DS473

FUNCTIONS AND PROCESSES OF THE REGULATORY BODY FOR SAFETY

RESOLUTION OF MEMBERS COMMENTS

On

DS473 Version 1 (DS473_Submission_SSC_16042015)

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	3.26 f	Provision of information to, and consultation with, parties affected by its decisions and~~, as appropriate,~~ the public and other interested parties	Considering the importance of the commitment to openness and transparency the wording could be strengthened by deleting "as appropriate"	Y			
2	3.358	The regulatory body should develop and implement a communication and consultation strategy and a culture of transparency and openness, and to involve~~, when appropriate,~~ interested parties in order to establish and maintain trust in its independence, competence, integrity and impartiality. Throughout this Safety Guide, it has been noted that the dissemination of information to the public and other interested parties is considered a good practice: this is included in requirement 34 of GSR Part1 [2] for	Considering the importance of the commitment to openness and transparency the wording could be strengthened by deleting "as appropriate"	Y			

		example. Increasingly, the consultation of the public to ascertain its views, whilst retaining the guidance and recommendations concerning regulatory body communication and consultation are covered in [13].					

FUNCTIONS AND PROCESSES OF THE REGULATORY BODY FOR SAFETY

DS 473 – Functions and Processes of the regulatory body

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Reviewer: ENISS Page 1 of 5 Country/Organization: ENISS Date: 21.05.2015							
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
	Over-arching	From our point of view, the draft needs revision, bevor submission to member states! The guide in the present form is not readable – it needs restructuring, needs to be shortened, repetitions should be avoided and it should be clarified in a couple of points. Our main points/suggestions are as follows:					
1	General	The guide is made for all facilities and activities – a lot of the recommendation are made for complex facilities with significant risk potential, which normally involve intensive regulatory activity – we suggest to keep the guiding text as general as possible and work with appendixes for showing examples of regulatory processes for different facilities or activities.				Y	The functions to be applied by a regulatory body are the same across all facilities and activities. However, their application varies according to the specific requirements and the graded approach based on the

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							radiation risk. The guidance is therefore aimed at the higher risk with the reference to the graded approach for applications at a lower risk.
2	General	Chapter 3 need splitting into different chapters – 300 paras in one chapter is not readable				Y	Current structure of DS473 is consistent with the approved DPP.
3	General	There is a lot of unnecessary repetitions, explaining the same information in a slightly different context and enlarging the volume of the guides unnecessarily (e.g. 3.35 and 3.38, 3.90(b)/(c) and chapter "scope and content of regulations and guides", 3.94 and chapter "scope and content of regulations and guides", 3.170f and 3.131, 3.172 and 3.133, 3.194ff already mentioned in chapter "Regulations			Duplication on records between 3.35 and 3.38		

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		and Guides") as well as misplaced information (3.119 belongs to "Notification and Authorization", 3.120 belongs more to "Inspection of facilities and activities" then to "stages in the authorization process", 3.197 belongs to chapter "Regulations and Guides")			addressed. Duplication on site evaluation between 3.131 and 3.170 addressed. Unable to identify duplication between 3.133 and 3.172, or between 3.90(b)/(c) and 3.94.		

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					3.119 moved to section addressing general principles of an authorization. 3.120 moved to section dealing with "Information needed in making notification		

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					and /or applying for authorization", as text deals with keeping document up to date. Propose to leave 3.197 where it is. The current structure and content of the Section "*Bases for*		

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					Review and Assessment " is based on the same section and content given in in GS-G-1.2. Prefer to keep the same as an already approved text.		
4	General	Terms like "is required" are used, without naming the source of the requirement – either cite the source or use the normal term "should" for guides (e.g. 3.140, 3.152)			Of the 28 instances of the use		

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					of "is required", 17 included the appropriate cross reference to the source and 3 instances were of general usage, i.e. not requiring a cross reference. However, 2 instances		

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					of failing to provide a cross reference were found, i.e. paras' 3.114 and 3.140, these have been corrected. 5 instances were removed by changing "is required"		

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					to “should” and 1 instance deleted as it was not necessary. The wording is consistent with the recommendations contained in the current IAEA safety standards approved		

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					by the IAEA Member States, i.e. SSG-16 and GS-G-1.4.		
5	General	IAEA Safety Standards are not reflected in the right way in the draft, as e.g. para 3.57 states, that national regulation should be based on IAEA safety standards or should be adapted (3.60) – this is in contradiction to current IAEA and member states position (see for example "iaea-safety-standards-brochure.pdf" source http://www-ns.iaea.org/standards/default.asp?s=11&l=90&w=1)				Y	The original text and the modified text (see USA comment No 11 and South Africa comment NO 4) was/is consistent with the current IAEA position.
6	General	Principle of mutual understanding between regulatory body and licensees should be mentioned, as stated in GSR Part 2 para 4.24				Y	In accordance with the approved DPP for DS472, DS472 will address GSR Part 1 Rev1,

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							Recommendation 21.
7	General	It is good practice in many member states that a hearing of the authorized party is initiated before issuing enforcement actions of a harsher kind – this practice is missing in the guide.			Following text incorporate into para 3.45. In some Member States, the regulations and guides require that a hearing of the authorized party is		

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					initiated before issuing significant enforcement actions		
8	General	New terms are introduced in this guide, which are not in line with IAEA safety glossary and other established terms: a. “fault conditions” (used in many paras) – this term add confusion, as the relevant requirements do not mention it – as a guide making recommendations the term established in the requirements should be used. b. “radiological safety records” (para 3.280) – unclear what is meant by this –records of the radiation protections program, radiological characterization of SSCs or something else			(a) To keep the text general when necessary, the term fault has been replaced with abnormal and/or		

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					accident conditions. Terms used are now consistent with SF-1. (b) Radiological safety records replaced by dose records.		
9	General	For notifications the guide shows different meanings: in para 3.78ff it is defined for “operate a facility or conduct an activity which involves the use of radioactive or nuclear material” – para 3.99 states, notification is for sources. This should be clarified.			Reference to sources added to 3.78.		

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10	General	The guide is giving disproportionate advice (e.g. 3.91 asks for unrestricted access to everything for granting authorization – for inspection and enforcement of an authorization its o.k., but not for the authorization process, 3.159 states, that the authorized party needs to comply with all recommendations – either these are recommendations and therefore not obligatory to follow or it is an requirement; 3.226(f) advises to inspect something not specified somewhere – on which basis should that be done; 3.284 misses a statement, that the regulatory test should in no case place the plant in an unsafe state; 3.324(b) normally depends on the legal system of the state)			3.91. It is not explained why unrestricted access to information etc. is not ok for the authorization process. Text in 3.91 is the same as that in the currently approved safety standard		

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					SSG-12. Use of the word "recommendation" removed from 3.159. 3.226(f) is consistent with the text in the currently approved safety standard GS-G-1.3, para 2.3(f).		

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					3.284. Proposed text added. 3.324(b) is consistent with the text in the currently approved safety standard GS-G-1.5, para 3.88.		
11	General	Emergency preparedness and response chapter should not deal with topics, which need to be considered in an authorization, during inspection or enforcement – these topics should be enclosed in the respective chapters – the chapter should deal with the emergency			General text referring to the process and		

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		preparedness for the regulatory body itself.			functions in the Chapter 3 moved from 3.334 to 3.332. The "topic" of EPR was included in the DPP.		
12	General	The guide asks for including information into an authorization, which should be part of the legal system (e.g. 3.109 last bullet point, 3.118(a), 3.118(c), 3.118(d))				Y	Leave the text as written to allow for instances when the law does not address the issue.
13	General	As being a guide, different forms of notifications and authorizations should be described shortly – in the chapter "Notification and Authorization" (starting para 3.75) – there are some information				Y	The guide does not provide specific recommendations

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		about authorization processes for complex facilities describing different authorizations, but there is nothing explained about differences between authorizations e.g. for transport casks, the transports itself, waste storage facilities, industrial irradiation facilities, X-ray devices,… We would expect a guide to give examples of possible authorizations as well as for notifications.					for each type of authorization or notification. As an example, para 3.99 states the minimum information required, but the regulatory body could request more depending on the complexity of the facility or activity or that required by regulations.
14	General	We wonder why the page with the contributors to drafting is missing in this guide – any special reason?			Not aware of any "special reason" for		

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					excluding the contributors list (Apology to the experts for not acknowledging their excellent work). It has been added.		
15	1.12	~~1.12. The terminology used by organisations involved in operating facilities and conducting activities and their regulation, has evolved over many years and specific usages have~~	Delete para 1.12 in Scope, because he describes only Terminology. The scope itself is already described in 1.13. Provide a new chapter	Y			

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		~~become attached to specific facilities and activities. In the text a limited number of terms are used for simplicity and economy. For example, the terms 'licence', 'authorization' and 'permit' are considered to be synonymous; authorization may take different forms, such as licensing, certification, granting of a permit, registration, agreement, consent or granting of another similar regulatory instrument, depending on the governmental and regulatory framework of the particular State. In the text only the words authorization, (which may be in the form of licensing or registration), and notification appear. The term "authorized party" is used in this Safety Guide to indicate~~	"Terminology" and combine all related text.				

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		~~the person or organization responsible for an authorized facility or an authorized activity, whether they are a licensee, registrant, operator or operating organization. Also, on grounds of simplicity and economy, the term "safety" is used throughout to mean "radiation protection and nuclear safety" and similarly "operation of facilities and conduct of activities" is used to cover all practices and applications of radioactive and nuclear materials. Finally, "lifetime of facilities and activities" is used to cover both the full "lifecycle of a facility" and the "duration of an activity". "Lifecycle" is used to cover the stages of site evaluation, design, construction, installation, commissioning, operation,~~					

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		~~decommissioning and removal from 7 regulatory control, though it is noted that whilst these stages apply for all facilities, they may not do so for all activities~~					

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	General	Ds473 should be in line with the requirements document DS456 under development and the safety guide SD472.	It is important that these three document form harmonized solid basis.	Y			Noted. Consistency will be ensured with DS456 and DS472 as the draft progress.

COMMENTS BY REVIEWER Country/Organization: FRANCE/ASN Date: 22 May 2015 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1.	General	Considering that the guide address regulatory body in general, whether they regulate or inspect complex/high risk facilities such as NPPs are simpler/low-risk activities (X-ray imaging by dentist…), it seems that some paragraphs may not always be relevant. Review the guide to ensure paragraphs in the main text are <u>always</u> applicable, whatever the regulated facility/activity is.	Not all recommendations seems relevant for regulatory body not regulating large facilities. For example, for a dentist or a radioactive gauge use: - Is siting relevant? - What are OLC? - Is PSR relevant? - Will a decommissioning plan be prepared and approved? There are some sections on complex facilities but specificities of radioactive sources			X	The suggested revision of the guide does not seem to be realistic. The current form of the draft, contains recommendations covering a complex nuclear programme, and reflects the Long Term Strategy for SSs, as well as the DPP. While the observation on the applicability of all recommendations to all facilities and activities is correct, it is presumed the reader will have been aware of and understood the Long Term Strategy for SSs AND the concept of graded approach (addressed in detail in Chapter 2). Last, the SSs are not comprised of stand-alone single paragraphs, but must be

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			are highlighted in the text of more general recommendations. Some recommendations in the main txt (e.g. 3.257) are very specific and would better be in an appendix				understood as a whole. Chapter 1 addresses these prerequisites in an appropriate manner.

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2.	General	Some paragraphs with long bullet lists, for example 3.90, 3.94, 3.105, 3.160 should be simplified so that key idea relevant to all facilities/activities are kept.	See previous general comment			X	The suggested paragraphs have been checked and, while extensive, we find the information is conveyed in an integrated manner and is uniformly valid, by the application of a graded approach.

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3.	1.2	~~Increasingly, the intention has been to bring together IAEA Safety Standards which deal with similar aspects of safety. Thus~~ the Safety Fundamentals covered all facilities and activities and, similarly, GSR Part 1 [2] was not restricted in its coverage. This Safety Guide will maintain the approach by providing guidance on safety regulation applicable to all facilities and activities1, and in so doing promote a more consistent approach to the regulation of radiation risks. ~~Clear consistent guidance is particularly important for those Regulatory Bodies having responsibilities covering a range of facilities and activities that give rise to radiation risks or when interfaces are needed between various Regulatory Authorities, in order to facilitate co-ordination and co-operation.~~	Superfluous Controversial statement.	30	X The Safety Fundamentals cover~~ed~~ all facilities and activities and, similarly, GSR Part 1 [2] ~~was~~ is not restricted in its coverage. This Safety Guide will maintain the approach by providing guidance on safety regulation applicable to all facilities and activities, and in so doing promote a more consistent approach to the regulation of radiation risks. ~~Clear consistent guidance~~ This is particularly important for ~~those~~ Regulatory Bodies having responsibilities covering a range of facilities and activities that give rise to radiation risks or when interfaces are needed between various Regulatory Authorities, in order to facilitate co-ordination and co-operation.		For clarity.

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4.	1.4	~~This graded approach has been increasingly used within IAEA Safety Standards so that the similarities of the requirements can be emphasised rather than the differences~~.	Superfluous	X			
5.	1.11	The Safety Guide covers the regulatory functions, and how they are discharged, during all the phases of the lifecycle of a facility or activity from initial design through to the release from regulatory control ~~by means of associated processes~~.	Superfluous		The Safety Guide covers the regulatory functions, and how they are discharged, during all the phases of the lifecycle of a facility or activity from initial design through to the release from regulatory control by means of ~~associated~~ processes.		The text retains the reference to processes further addressed throughout the body of the draft.

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6.	2.4		"the *detail* does not necessary apply in all situations." It is unclear what "details" are to be referred to? Are the details in the recommendations? Are they something else ? If they are details not always applicable, would they better be located in a annex?		whilst descriptions of the functions are generic, the ~~detail~~ degree of application varies in accordance with the facility or activity. ~~does not necessary apply in all situations~~.		For clarity. The approach of the safety guide reflects the Long Term Strategy for SSs, as well as the DPP.
7.	2.4	For example, the degree of review and assessment applied to a nuclear power plant would clearly not be ~~required in relation to~~ the same as the one for a medical X-ray unit.		X			

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8.	2.5	The approach should also take into account any exposures to radiation and discharges or releases of radioactive substances during normal operation and in an incident or an accident, ~~as well as the possibility of events~~ <u>including those</u> with a very low probability of occurrence.	"events" is unclear			X	"event" terminology is based on GSR Part 1 (rev 1), GSR Part 3 and Safety Glossary (2007)
9.	2.6	~~Both these factors need special consideration during decommissioning or clean-up activities which will involve new procedures and processes not used during other lifecycle stages, e.g. institutional controls, including continuing environmental monitoring programs and radiological status.~~	Superfluous. Example given are not specific only to decommissioning or clean-up…			X	Decommissioning and clean-up need special consideration of the factors mentioned above in the paragraph due to the fact that they involve new procedures and processes not used during other lifecycle stages. These procedures and processes need to be tailored accordingly.
10.	3.2 to 3.5	Merge 3.2 to 3.5 into a single paragraph.	Recopy of IAEA requirements		Paragraphs were deleted.		As per Germany comment no. 4, these citations of GSRPart 1 (rev 1) requirements are not actual text of the draft.

