCRIPTIONS**	The idea of presenting performance indicator at the end of each process is good in principle. However this is challenging topic and indicative nature of the indicators should be emphasized. Objective evaluation of indicators like successful communication, New or revised regulations shown to provide benefits for interested parties, demonstrated performance may be difficult. On the other hand indicators passed on number of product and timeline do not necessarily indicate the safety					"Could be used allows" Member States flexibility in using the guidance provided.

		significance of the oversight work.					
34.	TABLE A-9. REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES	Review and assessment to support the authorization process: 1. Extract relevant information from inputs; 2. Establish a review and assessment plan (identify key issues and tasks, milestones, and assigned resources, both internal and external); 3. Conduct review and assessment activities; 4. Collect and integrate assessment results, and request additional information if necessary; 5. Conduct verification activities (e.g. on-site inspection), as appropriate; 6. Document the conduct of the review and assessment and the results; 7. Propose authorization conditions; 8. Provide feedback to the authorization process; 9. Follow up of safety issues as necessary. Additional feedback: Please add foot note to clarify as presented in IAEA comment.	Please add: 5. The interface to inspections 9. follow up	X	Footnote at the results in step 4: Follow-up of review and assessment results should be conducted through regulatory compliance activities.		Interface with inspection is already included into the table under "Interfaces". The suggestion is technically valid, however follow-up is not a unique stand-alone element appropriate for the low level of detail intended for this Annex. As such, follow-up is already logically embedded into step 4 of "Review and assessment to support the authorization process", respectively step 3 of "Review and assessment to support regulatory oversight".
35.	TABLE A-10. INSPECTION OF FACILITIES AND ACTIVITIE	Please make the interface to the review and assessment process. Add the assessment of the finings and follow up to all inspections. Add review and assessment to		X	Interface with Review and Assessment added as number 3 under the "Interfaces".		

	S	interfacing processes.			Develop specific inspection plans for individual facilities and activities: 3. Record findings and follow-up.		

COMMENTS BY REVIEWER Reviewer: DANDRIEUX Page.... of.6. Country/Organization: FRANCE / MEEM Date: 10/05/2017				RESOLUTION			
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DS 472							
1	2.26	2.26. The regulatory body should ensure that regulations and requirements are applied in a consistent, predictable, transparent, balanced and proportionate manner. The regulatory body should establish policies to promote proportionality, transparency and consistency, and the broad sharing of information and ideas, to help ensure the highest standards of protection and safety while giving due account to the protection of sensitive information. Transparency and openness towards the general public	Need to take security of information into account	X			New para number is 2.27.
		also enhances confidence and trust in the regulatory body.					
2		Add new : 3.9 bis the RB should also ensure that his personel gains, through training and information, an appropriate level of nuclear security culture. In particular, the RB personel should be fully informed on the rules for protection of sensitive information				X	This paragraph addresses only the main aspects of responsibility and accountability for safety.

3	3.22	Add at the end of para : The policy of openness and transparency should however, subject to national requirements, duly take account for the need to protect sensitive information according to national law			interested parties (including multilateral and bilateral regulatory interactions), taking into account the need to protect sensitive information		National legal framework already mentioned, added the "sensitive information".
4	5.5	5.5. The integrated management system is an essential tool for ensuring the following: … add one bullet point : - compliance with requirements for protection of sensitive information			Added at the end of 5.68: … security, confidentiality and protection of sensitive information, be made available to interested parties.		Proposed text included in 5.68.

	COMMENTS BY REVIEWER Reviewer: **Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)** (with comments of GRS) Page 1 Country/Organization: **Germany** Date: 10.05.2017				RESOLUTION			
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2	1	2.17	… The objective should be to make informed decisions and to have competence to assess advice provided by advisory bodies, ~~and~~ information submitted by authorized parties ~~and~~, applicants and technical support by external experts.	TSO's are missing. To achieve consistency with IAEA GSG-4 "Use of external Experts by the Regulatory Body" para. 2.2.			X	Paragraph 2.16 addresses the potential use of TSO and falls in line with GSG-4. Para 2.17. addresses only the internal aspects of the knowledge and

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								information management inside the regulatory body, in the context of regulatory independence.
2	2	2.28 line 2	… The regulatory body's organization, staffing, competences and knowledge, as well as its integrated management system, should be designed to be able to adapt to such changes	Staff cannot be "designed".			X	The reference to "design" relates to organization, competence and IMS.
1	3	3.18 line 4	Responsibilities for fulfilling core regulatory functions ~~should~~ cannot be delegated.	"Should" is not adequate, because the responsibilities for fulfilling the core regulatory functions must stay with the regulatory body.			X	Safety guide specific language has to be used - "should" statements. Para 3.16 paraphrases GSR Part 1 (rev.1) req.18. The suggested replacement of "cannot" is ambiguous (the presumption is that it means

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								"must not" , but equally it could be taken as implying that something is impossible – which is clearly wrong) and hence this would not be allowed by the technical editorial review.
2	4	I.21 line 3	… Any changes ~~in staff~~ that might affect independence should be discussed with the regulatory body before they are made.	Causes affecting the independence of the TSO are not limited to changes in staff, as you can see by the cases listed further on in I.21.			X	Coming from GSG-4 (para 3.5). The statement is correct and does not imply that there could not be any other causes affecting TSO independence (but not all these causes should be mentioned here). GSG-4

	COMMENTS BY REVIEWER Reviewer: **Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)** (with comments of GRS) Page 1 Country/Organization: **Germany** Date: 10.05.2017				RESOLUTION			
Rele-vanz	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/reject ion
								addresses these aspects in further detail.

