DS473 FUNCTIONS AND PROCESSES OF THE 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.	Chapter 3.	The discussion of the regulations and guides as well as the RB guidelines is confusing. The RB guidelines should be discussed in the context of the related processes. Also the use of the regulations and guides in the processes could be clearly addressed. As an example para. 3.25, 3.46, 3.47, and 3.49 refers to RB internal guidelines/guidance. Regulations for inspections does not give any advice for the regulations and guides for the inspections. It is not self evident that the RB can make inspections.	The legal framework with fundamental requirements (constitution, law), safety requirements (regulations) and subordinate guides is a well known approach presented also in the IAEA Safety Standards. Similar hierarchic structure can be achieved if RB makes its internal assessment guidelines available for the licensee and the stakeholders. The procedures of the RB management system makes reference to the regulations and guides or the internal guidelines. It is proposed that: a) the working should be in line with the GSR Part 2 and DS472 in the description of the processes; b) the development of the internal guidelines is separated form the development of the	X			Paragraphs on internal guidance (former paras. 3.25, 3.46, 3.47, 3.48 and 3.49) have been collected and placed under a single header "Internal guidance" at the end of the section. Please see renumbering.

			regulations and guides.				
2.	3.11 (b)	Establish principles, requirements and the criteria to be used for ensuring safety ~~compliance~~;	All requirements and criteria should be established for the licensee and the RB verifies by reviewing and assessing that there is compliance.			X	The intent in this para was to ensure that the IMS process used by the regulatory body for the development of regulations and guides is detailed enough to provide principles, requirements and criteria needed to to assess whether or not authorized parties comply with them .
3.	3.14.	The safety objectives and regulatory requirements should specify the safety goals for the facilities and activities and the acceptance criteria to be demonstrated. ~~The safety objectives and regulatory requirements should specify the performance criteria for structures, systems and components, and management and operational procedures and processes, to be achieved in operating the facility or conducting the activity.~~ The regulatory body should refrain from prescribing specific designs, management systems or operational procedures.	Please rephrase: The paragraph jumps strait to the systems and structures and performance criteria.			X	Regulations do contain performance criteria based on the safety objectives and requirements to be developed or adopted as mentioned in para 3.13. Para 3.14 follows along and introduces the main categories of performance criteria, i.e. not only SSCs, but also

							management and operational procedures and processes. These paragraphs were originally in the Review and Assessment section (Bases for review and assessment) and have simply been moved upfront. Paragraphs originate from GS-G-1.2.
4.	3.15.	The safety objectives and regulatory requirements should include the following, as appropriate: (a) Emphasis on prevention of, rather than mitigation of, accidents; (b) Application of the concept of defence in depth; (c) Meeting the single failure criterion for safety systems; (d) Requirements for redundancy, diversity and separation; (e) Requirements for adequate safety demonstration of any passive systems that are used; (f) Criteria relating to human factors and the human–machine interface; (g) Dose limits and dose constraints (for both occupational exposure and public exposure), and limits on discharges to the environment; (h) Criteria for assessing radiation risks to workers and the public;	Please delete the para. 3.15 or rephrase so that it clearly represents examples in a systematic manner. If this is a list of examples it should be stated. The idea in behind blocking just there topics to the list is not clear. The points 3.15 (c) and (d) are related to reliability and availability of the safety systems. There is overlap to DiD presented in (b). Passive systems in (e) and the HMI interface in (f) are explicitly mentioned while such as leadership and management for safety, safety culture are missing.			X	Para 3.15. shows a list of principles and is extracted from GS-G-1.2. Terminology has been checked with technical editors for consistency with latest IAEA safety standards. The list is indeed not complete (nor it is intended to be presented as a complete item), however at this late stage there is not much we can do (especially after Member States

		(i) Minimization of waste and management of the waste generated, including waste from decommissioning; (j) Emergency preparedness. Additional feedback: There may be a need to discuss the topic in the committees?	In (g) dose constraints for medical exposure (GSR Part 3 Req 34 and 3.149) should be included. In (h) patients should be included. For patient safety there are many requirements in the GSR Part 3.Maybe there should be a separate point (x) Criteria for assessing patient safety.				consultations and comments). Keep current text.
5.	3.31	add for (a) …,[14, DS449] (b) A list clearly stating the regulations and <u>as appropriate</u> standards to be applied;	add. DS449 should be mentioned for the NPPs. <u>as appropriate</u> Also other approached should be considered. In many counties the standard of origin are used and the application of the standards should be justified.			X	As appropriate is included already in the umbrella-paragraph. IAEA will retain the suggestion and will check at the time of publication the applicability of the inclusion of DS449.
6.	3.66.	The process of developing regulations and guides should be described in clear procedures and should ~~be flexible enough to~~ permit revisions to be made to take account of changes in technological, legal and practical conditions.	clarity, The flexible enough could be misleading. The process should be assertive to complete the regulations and guides under development. However, there is also a need to update the regulations and guides in a systematic manner.		"…should be <u>sufficiently</u> flexible ~~enough~~ to permit revisions…"		Eliminated "enough" to provide for alternate expression, less ambiguous. We do not want to lose the idea of process flexibility. (GS-G-1.4)

7.	3.68	(f) Drafting of the regulations or guide. ~~The staff of the regulatory body, technical support organizations, consultants, professional societies or advisory committees may draft the initial version of the regulations or guide.~~ Regulations and guides should be written in a style that is clear and easy to understand. They should be relevant, precise and unambiguous so as to be readily applicable and enforceable. <u>The staff of regulatory body may use technical support from technical support organizations, consultants or professional societies in the process.</u>	Please clarify: The drafting of guidance and regulations should be at least separated. the RB may use support from the organizations mentioned in drafting. However, the RB should have the leading role in the process. If advisory body drafts the regulation or guide it is no more appropriate for the independent review in the later phase.		(a) Drafting of the regulations or guide. The staff of the regulatory body, ~~assisted by~~ technical support organizations, consultants, professional societies or advisory committees, ~~may~~ drafts the initial version of the regulations or guide. ……		We suggest accepting this change using the modified text (see left column).
8.	3.97	(e) A clear and explicit set of requirements, criteria and standards forming the basis for authorization should be defined <u>in the authorization process.</u> Additional feedback: There are differences in the national approached and for instance the standards applied can be defined during the authorization process. There are preset requirements, however requirements and criteria have a little pit different position from standards and this should be considered.	see. comment 3.31 The set of standard in not necessary predefined by the regulatory body.			X	The authorization basis is always pre-defined by the regulatory body (before the process actually begins, and according to the type of facility or activity). Keep current text.
9.	3.106 e)	new paragraph in between (e) and (f) Provisions for safety culture	Could the non conformance handling be included in the list? eg. in (iv) Safety culture related issues are missing.		A description of the arrangements for establishing and sustaining leadership and		We suggest introducing a provision for leadership and management for