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11.	3.7	The provision of regulations and guides~~, to be followed by the regulatory body itself or by the authorized parties,~~ should be a means for the regulatory body to ensure that regulatory control is stable and consistent, to emphasize the continuous enhancement of safety as its general objective and to build confidence among interested parties [2].	Superfluous	X			

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12.	3.7	… ensure that regulatory control is stable and consistent, to emphasize the continuous enhancement of safety as its general objective and to build confidence among interested parties [2]. The documents may be categorized as comprising legislation and regulations (mandatory by law), supporting guides (not mandatory by law) to be used either by the authorized parties or by the regulatory body (internal guidance) and other advisory documents.	Clarification Suggested text copied from 3.9			X	No added value.
13.	3.9	Delete 3.9	3.9 is not needed anymore is 3.7 is modified as proposed.			X	No added value.

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14.	3.11	~~The regulatory body should identify other documents that are required to be developed both by the regulatory body itself and by the authorized party (e.g. records of worker doses).~~	Guides to be developed by the regulators are addressed in previous paragraphs. Documents to be developed by licensee do not come under this section title.	X			
15.	3.12	The regulatory body should establish a system to ensure : - <u>The development of regulations and guide takes account a graded approach</u> - the implementation of regulations and guides based on a graded approach, such that the <u>development and</u> application of regulatory requirements <u>and guidance are</u> ~~is~~ commensurate with the radiation risks associated with the types of facilities and activities and the exposure situations.	It is questionable whether the grade approach should only be in implementing the regulations and guides or whether graded approach is also to be used in developing the regulations and guides			X	The development of regulations and guides should follow the same steps, regardless of their nature (review and revise as necessary to keep them up to date, consider relevant international standards and relevant experience gained, consult interested parties etc.). It is the coverage of regulations and guides that will be commensurate with the radiation risks, in accordance with a graded approach. GSR Part 1 (rev 1)

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16.	3.18	They also allow the regulatory body to promote learning by modifying its guides to include innovative good practices and to revoke ~~impractical or unnecessary features~~ provisions not necessary or not practicable anymore.	Alternative wording, avoiding use of "features"		Accepted, but modified as follows: They also allow the regulatory body to promote learning by modifying its guides to include innovative good practices and to revoke impractical or unnecessary ~~features~~ provisions.		For clarity.
17.	3.20	In issuing guides, recent operational experience and developments should be taken into account, including technological advances that have been proved by experience or shown by research results to be capable of providing ~~effective and reliable~~ appropriate means of satisfying regulatory requirements.	Alternative word.			X	"Effective" and "reliable" are stronger words, and implicitly include "appropriate". Effective = adequate to accomplish a purpose; producing the intended or expected result Reliable = that may be relied on or trusted; dependable in achievement, accuracy, honesty, etc.:

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18.	3.22	Consideration should be given to the extent to which the regulatory body's internal guides may be made available to authorized parties and the public. ~~Publication is an important aspect of communication with interested parties and~~ as, through openness, it helps them understanding ~~demonstrates~~ how the regulatory body is discharging its responsibilities in an appropriate manner.	Simplification Less ambitious !		Consideration should be given to the extent to which the regulatory body's internal guides may be made available to authorized parties and the public. ~~Publication~~ This is an important aspect of communication with interested parties and through openness, it demonstrates how the regulatory body is discharging its responsibilities in an appropriate manner.		This is an important aspect of communication with interested parties. "Publication" was removed, although the intention was to address all forms of publication, including websites.
19.	3.27 (d)		Deletion suggested as it is generally done in a not so detailed fashion.			X	Agree in principle, but this paragraph reflects a factor that needs to be taken into account, especially for embarking countries (for projects of developing or adopting regulations from other countries).

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
20.	3.27 (g)	(g) The financial ~~assurance~~ provisions for dealing with orphan sources, radiological accidents, decommissioning and waste management (including ~~decommissioning and~~ waste disposal);	Assurance is a narrow term. Clarification			X	Assurance is more accurate than provisions as it implies adequate provisions. It is not a narrow term as assurance can take varies forms, i.e. bonds, insurance, etc.
21.	3.32	Delete 3.32	Unnecessary. Furthermore, it may be in the legislation.	Y			
22.	3.33	Within regulations ~~and guides~~ the main content of an authorization should be specified. Regulations or guides may also, ~~as well as~~ provide generic or standard ~~the~~ authorization conditions~~,~~ ~~should be specified~~. Details regarding the content of authorization are given in the sub-section dealing with Notification and Authorization.	Clarification Authorization general content is set in regulations, not in guides. Generic (i.e. not specific to a designated licensee) licence conditions may be set in regulations or guides.		~~Within regulations and guides t~~The main content of an authorization, as well as the authorization conditions, should be specified within regulations and guides.		Simplified, for clarity. Regulations and guides generally follow the facility or activity type; and guides support the application of regulations (they might be called norms or similar).

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23.	3.35	Regulations and guides should indicate other documents that should be, periodically or at specific occasions, submitted to the regulatory body to confirm that the requirements established in the regulations and authorization conditions have been satisfied.	Clarification, to avoid overlap with 3.34			X	"as needed" in 3.34 This depends on the national practices and we consider it sufficient for the purpose of a guide.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
24.	3.37	*Reporting of changes and modifications as well as major non-conformance* 3.37. Regulations and guides should contain requirements for reporting to the regulatory body any changes ~~or major non-conformances~~ in the design, construction, commissioning or operation that may affect safety, prior to their implementation. A requirement for analyzing and ~~reporting~~ intended changes ~~and of any major non-conformance~~s should also be included. 3.## Regulations and guides should contain requirements for reporting to the regulatory body any major non-conformances in the design, construction, commissioning or operation that may affect safety. A requirement for analyzing and resolving any major non-conformances should also be included.	Refocus 3.37 on modifications and create a new paragraph on on-conformance as current text is unclear (can a non-conformance be reported prior to its implementation?). Reporting is addressed in the first sentence.		*Reporting of changes, ~~and~~ modifications and non-conformance* 3.37. Regulations and guides should contain requirements for reporting of, based upon their safety significance: • changes to the design, prior to their implementation; and • design deficiencies and non-conformances identified during commissioning or operation.		

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
25.	3.38	These records, ~~although~~ even if not formally submitted to the regulatory body for review and approval, should be made available upon request.	Clarification. These report may have to be submitted to the regulator		These records, ~~although~~ even if not formally ~~submitted to~~ requested by the regulatory body for review and approval, should be made available upon request.		
26.	3.39	If the regulatory body is not the sole entity responsible for the maintenance of these registers and inventories, it should ensure that ~~the authorized party has~~ arrangements for their proper retention and retrieval have been established. The responsibility of the regulatory body to maintain safety related records at the national level should not diminish the responsibility of authorized parties to keep their own records, as explained in the following sections of this guide.	To allow flexibility to accommodate both licensee role or other governmental agencies or TSO role in the process…			X	The only way to establish regulatory control is through authorization. That is how one becomes an authorized party. All the provisions that must be met, are aimed at the authorized party. The regulatory body is not responsible for any arrangements the authorized party might make (such as TSO), as the responsibility for safety never leaves the authorized party.

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27.	3.41	~~It is considered good practice that the review and assessment procedural and technical guidance documents should be made available to regulatory bodies worldwide.~~	Too strong. Some may be made available but it is unlikely all will be. Furthermore, procedural guidance may not be relevant in a different regulatory framework…			X	This is coming from IRRS good practices and has no enforcement title.
28.	3.42	The regulatory body should issue guides for its inspectors for performing regulatory inspections, in order to ensure a ~~systematic and~~ consistent approach to inspection while allowing sufficient flexibility for inspectors to take the initiative in dealing with new concerns that arise; each inspector should be given adequate training in following this guidance.	Consistency is the key goal. How systematic is a process is depending on many aspects…	X			

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
29.	3.43	Add a bullet " (##) Follow-up on inspection finding"	Follow-up on inspection findings is necessary, whether or not enforcement action is initiated.		Agreed; we have added it under (e) for consistency (implementation of the inspection programme)		

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
30.	3.45	Regulations and guides governing the use and implementation of enforcement actions should be issued by the Government and regulatory body, as appropriate, stating the policy for the use of regulatory and enforcement measures and the associated authority delegated to inspectors and other regulatory body staff. ~~Depending on national practices,~~ the need to allow the authorized party to state a point of view on regulatory decisions, to respond to enforcement notifications and to appeal against enforcement decisions should be recognized and taken into account in regulations and guides.	This is a general principle. How it is possible actually depends on national practices			X	This is exactly what the original phrase is saying.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
31.	3.45	~~Guides should cover in detail the decision making approach of the regulatory body in determining the level of actions to be taken and the way in which the actions should be taken, including dealing with failure of the authorized party to comply with requirements for regulatory enforcement.~~	Would be more relevant in 3.47 as 3.47 deals with the regulator internal guidance. Move to 3.47			X	There are two type of guides addressed by the two paragraphs: public guides in 3.45 and internal guides in 3.47. We prefer to keep the paragraphs unchanged.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
32.	3.47	Guides should cover in detail the decision making approach of the regulatory body in determining the level of actions to be taken and the way in which the actions should be taken, including dealing with failure of the authorized party to comply with requirements for regulatory enforcement. The regulatory body should issue internal guides for its staff, in order to ensure a systematic and consistent approach to the enforcement process.	See comment on 3.45			X	See above.
33.	3.50	In the regulations and guides generic release criteria ~~should~~ may be included for the evaluation of potential radiological consequences associated with a site after its release.	It is not France practice to set *a priori* generic release criteria.			X	This is an existing IAEA safety recommendation and has been part of the IAEA safety standards since 2006, see WS-G-5.1.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
34.	3.55	Whilst regulations may be established, in whole or part, by government, the regulatory body should ~~generally~~ be involved in the development process. In the following paragraphs, it is the role of the regulatory body that is covered in the development process.		X			
35.	3.56	n order to develop regulations and guides, the regulatory body should have two basic resources: ~~qualified~~ competent staff and information.	Clarification			X	Deleted due to comments from Germany (no.5) and South Africa (No 3 & 6)
36.	3.57	Regulations and guides should ~~be based on~~ take account of the IAEA safety standards, which are issued in the form of specific requirements and recommendations so as to facilitate their incorporation into regulations.	Regulations is primarily based on national legislation and guides on national legislation and regulations		In developing regulations and guides, consideration should be given to adopting, as a reference, the IAEA's safety standards. The IAEA's safety standards are issued in the form of…		Due to comments from USA (no 11) and South Africa (no 4)

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
37.	3.57	~~The~~ Although IAEA safety standards may be adopted individually or collectively~~.~~ ~~However~~, adaptation and rewording may be necessary, depending on the national legal system. IAEA safety standards that are expressed in a general way may be implemented in a State by introducing appropriate requirements into regulations or by adapting the standards as national guides.	Simplification		…adaptation, rewording and amending…		
38.	3.57	In addition ~~particular~~, States embarking on a nuclear programme should also consider ~~adapting the IAEA's safety standards or~~ regulations developed by ~~other States (usually those of~~ the State supplying the facility~~), or a combination of these~~.	Clarification and simplification (avoid redundancy with first part of paragraph).	X			

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39.	3.59	Regulations, guides and other relevant information produced by regulatory bodies in other States ~~should~~ may also be considered in the development of regulations.	Unrealistic to consider all regulations and guides developed worldwide…		When regulations, guides and other relevant information produced by regulatory bodies in other States is considered in the development of regulations, particular attention should be paid to the		South Africa comment no.5
40.	3.60	~~In~~ If adapting IAEA safety standards or regulations of other States, the regulatory body should: ~~- make its regulations compatible with its national legal and regulatory framework;~~ ~~- include appropriate requirements specific to national conditions~~; - promptly evaluate amendments made to the reference regulations or standards and, if needed, issue amendments to its own regulations as appropriate.	Already addressed by suggested modified 3.57 Enable to focus 3.60 on update of national regulations		Delete 3.60 and Put in 3.57 "adaptation, rewording and amending may be necessary"		For clarity and avoiding duplication. (see France comment no 37)

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
41.	3.64	The regulatory body should follow a general and consistent approach ~~procedure~~ for establishing, reviewing and revising regulations and guides. It should be well documented, comprehensive for the different activities and facilities regulated ~~applicant and authorized parties~~, with clear organization and responsibilities for each and overall coordination.	Alternate wording		The regulatory body should follow a general and consistent process ~~procedure~~ for establishing, reviewing and revising regulations and guides. It should be well documented, comprehensive, ~~for the~~ covering ~~different~~ all regulated activities and facilities ~~regulated applicant and authorized parties~~, with clear allocation of ~~organization and~~ responsibilities ~~for each and overall coordination~~.		For clarity, in line with "Process for developing regulations and guides".