COMMENTS BY REVIEWER Reviewer: Japan NUSSC member Page of 2 Country/Organization: Japan/NRA Date: 11 May 2017				RESOLUTION			
No.	Para/Line No.	Proposed new text	Reason				
1.	General	Clarification for keeping a consistency. There are dozens of keywords such as “leadership”, “management system” and “safety culture” used in GSR Part 2 in this draft. On the other hand, GS-G-1.3 and GS-G-3.5 are now being revised as guides under the requirements of GSR Part 2. So, how is it keeping a consistency with them after published this guide?					Guides currently under revisión/development are using the existing terminology (in already published safety standards). The IAEA publication process ensures consistency in terminology between safety standards, horizontally and vertically. In the current case, GSR Part 2, a Requirement document, is [Ref. 10] to DS472. As such, terminology used in GSR Part 2 does appear in this safety guide.

COMMENTS BY REVIEWER Reviewer: Japan NUSSC member Page of 2 Country/Organization: Japan/NRA Date: 11 May 2017				RESOLUTION			
No.	Para/Line No.	Proposed new text	Reason				
2.	Contents Sec.5 6th subtitle & Page.40	Delete "Evaluation" as follows; MEASUREMENT, ASSESSMENT~~,~~ ~~EVALUATION~~ AND CONTINUOUS IMPROVEMENT	Consistency with Req.14 of GSR Part 2	X			
3.	3.1./2nd bullet & 3.7.	Replace "acceptance of personal responsibility" with "acceptance of personal accountability"	Consistency with description of GSR Part 2, in which "acceptance of personal accountability" is used.	X			
4.	5.4./L11	The integrated management system of the regulatory body is required to clearly specify its organizational structure, resources and processes [10]. A set of coherent processes and procedures should be used to help carry out the regulatory functions in an effective and efficient manner, with account taken of all internal and external requirements, such as the following: ……. - Economic ~~requirements~~ elements	To keep a consistency with GSR Part 2 footnote 3. "Economic objectives are included in the list of elements that have to be integrated, as it is recognized that economic decisions and actions may introduce, or may mitigate, potential risks."	**X**			Consistent with Requirement 6 of GSR Part 2
5.	5.32., 5.33./ Sub-title	~~MAINTENANCE~~ IMPLEMATION AND IMPROVEMENT PHASE OF THE INTEGRATED MANAGEMENT SYSTEM	Merge para. 5.34 to 5.69 as implementation and improvement phase in PDCA cycle.			X	The PDCA four-step model for carrying out a change represents a good example of tools to be applied for the Management of Change process. However, the

COMMENTS BY REVIEWER Reviewer: Japan NUSSC member Page of 2 Country/Organization: Japan/NRA Date: 11 May 2017				RESOLUTION			
No.	Para/Line No.	Proposed new text	Reason				
							document does not consider Measurement, Assessment and continuous improvement as a phase of the IMS, but a continuous process monitoring the entire IMS. It is intentional that there is a special section dedicated to this aspect (in line with GSR Part 2 requirement 13).

COMMENTS BY REVIEWER Reviewer: Page.... of.... Country/Organization: ROK/KINS Date:				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	Para 1.2, 2nd line	- - - the regulatory body for confirming the safety of facilities and activities	For the clarity of the prime responsibility of authorized party			X	Language as used in GSR Part 1 rev.1 (regulatory control of facilities and activities)
2	Para 1.7, 3rd line	Delete the sentence "Such States - - - a new regulatory body."	To avoid the duplication of the contents with the 1st sentence			X	It is not a duplication, because "such States" refers to countries having already in place a

							regulatory body for radiation protection.
3	Para 2.17, 4th line	Add a phrase to be " - - - advice provided by advisory bodies, service by external support, and information submitted - - -"	To include the additional way of obtaining the technical inputs of regulatory body		…advisory bodies, providers of external expert support and…		Accepted, please see text.

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer:			Page.... of....				
Country/Organization: ONR			Date:				
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
	Section 2 Independence	There is nothing about the role of the regulatory body providing advice to government on necessary legislation to enable it to perform its role to match new challenges or to better regulate existing facilities & activities				X	Based on GSR Part 1 rev 1, the responsibility for ensuring the adequacy of an effective governmental, legal and regulatory framework for safety resides with the government (para 2.5.). There is no need to transfer this responsibility to the regulatory body, in particular because GSR Part 1 rev 1 does not include a requirement that can be used for this purpose.
	Section 3 Safety	The characteristics of a safety culture in the regulatory body are				X	The characteristics of safety culture

	Culture	inadequate. The document just states that the regulator should be interested in safety! It does not describe the desired behavioural characteristics that help foster safety & safety culture within the bodies they regulate, nor how the regulator needs to consider long term safety improvements compared with short term issues that might conflict					used in DS472 are fully aligned with safety culture characteristics defined in GS-G-3.1 Application of the Management System for Facilities and Activities. This guide applies to organizations responsible for operating facilities and activities, as well as for the regulatory bodies. Additional and specific guidance for the application of culture for safety in regulatory bodies will be provided in the guides to be developed to support GSR Part 2. No modification is necessary in this document.
	Section 4 Core functions	Given the level of specification in this document it doesn't address major new build construction explicitly. It should consider what role the regulatory body has in ensuring future nuclear safety.				X	The documents contains considerations for regulatory body with an expanding or new mandate, including new-build

							NPPs in various sections of the document (e.g. 4.15, 4.55, 5.35, 5.59, 6.22, 6.24, 6.38, 6.59, 6.71, 6.72, Tables A-1, A7, A-15 and A-18). No modifications required.