					management on the part of organizations and managers responsible for facilities and activities that give rise to radiation risks		safety (see the left column). Definitely the non-conformance element is a key part of the safety-related aspects to be tracked during authorization. Given this guide is large and encompasses all facilities and all activities, management of non-conformance is captured under the area reporting of design changes and modifications. This is specified more clearly only in paragraph 3.36. It is also covered under (e)(vii) Safety culture is not enforced. Safety culture is observed by regulatory body.
10.	3.152	… The review and assessment process should have interface with the inspection process including checks on site to verify the claims made in the submissions.	The interface in between review and assessment and inspection should be mentioned.			X	The comment is valid and is covered by "The review and assessment process is a critical appraisal, ….or information

							that comes from inspection". The process-related information (inputs, outputs, interfaces) strictly from the point of view of the integrated management system is covered in DS472.
11.	3.160	ADD: To determine safety issues are receive the attention warranted by the related radiation risk and safety observed in the organizations culture	Please add: topic on safety management and safety culture.		To determine whether the authorized party has put in place the necessary arrangements for establishing, sustaining and continuously improving leadership and management for safety		We suggest modifying to add the provisions for leadership and management for safety.
12.	3.163	During its inspection activities, the regulatory body will ~~collect~~ obtain on-site information, for example when examining records kept by the authorized party. This information should be collected in a systematic manner so that such information may be subjected to review and assessment by the regulatory body, in addition to any information associated with non-compliances with regulatory requirements or	Compared to 3.152 this is an other type of interconnection from in between review and assessment processes. The special case of collecting information to get a view of the safety culture could be mentioned.			X	"obtain" (to get hold of) is much stronger than "collect" (gather). More neutral words are preferred. Chapter 2 of DS473 addresses the principle of graded approach, so as to avoid repetitions

		violations of the authorization conditions. Although this source of information may only represent a small part of the review and assessment, it is essential as it provides factual insights on how the authorized party complies with regulatory requirements. Also the review and assessment of this type of information enables the regulatory body to get view of the safety culture of the authorized party.					throughout the text. Oversight of safety culture will be addressed in a separate guide supporting GSR Part 2 and the current text 'on-site information' is broad enough to cover relevant information on safety culture, leadership and management for safety, etc. This paragraph addresses information collection only.
13.	3.165.	(6) Reporting and documentation. (7) Follow up and closing the case Additional feedback: It is not clear that the follow up is included in the step 3). Please add a foot note that describes the process cycle as well as the verification in inspection process. foot note, process can cycle 3)-5), reporting is after closure of the topic, steps 3) may include a verification in an inspection process	Add: (7) Follow up and closing the case the follow up of the actions either new submissions of the inspections should be considered in the process.		Add footnote under Decisions in step 5 (footnote like in DS472)		The comment belongs to DS472 and has been addressed there. Follow-up is not a unique stand-alone element.
14.	3.165 a	The interface of the review and assessment and the inspection processes	Add new paragraph.			X	Already mentioned in paragraphs 3.152

		should be clearly presented. The inspections are used to verify the compliance with the applications but on the other hand also information collected from the licensees during inspections are reviewed.	The interface in between review and assessment and inspections should be presented.				and 3.154. Please note that DS473 is complementary to DS472 (not overlapping). They should be read in conjunction with one-another.
15.	3.168	… Consideration of the proposals may lead to the establishment of additional regulations and guides or the modification of existing regulations and guides (see also paras 3.42–3.46). Additional feedback: Please consider moving this sentence to regulations experience feed back.	This is true. However the last sentence should be in section of regulations and guides. The impression that the regulations and guides as changes due to license application is not good.		Consideration of the proposals may ~~lead~~ provide input for the development of ~~to the establishment of~~ additional regulations and guides or the modification of existing regulations and guides (see also paras 3.42–3.46).		Text was modified to address the observation.
16.	3.170.	The equipment may be so. called “type approved” or “certified” by recognized body in accordance with industrial standards or other nationally recognized equivalent standards. However the suitability of the equipment to the facility of activity under review and assessment should be always demonstrated by the authorized party. ~~The~~ ~~The regulatory body should not issue an authorization solely because a specific model of equipment was ‘type approved’ or carried a certificate of compliance,~~	Please rephrase to clarify. The guidance could be presented in an positive way. It should be made clear weather the paragraph is related to facilities and activities or equipment.			X	Coming from GSG 1.5 Keep current text.

		Also other factors such as the qualification and training of the staff, and management and operational procedures and processes are required for safety. Additional feedback: Actually the sentence is not deeded.					
17.	3.175	Before authorization of construction, review and assessment will concentrate on the applicant's or authorized party's approach to safety and to compliance with safety ~~standards~~ requirements, and how these have been applied in developing the design of the facility or activity. Special attention should be paid to the design envelope of the facility of activity thus this forms the basis for safety. Features such …	Clarity, Replace standards with requirements. The review of the design envelope should be emphasized.	X		X	We accept the proposed change (replace standards with requirements). Text is coming from SSR-2/1 (Rev. 1), IAEA, Vienna (2016), which is a safety requirement. The suggestion repeats the text of the previous sentence.
18.	3.180	ADD: The regulatory body should assure itself that the licensee has organizational readiness for safe operation of the plant. Additional feedback: The focus of 3.179 is the commissioning activities themselves.	Please add the organizational factors such as leadership for safety?			X	This paragraph addresses only specific aspects pertaining to the end of commissioning. Checking of organizational aspects of the authorized party is addressed in 3.179. Leadership and management for safety related aspects are addressed under

							3.160 (to be modified as suggested – see response to comment # 11). Oversight of safety culture/ leadership and management for safety will be addressed in a separate guide supporting GSR Part 2.
19.	3.193	To facilitate the review and assessment process for a facility or activity, the regulatory body should consider developing lists of approved equipment containing radiation sources, based on the submission of a certificate confirming compliance with international industry standards (e.g. of the International Electrotechnical Commission and the International Organization for Standardization). An expert with the appropriate skills or an independent ~~accreditation~~ accredited laboratory of the State concerned, or of another State or an international organization, should issue the certificate in accordance with the results of a review of a generic safety assessment for the type of facility or activity. The generic safety assessment should be documented, together with a summary of the conditions of use of the equipment and any appropriate limitations on its use.	typo, accredited, What is the purpose of the list? Is it publicly available?			X	Not a typo, it reads: a laboratory which is able to issue/assess accreditations/certificates. Text is coming from GS-G 1.5. The purpose of the list is "to facilitate the review and assessment process for a facility or activity". Keep current text.