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
42.	3.65	Delete 3.65	Too detailed…		3.65. The process should be based on clear procedures ~~should detail the general format and style of language to be used in the regulations and guides. This procedure should be distributed to members of working groups engaged in drafting and should be adhered to by all parties involved. These procedures should be efficient~~ and should be flexible enough ~~to permit revisions to be made~~ to take account of changing technological, legal and practical conditions~~, or as justified by advances in technology~~. ~~Because of~~ Due to variations ~~differences~~ in the legal systems and practices of States, it is impossible to provide detailed…		Simplified and correlated with DS472.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
43.	3.66 (c)	(c) *Determination of the scope of the regulations and guides*. The first step towards the development of regulations should be to identify clearly the facilities and activities to which regulatory requirements are to be applied as well as the stage of the authorization process to be covered and the technical topic to be addressed. ~~The scope should be as unambiguous as practicable.~~	Superfluous	X			
44.	3.66 (d)	(d) *Determination of the resources necessary*. Development of regulations and guides requires sufficient suitably ~~qualified~~ competent and experienced people ~~staff, either from the regulatory body or employed as external experts,~~ to be available and adequate financial resources	Too detailed.		Development of regulations and guides requires sufficient suitably qualified, ~~and~~ competent and experienced people ~~staff, either from the regulatory body or employed as external experts,~~, to be available and adequate financial resources		In line with GSR Part 1 and correlated with DS472.
45.	3.66 (g)	(g) *Review of the regulations and guides*. Although			A draft version may also be published provisionally with		For consistency with the idea (including the final

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		practices vary widely, legal staff and special advisory committees, as appropriate, would usually review the initial versions of the proposed regulations and guides. In some States, authorized parties, professional societies or other organizations participate in these reviews. A draft version may also be published provisionally with an invitation for comment from interested parties ~~the public~~. Comments received as a result of the review should be analyzed, evaluated and resolved as appropriate. ~~A review of the final draft for quality control should be carried out before formal approval. One way in which the regulatory body could do this is to publish the regulation in its revised form for comment in advance of the effective~~	Licensees and the public should be able to comment. Switching to interested parties enable to shorten the following text		an invitation for comment from interested parties ~~the public~~. Comments received as a result of the review should be analyzed, evaluated and resolved as appropriate. A review of the final draft for quality control should be carried out before formal approval. ~~One way in which the regulatory body could do this is to publish the regulation in its revised form for comment in advance of the effective date. Whichever review process is adopted, a formal procedure should be established to ensure that advice on the proposed regulations is obtained from all concerned parties. The regulatory body should then make the resolution a final decision with regard to the advice before the regulations are finalized.~~ At this stage consideration should also be given to the implications of		QA check of the final draft is an important step in the process. Final resolution is part of this step.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		~~date. Whichever review process is adopted, a formal procedure should be established to ensure that advice on the proposed regulations is obtained from all concerned parties.~~ The regulatory body should then make a final decision ~~with regard to the advice before~~ so that the regulations or guides are finalized. At this stage consideration should also be given to the implications of the regulations for existing facilities and activities;			the regulations for existing facilities and activities;		
46.	3.66 (h)	(h) *Establishing and issuing the regulations and guides*. Regulations should be established and promulgated in a manner that makes them legally binding according to the national legal system, thereby ensuring that their provisions can be enforced by the regulatory body. The procedure for issuing safety	Add a sentence on making the regulations and guides available to interested parties.			X	3.66 addresses only the development of regulations and guides.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		guides should follow steps similar to those for regulations, but a guide can be formally issued with a lower level of approval, since its contents are only advisory in nature. Regulations and guides should be publicly available, for example through the regulatory body website.					
47.	3.67		Suggested categorisation is questionable. Consider deleting or transferring to an annex.		Consideration should be given to grouping the guides ~~Guides should be grouped, inter alia,~~ into several broad categories as follows, but not limited to:		We prefer to keep the categories as suggested in GS-G 1.5

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48.	3.70	The procedures applicable in the development of regulations can also be followed when making any necessary revisions. ~~Advice should be obtained from all parties concerned. Authorized parties and others potentially affected by the revised regulations should be given adequate time to complete any preparations that may be necessary to enable them to comply with newly established requirements.~~	Already addressed in 3.66		The procedures applicable in the development of regulations can also be followed when making any necessary revisions. ~~Advice should be obtained from all parties concerned.~~ Authorized parties and others interested parties potentially affected by the revised regulations should be given adequate time to complete any preparations that may be necessary to enable them to comply with newly established requirements.		Noted. We maintain the paragraph addressing the adequate time to complete any preparations to comply with newly established requirements.
49.	3.72	It is required that the regulatory body should recognize the ~~risks~~ potential drawbacks associated with making modifications to well-established procedures and processes.	Clarification			X	In particular concerning potential decrease in safety, the term “risks” is more appropriate.

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50.	3.74	The extent to which the proposed changes should be applicable to facilities and activities that have already been authorized and the degree of back-fitting to be required should also be considered and made explicit.	For consistency with 3.66 (g)			X	Covered in 3.72
51.	3.87	The regulatory body should specify the conditions under which consumer products with intentionally added radioactivity may be made available to member of the public who have no regulatory obligation with respect to the product.	Clarification		The regulatory body should specify the conditions under which consumer products that contain radioactive materials may be made available to ~~member of~~ the public who have no regulatory obligation with respect to the product. In this context, the consumer product~~, whilst containing radioactive or nuclear material,~~ can be used and…		For clarity and flow of phrase.

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52.	3.89	The objective of granting authorizations is for the regulatory body to establish effective <u>specific</u> regulatory control throughout the lifetime of a facility or activity in relation to safety.	Regulations can also provide for effective control but regulations are generic, not specific.			X	No added value. This paragraph is about authorization. There is no generic or specific regulatory control.
53.	3.90	Need to simplify and shorten 3.90, in particular to avoid redundancy	Not all bullets are relevant to <u>any</u> activity or facility.			X	No useful suggestion provided. The approach of the safety guide reflects the Long Term Strategy for SSs, as well as the DPP.
54.	3.91	Consider deletion	Access to dwelling is generally limited to day time…. Furtherore, access to private properties is limited to formally designated inspectors and not to any staff		The legislative and regulatory framework should require unfettered access for <u>designated</u> regulatory staff at any time, to any <u>authorized</u> facility<u>~~, any~~</u> <u>or</u> activity and any documents related to safety and considered necessary for granting authorizations		The time assumption is not correct, and partially nor is the second, referring to the authorized party.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
55.	3.94	Need to simplify and shorten 3.94, in particular to avoid redundancy	Not all bullets are relevant to any activity or facility.			X	No useful suggestion provided. The approach of the safety guide reflects the Long Term Strategy for SSs, as well as the DPP.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
56.	3.95	An additional requirement to be included in the regulations is that the authorized party should put into place procedures within its management system for each stage of the lifetime of a facility or activity, including, where appropriate, procedures for the provision of independent advice. Procedures should be put into place: (a) For controlling the facility or activity within the limits specified in the regulations <u>and the authorization</u>; (b) For managing incidents and accidents and ~~response;~~ ~~(c) For~~ responding to a nuclear or radiological emergency.	Licence conditions should also be considered. Simplification	X			

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
57.	3.97	Delete 3.97				X	SSG-12; this is a very important aspect that must not be left out. Rephrased for clarity as below: "Regulatory provisions should be put in place to ensure that, if authorization expiry dates are established, they are such that the authorized party is not relieved of the prime responsibility for safety until the regulatory body so decides." SSG-12 2.37
58.	3/103	For complex facilities or activities, before an applicant submits an application, the regulatory body should implement a preparatory phase, during which basic safety requirements ~~are set out~~ and the authorization process to be followed is made clear to the applicant.	Superfluous (basic safety requirements may have previously been set)		For complex facilities or activities, before an applicant submits an application, the regulatory body should consider implementing a preparatory phase, during which basic safety requirements ~~are set out~~ and the…		For clarity.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
59.	3.103	~~Basic safety requirements set out in the preparatory phase should be design neutral so that several designs may be considered at the beginning of a project to build a facility or should be taken into consideration in planning the activity.~~	It depends whether a unique design is being considered or whether several design are "competing"…	X			
60.	3.105	Need to simplify and shorten 3.105. Suggestion is to keep only the first level of bullets and transfer details into the appendixes.	Not all bullets are relevant to <u>any</u> activity or facility.			X	The approach of the safety guide reflects the Long Term Strategy for SSs, as well as the DPP. Numerous similar comments suggest the guide should be a collection of appendixes, which would contradict the DPP. Have made the following modification: "application for authorization should take into account the <u>type</u> ~~kind~~ of facility <u>or activity</u>."

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
61.	3.109	Refocus content to minimum authorization process which is relevant to any activity or facility: - Statutory authority - Issuing authority - Documentary basis provided by the applicant - Authorized party - Authorized activity. - Period of authorization (if any).	List not relevant for any activity or facility authorized			X	The approach of the safety guide reflects the Long Term Strategy for SSs, as well as the DPP. These are well established elements of the authorization and have to date been reflected in SGG-12 (2010).
62.	3.110	In some States, the legislation determines that an authorization in terms of qualification is needed for a person to perform specific functions. In that case the ~~authorization~~ application review should be the means of verifying the competences of the personnel to carry out those specific activities.	Clarification			X	This paragraph addresses the authorization itself as a basis for verification of specific personnel competences.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
63.	3.111	Authorization for objects should be considered where it is ~~necessary to operate a~~ more effective for regulating facilities~~y~~ or ~~to conduct an~~ activities~~y~~.	Effctiveness is the overall guiding principle.	X			
64.	3.117	Consider shortening 3.1I7 by keeping only the first level of bullets and transfer details into the appendixes.			See also language corrections in the text of the paragraph.		The approach of the safety guide reflects the Long Term Strategy for SSs, as well as the DPP. This is a challenge to the layout, not to the content.
65.	3.118	Delete 3.118	3.117 is enough			X	Different type of conditions. Swap 3.117 with 3.118 for logical flow (general then specific).

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
66.	3.124	~~Some meetings should be held in the vicinity of the facilities to provide the public with information on the initial licence application and subsequent renewal processes, solicit input on the environmental review and to provide the results of the regulatory body inspections~~.	True for NPP and large installations. Not true for all facilities/activities requiring authorization.		In some Member States the authorization renewal process is carried out in a transparent manner. The regulatory body should consider holding meetings with interested parties providing information on the authorization renewal processes.		Paragraph has been reworded to better reflect good practice identified during an IRRS mission, that we would prefer keeping. Please see new text.
67.	3.125	Whenever submissions for a particular type of facility (or parts thereof) may be repeated many times, it may be appropriate for an authorized party ~~(or in some cases a contractor, which may be in another State)~~ to provide a submission for a 'reference facility' or a 'generic facility'.	Superfluous	X			
68.	3.130	~~It is good practice in many States that all facilities and activities on a site should be under the control of a single authorized party.~~	Superflous. Remaining text in 3.130 is enough.	X			

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
69.	3.130	Where there are different authorized parties on the same site, or on neighboring sites, the regulatory body should ~~ensure~~ promote co-operation between the authorized parties. Whilst	"Ensure" is too strong			X	The regulatory body has the power to ensure cooperation.
70.	3.131	However, general requirements concerning ~~remoteness~~, environmental concerns, local population density and transport arrangements will apply, usually at a governmental level.	Redundant (low local population density)			X	No redundancy found.
71.	3.140	~~The regulatory body is required to ensure that relevant documents and records are prepared by the authorized party, kept for an agreed time and maintained to a specified quality before, during and after decommissioning~~	True but not specific to this phase.			X	The first part of the paragraph introduces the maintenance of records for future users of the sites, of particular importance for this stage. We prefer to keep it.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
72.	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. The regulatory body should review the authorized party's demonstration, confirm compliance with the criteria and only then release the site from regulatory control. ~~If the site meets the release criteria, the site may be appropriate for release without further cleanup after the approval of the regulatory body.~~	Simplification	X			
73.	3.142	If the site does not meet the release criteria, ~~the authorized party should determine whether a cleanup needs to be performed to meet the release criteria or whether, even after clean-up~~, restrictions should be imposed in relation to future use of the site (‘restricted	Simplification	X			

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		use' option). If after further cleanup and survey demonstrate that the site meets the release criteria, restrictions are not needed, the selected option should be 'unrestricted use'; ~~if restrictions are required, the 'restricted use' option should be selected. In both cases, the authorized party should develop cleanup activities for release and should obtain approval from the regulatory body. Having implemented these cleanup activities, the authorized party should perform a survey to demonstrate that the site meets the release criteria and should submit this demonstration to the regulatory body for approval.~~					
74.	3.143	For restricted use, the type, extent and duration of the restrictions and controls for release of the site can range			The restrictions should be proposed by the authorized party on the basis of a graded approach ~~and~~ ~~in~~ after		For language reasons.

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		from monitoring and surveillance to restriction of access to the site. The restrictions should be proposed by the authorized party ~~on the basis of a graded approach and in~~ after consideration of factors such as the type and level of residual contamination after the completion of cleanup, the relevant dose constraints and release criteria, and the human and financial resources needed to implement the restrictions and controls. The restrictions proposed by the authorized party should be submitted to the regulatory body for their agreement and should be of a form that is enforceable. ~~The cleanup plan should specify~~ It should be clear which organization will ensure that the restrictions are maintained. In addition, the way in			consideration of factors such as…		

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		which the restrictions would be removed when they are no longer necessary should be specified in the cleanup plan.					
75.	3.146 3.147	Create a section on radiation sources (similar as the section on complex facilities)				X	Already covered.
76.	3.152	The regulatory body ~~is~~ may required to review this assessment.	Only significant modifications are likely to be reviewed by the regulator.		Deleted. ENISS comment no 4.		Superfluous. See new 3.152.
77.	3.153	Locate 3.153 after 3.154	More logical location.	X			
78.	3.156		Use "facility or activity" throughout the paragraph (no reason to limit to facilities)	X			

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
79.	3.156	Where relevant, The review and assessment process should include checks on the site and elsewhere to validate the claims made in the submissions. For complex facilities, The authorized parties often have external peer reviews conducted at their facilities by national or international organizations. The results of such reviews could provide the regulatory body with additional insights into the activities of the authorized party.	Clarification as it is not the practice for low risk activities…		For facilities or activities with significant risks, The authorized parties often have external peer reviews conducted at their facilities		

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
80.	3.159	The basic objective of regulatory review and assessment should be to determine whether the authorized party's submissions demonstrate that, throughout the lifetime of the facility or activities, it complies with all safety requirements and recommendations which are stipulated or approved by the regulatory body and that, unless appropriate justification is provided, regulatory guidance has been followed.	Clarification to capture the status of guides		The basic objective of regulatory review and assessment ~~should be~~ is to determine whether the authorized party's submissions demonstrate that, throughout the lifetime of the facility or activities, it complies with all safety requirements and recommendations which are stipulated or approved by the regulatory body ~~and that, unless appropriate justification is provided, regulatory guidance has been followed.~~		We prefer to keep the initial text, as, either way, the requirements must be met. There cannot be half-measures in meeting the requirements.
81.	3.160		Consider deletion as 3.160, which details 3.159, may be considered exhaustive.		Examples of these specific objectives include but are not limited to the following		General objective versus specific objectives.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
82.	3.167	During its inspection activities, the regulatory body inspectors will collect information that show the actual situation on the site rather than that set out in safety assessments, for example when examining records kept by the authorized party. Such information~~, which~~ should be subjected to review and assessment ~~by specialist in the regulatory body~~. ~~In addition, violations and non-compliance should be assessed. Whilst this source of information may only represents a small part of the review and assessment it is a vital part as it represents the actual situation on the site rather than that set out in safety assessments~~.	Simplification		During its inspection activities, the regulatory body inspectors will collect on-site information, for example when examining records kept by the authorized party. Such information~~, which~~ should be subjected to review and assessment ~~by specialist in~~ by the regulatory body~~.~~ In addition~~,~~ to any violations and non-compliances~~.~~ ~~should be assessed.~~ Whilst this source of information may only represent~~s~~ a small part of the review and assessment, it is ~~a vital~~ an essential part as it provides factual insights on how the authorized party complies with regulatory requirements. ~~it represents the actual situation on the site rather than that set out in safety assessments.~~		Simplified.
83.	3.169	Safety Guide covers a wide range of types of facility and activity…	Clarification		…this Safety Guide covers a wide range ~~of types~~ of facilities~~y~~ and activities,…		Accepted, language modification made.

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84.	3.170	~~In all cases~~ For nuclear installations, the site of the facility or where the activity is to be conducted should be qualified by review and assessment	Not true for any activity or facility		~~In all cases,~~ tThe site of the facility or where the activity is to be conducted should be qualified by review and assessment…		Site may not necessary involve the extensive dimensions of an NPP site.
85.	3.172		The second part of the paragraph is not relevant to any activities. How is construction of a new X-Ray at a dentist controlled ?			X	"or installation". Control is ensured through the authorization, in whatever form it might be applicable. Have changed the following: "…Once construction ~~and~~ or installation has started,…"
86.	3.175	~~The results of inactive commissioning should also confirm the operational features and should lead to the development of detailed instructions for operators, which should be confirmed during the active stage.~~	Development of detailed instruction should not wait inactive commissioning		The results of inactive commissioning should also confirm the operational features and should lead to the finalization ~~development~~ of detailed instructions for operators, which should be confirmed during the active stage.		
87.	3.182	Decommissioning comprises: the preparation ~~and approval~~ of a detailed	Clarification Role of the regulator is addressed in the		Decommissioning of a facility or cessation of an activity, such that regulatory	X	The proposal implies the plan does not need to be approved.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		decommissioning plan; the actual decommissioning activities; and the management of waste arising from these activities. Just before the permanent shutdown of the facility or cessation of the activity, a detailed plan should be prepared by the authorized party ~~for authorization or approval by the regulatory body~~.	second next sentence.		controls may be removed, includes decontamination and the dismantling and/or removal of radioactive materials, radioactive waste, structures, systems and components ~~and structures~~. Decommissioning comprises: the planning for decommissioning, ~~the preparation and approval of a detailed decommissioning plan~~; the conducting of the ~~actual~~ decommissioning activities; including ~~and~~ the management of waste arising from these activities ; and the termination of the authorization for decommissioning. Just before the permanent shutdown of the facility or cessation of the activity, a detailed plan should be prepared by the authorized party and submitted to the regulatory body for authorization or approval ~~by~~		Please see alternate text, in conjunction with Japan comment no 3.

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					~~the regulatory body~~.		
88.	3.182	The decommissioning plan should be reviewed and assessed by the regulatory body in order to ensure that decommissioning can be accomplished safely with a progressive and systematic reduction in radiological hazards.	Clarification (to account for previous comment)	X			

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89.	3.186	The process of review and assessment is conducted by means of exchanges between the regulatory body and the authorized party, which should be formally recorded. The records will concern mainly: ~~- requests for additional information by the regulatory body;~~ - questions formulated by the regulatory body; - responses by the authorized party (including those provided by its contractors); - records of meetings between regulatory body staff and authorized party personnel.	Duplication with second bullet		The records will concern mainly: - requests for additional information and questions by the regulatory body;		Not a duplication, but merged into 1 bullet.
90.	3.187	~~This information should be kept in an organized way that permits retrieval according to different criteria such as subject, type, date or originator.~~	Too detailed			X	Management of documentation and records is an important aspect. Added reference to DS472 [4].

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91.	3.188	The regulatory body should be prepared to suspend or terminate its review and assessment if, in its judgment, such action is justified because of deficiencies in the information provided. The regulatory body should request any necessary additional information ~~and should be prepared to suspend or terminate its review and assessment if, in its judgment, such action is justified because of deficiencies in the information provided~~.	Change in the order (more locigal)			X	The logic follows request of information and, if the case, termination of R&A. For clarity, have moved the last phrase in 3.188 to before 3.186.
92.	3.191	In carrying out a review and assessment of an applicant's or authorized party´s safety documentation, the regulatory body should ensure ~~employ a systematic plan to provide assurance~~ that all topics significant to safety will be covered and this should be done	Too detailed		In carrying out a review and assessment of an applicant's or authorized party´s safety documentation, the regulatory body should employ a systematic process ~~plan~~ implemented through specific procedures, to provide assurance that all topics significant to safety		Simplified. In line with DS472.

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		consistently in relation to submissions for similar facilities or activities. ~~This plan should include a series of procedures that the regulatory body will follow for all aspects and topics covered by the documentation in order to identify those items for which applicable safety objectives and requirements have been met and those for which they have not~~. An outline for such a ~~plan~~ process might be as follows:			will be covered ~~and this should be done~~ consistently ~~in relation to~~ with submissions for similar facilities or activities. This ~~plan~~ process should ~~include a series of procedures that the regulatory body will follow for all aspects and topics covered by the documentation in order to identify those items for which applicable safety objectives and requirements have been met and those for which they have not. An outline for such a plan might be as follows~~ encompass the following steps:		

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93.	3.192	A major feature of the authorized party´s safety documentation will be its safety assessment, including the analysis of normal and fault conditions[3].	Clarification. It might however be better to refer to the definition of the safety glossary where "safety analysis" and "safety assessment" are defined : "***safety analysis***. *Evaluation of the potential hazards associated with the conduct of an activity. Safety analysis is often used interchangeably with safety assessment. However, when the distinction is important, safety analysis should be used for the study of safety, and safety assessment for the evaluation of safety — for example, evaluation of the magnitude of hazards, evaluation of the performance of safety measures and judgement of their adequacy, or quantification of the overall radiological impact or safety of a facility or activity*." *"***assessment:*** 1. The *process*, and the result, of analysing systematically and evaluating the hazards associated with *sources* and *practices*, and associated *protection and safety* measures. *Assessment* is often aimed at quantifying performance measures for comparison with criteria. In *IAEA publications*, *assessment* should be distinguished from *analysis*. *Assessment* is aimed at providing information that forms the basis of a decision on whether or not something is satisfactory. Various kinds of *analysis* may be used as tools in doing this. Hence an *assessment*	X 81			

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
94.	3.192	~~The value of safety analysis is in extending knowledge and understanding of the facility or activity and the behavior under a range of conditions and in identifying shortcomings in areas in which safety can be improved.~~	Superfluous	X			
95.	3.194	~~Safety objectives and regulatory requirements should specify safety goals for levels of performance of the safety SSCs and managerial 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, safety management systems or operational procedures.~~	This is too ambitious.			X	The first part of the paragraph refers to established practices (see GS-G 1.2 para 3.22) We retain the last part of the paragraph. The regulatory body cannot prescribe specific "designs,…" because this would imply the RB takes responsibility for safety.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
96.	3.197	The safety objectives and regulatory requirements should cover, among other things, as appropriate: ~~- Prevention of faults rather than mitigation of their consequences;~~ - Application of the principle of defence in depth; ~~- Meeting the single failure criterion for safety related systems;~~ - Requirements for redundancy, diversity and separation; ~~- Preference for the use of passive systems over an active or operator based safety systems;~~ - ~~Criteria relating to~~ human factors and the human–machine interface; - Dose limits and dose constraints (both occupational and public~~),~~ ~~amount of discharges to the environment~~ and ALARA considerations; ~~- Criteria for assessing radiological risks to workers and the public;~~ - Minimization and management of waste	Simplify the list as there are several duplicationq (DiD and redundancy/diversity or DiD and prevention, ALRA and risks to the workers and the pubic….). No reason to promote passive system where there function is not known.	83	-Prevention of, ~~faults~~ rather than mitigation of ~~their consequences~~ accidents;		First bullet modified based on the terminology used in SF1. See comment 8 of ENSSI We prefer to keep the rest of the bullets as described in SG-G-1.2 since they depict established practice and do not duplicate one another.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
97.	3.198	The regulatory body should evaluate the acceptability of the proposals put forward by an authorized party <u>or applicant</u> on a case-by-case basis against general principles.	Clarification	X			

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
98.	3.200	The regulatory body should establish which requirements, regulations, guides and industrial standards are applicable to the facility or activity in question ~~and should determine the requirements to be placed on the authorized party~~. Where no such requirements, regulations, guides ~~and industrial standards exist~~, the regulatory body should consider developing them. In carrying out its review and assessment, the regulatory body should use the applicable requirements as a reference in deciding on the acceptability of an authorized party´s submissions.	Superfluous The regulator does not develop industrial standard. This the role of ISO or other (inter)national standard organisations		The regulatory body should establish which requirements, <u>based upon</u> regulations, guides and industrial standards<u>,</u> are applicable to the facility or activity in question and ~~should determine the requirements~~ to be placed on the authorized party. Where no such requirements~~,~~ ~~regulations, guides and industrial standards~~ exist, the regulatory body should consider developing them. In carrying out its review and assessment, the regulatory body should use the applicable requirements as a reference in deciding on the acceptability of an authorized party´s submissions.		Unfortunate spelling. It is not implied that the regulator should develop industrial standards, but requirements.
99.	3201	Delete 3.201	Development of regulations and guides is addressed in a previous chapter.	X			Covered under 3.17 – 3.21

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
100.	3.202		The term "audit calculation" is unclear. Could "confirmatory calculation" be used ?	X			Consistency with USA comments.
101.	3.203	~~Much effort that the regulatory body will need to expend in~~ the review and assessment process by the regulatory body ~~will be concentrated on the performance of a step by step review and assessment procedure to determine whether the applicable safety objectives and requirements for each aspect or topic have been met. This stage of the process~~ consists in examining the submissions from the authorized party on its managerial arrangements, engineered systems and operational procedures and on the safety analysis for the facilities or activities…	Simplification	X			Simplified.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
102.	3.204	Delete 3.204	Not relevant for <u>all</u> activities and facilities.		In carrying out its review and assessment, the regulatory body should determine<u>, if applicable,</u> whether the authorized party has defined		The graded approach (Chapter 2) has to be taken into account when using this safety guide. In line with the Long Term Strategy for SSs.
103.	3.205	<u>For a nuclear installation,</u> The general aim of the regulatory review of the safety analysis report [9], ~~whether based on deterministic or probabilistic analyses~~, should be to verify that for each identified barrier to the release of radioactive material the safety measures…	No SAR for a dentist or a radiotherapy unit. Both deterministic and probabilistic insight are expected.		The general aim of the regulatory review of <u>a</u> ~~the~~ safety analysis…		[9] GSR Part 4
104.	3.205 bullet list		The bullet lit seems somehow narrow as it focuses on barriers. What about implementation of defense in depth? Diversity against common cause failure ? Adequate modeling of PSA….			X	This paragraph is addressing the strategy for defence in depth, as per INSAG-10.

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105.	3.206		It is likely that such paragraph was written for nuclear installations and not simpler activities…. Rewording or narrowing application to nuclear installations is suggested				No useful suggestion was made. The approach of the safety guide reflects the Long Term Strategy for SSs, as well as the DPP. The graded approach should be applied uniformly when taking into account the suggestions of the guide.
106.	3.207	Break 3.207 into 2 paragraphs 3.### The regulatory body should ensure that an effective system for the feedback of operational safety experience is in place, that no safety related event will go undetected and that corrective measures will be adopted to prevent the recurrence of safety related events 3.207 The regulatory body should review reports	To state first the expectation of a OEF process at licensees then to express what regulator has to do with reported events.	X			

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		submitted periodically by the authorized party, in compliance with established requirements, so as to monitor the operational safety performance of the facility or activity. Additionally, reports on safety significant events should be thoroughly reviewed by the regulatory body. ~~The regulatory body should ensure that an effective system for the feedback of operational safety experience is in place, that no safety related event will go undetected and that corrective measures will be adopted to prevent the recurrence of safety related events~~. If the severity of the event warrants it, the regulatory body may conduct or arrange for an independent investigation, …					

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
107.	3.207	The regulatory body's review should cover the identification of lessons to be learned and the sharing of safety related information. ~~Operational safety performance should not be restricted to considering the facility or activity itself but should consider a wide range of both radiation and non-radiation based facilities and activities from which lessons may be learnt.~~	Deletion proposed as the paragraphs deals with information reported by licensee.			X	We prefer to keep the reference to taking into account relevant national and international experience.
108.	3.209		It is likely that such paragraph was written for nuclear installations and not simpler activities…. Rewording or narrowing application to nuclear installations is suggested			X	The approach of the safety guide reflects the Long Term Strategy for SSs, as well as the DPP. The graded approach should be applied uniformly when taking into account the suggestions of the guide.

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109.	3.211 (5)	(5) Discharge~~, dilution~~ and dispersion of radioactive effluents.	Dilution of radioactive effluents (with fresh water or air) is not allowed in France			X	In some Member States, dilution is used as a strategy in discharging radioactive effluents. This established practice is reflected in GS-G-1.2 para 3.48
110.	3.212	In considering these items, the regulatory body should satisfy itself that radiation doses to workers and the public and radioactive releases to the environment are acceptable and ALARA.	ALARA principle has to be implemented			X	See bullet 3.
111.	3.127	This documentation should summarize the review and assessment performed ~~and should present a clear~~ its conclusion about the safety of the activity authorized.	Simplification			X	3.217 No added value.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
112.	3.127 bullet list	Typically, the following topics should be covered: -Reference to the documentation submitted by the authorized party; - The basis for the evaluation; - The evaluation performed; - Comparison with regulatory requirements, regulations and guides; - Comparison with another similar (reference) facility or activity where appropriate; - Independent analysis performed by the regulatory body's staff, or by consultants or dedicated support organizations on its behalf; - Conclusions with respect to safety, including any Additional requirements to be fulfilled by the authorized party	Create sub-bullets Merge the two last bullets			X	No sub-bullets suggested. The last two bullets pertain to separate topics, therefore they are not merged.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
113.	3.229		Reconsider the location of this paragraph (transfer to review and assessment ?). Anyway, it should not be the first para of the section on inspection			X	3.229 is intended for inspection.
114.	3.222	Locate 3.222 after 3.225	More logical location			X	This paragraph addresses unforeseen circumstances and we believe the sequence is logical.
115.	3.222 bullet list	In conducting inspections, the regulatory body should consider a number of aspects, including: - Radiation risks associated with the facility or activity, including areas of higher potential risks - Structures, systems and components important to safety; - Management systems, including aspects related to contractors and other service	Rationalize the list and ensure it is adequately covering all activities and facilities. For example, what about emergency preparedness or patient exposure ? Separate the bullet on liaison with other (regulatory) organizations as the other bullets are		- Radiation risks associated with the facility or activity, including areas of higher potential risks - Structures, systems and components important to safety; - Management systems; - Operational activities and procedures; - Records of operational activities, performance and results of monitoring; - Corrective actions; - Liaison with contractors		No reason why the bullet on liaison with other (regulatory) organizations should be separated. It is one of the aspects that needs to be taken into account. Emergency preparedness is a topic for inspection. Similarly, patient exposure is included in the bullets. Last two bullets: USA comment no 42 (moved from 3.248)

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		providers; - Operational activities and procedures; - ~~Records of operational activities and results of monitoring;~~ - ~~Liaison with contractors and other service providers;~~ - Competence, performance and resources of staff; - Safety culture; - ~~Liaison with the relevant organization for joint inspections, where necessary.~~ - ~~Radiation risks associated with the facility or activity~~ - Areas of poor performance - ~~Areas of higher potential risks~~ The regulatory body should also consider, where appropriate, liaison with the relevant organization for joint inspections, where necessary.	directed at licensee.		and other service providers; - Competence, performance and resources of staff; - Safety culture; - Liaison with the relevant organization for joint inspections, where necessary. - ~~Radiation risks associated with the facility or activity~~ ~~- Areas of poor performance~~ - ~~Areas of higher potential risks~~ □ misadministration of radiopharmaceuticals to patients; and □ theft or diversion of radioactive material.		