		Additional feedback: The term accreditation is used in different ways. There is global accreditation organization IAE and well specified approached for the use of accreditations. In Europe the term is reserved to one national body that shall fulfil the ISO/IEC/EN 17011 requirements. The certification, inspection and testing organizations can get accreditations against ISO/IEC/EN 17000 series standards and some specific standards/requirements for the demonstration of competent at certain areas. In US terms accreditation may be used also for certifications. It is proposed that clear separation of accreditation and certification is made. Usually the accredited bodies need to have a public list of their decisions. Thus it would be preferable that the regulator does no keep such lists. However if the regulatory body approves those bodies the related decisions could be as an example at the regulators web site. The idea of keeping such a list is nice. However keeping the list could be controversial and may require resources.					
20.	3.211.	… (h) Additional requirements to be met by the authorized party <u>(i) Record for the follow up and closure of open issues</u>. Additional feedback: see comment 13.	ass: follow up of open issues			X	This paragraph focuses on topics to be covered for documentation summarizing the review and assessment.
21.	3.211 a	<u>A programme to systematically analyze</u>	The follow up of the review			X	The section is

		and follow up review and assessment findings should also be established. The programme should include provisions for periodic review and surveillance of the follow-up actions to verify that the authorized party is taking necessary actions in response to review and inspection findings. Upon satisfactory completion of the actions, the review and assessment findings should be closed in writing and necessary documents and records should be maintained. Additional feedback: see comment 13.	and assessment findings should be included as it is for inspection findings in para. 3.296.				"Records of review and Assessment".
22.	INSPECTION OF FACILITIES AND ACTIVITIES	Paragraphs describing the inspection process are missing. However there are element of the process in the document.	Please harmonize the text with other regulatory functions by describing the inspection process.			X	The technical observation is valid, and is addressed in DS472. DS473 addresses practical aspects of the inspection function. Paragraphs 3.224. explains precisely this.
23.	3.263	Whenever the authorized party makes use of the safety related services or products of a contractor, the regulatory body should include the ~~contractor's~~ contracted activities in its inspection programme in all steps of the authorization process. This may comprise inspection of the design and manufacturing of components, including, where appropriate, activities performed in other States. Inspection at the authorized party's	Clarity, the special nature of the regulatory inspections at the authorized party's contractors should be emphasized.			X	It is implicit that the regulatory body's inspection will address only the contractor's activities which are covered by the licence issued to the authorised party. Specifying the location where the

		contractors' premises or contractors activities should only be performed in conjunction with inspection of the authorized party, so that the authorized party is not relieved of the prime responsibility for safety. The focus of the regulatory inspection should be in line with para. 3.212 and para. 3.213.					inspection is taking place is not so important, because the focus is that the inspection will be conducted in conjunction with the inspection of the authorized party Last phrase is not needed – it is coming from GSR Part 1 rev. 1 and is already mentioned/governs the chapter.
24.	3.275	Examination of the authorized party's documentation contributes to the regulatory body's verification of the authorized party's compliance without unduly disrupting work schedules or interfering with the authorized party's prime responsibility for safety. Documentation examined by regulatory inspectors may include the following: (a) Procedures and schedules for maintenance and testing; (b) Quality assurance records; (c) Test results and data; (d) Operational and maintenance records, and results of workplace monitoring; (e) Records of deficiencies and incidents; (f) Modification records, including	The verifications of the review and assessment should be considered also. As an example usually the plant specific data for PSA is available only at the plant site. Recently the topic of counterfeit components has drawn a lot of interest in the international discussion. The licensees inspections and regulatory oversight should take into account this possibility.			X	This paragraph (and section) addresses inspection only. Although it is logical that inspection and review and assessment are very much interfacing, the document needs to present the distinct elements of every core function. Plant specific data may or may not be available at the plant site only.

		records of modifications to management and operating procedures; (g) Training records; (h) Shift schedules; (i) Dose record (j) Design and qualification of systems, structures and components (k) Safety analysis, analysis tools and input information The possibility of counterfeit items should be considered at least in connection of (b) and (c). Additional feedback: The IAEA guidance should allow different national approached. It is odd if the safety analysis, analysis tools are only inputs for review and assessment. The interoperation of QA is very wide and not necessarily understood by all.					b) quality assurance activities may cover the topic of counterfeit components (and not only QA activities). Design and qualification of SSCs is also captured under b), d) and (f) Safety analyses, analysis tools and input information are reviewed under the review and assessment process, not by the inspection process.
25.	**APPENDIX III TOPICS TO BE COVERED BY REVIEW AND ASSESSMENT** III.11.	The authorized party should be required to demonstrate that it has in place: … (o) Systematic approach to fostering strong safety culture, including training in safety culture, particularly for managers;	Please widen the scope of (o). There are other aspect than training that should be considered.		o) Systematic approach to fostering leadership and management for safety, including training in safety culture, particularly for managers;		Suggest modifying (please see the left column)

COMMENTS BY REVIEWER Country/Organization: FRANCE /ASN Date: April 2017 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1.	General	Review recommendation for applicability to radiation sources and radiation generators and for activities controlled under a notification process.	Several recommendations seems to be relevant for nuclear installations but not to medical practices or to industrial practices with radioactive sources.				No specific "recommendations" which are not relevant to medical or industrial practices have been identified. A graded approach in the implementation of functions and processes should be applied.
2.	1.11	For complex facilities or activities, each stage of the authorization process may include one or more steps (~~also~~ sometimes referred to as 'hold points' or 'reporting point') at which additional information is required by the regulatory body.	Holdpoints may be one way to split an authorization process. Reporting points, without a need for a "green light" of the regulator may also be used.			X	The focus of this para is to highlight the importance of hold-points and the role of regulatory bodies to participate/witness the relevant activities.
3.	2.1 to 2.6	Merge 2.1 to 2.6 in a ingle para as they are all quotations from Safety Requirements without any additional guidance	Simplification			X	Each paragraph belong to a different Safety Requirement or Safety Fundamental publication.

COMMENTS BY REVIEWER Country/Organization: FRANCE /ASN Date: April 2017 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
4.	2.8	The approach should take into account any exposures to radiation, and discharges or releases of radioactive substances in normal operation, anticipated operational occurrences and accident conditions, as well as the possibility of events with a very low probability of occurrence. <u>However low probability events with potentially high consequences should not be neglected.</u>	Lesson learned from Fukushima accident		… the possibility of events with a very low probability of occurrence, <u>without neglecting very low probability events with potentially high consequences.</u>		
5.	2.9	~~An approach to screening of events based on their probability is included in External Human Induced Events in Site Evaluation for Nuclear Power Plants, IAEA Safety Standards Series No. NS-G-3.1 [13].~~	Too detailed for a guide covering the full scope of regulatory functions, including for countries where no nuclear installation exists….			X	Para just makes reference to another publication, which should be used as appropriate/necessary.
6.	2.10	The application of the graded approach should be reassessed as a better understanding is obtained of the radiation risks arising from the facility or activity <u>and of the impact of current regulatory controls</u>.	Effectiveness and efficiency of the current controls should also be taken into account				Specific guidance for the effectiveness and efficiency of regulatory control is not provided in this guidance. However these aspects are included in the evaluation of regulatory body processes as part of the integrated management system, and is addressed in DS472, the complementary guide to DS473.