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
116.	3.226	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~~ and to determines whether the authorized parties are in compliance with the safety objectives prescribed or approved by the regulatory body.	Clarification			X	The intention of the paragraph is to state that inspection will increase the confidence that the APs are in compliance with the regulatory requirements (complementing the other core regulatory functions), not determine compliance (by itself). This is the expectation addressed in GS-G 1.3
117.	3.226 bullet list	(a) ~~All~~ applicable laws, regulations and license conditions and ~~all~~ relevant codes, guides, specifications and practices are complied with; (b) The authorized party has a strong and effective management system, strong safety culture~~ and self-assessment systems for ensuring the safety of the facility or activity and the radiation protection of workers, the public and the~~	Clarifications. Some bullets from 3.227 might have to be included as affectation key between 3.226 and 3.227 is not so clear…. "All" is excessive as inspections are not often exhaustive… Self-assessment are part of management	Accepted for (a) and (d)	(b) The authorized party has in place an ~~strong and~~ effective management system and strong safety culture;		Rejected for (c) – quality and performance must be also (at least) maintained

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		~~environment~~; (c) The required quality and performance are achieved ~~and maintained~~ in the safety related items and activities of the authorized party throughout the lifetime of the facility or activity; (d) Persons employed by the authorized party ~~(including~~ and contractors~~)~~ possess the necessary competence for the effective performance of their functions ~~throughout the whole lifetime of the facility and activity~~; (e) ….	systems. For a contractor, the licensee is not the employer.				
118.	3.227	Specific responsibilities of the regulatory body in respect of inspection should include: - conducting planned inspections at all stages of the authorization process and - carrying out reactive inspections, if appropriate, in response to events, incidents or accidents; - preparing reports to document its inspection activities and	Redundancies with 3.226 Affecting bullets to 3.226 or 3.227 should be reconsidered.		Deleted: - verifying the authorized party's compliance with regulatory requirements and confirming adherence to safety objectives;		The rest of the bullets depict specific responsibilities.

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		their findings; - identifying and recommending necessary changes to the requirements approved by the regulatory body, specified in the authorization or contained in the regulations; ~~- preparing reports to document its inspection activities and their findings;~~ ~~- verifying the authorized party's compliance with regulatory requirements and confirming adherence to safety objectives;~~ ~~- ensuring that the authorized party has adequate, comprehensive and up-to-date information on the status of the facility or activity and information for demonstrating its safety, and a procedure to maintain this information up to date;~~ ~~- verifying that corrective actions have been undertaken by the authorized party to resolve safety issues identified previously;~~ ~~- tracking recurrent problems~~					

FUNCTIONS AND PROCESSES OF THE REGULATORY BODY FOR SAFETY

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		~~and non-compliance;~~ - developing procedures and directives as necessary for the effective conduct and administration of the inspection programme; - determining and recommending suitable enforcement actions when non-conformance with requirements is encountered.					

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
119.	3.232	For all areas of responsibility, the regulatory body's inspection programme should include as key elements: - a system of prioritizing inspections based on a graded approach; - on-site visits of inspectors; ~~- the review of radiation safety assessments made by the authorized parties;~~ ~~- the investigation and follow-up of events and deviations from normal operation; and~~ ~~- the submission of information on key operational safety parameters by authorized parties~~. On-site inspection[4] is the one element of the regulatory regime closest to actual operations, and a significant proportion of the regulatory body's resources should be allocated to this task.	These bullets would be more appropriate under "review and assessment" than under "inspection". In fact, there are already discussed under "review and assessment".		Deleted - the review of radiation safety assessments made by the authorized parties;		Note: Inspection also includes review of information submitted by the authorized party. Not to be confused with the review of information as part of the review and assessment process.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
120.	3.234	The more common indicators of degraded performance include: - poor housekeeping; - poor financial stability; - insufficient staffing; - high turnover of staff; ~~- poor record retrieval systems;~~ ~~- lack of set investigation levels;~~ ~~- lack of procedures to be followed in the event that investigation levels are exceeded;~~ - inadequate training; - lack of retraining of staff; and - higher than average occupational exposures for the type of facility or activity.	These 3 points are less relevant than the others.			X	We feel all indicators listed are relevant in what regards degraded performance. Please see new text.
121.	3.238	~~The authorized party should be required to inform the regulatory body as prompt as is warranted by the situation according to established procedures.~~	Superfluous as already covered by first sentence of 3.238	X			

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
122.	3.239	~~The regulatory body should compile and analyse data on the performance of authorized parties.~~ As part of continuous improvement program, the regulatory body should compile~~,~~ ~~analyze~~ and assess~~,~~ ~~periodically and~~ regularly, data on the performance of authorized parties, outcome of regulatory inspection programme….	Simplification	X			
123.	3.243	Planned inspections, either announced or unannounced, are carried out in fulfilment of, and in conformity with, a structured and largely prearranged or 'baseline' inspection programme developed by the regulatory body.	Clarification	X			

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
124.	3.243	~~Considerations in relation to performing planned inspections should include:~~ ~~- the requirements of the authorization regime;~~ ~~- the safety significance of the areas to be inspected;~~ ~~- the authorized party's overall performance in the areas to be inspected;~~ ~~- operational experience and lessons learned from events or problems at other facilities or activities in other States.~~	Already addressed in 3.222 to 3.233	X			

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
125.	3.244	Delete 3.244	Controversial. Planned inspection do also look at paperwork and programmes…		In planned inspections, emphasis should ~~usually~~ be given to the observation and assessment of continuing safety activities in order to assess the effectiveness of the authorized party's performance. ~~Less emphasis is usually placed on carrying out detailed 'desktop' reviews of programme descriptions and related procedures for reviewing paperwork.~~		

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
126.	3.247	~~All available resources may be needed in responding to a serious event, whereas in the simplest of cases only one inspector may be needed. A pre-established graded approach in responding to special circumstances will assist in determining the appropriate level of resources for use in inspections~~.	Too detailed. Reactive inspections are decided on a case by case basis and their scheduling takes account of relevant inspector availabilities.			X	The paragraph is explaining the importance of a graded approach in dealing with reactive inspections.
127.	3.248	Locate 3.248 after 3.239	More logical location		Have merged 3.248 bullets with 3.222 bullets. New text of 3.248 is: The regulatory body should use the authorized party's reports of safety related activities or events for assistance in preparing for both planned and reactive inspections. Matters to be included in reports from the authorized party should be clearly defined so that difficulties in interpretation can be avoided. <u>A suggested list is given in para 3.222.</u>		

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
128.	3.251	Delete 3.251	This is review and assessment, not really inspection…			X	Inspection also includes review of information and documentation as part of investigation. Not to be confused with the review of information as part of the review and assessment process.
129.	3.255 3.256		It is unclear when an inspection performed by more than one inspector becomes a team inspection. France normal practice is to perform inspections with 2 inspectors. However, some inspections do involve up to 10 inspectors: are those the "team inspection" addressed in the guide ?			X	Size of team and scope of inspections may vary.

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Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
130.	3.257	Delete 3.257	Too specific. (Consider transferring in an annex?). These are planned inspection and general recommendations apply…	X			USA comment 46
131.	3.262	Delete 3.262	Too detailed. Not so much relevant with current telecommunication means…			X	This paragraph addresses the effective use of resources.

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COMMENTS BY REVIEWER Country/Organization: FRANCE/ASN Date: 22 May 2015 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
132.	3.263	When several inspections are to be performed at a facility, The regulatory body should have an overall plan for the programme of inspections that it is to undertake ~~at a facility or during an activity~~. The plans for inspection specific facilities or activities should be determined using a graded approach. For activities where risk is lower or where a large number of registrants/authorized parties exist, the regulatory body should, taking into account a graded approach, establish a programme of inspections for these activities.	Overall plan for the programme of inspections is relevant for large facilities where several inspections will be performed. For small scale activities, where only a part of authorized party will be inspected (e.g. gauge users, dentist…), the plan may be more relevant if directed at the type of activity rather than specific licencees.			X	Graded approach.
133.	3.266	Delete 3.266	Altough true, does not bring much…			X	3.266 has the role to introduce Appendix 4 (and provide rationale for the Apprndix in question).

COMMENTS BY REVIEWER Country/Organization: FRANCE/ASN Date: 22 May 2015 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
134.	3.269	To ensure that all authorized parties are inspected to a common standard ~~and that the level of safety is consistent~~, the regulatory body should provide its inspectors with written guidelines and procedures in sufficient detail. Appropriate subjects for guidance and instructions for inspectors are covered in paragraph 3.43.	The expected level of safety may be consistent but the inspection may conclude the actual level is not…	X			
135.	3.272	Preparations should be made by the individual or team (including any external experts) who will be conducting the inspection. ~~Furthermore, it may be~~ it is generally useful to establish a detailed agenda or special plan for the inspection and to compile a questionnaire and a list of the documents to be reviewed with the authorized party.	Clarification		Preparations should be made by the individual or team (including any external experts) who will be conducting the inspection. ~~Furthermore, it may be~~ It is generally useful to establish a specific ~~special~~ plan for the inspection ~~and to compile~~ by compiling a questionnaire and a list of the documents to be reviewed with the authorized party.		See merge with USA comment 52.

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COMMENTS BY REVIEWER Country/Organization: FRANCE/ASN Date: 22 May 2015 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
136.	3.274	The inspection <u>methods</u> ~~programme of the regulatory body~~ should include provision for direct monitoring of items, human factors significant to safety (performance of personnel, managerial attitudes), tests and other safety related activities carried out by the authorized party.	Clarification	X			
137.	3.278	~~The authorized party's personnel should be kept appropriately informed of inspection activities and it should be ensured that the authorized party responds to inspection findings.~~ These considerations can be partly satisfied by means of discussions and interview	This sentence is not really on gathering facts during an inspection. It addresses more the wrapped-up meeting and follow-up process		The authorized party's personnel should be kept appropriately informed of inspection activities. ~~and it should be ensured that the authorized party responds to inspection findings~~.		

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COMMENTS BY REVIEWER Country/Organization: FRANCE/ASN Date: 22 May 2015 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
138.	3.278	Interviews[5] with <u>workers,</u> the facility or activity manager and, as appropriate, with other senior managers should be standard features of most inspection visits. ~~However, inspection procedures should include interaction and discussion with all levels of the authorized party's staff~~. In interacting with the authorized party's staff, the inspector should exercise mature judgment concerning the prerogatives and responsibilities of the facility's management.	Interview, as defined in footnote 5, should not be limited to managers.	Y			

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COMMENTS BY REVIEWER Country/Organization: FRANCE/ASN Date: 22 May 2015 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
139.	3.281	The regulatory body should examine samples of the authorized party's documentation sufficient to satisfy itself that the authorized party is fulfilling the requirements for authorization and is operating in accordance with the practices proposed by the authorized party and approved by the regulatory body and that, where deviations or deficiencies have been detected, they have been adequately addressed.	Deviation management is a topic to address during inspection.	Y			

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COMMENTS BY REVIEWER Country/Organization: FRANCE/ASN Date: 22 May 2015 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
140.	3.291	The purposes of inspection reports are <u>to record any positive or negative findings or conclusions reached by inspectors (either directed at the licensee or at the regulatory body), inform other members of the regulatory body and contribute to maintaining an organizational memory.</u>: ~~- record the results of all inspection activities relating to safety or of regulatory significance;~~ ~~- document and record an assessment of the authorized party's activities in relation to safety;~~ ~~- record discussions held with authorized party's staff, management and other concerned persons;~~ ~~- provide a basis for informing the authorized party of the findings of the inspection and of any non-compliance with regulatory requirements, and to provide a record of any enforcement actions taken;~~ ~~- record any findings or conclusions reached by inspectors;~~	Many duplications with 3.292. Simplification is suggested			Y	The text in 3.291 is taken from the existing text in approved safety standard GS-G-1.3, par 4.31.Such a significant simplification results in the loss of too much information.

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COMMENTS BY REVIEWER Country/Organization: FRANCE/ASN Date: 22 May 2015 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
141.	3.293	Inspection reports should be distributed or made electronically available according to established procedures in order to provide for the following: - a basis for future regulatory action; for example for a basis for identifying major or generic issues which necessitate special inspections, changes to inspection plans or regulations or guides ~~- a contribution to maintenance of the regulatory history by providing a record of inspections, discussions and associated findings and conclusions;~~ ~~- a basis for identifying major or generic issues which necessitate special inspections, changes to inspection plans or generic regulatory action;~~ - information to regulatory staff responsible for review and assessment; ~~- information to regulatory staff responsible for reporting incidents;~~ ~~- information to regulatory~~	Simplification suggested	113	Reference to electronically available added to para.		The text in 3.293 is taken from the existing text in approved safety standard GS-G-1.3, par 4.33.Such a significant simplification results in the loss of too much information.

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COMMENTS BY REVIEWER Country/Organization: FRANCE/ASN Date: 22 May 2015 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
142.	3.294	Inspection findings should typically be discussed at regular meetings attended by groups of inspectors. It is also a good practice in many States to include those regulatory body staff involved in review and assessment activities or licensing activities in such meetings.	Clarification		Authorization used instead of licensing.		
143.	3.296	Delete 3.296	Too detailed			Y	Text was taken from existing GS-G-1.3

COMMENTS BY REVIEWER Country/Organization: FRANCE/ASN Date: 22 May 2015 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
144.	3.299	Although it may be the practice in some States to publish individual inspection reports or inspection follow-up letter sent to the authorized party, ~~some inspection reports~~ they may contain confidential information, such as security information, ~~information which the regulatory body may wish to~~ use in connection with future regulatory actions, proprietary information, personal or medical information relating to individuals and proprietary information. Such information should be withheld. ~~However, in the interests of confidentiality it may be undesirable to show which information has been withheld. In such cases, therefore, only the general findings of the inspection and regulatory decisions should be made available to the general public.~~	France practice is to publish on ASN website the follow-up letter but not the inspection report. Simplification	Y			

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COMMENTS BY REVIEWER Country/Organization: FRANCE/ASN Date: 22 May 2015 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
145.	3.305	~~The authorization process itself is a form of enforcement as refusing an application for an authorization means that operation of the facility or conduct of the activity is prohibited and legal sanctions can be used if the prohibition is not complied with. However,~~ in most States the term "enforcement process" is restricted in use to actions in connection with non-compliances and violations of legally binding requirements occurring during operation of a facility or conduct of an activity.	Superfluous Clarification		Retained the proposed deleted text as it does highlight the potential impact of the authorization process. Modified the final sentence as proposed.		