COMMENTS BY REVIEWER Country/Organization: FRANCE /ASN Date: April 2017 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
7.	3.1	The first subsection contains guidance on establishing and maintaining regulations and guides that set out the safety requirements/expectations and regulator recommendations or operating a facility or conducting an activity and the procedures and processes that should be carried out by the regulatory body and authorized parties.	Guides don't set requirements (see 3.6). Furthermore, guides could be internal guides that govern regulator internal processes or external guides to be followed by licensees to ease the interactions with the regulator		and maintaining regulations ~~and guides~~ that set out the safety requirements for operating a facility or conducting an activity and guides that set out the procedures and processes that		
8.	3.2	Where non-compliance or violations exist, enforcement is used to formally identify and notify it and to have correct them.	Non compliance is identified before enforcement is initiated. It is up to the licensee to correct a non-compliance.		Where non-compliance or violations exist, enforcement is used to identify and document their nature and require corrective actions to be taken by authorized parties ~~correct them~~.		
9.	3.3	The regulations and guides should specify the legally binding requirements and associated regulatory expectations/recommendations for ensuring the protection of people and the environment.	Guides don't set requirements. See 3.6		…the requirements and associated criteria for ensuring…		Modified to align with GSR Part 1 rev 1 Req. 32

COMMENTS BY REVIEWER Country/Organization: FRANCE /ASN Date: April 2017 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
10.	3.11	(c) Are consistent (including with already applicable legislation and regulations) and comprehensive; … (h) Are reviewed, and revised where necessary to be ~~and are~~ kept up-to-date.	Clarification		(h)… reviewed and revised as necessary and are kept…		c) is already implicitly addressed
11.	3.36	*Reporting of design changes, modifications ~~and non-conformances~~* 3.36. The regulations and guides should specify the requirements for the reporting of, and where necessary authorization of, changes to the design, prior to their implementation~~, and design deficiencies and non-conformances identified during commissioning or operation~~. The requirements for such reporting should be applied in accordance with the safety significance of the change, modification ~~or non-conformance~~	With regard to design deficiencies and non-conformance, what is the difference between 3.36 and 3.35 Deletion suggested… Authorization of changes may be needed.			X	Each regulatory body defines its own requirements for reporting events. Para 3.35 is addressing events, and para 3.36 is addressing specifically modifications and non-conformances (which may not be included in the definition of the "events" category). The regulatory approval of modifications is addressed in para. 3.106.
12.	3.38 3.39	Merge 3.38 and 3.39	Both are quotation without additional guidance.			X	Each paragraph belong to a different GSR Part 1 rev1 Requirement.

COMMENTS BY REVIEWER Country/Organization: FRANCE /ASN Date: April 2017 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
13.	3.46	~~The regulatory body's internal guidance on review and assessment should be made available to other regulatory bodies worldwide.~~	Excessive			X	His paragraph is intended to foster the exchange of regulatory experience but it is the decision of each regulatory body on how to proceed.
14.	3.48	(d) The development of an inspection programme <u>if such responsibility lies with inspectors</u>.	Inspection programme is developed at the corporate or reginaol office level, not at the inspector level			X	The audience of these guidance includes inspectors, but the documents are developed at an organizational level.
15.	3.49	The regulatory body should stress in the guidance the importance of objectivity and fairness on the part of inspectors, together with the need to respect the rules of the facility or activity as established by the authorized party <u>(as long as they don't unduly impede inspection)</u>.	Clarification			X	The rules of the facility are related to safety and operational aspects and the regulatory body staff (inspectors) should abide by them. In addition, these rules are reviewed/approved by the regulatory body as part of the review and assessment prior to issuing an authorization.

COMMENTS BY REVIEWER Country/Organization: FRANCE /ASN Date: April 2017 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
16.	3.51	Considering the level of detail of legislation and regulations, Guides should describe ~~in detail~~ the decision making approach of the regulatory body in determining the type and extent of the enforcement actions to be taken and the way in which the actions are to be taken, including how the failure of the authorized party to comply with requirements for regulatory enforcement is dealt with. Guides should also indicate which other governmental organizations, if any, are to be informed in the event of enforcement actions.	Legislation and regulation do include several requirements on enforcement process and maximum actions	X			
17.	3.54	The regulations and guides ~~should~~ may specify generic release criteria for use in the evaluation of potential radiological consequences associated with a site after its release.	Not always true.			X	The position of the IAEA is a stronger encouragement for regulatory bodies to establish generic release criteria.
18.	3.57	In some States, for example, detailed guidance is preferred to prescriptive regulations even if enforcement possibilities may be, as a consequence, be made more limited.	Clarification			X	General statement, which is not specific to enforcement.
19.	3.59	IAEA Safety Standards may be adopted into national regulations by the addition of appropriate specific requirements or by reference, or by adapting the Safety Standards as necessary ~~and~~ or by issuing them as national guides or incorporating them in guides.	More options are available	X			

COMMENTS BY REVIEWER Country/Organization: FRANCE /ASN Date: April 2017 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
20.	3.61	When regulations, guides and other relevant information issued by a regulatory body in another State are considered in the development of regulations, particular attention should be paid to the legal framework of that State and long term consequences of such option.	This choice will have long term consequences….			X	The focus of this paragraph is the compatibility with the national legal framework in the country which is planning to use the regulations and guides.
21.	3.64	The regulatory body may find it useful to gather industry and other stakeholders' views or set up an advisory committee to advise on the need for regulations and on their technical content.	Industry view and other stakeholders views may be helpful in this matter			X	This paragraph addresses specifically the GSR Part 1 rev 1 Req 20. The decision related to the composition of advisory bodies is made by the regulatory body, and may include or not industry and other stakeholders. Involvement of interested parties is addressed by paras. 3.51 and 3.63
22.	3.64	The members of the advisory committee should be independent of the regulatory body and of authorized parties to ensure separate and unbiased safety reviews.	This recommendation creates an unbalanced expectation…		independent of the regulatory body and of authorized parties to ensure separate and unbiased ~~safety~~ reviews.		

COMMENTS BY REVIEWER Country/Organization: FRANCE /ASN Date: April 2017 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
23.	3.66	The process of developing regulations and guides should be described in ~~clear~~ procedures and should be flexible enough to permit timely revisions to be made to take account of changes in technological, legal and practical conditions.	Clarifications	X			
24.	3.68 (b)	the need for, benefits and the ~~costs~~ potential drawbacks associated with ~~improvements in safety~~ new or revised regulation or guidance;	Cost is often difficult to assess…. Furthermore, cost is not the only "drawback"…			X	Cost considerations (cost-benefit analysis) are one of the elements to be considered. Regulatory bodies may develop specific guidance for the licensee on this topic.
25.	3.68 (c)	Determining the scope of the regulations or guide and whether a regulation or a guide is to be developed. This involves clear identification of the facilities and activities to which regulatory requirements or recommendations are to be applied, as well as the stage of the authorization process to be covered and the technical topic to be addressed.	Choosing whether a legally binding text or a guidance will be developed is a key step.		First modification rejected – see justification.		The need has already been identified in (a).
26.	3.68 (e)	Collection of information. The information necessary to prepare the proposed regulations or guide should be collected. In particular the state of the art in technology and relevant good practices should be taken into account.	State of the art in technology is not the sole input. Further more, regulations and guides do address human and organizational factors, financial resources….			X	Each regulatory body should describe in its process the sources of information for the development of regulations and guides. This may include good practices.