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COMMENTS BY REVIEWER Country/Organization: FRANCE/ASN Date: 22 May 2015 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
146.	3.308	Regulatory enforcement actions are actions taken by the regulatory body to force an authorized party to restore ~~deal with non-~~ compliance ~~by the authorized party~~ with specified conditions and requirements. These actions should be taken to have an authorized party modify or correct any ~~aspect~~ non-conformance in its ~~of an authorized party's~~ procedures and practices, ~~or of a~~ facility or activity's SSCs or managerial or operational procedures and processes that are necessary to ensure safety….	Clarification		Regulatory enforcement actions are actions taken by the regulatory body to address ~~deal with~~ non-compliance by the authorized party with specified conditions and requirements. These actions should be taken to ensure that the authorized party modifies or corrects any aspect of its ~~an authorized party's~~ procedures and practices…….		
147.	3.309	As the main purpose of enforcement is to ~~improve~~ ensure safety and not to punish, enforcement actions should be chosen to achieve this end.	Clarification	Y			

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COMMENTS BY REVIEWER Country/Organization: FRANCE/ASN Date: 22 May 2015 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
148.	3.317	The extent of the authority of the regulatory inspectors to take on the spot enforcement actions should be determined by the regulatory body, considering the national legislation and regulations. The authority given to an inspector may depend on the structure of the regulatory body and on the inspector's duties and experience.	Clarification	Y			

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COMMENTS BY REVIEWER Country/Organization: FRANCE/ASN Date: 22 May 2015 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
149.	3.138 bullet list	The review and assessment should consider, but it is not limited to that the on-site emergency arrangements: - Are based on a hazard assessment that identifies all reasonably foreseeable nuclear or radiological emergencies that might occur in relation to the facility or activity, including those of very low probability; - Include emergency arrangements for managing the on-site emergency response and for coordination with off-site response; - ~~As applicable, the operability and habitability of emergency response facilities (e.g. emergency centre, technical support centre, operational support centre) under the range of postulated emergency conditions (as identified in the hazard assessment);~~ ~~- Include emergency procedures covering all postulated nuclear or radiological emergencies, including where necessary severe accident management guidelines [12], which satisfactorily cover the necessary operator actions and functions in emergency response (including procedures for notification and activation of off-site emergency response);~~ ~~- Identify tools, instruments, supplies, equipment and communication systems needed for response to a nuclear or radiological emergency and demonstrate their adequacy for the usage expected;~~	Simplification of the list as some bullets are detailing other bullets.			Y	Note, comment is on para 3.338. The text was specifically added by the IEC expert to cover the recently issued GSR Part 7.

COMMENTS BY REVIEWER Country/Organization: FRANCE/ASN Date: 22 May 2015 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
150.	3.340	Delete 3.340	Such recommendation is not applicable to <u>all</u> activities and facilities….			Y	Not all, but may be some. The application of the recommendation in the para should be subjected to the graded approach.
151.	Appendix 1	Delete Appendix 1	Practice specific. Would be better on safety guide on commodities			Y	Appendix added so that regulatory functions associated with consumer products could be located in one place.
152.	Appendix 2	Delete Appendix 2	There are other IAEA safety standards dealing in details with licensing, content of safety case, review and assessment of complex facilities			Y	Text originated from GS-G-1.4 (which is being deleted) and it was decided during the consultancies to retain the text as it provided additional information to those general authorization conditions provided in the main text.
153.	Appendix 3	Delete Appendix 3	There are other IAEA safety standards dealing in details with review and assessment			Y	This safety guide is targeting **regulatory bodies functions** and will absorb GS-G-1.2, as per the DPP. The content of the draft reflects the approved DPP and overall strategy.

FUNCTIONS AND PROCESSES OF THE REGULATORY BODY FOR SAFETY

COMMENTS BY REVIEWER Country/Organization: FRANCE/ASN Date: 22 May 2015 pages				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
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DS473

FUNCTIONS AND PROCESSES OF THE REGULATORY BODY FOR SAFETY

COMMENTS BY REVIEWER Reviewer: France - NSGC Country/Organization: France				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1		Add in the references the NSS 20			Reference to NNS 20 added to para 1.13, which included the existing references to the security documents.		

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COMMENTS BY REVIEWER Reviewer: France - NSGC Country/Organization: France				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
2	Page 94 3.358)	Add the need for interfaces between authorities, in particular for safety and Security				Y	The coordination and interaction between different authorities is specifically addressed in DS472 in Chapter 3 "Interactions with Interested Parties." The inclusion in DS473 of Chapter 3 of section "Communication and Consultation with Interested Parties" is, as explained in footnote 6, a place holder awaiting a decision by the safety committees to include this topic in DS473 or not. See 35th WASSC minutes.

FUNCTIONS AND PROCESSES OF THE REGULATORY BODY FOR SAFETY

	COMMENTS BY REVIEWER Reviewer: **Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)** (with comments of BfS) Page 1 of 7 Country/Organization: **Germany** Date: 21st May, 2015				RESOLUTION			
Rele-vanz	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
2	1	all		Referencing to existing safety standards is inadequate.		References from the source safety standards reviewed and incorporated into the document and reference list.		
1	2	1.1	Introduction: Regulation is essential to ensure safety for all facilities and activities that give rise to radiation risks <u>for workers, the public or the environment.</u>	The first sentence of the introduction only describes that regulation is essential to ensure safety for all facilities and activities **that give rise to radiation risks.** But the essential function of the regulatory body is also to ensure the protection of health of the workers, the public and		Modified as shown below. Reference to "People" used to include patients as well as workers and public. This is consistent with the use in SF-1. "Regulation is essential to ensure		

	COMMENTS BY REVIEWER Reviewer: **Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)** (with comments of BfS) Page 1 of 7 Country/Organization: **Germany** Date: 21st May, 2015				RESOLUTION			
Rele-vanz	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
				the environment.		safety for all facilities and activities that give rise to radiation risks for people and the environment." Rest of the document reviewed and now consistent with this usage		
2	3	all		IAEA Glossary should be applied for all kind of terms in the draft.		Noted.		
2	4	3.3-3.5	The provision of regulations and guides are subject to Requirements	Many citations of GSR-1 requirements (32-34) but no		Paras 3.3 – 3.5 deleted.		

	COMMENTS BY REVIEWER Reviewer: **Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)** (with comments of BfS) Page 1 of 7 Country/Organization: **Germany** Date: 21st May, 2015				RESOLUTION			
Rele-vanz	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
			32-34 of GSR Part 1[2]. ~~3.3. Requirement 32 states "The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgments, decisions and actions are based."~~ ~~3.4. Requirement 33 states "Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant~~	own text of the draft. Repetition: It makes no sense to repeat GSR-1 requirements. Only repeating the reference should be sufficient. Deletion of 3.3-3-5 is recommended. This should be intended for the whole draft of the guide.				

FUNCTIONS AND PROCESSES OF THE REGULATORY BODY FOR SAFETY

	COMMENTS BY REVIEWER Reviewer: **Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)** (with comments of BfS) Page 1 of 7 Country/Organization: **Germany** Date: 21st May, 2015				RESOLUTION			
Rele-vanz	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
			~~experience gained.”~~ ~~3.5. Requirement 34 states “The regulatory body shall notify interested parties and the public of the principles and associated criteria for safety established in its regulations and guides, and shall make its regulations and guides available.”~~					

DS473

FUNCTIONS AND PROCESSES OF THE REGULATORY BODY FOR SAFETY

	COMMENTS BY REVIEWER				RESOLUTION			
	Reviewer: **Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)** (with comments of BfS) Page 1 of 7 Country/Organization: **Germany** Date: 21st May, 2015							
Rele-vanz	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
2	5	3.56	In order to develop regulations and guides, the regulatory body should have two basic resources: qualified staff and at least the same information as the applicant or licensee. It should have unrestricted access to all information according to the licencing or surveillance process.	What sort of information? Please clarify and distinguish. The regulatory body should have unrestricted access to any information of the licensee regarding his licence (see 3.91 in the draft).			Y	The text in subsection "Sources of information and general guidance," which is derived from GS-G-1.4 paras 3.18 – 3.23, is recommending sources of information that the regulatory body could use in developing its regulations and guides. The subsection is not dealing with information from the authorized party or the access to it. However, the para is out of place and has therefore been deleted.

FUNCTIONS AND PROCESSES OF THE REGULATORY BODY FOR SAFETY

	COMMENTS BY REVIEWER Reviewer: **Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)** (with comments of BfS) Page 1 of 7 Country/Organization: **Germany** Date: 21st May, 2015				RESOLUTION			
Rele-vanz	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
2	6	3.68	The regulatory body should ensure that regulations and guides are kept up to date and should establish procedures for their periodic review. Therefore it should be realized within the management system.	The management of modifications of all sort of publications (not only guides and regulations) should be part of the revision management for all documents published by the regulatory body. All these actions are part of the quality management of the regulatory body. See also *impact of revision of regulations (3.72-3.74)*.		Modification to para 3.68: The regulatory body should ensure that regulations and guides are kept up to date and should establish procedures, within its integrated management system, for their periodic review. Modification to 3.72: It is required that the regulatory body should recognize the risks associated with		

	COMMENTS BY REVIEWER Reviewer: **Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)** (with comments of BfS) Page 1 of 7 Country/Organization: **Germany** Date: 21st May, 2015				RESOLUTION			
Rele-vanz	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
						making modifications to well-established procedures and processes. Prospective changes in regulatory requirements should be subject to careful scrutiny, in accordance with the procedures in the integrated management system, to evaluate the possible enhancements in safety that it is		

	COMMENTS BY REVIEWER Reviewer: **Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)** (with comments of BfS) Page 1 of 7 Country/Organization: **Germany** Date: 21st May, 2015				RESOLUTION			
Rele-vanz	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
						intended to achieve.		
2	7	3.76	The terms notification and authorization (by registration or licence) indicate broadly …	Terms should generally refer to the actual IAEA Safety Glossary, there should be no interpretation possible in the guide.			Y	The text used in para 3.76 is consistent with that used in GS-G-1.5 para 3.23 and is not inconsistent with that used in GSR Part 3.
2	8	3.99	The minimum information required to be submitted in support of notification is the following: (a) Clear identification of the applicant submitting the notification;	See IAEA Glossary for the term *Notification.*				Para 1.12 includes the terminology used in the safety guide. Reference to "facility and/or activity", is used to cover all practices and applications of

	COMMENTS BY REVIEWER Reviewer: **Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)** (with comments of BfS) Page 1 of 7 Country/Organization: **Germany** Date: 21st May, 2015				RESOLUTION			
Rele-vanz	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
			(b) Specification of the system to be used for the practice or for source management; (c) Clear specification of the source(s) or the practice and associated equipment to be used in the facilities or activities; (d) The location(s) where the source(s) will be stored and where they will be used or where the practice(s) will take place.					radiation sources.
2	9	3.104	The early assessment of the competence and capability of the applicant should be a requirement in laws and/or regulations within the legal and regulatory framework and ~~Early assessment of the competence and capability of the applicant~~ should be conducted to ensure the applicant	The early assessment of the competence and capability of the applicant should require from laws and/or regulations in the regulatory framework.			Y	DS473 does not address the requirements in the law. However, the recommendations in DS473 cover the need for the regulatory body to

	COMMENTS BY REVIEWER Reviewer: **Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)** (with comments of BfS) Page 1 of 7 Country/Organization: **Germany** Date: 21st May, 2015				RESOLUTION			
Rele-vanz	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
			will be able to manage the later phases of the project of the facility or to carry out the activity.					address the competence and capability of the authorized party.
1	10	3.105	Safety activities: … (i) … (j) <u>The Implementation of site specific accident management measures;</u> (<u>k</u>) A description of the safety relevant …	Additional item (j) proposed. Accident management measures (site specific preventive and mitigative measures) are nowadays state of the art (see lessons learned from Fukushima).			Y	Emergency preparedness and response is dealt with in the next topic below "Emergency arrangements."
2	11	3.131	Site evaluation:	The regulatory body should not only be involved in the		Reference to site evaluation safety		

	COMMENTS BY REVIEWER Reviewer: **Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)** (with comments of BfS) Page 1 of 7 Country/Organization: **Germany** Date: 21st May, 2015				RESOLUTION			
Rele-vanz	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
				formulation of the site selection for waste disposal sites, regarding seismic, flooding, air crash or other major factors for site evaluation. It is recommended to refer to existing guides related to siting.		requirements and safety guides added, see refs 20-27.		
1	12	3.139 (new)	<u>During the full operational lifetime of the facility a system for operating experience feedback should be established. This should occur before the commissioning phase (refer to NS-G-2.11).</u>	New item. Operating experience feedback is missing.			Y	The recommendations covering the regulatory involvement in the feedback of operational experience in NS-G-2.11 are covered in DS473 already.

FUNCTIONS AND PROCESSES OF THE REGULATORY BODY FOR SAFETY

	COMMENTS BY REVIEWER Reviewer: **Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)** (with comments of BfS) Page 1 of 7 Country/Organization: **Germany** Date: 21st May, 2015				RESOLUTION			
Rele-vanz	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
2	13	3.157	(b) the information contained in the authorized party submissions is up to date, accurate and sufficient to enable confirmation of compliance with regulatory requirements;	For completeness.	Y			
2	14	3.160	(c) To determine whether the authorized party's personnel meet the regulatory requirements, in terms of ~~both~~ number, ~~and~~ competence and reliability;	Aspect of reliability of the authorized party's personnel is missing?	Y			
3	15	3.168	~~198.~~ This section…..	Editorial, doubling?	Y			
2	16	3.172	Review and assessment will be concentrated on the applicant's or authorized party's approach to safety and safety standards, and how these have been applied in developing the design. Features such as the physical	Is there a comprehensive safety analysis report to be submitted to the regulatory body before construction and installation? See 3.203 in the draft – *Verification of the*		Before authorization of construction, review and assessment will be concentrated on		

	COMMENTS BY REVIEWER Reviewer: **Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)** (with comments of BfS) Page 1 of 7 Country/Organization: **Germany** Date: 21st May, 2015				RESOLUTION			
Rele-vanz	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
			layout and the construction of the facility or activity systems and the key process elements should be carefully considered, and their effects on the safety of the facility throughout its lifetime should be assessed at the design stage. A comprehensive safety analysis report should be submitted to the regulatory body before construction and installation. In addition, before authorizing construction or installation, the regulatory body should review and assess the authorized party's arrangements for the control of activities in construction, manufacture and installation. …	*Safety Analysis*.		the applicant's or authorized party's approach to safety and safety standards, and how these have been applied in developing the design……..		