COMMENTS BY REVIEWER Country/Organization: FRANCE /ASN Date: April 2017 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
27.	3.68 (f)	They should be relevant, precise and unambiguous so as to be readily understandable and applicable ~~and enforceable~~.	Guides are not enforceable.		applicable and enforceable, as appropriate.		
28.	3.69	Delete 3.69	The goal of this recommendation is unclear. What is the purpose of grouping guide?			X	This paragraph was developed based on the inputs received during the development of this guide. It is aimed to increase the efficiency of the regulatory framework.
29.	3.76	The extent to which the proposed changes are to be made applicable to facilities and activities that have already been authorized and the degree of back-fitting to be required should also be considered, either by general provisions already established, dedicated provisions incorporated in the nex regulation or case by case decisions.	Clarification			X	The regulatory bodies should develop guides to address this topic.
30.	3.94	After having determined that the justification principle has been implemented, The regulatory body should specify the conditions under which consumer products that contain radioactive material may be made available to the public, who have no regulatory obligation with respect to the product. In this context, the presumption is that the consumer product can be used and disposed of without any special safety measures being required. The provision of consumer products to the public is subject to authorization by the regulatory body unless their use has been exempted (see Requirement 33 of GSR Part 3 [3]).	The Radiation Safety principle of justification is to be reminded.	X			

COMMENTS BY REVIEWER Country/Organization: FRANCE /ASN Date: April 2017 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
31.	3.100	~~(d) Specification of the management system for the facility or activity~~;	Excessive (for example for a dentist…)			X	It is applicable, based on the graded approach.
32.	3.106 (d)	~~(iv) Evidence of trustworthiness of all staff who will be engaged in responsible or sensitive positions.~~	Not a safety question. Licensing from a security point of view is not within this guide…			X	It is not related to security; trustworthiness is a characteristic for a leader/manager/staff with safety function.
33.	3.107	3.107. The information required for notification (see para. 3.100) may be described in a 'notification form', which could be paper based or web based.	Clarification. Notification through Internet should be encouraged…			X	Up to member states to decide and specify.
34.	3.110	The format of an authorization will depend on the type of authorization (registration or licence) and its content and, for complex facilities or activities, on the conditions deemed necessary by the regulatory body for a given stage of the authorization process in accordance with national legal procedures.	Clarification			X	The term "authorization" has already been defined to include various options (see para 1.6).
35.	3.122	For relevant activities and facilities, The authorization process, including any processes for renewal of authorizations, should be carried out in a transparent manner, providing opportunities for communication and consultation with interested parties such as the public The regulatory body should consider holding meetings with interested parties to provide information on the authorization renewal processes of nuclear installations.	This is true for major installations, not for dentists…			X	This safety guide covers all facilities and all activities The regulatory bodies define the specific elements of the authorization process, based on a graded approach..

COMMENTS BY REVIEWER Country/Organization: FRANCE /ASN Date: April 2017 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
36.	3.123	The review and assessment by the regulatory body of a submission in terms of a generic design in a pre-authorization assessment, if completed satisfactorily, means that it may be accepted as the basis for granting an authorization <u>once site specific and applicant specific matters have been found satisfactory</u>.	Clarification and consistency with 3.124			X	Para 3.123 addresses the generic design only as basis, and is supplemented by specific information in 3.124.
37.	3.124	Such limited submissions should concentrate on those aspects for which the particular facility under consideration differs from the reference facility or the generic design, and in particular on those features that are particular to the chosen location or site <u>and those related to the applicant organization and capabilities to safely construct, commission and operate the facility.</u>	In an authorization process, both the facility and its future operator have to be reviewed….			X	Organizational capabilities are not part of the submission for this stage of the authorization.
38.	3.126	Combining the authorizations (e.g. for construction and operation) may also give more predictability to the process for the authorized party <u>but will also require some information to be submitted earlier in the licensing process.</u>	For the applicant, a drawback is to provide early in the process information about the facility operation, not only its desgn…		<u>…earlier in the process.</u>		
39.	3.128	Once an initial authorization has been issued <u>for a facility</u>, subsequent activities and arrangements should be undertaken by the authorized party and the regulatory body, as part of the authorization process. ~~These may include requests to conduct further activities, including construction of additional facilities on the site.~~	The last sentence brings ambiguity as the authorization is for one (or several) designated facility(ies). If additional facilities are to be built, a new initial authorization is required…	X			
40.	3.129	On a particular site, there may be different facilities and/or activities at different stages of their lifetimes. Where there are different authorized parties on the same site, or on neighboring sites, the regulatory body should <u>foster, and if necessary</u> ensure <u>through licence conditions,</u> cooperation between the authorized parties.	Clarification on both type of drivers to ensure cooperation.			X	Regulatory body should take the necessary measures to ensure this cooperation.

COMMENTS BY REVIEWER Country/Organization: FRANCE /ASN Date: April 2017 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
41.	3.129	In cases where several authorized parties are permitted to share common safety related items, arrangements should be reviewed ~~made~~ to ensure that overall safety is not compromised.	To focus on regulator's job	X			
42.	3.130	Site evaluation for many facilities or activities, when the location bears a safety significance, is initially determined by general processes rather than by highly prescriptive technical criteria.	Site location for a dentist is not so important….			X	This safety guide covers all facilities and all activities The regulatory bodies define the specific elements of the authorization process, including site evaluation, based on a graded approach.
43.	3.130	General requirements concerning remoteness, environmental concerns, local population density and transport arrangements may apply, which may not be within regulatory control. Geological and hydrogeological considerations should be major factors in site evaluation~~, particularly for radioactive waste disposal facilities~~. The regulatory body should consider being involved in the formulation of site selection criteria and in the process of determining the general suitability of a site. Further recommendations on site evaluation are provided in Refs [22–31].	True also for NPP, fuel cycle facilities….			X	The intention is to highlight considerations for radioactive waste disposal facilities.
44.	3.133	There is some overlap between the construction and commissioning stages, in that individual structures, systems and components might be commissioned before completion of the construction of the entire facility or the installation of all systems required for the ~~activity~~ commercial operation.	To avoid confusion between facilities and activities		…for ~~the~~ an activity.		The activity here does not mean "operation of facility". It suggest a generic activity not associated to a nuclear facility .

COMMENTS BY REVIEWER Country/Organization: FRANCE /ASN Date: April 2017 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
45.	3.133	However, for a nuclear installation, the introduction of fissile material or other radioactive material into the facility or activity marks a significant step within the commissioning stage and is often considered the main point at which regulatory decisions are made.	Clarification			X	The paragraph is applicable, based on a graded approach, to all facilities and activities.
46.	3.134	Commencement of operation of a nuclear installation should be authorized only once commissioning tests have been completed and their results assessed, and operational limits and conditions have been reviewed and assessed by the regulatory body.	Not true for a dentist…			X	The paragraph is applicable, based on a graded approach, to all facilities and activities.
47.	3.135	Over the full operational lifetime of the facility or activity with significant safety stakes, the regulatory body should require the authorized party to provide evidence at appropriate intervals, in the form of a comprehensive safety review, such as a periodic safety review [36], that the facility or the activity is still fit to continue in operation.	Not true for a dentist…			X	The paragraph is applicable, based on a graded approach, to all facilities and activities.
48.	3.137	This categorization should follow an established procedure, which should be subject to agreement or approval by the regulatory body if not already established in regulations or regulatory guidance.	Categorization scheme may be set by regulations…			X	The categorization of safety significance by the authorized parties is made based on the regulatory requirements.
49.	3.138	For relevant facilities and activities, Plans for radioactive waste management and decommissioning (including technical solutions, waste streams, the governmental and regulatory policies for disposal, and funding) should be reviewed and updated periodically during operation.	Decommissioning plan for a dentist is not reviewed nor updated…			X	The paragraph is applicable, based on a graded approach, to all facilities and activities.

COMMENTS BY REVIEWER Country/Organization: FRANCE /ASN Date: April 2017 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
50.	3.141	Before release from regulatory control, the authorized party should be required to demonstrate to the regulatory body that the site meets the release criteria and that any other requirements related to termination of activity are met.	Make it a bit broader at site release may not be the only criteria (e.g.: rad waste removal…) See 3.188			X	Release criteria includes all the necessary elements to be met.
51.	3.145	Essential documents to be prepared by the authorized party in the authorization process should be identified in the legislation or regulations and their detailed contents should be described in guides issued by the regulatory body.	Clarification		Regulations and their content should be described in…		The compliance is assessed based on the regulatory requirements set out in the regulations.
52.	3.159	The basic objective of regulatory review and assessment is to determine whether the authorized party's submissions demonstrate that, throughout the lifetime of the facility or duration of an activity, safety will be ensured. It includes verification that the facility or activity ~~it~~ will comply with all safety requirements established in the legislation and regulations or stipulated or approved by the regulatory body.	Compliance is a subset within review and assessment as some requirements are qualitative and leave room for interpretation. Some requirements may not be established by the regulatory body.				Paragraph does not focus on verifications.
53.	3.165	(2) Specification of the purpose of and ~~technical~~ bases for the review and assessment ~~process (these could be considered acceptance criteria for the review and assessment)~~;	Bases may include administrative points, not only technical.			X	The administrative aspects are part of the process flow. The paragraph focuses on the technical content to be addressed.
54.	3.165	(3) Identification of the additional information, if any, necessary for the review and assessment;	There may not be a need for further information.		Identification of ~~the~~ additional information, if necessary, for the review and assessment		

COMMENTS BY REVIEWER Country/Organization: FRANCE /ASN Date: April 2017 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
55.	3.172	~~However,~~ this section provides a general overview of major areas for review and assessment <u>for a nuclear installation</u>.	To be consistent with the example given in the following paragraphs			X	Modification not needed because graded approach is to be applied, as specified in the first part of para 3.172.
56.	3.173	~~Natural phenomena to be considered should include earthquakes, high winds, flooding, and other phenomena as appropriate for the geographical location of the facility or activity.~~	Too detailed and not applicable to all facilities and activities. Idea already covered in the previous sentence.			X	Modification not needed because graded approach is to be applied.
57.	3.177		Radiation risks may be present during the construction or inactive commissioning, for example due to non-drestructive tests with X-ray or gamma source.		~~Clearly,~~ Radiation risks are present <u>mainly</u> ~~only~~ in the second stage.		We believe suggestion addresses the concern appropriately.
58.	3.193	To facilitate the review and assessment process for a facility or activity, the regulatory body should consider developing lists of approved equipment containing radiation sources, <u>for example</u> based on the submission of a certificate confirming compliance with international industry standards (e.g. of the International Electrotechnical Commission and the International Organization for Standardization) <u>with proper substantiation</u>. ~~An expert with the appropriate skills or an independent accreditation laboratory of the State concerned, or of another State or an international organization, should issue the certificate in accordance with the results of a review of a generic safety assessment for the type of facility or activity. The generic safety assessment should be documented, together with a summary of the conditions of use of the equipment and any appropriate limitations on its use.~~	Too detailed. Keep the general idea of an approved list of equipement			X	This paragraph is coming from GS-G-1.5. No changes are required.

COMMENTS BY REVIEWER Country/Organization: FRANCE /ASN Date: April 2017 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
59.	3.202	A well-engineered facility or activity will not achieve the required level of safety if it is not properly built, operated and managed.	Clarification	X			
60.	3.204	The review and assessment by the regulatory body should cover ~~all~~ key aspects of the authorized party's management and organizational procedures and systems that have a bearing on safety,	Excessive			X	The regulatory body will define in its review and assessment program which aspects to be reviewed, based on safety significance.
61.	3.222	Regulatory inspection is performed to make an independent check on the authorized party and the state of the facility or activity, and to provide ~~a high level of~~ confidence that the authorized party is in compliance with the safety objectives prescribed or approved by the regulatory body.	Excessive	X			
62.	3.222	(a) The authorized party is in compliance with ~~all~~ applicable laws, regulations and authorization conditions, and all relevant codes, guides, specifications and practices;	Excessive	X			
63.	3.223	(a) Conducting planned inspections, at ~~all~~ relevant steps of the authorization process;	Excessive	X			
64.	3.224	~~The major activities of the inspection process are related to the steps of the authorization process.~~	Superfluous Redundant with 3.224		major activities of the inspection ~~process~~ programme		Modified to make the link between the inspection progrtamme and stepf of authorization.

COMMENTS BY REVIEWER Country/Organization: FRANCE /ASN Date: April 2017 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
65.	3.227	The inspection programme should be thorough enough to ensure that the regulatory objectives and requirements are being met, thereby providing the regulatory body with ~~a high level of~~ confidence that the authorized party is effectively maintaining the safety of the facility or activity. The inspection programme should also be developed so that the regulatory body can determine whether the authorized party conducts activities in accordance with previously established ~~high quality~~ procedures, and has an effective self-assessment process capable of prompt identification and correction of actual and potential problems.	Excessive	X			
66.	3.231	In addition to verifying compliance with regulatory requirements, <u>if not already reported by the authorized party,</u> the regulatory body's inspection programme should be able to obtain a general indication of safety performance at the facility or activity….	There are other means than inspection to collect such information….			X	The performance reported by the authorized party is taken into account by the regulatory body when conducting integrated safety assessment, as per GSR Part 1 rev 1, para 4.46.
67.	3.258	Transfer "On major facilities, many States allow for 25% of the inspection time to be available for reactive inspections." into a footnote	Both "major facilities" and "many States" offer a wide range of interpretation…. This is not a strong recommendation and a footnote would be preferable.			X	Guidance is needed to give an indication about reactive inspections.

COMMENTS BY REVIEWER Country/Organization: FRANCE /ASN Date: April 2017 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
68.	3.263	Whenever the authorized party makes use of the safety related services or products of a contractor, the regulatory body should include the authorized party contractor supervision and contractor's activities in its inspection programme in all steps of the authorization process.	To recognize prime responsibility for safety is by the licensee, the first are of inspection should be contractor supervision by the licensee, not contractor performance.		…should include the contractor's supervision by the authorized party and the contractor's activities…		
69.	3.269	In individual inspections, one or more of these methods should be employed ~~in a balanced way~~, depending on the specific issues being considered.	Unnecessary.	X			
70.	3.286	The report should be reviewed and approved in accordance with the regulatory body ~~established~~ internal procedures.	Clarification		procedures of the regulatory body		
71.	3.294	Although it may be the practice in some States to publish individual inspection reports or inspection follow-up letters sent to the authorized party, as long as such reports and letters ~~may~~ do not contain confidential information, such as nuclear security information, information that the regulatory body may wish to use in connection with future regulatory actions, proprietary information, or personal or medical information relating to individuals. ~~Such information should not be made publicly available.~~	Simplification		Such information should ~~not~~ be ~~made publicly available~~ processed in accordance with the relevant national requirements.		
72.	3.296	Upon satisfactory completion of the actions, the inspection findings should be formally closed ~~in writing~~ and necessary documents and records should be maintained.	To enable flexibility	X			