FUNCTIONS AND PROCESSES OF THE REGULATORY BODY FOR SAFETY

	COMMENTS BY REVIEWER				RESOLUTION			
	Reviewer: **Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)** (with comments of BfS) Page 1 of 7 Country/Organization: **Germany** Date: 21st May, 2015							
Rele-vanz	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3	17	3.194	Safety objectives and regulatory requirements should specify safety goals for levels of performance of the safety structures, systems and components ~~SSC's~~ and….	What are SSC's? Systems, structures and components? Please write out like in 3.202 (c) or perform a list of abbreviations.		All references to SSC, 32 instances, replaced with "structures, systems and components"		
2	18	3.260	On major facilities, many states allow for 25 % of the inspection time to be available for reactive inspection.	Is there a reference available?			Y	The text is taken directly from existing safety standard GS-G-1.3, par 4.12. As this standard is to be deleted, a reference to it will not be added.

FUNCTIONS AND PROCESSES OF THE REGULATORY BODY FOR SAFETY

	COMMENTS BY REVIEWER Reviewer: **Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)** (with comments of BfS) Page 1 of 7 Country/Organization: **Germany** Date: 21st May, 2015				RESOLUTION			
Rele-vanz	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
2	19	3.337	This review and assessment should ensure … of postulated nuclear or radiological emergencies, including **those of very low probability**."	The wording of "including those of very low probability" is very interpretable and needs more specific explanation.		As proposed by USA comment No 2, reference has been added, in paras 2.5, 3.337 and 3.338, to NS-G-3.1, which contains an approach to screening events based on probability.		
2	20	3.334	The Regulatory body should have the responsibility for ensuring that the authorized party has adequate on-site arrangements, <u>including accident management measures if applicable</u>, to prepare for and respond to a nuclear or radiological emergency.	Does "on-site arrangements" include accident management measures, e.g. of a nuclear power plant? Then they should be mentioned.			Y	Yes, it does, as defined in the "Definitions" section of GSR Part 7.

FUNCTIONS AND PROCESSES OF THE REGULATORY BODY FOR SAFETY

	COMMENTS BY REVIEWER Reviewer: **Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)** (with comments of BfS) Page 1 of 7 Country/Organization: **Germany** Date: 21st May, 2015				RESOLUTION			
Rele-vanz	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
			Much of this is carried out through the functions and processes described in earlier sections.					

COMMENTS BY REVIEWER Reviewer: Japan NUSSC Page 1 of Country/Organization: Japan/NRA Date: 22 May. 2015				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~~s~~ supersedes the following Safety Guides: Review and Assessment of Nuclear Facilities by the Regulatory Body (GS-G-1.2); Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body (GS-G-1.3); Documentation for Use in Regulating Nuclear Facilities (GS-G-1.4); Regulatory Control of Radiation Sources (GS-G-1.5) (part of); Licensing Process for Nuclear Installations (SSG-12) (part of) and Release of Sites from Regulatory Control upon Termination of Practices (WS-G-5.1) (the regulatory component only).	To be consistent with the DPP (DS473 Version 7).	Y			
2.	3.334	**Ensuring ~~O~~on-site emergency arrangements**	Editorial. Use the general heading defined in para 3.332 "Ensuring on-site emergency arrangements"	Y			
3.	3.336/6	… emergency response; ~~for~~ terminating the emergency; …	Editorial. "for" is not necessary.	Y			
4.	3.338	(It is necessary to rewrite the whole paragraph.)	All phrases following hyphens should have the form that follows "The	Y			

COMMENTS BY REVIEWER Reviewer: Japan NUSSC Page 1 of Country/Organization: Japan/NRA Date: 22 May. 2015				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
			review and assessment should consider:" and they shouldn't begin with verbs.				
5.	3.339/4	… some of the emergency exercises, in accordance with GSR Part 7, paragraph 6.30 [11].	Editorial. "in accordance with" or other appropriate words should be inserted to be a clearer sentence.	Y	, (GSR Part 7, paragraph 6.30 [11]).		Brackets have been added to be consistent with the whole document.
6.	3.340	The regulatory body should ~~include~~ ensure that the authorized party demonstrates ~~a demonstration of~~ the effectiveness of the on-site emergency arrangements as a pre-cursor to issuing the authorization to bring nuclear and radioactive material on the site and to be completed before the start of commissioning or operation of a facility or commencement of the activity.	Clarification. Role of the regulatory body.	Y			
7.	3.346	An important aspect of the regulatory body evaluation of the national exercises should be to assess the interface ~~between~~ among the authorized party, off-site response	Editorial. More than two items are present after "between".			Y	The use of "between", does not imply only two items.

COMMENTS BY REVIEWER Reviewer: Japan NUSSC Page 1 of Country/Organization: Japan/NRA Date: 22 May. 2015				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		organizations and itself.					
8.	3.358/2	… and a culture of transparency and openness, ~~and~~ to involve, …	Grammatically wrong.			Y	The and provides division in the two different actions develop and implement a strategy and to involve interesting parties. These are two different issues
9.	3.358/6-8	Increasingly, the consultation of the public to ascertain its views, whilst retaining the guidance and recommendations concerning regulatory body communication and consultation ~~are~~ is covered in [13].	Grammatically speaking, if "the consultation of the public" is the subject and "are covered" is its predicate, the verb should be "is". We suggest rewriting this sentence because it is not easy to understand.		The sentence has been re-written to introduce ref [13].		

COMMENTS BY REVIEWER Reviewer: Country/Organization:				RESOLUTION Page.... of.... Date:			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	3.166 First and third bullet Line 6	- results of **final radiological survey** ~~environmental monitoring~~ and other performance confirmation programmes. Where necessary owing to the nature of the facility (for example, for a waste disposal site), reports **or safety case** should also include **such as** details of:	See GSR Part6. See SSR-5 (i.e. for disposal site) Items to be included in the safety case are not limited these three items.		-= results of environmental monitoring and other performance confirmation programmes. Where necessary owing to the nature of the facility (for example, for a waste disposal site), reports or safety case should also include such as details of:		Final Radiological survey is limiting the possible monitoring that has to be taken.
2	3.171	For waste disposal facilities, ~~the geological barrier is an important element of the very long term safety assurance necessary~~ **the safety of any disposal facility depends primarily on the favourable characteristics or properties of natural barriers and the engineered barriers.** The arguments to be made will depend on an understanding of ~~the natural environment~~ **the features of the facility and its host environment and of the factors that influence its safety after closure**. The process of review and assessment of the	Current text deems to focus on only geological disposal. See para.4.46 of SSG-23. See Req.6 of SSR-5. More appropriate term.	Y			This makes consistent the para with the SSG-23 and SSR 5

COMMENTS BY REVIEWER Reviewer: Page.... of.... Country/Organization: Date:				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		site **characteristics** ~~qualification~~…					
3	3.182/3 3.182/3-5 3.182/9	…removal of radioactive materials, radioactive waste, **structures, system and** components ~~and structures~~. Decommissioning comprises: **the planning for decommissioning** ~~preparation and approval of a detailed decommissioning plan~~; the **conducting decommissioning actions** ~~actual decommissioning activities; and~~ **including** the management of waste arising from these activitie**s; the termination of the authorization for decommissioning**. In **the** ~~those~~ case**s of** ~~for which it is proposed to~~ defer**red dismantling strategy** ~~decommissioning~~ in whole or in part, it should be **demonstrated** ~~shown~~ that **no undue burdens will be imposed on future generations** ~~there will be no undue burden on future generations~~.	See para.1.5 of GSR Part6. See paras.1.6-1.8 of GSR Part6. More appropriate text. Terminology More appropriate text.	Y			This comments makes the para consistent with other safety guides

COMMENTS BY REVIEWER Reviewer: Country/Organization:			Page.... of.... Date:	RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
4	3.183/1-3	…~~ancillary~~ surface facilities should be decommissioned… **The safety case** ~~Detailed proposals~~ for closure ~~and for assessment of the safety of a disposal facility in the long term~~…[X,Y] [X] SSG-29 Near Surface Disposal Facilities for Radioactive Waste [Y] SSG-14 Disposal Facilities for Radioactive Waste	More appropriate text. Clarification	Y	…~~ancillary~~ surface facilities should be decommissioned… Detailed proposals for closure and for assessment of the safety of a disposal facility in the long term should be reviewed and assessed by the regulatory body …[X,Y] [X] SSG-29 Near Surface Disposal Facilities for Radioactive Waste [Y] SSG-14 Disposal Facilities for Radioactive Waste.		The text provides better understanding of the para , however assessment of safety should remain in the text for consistency with the DS472
5	3.215/3	…that may affect the performance of the facility ~~or activity~~.	This text focuses on the disposal "**facility"**.	Y			Disposal applies only to facilities
6	A.4.44	- sealing arrangements for the facility including any measures to prevent **human** intrusion;	Terminology	Y			Human should be mentioned

COMMENTS BY REVIEWER Reviewer: Page.... of.... Country/Organization: Date:				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
7	A.4.45	This will include review of the cleanup and monitoring procedures, review of the management system, independent monitoring and analysis of compliance with the release criteria for the site or review of the implementation of restrictions at the site [Z]. [Z] WS-G-5.1 Release of sites from regulatory control on termination of practices	Clarification This text is derived from para.5.21 of WS-G-5.1.			Y	WS-G-5.1 is being withdrawn.

Functions and Processes of the Regulatory Body for Safety (DS473)

COMMENTS BY REVIEWER Country/Organization: Republic of Korea / Korea Institute of Nuclear Safety (KINS) Date: May 20, 2015				RESOLUTION			
Comment No.	Para/Line No.	Identified problem/Proposed new text	Reason/Description	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	Page 87 §3.316 (a), (b)	"3.316. The factors to be taken into account by the regulatory body in deciding which type of enforcement action is appropriate in each case should include: (a) The safety significance of the deficiency and the complexity of the corrective action needed, (b) The seriousness of the violation," [Comments] This paragraph explains general aspects to be considered in the determination of level of enforcement action to be taken in response to a violation of or non-compliance to regulations. It is desirable that this guide should provide how to assess and determine the significance or seriousness of a violation especially when identified by regulatory inspections.	It is note-worthy that many of the violations that result in significant enforcement actions are identified by regulatory inspections. To enhance the predictability and consistency of enforcement actions, it is essential to establish a systematic and sound process to determine the safety significance of inspection findings. That process usually considers whether the inspection finding is related to the violation of Technical Specifications, Limiting conditions for operation, loss of fundamental safety functions, etc.			Y	No proposed new text provided. However, it is noted that DS473 includes reference to the use of the graded approach to enforcement action based on the significance for safety and the recommendation for the regulatory body to develop guidance and procedures on the regulatory body decision making approach in determining the level of action to be taken. Such procedures would ensure a

COMMENTS BY REVIEWER Country/Organization: Republic of Korea / Korea Institute of Nuclear Safety (KINS) Date: May 20, 2015				RESOLUTION			
Comment No.	Para/Line No.	Identified problem/Proposed new text	Reason/Description	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
							consistent approach to enforcement action. Finally, section "Methods of Enforcement", provides some guidance on the enforcement options based on the degree of non-compliance, i.e. from minor safety significance to serious violations presenting an imminent radiation risk.

DS473 - Safety Guide: Regulatory Body Functions and Processes

COMMENTS BY REVIEWER Reviewer: NUSSC Page.... of.... Country/Organization: South Africa Date:				RESOLUTION			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	3.13	"are based."	Delete double full stop.	Y			
2	3.51	"review, asses and approve if considered adequate"	Restructure wording.	Y			
3	3.56	"the regulatory body should have information and competent staff"	Replace qualification with competent and reword sentence.			Y	GSR-part 1 Para 2.34, refers to "maintaining the competence of a sufficient number of suitably qualified and experienced staff …..". Note that this para has been deleted based on Germany comment No 5.
4	3.57	"standards, issued in the…)	Delete "which are	Y			
5	3.59	When regulations, guides and other relevant information from regulatory bodies in other States is considered in the development of regulations then the legal framework…..	Consider rewording as the information is duplicated from 3.57. Reworded to support the statement.		When regulations, guides and other relevant information produced by regulatory bodies in other States is considered in the development		The wording has been changed in order to leave open the use of regulations in other states.

COMMENTS BY REVIEWER Reviewer: NUSSC Page.... of.... Country/Organization: South Africa Date:				RESOLUTION			
					of regulations, particular		
6	3.66 (d)		The section deals with resources and the detail is duplication of 3.56 into qualified and experienced staff. If consider adequate then propose deletion of previous 3.56.	Y			Note that this para has been deleted based on Germany comment No 5
7	3.80		Delete 110.	Y			
8	3.156	"facility or activity'	Add activity to the sentence.	Y			
	3.168		Remove 198 from start of paragraph and change Appendix III to 3 to align with appendix numbering.	Y			
	3.203		Change Appendix III to 3 to align with appendix numbering.	Y			
			Change Appendix III to 3 to align with appendix numbering.	Y			
9	3.219		Please rewrite first section of paragraph as it points towards review	Y			

COMMENTS BY REVIEWER Reviewer: NUSSC Page.... of.... Country/Organization: South Africa Date:				RESOLUTION			
			and assessment. The second section is clear.				
10	3.222		Editorial corrections ";" to last 4 bullets.	Y			
11	3.266	Appendix 4	Change IV to 4 to align with appendix numbering.	Y			
12	3.278	Note 5 of Paragraph	Editorial in note 5 at bottom of page, "a t" to be "at".	Y			
13	3.286	…authority and resources [4]….	Add reference to [4] to be consistent with reference to resources in other parts of the guide.	Y			
14	3.290		Editorial corrections ";" to last 2 bullets.	Y			
15	3.303/3.304		Propose swopping paragraphs around to reference requirement 30 first, then requirement 31 of GSR Part 1.	X			
16	3.342		Remove italics from paragraph for consistency with other paragraphs where references are quoted.	Y			

COMMENTS BY REVIEWER Reviewer: NUSSC Page.... of.... Country/Organization: South Africa Date:				RESOLUTION			
17	3.342		Align quoted text with latest draft Part 7. Ie remove “all” from “all roles and responsibilities	Y			
18	3.349	Reference [4]		Y			
19	Appendix 1& 2		The Appendixes is not referenced from within the guide.	Y			