COMMENTS BY REVIEWER Country/Organization: FRANCE /ASN Date: April 2017 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
73.	3.312	~~In many States,~~ When inspectors are not empowered to implement immediate enforcement actions for non-compliances with regulatory requirements or violations of authorization conditions~~, to enable a more rapid response and improvement in safety. Where immediate enforcement authority is not granted to individual inspectors,~~ the transmission of information to the regulatory body should be quick enough ~~commensurate with the urgency of the situation~~ so that necessary actions are taken in a timely manner. Information should be transmitted immediately if an inspector judges that the health and safety of workers or the public are at risk, or that the environment is endangered.	For consistency with 3.311			X	3.312 provides additional information on the immediate enforcement and reflects the current practice in many States.
74.	3.324	Delete 3.324	Not focus on regulatory body action.			X	This paragraphs is relevant for the regulatory body role in the EPR.
75.	3.326	The functions and processes in which the regulatory body will have a role can be considered under the following four general headings: (a) Ensuring that on-site emergency arrangements are in place; ~~(b) Ensuring coordination with off-site response organizations;~~ (c) Establishing and maintaining internal arrangements for emergency preparedness and response, including for ensuring coordination with off-site response organizations; (d) Discharging its assigned responsibilities in emergency response.	Bullet (b) is unclear as there is ambiguity on whether it the licensee's coordination with off-site organizations or the regulator's coordination.			X	The focus of b) is on coordination with response organizations (not internal).

COMMENTS BY REVIEWER Country/Organization: FRANCE /ASN Date: April 2017 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
76.	3.332	As part of its inspection plan, the regulatory body should inspect and evaluate the on-site emergency arrangements against pre-determined criteria ~~and checklists~~.	Superfluous			X	Checklists are specific tools part of the logistical support for emergency response.
77.	Appendix I	Transform Appendix I into an annex	Detailed guidance would better fit under a Safety Guide under GSR Part 3….			X	Considering the difference between an annex and an appendix, maintain current configuration.
78.	I.2	The documentation should include the following: (a) A description of the consumer product, its intended uses and benefits, the radionuclide(s) incorporated and the function served by the radionuclide(s). Documentary evidence that the radioactive substance fulfils its function should also be provided; (b) Information supporting the implementation of the justification principle established in requirements 10 and 33 of GSR part 3; (c) The activity of the radionuclide(s) to be used in the consumer product.	To help in reviewing whether the justification principle is or not met			X	Justification is addressed in the next paragraph on additional information. Renumbering performed.
79.	Appendix II	Transform Appendix II into an annex	A flexibility is needed with regard to the type of facility or nuclear installations			X	Considering the difference between an annex and an appendix, maintain current configuration.
80.	Appendix III	Transform Appendix III into an annex	A flexibility is needed with regard to the type of facility or nuclear installations			X	Considering the difference between an annex and an appendix, maintain current configuration.

COMMENTS BY REVIEWER Country/Organization: FRANCE /ASN Date: April 2017 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
81.	Appendix IV	Transform Appendix IV into an annex	A flexibility is needed with regard to the type of facility or nuclear installations			X	Considering the difference between an annex and an appendix, maintain current configuration.

COMMENTS BY REVIEWER Reviewer: DANDRIEUX Page.... of.6. Country/Organization: FRANCE / MEEM Date: 10/05/2017				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
DS 473							

1	Page 12	Add new 3.5 bis : Projects of new regulation should be submitted for comments to the authority in charge of regulating nuclear security to avoid conflicting requirements.	need to coordinate regulations.			X	Provision of regulations and guides is subject to para. 3.3., addressing R 32 to 34 of GSR Part 1 rev 1. Paragraph 4.61 of GSR Part 1 rev 1 indicates that the processes for developing regulations and guides includes consultations with interested parties. The authority in charge of regulating nuclear security may be one of them. This is a responsibility of the
2	p36	(xvi) Arrangements to ensure safety ~~and security~~ of radiation sources in order to prevent loss of control due to theft, diversion or severe environmental conditions	This guide is on safety not security			X	Information on arrangements for the security of sources needs to be submitted to the regulatory body in support of an application for authorization (or

3	p37	(a) For a specific time period (e.g. 10 years, 40 years) or for a specific stage in the lifetime of the facility (e.g. construction, operation) or for the duration of an activity. In such a case, a mechanism should be put in place to ensure that the authorized party responsible for the facility or activity retains the prime responsibility for safety ~~and for the implementation of security measures~~ at the facility or for the activity, even if the authorization has expired,unless the site has been removed from regulatory control.	This guide is on safety not security			X	Security measures must be demonstrated to ensure the authorized party is responsible and accountable for the facility or activity, especially for the case in which the authorization has expired. The paragraph mentions the need
4	3.349.	The regulatory body should develop and implement a communication and consultation strategy and should be committed to a high level of transparency and openness, while ensuring adequate level of protection of sensitive information, in order to address the legitimate concerns of interested parties in nuclear and radiation safety matters, to enable the regulatory body to make informed decisions and to contribute to ensuring its freedom from undue influences that might adversely affect safety.	Need to take security of information into account in the communication and consultation strategy	X			

	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: 2017-05-10				RESOLUTION			
Rele-vanz	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/reject ion
2	1	1.4	“The recommendations provided in	Usage of the more	X			Same

			this Safety Guide and DS472 [4] are intended mainly to be used by regulatory bodies, but can be also useful for governments that are developing a regulatory framework for radiation and nuclear safety. This Safety Guide will also assist authorized parties and others dealing with ~~nuclear and other radioactive materials~~ radiation sources in understanding regulatory procedures, processes and expectations.”	general wording. The guide is intended ensure safety for all facilities and activities that give rise to radiation risks. This also includes devices like radiation generators, not only radioactive materials.				modification was performed for DS472 para 1.6.

COMMENTS BY REVIEWER Reviewer: T. Homma Page.1.. of..1.. Country/Organization: JAPAN/Nuclear Regulation Authority Date:10.05.2017				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	3.341	(a) Send staff to appropriate locations during a nuclear ~~and~~ or radiological emergency;	To conform to the wording of GSR Part7.	X			
2	3.344	The regulatory body should collect information and analyse the situation and compare its ~~prognosis~~ observable conditions with that of the authorized party.	Because it is too difficult to estimate the prognosis of an accident, the regulatory body should make decision based on the observable conditions.		The regulatory body should collect information, ~~and~~ analyse the situation and compare its ~~prognosis~~ findings with that of the authorized party.		To avoid confusion while avoiding to undermine the necessity for making such analysis (which generally is expected to cover what happened, what is happening and how is expected to evolve), we accept this comment with

							modification and change the 'prognosis' with 'findings'. For consistency with GSR Part 7 in line with above explanation.

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.	1.6.	**The objective of this Safety Guide is to provide recommendations on ~~meeting the requirements of GSR Part 1 (Rev. 1) [2] on~~ the regulatory body's core functions and the associated processes to implement those functions. The core functions addressed in this Safety Guide are those described in GSR Part 1 (Rev. 1) [2] ~~and in Preparedness and Response for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GSR Part 7 [7]~~ and comprise:** (a) **The development and/or provision of regulations and guides;** (b) **Notification and authorization, including licensing procedures;** (c) **Regulatory review and assessment;** (d) **Regulatory inspection;** (e) **Enforcement;** ~~(f) Emergency preparedness and response~~ (f) **Communication and consultation with interested parties.** **The function on preparedness and response for a nuclear or radiological emergency described**	The nature of emergency preparedness and response is different from that of other functions assigned to regulatory body, as GSR part 1 (Rev. 1) defines that emergency preparedness and response is one of the responsibilities and functions of government, meanwhile another elements (bullets (a) – (f)) are those of regulatory body.			X	Emergency Preparedness and Response is a core regulatory function, regardless of the magnitude of this function (as per GSR Part 1 Requirement 8).

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				
		in GSR Part 1 (Rev.1) [2] and GSR Part 7 [7] is performed with participation of many governmental agencies including a regulatory body. Also, national regulatory framework for emergency preparedness and response varies among the States. In this Safety Guide, some of the aspect which could be assigned to the regulatory body as its core function are described.					
2.	3.15. /(j)	**The safety objectives and regulatory requirements should cover, among other things, as appropriate:** **(j) Some aspect of ~~E~~emergency preparedness and response.**	All of the regulatory requirements for emergency preparedness and response may not be governed by the regulatory body, depending on national legislation.			X	This is clearly stated in the end of the paragraph: "as appropriate"

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	§2.5/15	[t]he → the	Typing error			X	Editorial marking of replacing of a capital letter in the original text from GSR Part 1 rev.1

							para 4.54.
2	§3.16/7	For the entire lifetime of the facility or the duration of activity	Contextually consistent		…or duration of the activity.		
3	§3.24/4	(see para. 3.113→(see para. 3.116)	Authorization condition can be referred in para. 3.116	X			
4	§3.28/1	The ~~government or the~~ regulatory body should	In the requirement 3 of GSR Part 3, the responsibility of the regulatory body may be regulated.			X	The bullets under this sentence contain recommendations for both regulatory body and government (e.g. c, d are for governments)
5	§3.161/5	~ framework [of the ~ → framework of the ~	Typing error	X			
6	Para 3.213	Delete this paragraph	Too much specific to be described, separately, and covered by Para 3.222, in general			X	Paragraphs 3.213 and 3.222 do not overlap. Para 3.213 is based on Req.27 of GSR Part 1 Rev 1 and para 3.222. addresses objectives of inspection.
7	Para 3.214	Delete this paragraph	Too much specific and covered by Para 3.216			X	
8	Para 3.223	Rewrite the items of (a) thru. (h) with those items in page 14 of SRS No. 81	For a better understanding		(h) Verifying that corrective actions have been undertaken by the authorized party to resolve safety issues identified		Items are coming from GS-G-1.3 para. 3.2. Added bullet on verification of corrective action program.

					previously;		The bullet on verification of compliance was removed because it is covered in the general objectives of inspection.
9	Para 3.225	Make bold the subtitle, "Inspection programme"	For the consistency of form			X	Sub-sub-title. Order is correct.
10	Para 3.228 (c) and (d)	The investigation and follow-up of the past event and deviations from normal operation	For the clarity of elements			X	"Follow-up" involves tracking of past events.
11	Para 3.228 (c) and (d)	The information on the compliance of licensing bases by authorized parties	To focus on the elements			X	Compliance with licensing basis is addressed in through demonstration of compliance with regulatory requirements and with any conditions specified in the authorization (para 3.226). The submission of information on key operational safety parameters by authorized parties (para 3.228 (d)) includes any deviations from compliance with with regulatory requirements and with any conditions

							specified in the authorization. The requirements for reporting such deviations are established by each regulatory body (see also paras 3.34, 3.35).
12	§3.302/3	all stages of the lifetime of the facility or the duration of the activity	Contextually consistent		…or duration of the activity…		

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Robert Moscrop Country/Organization: UK/ONR			Page 1 of 2 Date:19/5/17				
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	3.137	Change "…which should be subject to agreement or approval by the regulatory body." To "…which may be subject to agreement or approval by the regulatory body."	In the UK we would not necessarily formally approve a licensee's arrangements for modifications.	X			
2	II.3 (b)	Change "The facility should be constructed in accordance with the design that has been approved by the regulatory body. The authorized party should not deviate from the approved design in any way that might affect safety without the prior approval of the regulatory body." To	In the UK we do formally approve designs, only activities such as construction or commissioning. Likewise, the need for formal regulatory approval of a modification is based	X			

		"The facility should be constructed in accordance with the design that has been justified in a safety case. The authorized party should not deviate from this design in any way that might affect safety without following a modification process that requires categorization of the modification according to safety significance. This modification process may require approval or agreement from the regulatory body depending upon the safety significance of the modification."	upon the safety significance of the modification.				
3	III.12 (a)	Change "(a) formal approval and documentation for all.." To "(a) formal approval and documentation where required by the regulatory body for all.."	In the UK the regulatory body would not formally approve the licensee's operational procedures.	X			

COMMENTS BY REVIEWER Reviewer: Cynthia Jones, NUSSC Member Page.... of.... Country/Organization: USA/Nuclear Regulatory Commission Date: May 16, 2017				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	p. 55 3.145 (of marked up version DS473V6)	Following the quote from GSR Part 1, insert: The authorized party is fully responsible for the work performed on its behalf by vendors or contractors. Recommend revision it to state: "The regulatory body shall review and assess relevant information~~— whether submitted~~	There is a need to ensure that the authorized party takes full responsibility for the work performed on its behalf by a vendor or contractor; this cannot be done by the regulator. The reason for the rejection of			X	The paragraph proposed for modification is now 3.151. (see DS473V7 (April 2017) submitted for Step 11 following

		~~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. The authorized party is responsible for work performed by its vendors or contractors and for ensuring compliance with the reguirements."	this comment is not clear. We understand that this para covers the responsibilities of the regulatory body, but it is the Authorized party, not the regulator that is responsible for determining compliance with the regulatory requirements.				Technical editorial review) and quotes GSR Part 1 rev 1. R25 verbatim, thus cannot be changed.
20	p. 76 3.212 Inspection Objectives (of marked up version DS473V6)	While we understand that the purpose of inspection is to verify compliance, we strongly recommend item (f) be modified to include inspection efforts made in prevention of non-compliances or performance degradation (so-called 'look ahead') functions	Inspection programs should foster a questioning attitude and forward thinking, as well as attention to detail for current or past non-concurrences. Identification of non-compliances or degradation that has already occurred and imposing consequences is only reactionary, while the inspector should be forward thinking as well.		(new f)<u>Detecting degraded performance and potential non-compliances;</u> (New g) Tracking recurrent problems and non-compliances;		The paragraph proposed for modification is now 3.223. (see DS473V7 (April 2017) submitted for Step 11 following Technical editorial review). Please see proposed modification.