COMMENTS BY REVIEWER **Reviewer:** U.S. Nuclear Regulatory Commission **Country/Organization:** USA **Date:** 22 May 2015				RESOLUTION			
Comment No.	**Page / Section / Line No.**	**Proposed new text**	**Reason**	**Accepted**	**Accepted, but modified as follows**	**Rejected**	**Reason for modification/ rejection**
1	1.10	After bullet #1, add a new bullet: - Safety culture, self-assessment, peer reviews, and international cooperation;	Completeness to address important supporting functions.			Y	To ensure consistency with the supporting functions listed in DS472, i.e. DS472 para 1.11.
2	2.5 Also 3.101, 3.337, 3.338	Where the expression, "very low probability of occurrence" is used, insert a reference to NS-G-3.1.	The term "very low probability of occurrence" is highly subjective. Reasonable constraints (such as in NS-G-3.1 at 4.3) are needed to prevent unbounded speculation.	Y			
3	2.6	Replace "proven" with "established"	The term "proven" is not a suitable metric for regulatory decision.	Y			
4	3.13	Replace "prevent subjectivity" with "provide transparency and traceability in"	Subjectivity, such as engineering judgment, is a part of regulatory decision making and cannot be prevented.			Y	Para 3.13 is paraphrasing Requirement 22 in GSR part 1 Rev1, which

COMMENTS BY REVIEWER **Reviewer:** U.S. Nuclear Regulatory Commission **Country/Organization:** USA **Date:** 22 May 2015				RESOLUTION			
Comment No.	**Page / Section / Line No.**	**Proposed new text**	**Reason**	**Accepted**	**Accepted, but modified as follows**	**Rejected**	**Reason for modification/ rejection**
							uses the phrase "prevent subjectivity."
5	3.20	Replace "proved by" with "tested through"	Experience does not provide proof that technology is suitable.		……..including technological advances that have been shown ~~proved~~ by experience or shown by research results to be capable of providing effective and reliable means of satisfying regulatory requirements.		
6	3.27	Add a new item as described below: (j) Safety criteria, planning, predisposal radioactive waste management, discharge monitoring, as well as aspects of institutional controls at different phases of licensed facility lifecycle, and license termination.	These aspects are important to consider for technical, administrative, and procedural topics and requirements that need to be listed.		(j) Safety criteria and planning for predisposal radioactive waste management and discharge monitoring, as well as aspects of		

COMMENTS BY REVIEWER **Reviewer:** U.S. Nuclear Regulatory Commission **Country/Organization:** USA **Date:** 22 May 2015				RESOLUTION			
Comment No.	**Page / Section / Line No.**	**Proposed new text**	**Reason**	**Accepted**	**Accepted, but modified as follows**	**Rejected**	**Reason for modification/ rejection**
					institutional controls at different phases of the authorized facility lifecycle, and license termination.		
7	3.28 & 3.50, 3.51, 3.52	Para 3.28 states: "*It is required that the regulatory body establish or adopt regulations and guides for safety covering the three exposure situations namely, planned, emergency and existing exposure situations, (GSR Part 3, Requirement 2 [3]).*" We recognize that emergency exposure situations regulations and guides could be different from planned exposure situations. However, this Para contemplates that safety regulation (e.g.; safety criteria for protection of the public and the environment) for existing exposure situations should be established as different from the planned exposure situations. We recognize that this concept/approach	Clarification and completeness to provide an alternate option of using end-state and risk-informed concept.		To cater for the possibility that some regulations and guides may apply to one or more exposure situations, the word "different" has been introduced. Proposed text on existing exposure situations added as a footnote.		

COMMENTS BY REVIEWER **Reviewer:** U.S. Nuclear Regulatory Commission **Country/Organization:** USA **Date:** 22 May 2015				RESOLUTION			
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		has been developed by ICRP and adopted by IAEA. Nevertheless, *for existing exposure situations, we believe the concept of end-state based on a risk-informed approach, considering site specific conditions, is more appropriate to use, particularly when considering costs, socio-economic factors, and stakeholder input as key factors in developing end-state safety criteria and implementation aspects."* Therefore, we recommend adding the above underlined text as a footnote to provide the reader with options to use the end-state and risk-informed concept, as an alternate approach to developing different criteria or regulations for existing exposure situation. The above comment is also applicable to the "Release Criteria" Section under Para's 3.50, 3.51, and 3.52.					
8	3.28	Replace "the three" with "all"	GSR-3, Requirement 2, is for "all" exposure			Y	To cater for the possibility that

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			situations, not just the 3 (for example, "faulted" condition is missing from 3.28)				some regulations and guides may apply to one or more exposure situation, the word "different" has been introduced.
9	18/ 3.38	3.38 Regulations and guides issued by the regulatory body should include the requirements for the authorized party to keep records that contain information used to demonstrate the safety of the facility design and construction (technical safety basis) that contributed to the safety conclusions presented in the application for an authorization submitted to the regulatory body for review and approval ~~are considered to be safety related.~~ These records, although not formally submitted to the regulatory body for review and approval, should be made available ….	The term "safety related" has very specific meaning in some member states. The records that this paragraph intends be retained may not fit a specific definition of "safety related."		In GSR Part 1 Rev 1, the provision of safety related records is covered by Requirement 35: Safety related records. For consistency with GSR Part 1 Rev 1, it is intended to use the same terminology and so para 3.38 has been modified as given below:		

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					Regulations and guides issued by the regulatory body should include the requirements for the authorized party to keep adequate records relating to the safety of facilities and activities. ~~that are considered to be safety related.~~ i.e. the use of the term "safety related" is not used.		
10	3.39	Include bullet for "Records relating to the safety of facilities and activities."	This important point is included in GSR Part 1 Requirement 35.	Y			
11	3.57	Replace "Regulations and guides should be based…" with "Regulations and guides may be based…"	Consistency with presentation of IAEA standards in GSR-1 (Foreword) "...which States		In developing regulations and guides, consideration		

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			can apply" and also "many States have decided to adopt the IAEA's standards.		should be given to adopting, as a reference, ~~based on~~ the IAEA's safety standards……..		
12	3.66(b)	Replace "need for improvements" with "need and associated costs for improvements"	Cost-benefit considerations are important (e.g., backfitting).	Y			
13	3.90(a), 3.102, 3.109	Replace "undue" with "unacceptable"	Consistency with Fundamental Safety Principal 6.	Y			
14	31/ 3.94(a)	a) Prepare and submit a comprehensive application to the regulatory body that demonstrates that priority is given to safety as evidenced by compliance with all applicable legal and regulatory requirements and ; ~~that is, that the level of safety is as high as reasonably achievable and that safety~~ that will be maintained for the entire lifetime of the facility or activity, until this is released from regulatory control by the regulatory body;	The criterion for an applicant to provide "the level of safety is as high as reasonably achievable," is subjective given that what is reasonable one authorized party is not necessarily reasonable to other authorized parties. The minimum level of safety should be defined through precise (not subjective) legal and regulatory requirements based on the			Y	This proposal does not appear to comply with the requirement in GSR Part 1 Rev1 for the regulatory body to seek continuous enhancement of safety. The current text is taken from

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			risk or hazards presented by the type of facility or activity.				existing text in the safety standard SSG-12, para 2.38
15	3.105, Staff (d)	Replace "proof" with "evidence"	"Proof" of trustworthiness is unobtainable.	Y			
16	3.105 (pg. 37), Safety activities, (p)	(p) Arrangements to ensure safety and security of sources in order to prevent loss of control due to theft, diversion or severe environmental conditions;	Completeness.	Y			
17	3.113	Delete 3.113	Reiteration of 3.112	Y			
18	40/ 3.116	Authorization conditions should cover, as appropriate, safety ~~related~~ aspects affecting the facility or activity throughout its lifecycle encompassing …	The term "safety related" has very specific meaning within the regulatory structure of some member states. Therefore, changing "safety related aspects" to "safety aspects" should eliminate any confusion.	Y			
19	3.133	Replace "basic" with "initial" design	Consistency with subsequent use of "final design"	Y			
20	3.136	Replace "a periodic safety review that…" with "a periodic safety review, or its equivalent [8] that…"	Citation needed, and consistency with presentation of PSR concept		Over the full operational lifetime of the facility or		The proposed text is consistent with

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			in SSG-25.		activity, the regulatory body should require the authorized party to provide evidence at appropriate intervals, in the form of a comprehensive safety review ~~reassessment~~, such as ~~termed~~ a periodic safety review [8]……..		the text in GSR Part 1 Rev 1 para 4.39(a).
21	49/ 3.152	3.152. The regulatory body should require notification by the authorized party ~~to notify~~ of any significant changes to the safety ~~related~~ aspects of the facility or activity…	The term "safety related" has very specific meaning within the regulatory structure of some member states. Therefore, changing "safety related aspects" to "safety aspects" should eliminate any confusion.	Y			
22	49/ 3.152	3.152 …. Any modification to safety ~~related~~ aspects of a facility or an activity should be subject to an …	The term "safety related" has very specific meaning within the regulatory	Y			

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			structure of some member states. Therefore, changing "safety related aspects" to "safety aspects" should eliminate any confusion.				
23	3.156	Replace "validate" with "verify"	Verification is consistent with regulatory function.	Y			
24	3.157(c)	Replace "proven" with "verified"	Proof is not realistically obtainable.	Y			
25	53/ 3.168	3.168. Review and assessment should be carried out in a formalized approach. ~~198~~. This section outlines the areas in which review and assessment should be concentrated.	Delete "198" at the beginning of the sentence. Grammatical error.	Y			
26	3.170	Add: "Natural phenomena should include earthquake, high winds, flooding, and other phenomena as appropriate for the geographical location of the activity."	Completeness.	Y			
27	3.171	Replace "provide" with "complete"	The initial (but potentially incomplete) technical basis already has been provided in the application.	Y			
28	55/ 3.179/	While the need for reassessment may arise in a number of ways (see para	As originally written, this section presented the PSR,	Y			

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		3.189), systematic safety reassessments, ~~termed~~ such as Periodic Safety Reviews (PSRs) [8], should be carried out by the authorized party ….	the favored option of the IAEA, as the only option. As modified, the section is more methodology-neutral with respect to the type of systematic safety reassessments. Not all Member States conduct PSRs.				
29	56/ 3.179	…The ~~PSR~~ safety reassessment should enable the regulatory body to judge whether it is acceptable for the facility to continue to be operated until the next ~~PSR~~ reassessment is carried out.	As originally written, this section presented the PSR, the favored option of the IAEA, as the only option. As modified, the section is more methodology-neutral with respect to the type of systematic safety reassessments.		The comprehensive safety review ~~PSR~~ should enable the regulatory body to judge whether it is acceptable for the facility to continue to be operated until the next comprehensive safety review ~~PSR~~ is carried out		To also ensure consistency with GSR Part 1 Rev 1.
30	3.179	Replace "against current regulatory requirements and practices…" with "against current national and/or international safety standards and	Current text is contrary to intent in SSG-25, which provides alternative text. The PSR is not designed to	Y			

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		operating practices…"	be a licensing reevaluation.				
31	3.179	Replace "meet current regulatory requirements, the significance of the shortcomings should be assessed and possible ways of meeting the requirements should…" with "meet current standards and operating practices, the significance of the shortcomings should be assessed and possible ways of meeting the standards or practices should…"	Current text is contrary to intent in SSG-25, which provides alternative text. The PSR is not designed to be a licensing reevaluation.	Y			
32	65 / 3.213 / 19	3.213. If allowed under the State's legal and regulatory framework, the ~~The~~ regulatory body should at all times require reasonably achievable improvements to be made in the design or operating procedures of the facility or activity with the aim of reducing potential radiological consequences.	There are States with laws and regulatory requirements that would prohibit the actions proposed in this section. Under urgent conditions for reasons to provide adequate protection, those States typically have means to direct the authorized party to take immediate action by order. Otherwise, to introduce a new requirement will require the			Y	This proposal does not appear to be consistent with the requirements in GSR Part 1 Rev 1 for the regulatory body to seek continuous enhancement of safety. The current text

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			regulatory body to invoke a lengthy process to establish a rule before such action can be taken.				is taken from existing text in the safety standard SSG-12, para 3.50
33	Page 67/ S 3.219	Delete or modify the following: For significant risk sources or unusual or complex activities, the regulatory body should also verify the contents of the documents submitted by means of inspection of the site where the radiation sources are to be installed or used.	Question: Why specific to radiation sources? The lead-in sentence specifies complex activities, too. Inspections of nuclear plants are more comprehensive and not limited to radiation sources		In accordance with the graded approach, for facilities and activities with a significant risk, the regulatory body should also verify the contents of the documents submitted by the applicant by means of inspection of the facility and activity where radiation sources are to be installed or used. These inspections will also allow the regulatory body to		Text made more general. See also South Africa comment No 9

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					supplement the information and data needed for review and assessment.		
34	Page 67/ S 3.222	Is the list a copy from the GSR? If not, authors may consider including corrective action program in the list.	Because of the size and complexity of NPPs, a corrective action program is important to plant safety	Y			
35	Page 68/ S 3.227	Specific responsibilities of the regulatory body ~~in~~ with respect ~~of~~ to inspection should include	Grammatical error	Y			
36	69/3.231/ 30	3.231. Regulatory inspection programmes should be comprehensive and consistent with ~~should be developed~~ within the overall regulatory strategy. ~~These~~ Inspection programmes should be thorough enough to ensure that regulatory objectives and requirements are met thereby providing the regulatory body with ~~provide~~ a high level of confidence that authorized parties are effectively maintaining the safety of their facility and activities ~~in compliance with the regulatory~~	Written to clarify the expectations of the inspection programme.	Y			

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		~~requirements and are identifying and solving all actual and potential problems in ensuring safety~~. The inspection programme should also be developed so that the regulatory body can determine ~~whether~~ if the authorized party has an effective ~~functional~~ self-assessment ~~system~~ process capable of prompt identification and correction of actual and potential problems ~~of high quality and is~~ and ~~conducting its~~ conducts activities in accordance with ~~its own~~ previously established high quality procedures ~~for ensuring that regulatory objectives and requirements are met~~.					
37	70/ 3.234	…~~The more~~ Common indicators of degraded performance include but are not limited to: Add the following 2 bullets: • Repetitive failures of important facility equipment (reliability) • Frequent unavailability of the facility	List is not all inclusive. Revised to note that there could be other indicators. Also, recommend the addition of two important example indicators related to reliability and availability of the facility.	Y			

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38	3.234	Insert additional bullet for "Increasing frequency of safety allegations or other enforcement actions."	Safety allegations are an important indicator of degraded performance	Y			
39	Page 70 and 71/3.234	The regulatory body should require authorized parties to pay attention to such indicators of degraded safety performance. This focus on indicators and the underlying performance issues ~~and this~~ should enhance the safety culture.	This will show the tie between a focus on "fixing" the cause of declining performance indicators which will result in enhancing the safety culture.	Y			
40	71/ 3.239	3.239. The regulatory body should compile and analyse data on the performance of authorized parties. As part of ~~continuous improvement~~ the inspection program, the regulatory body should…	Not all regulators have a "continuous improvement program" but assessment activities as discussed in this Section would seem appropriate for inclusion in the inspection program if allowed under the State's legal and regulatory framework.	Y			
41	3.242	Comment: It should be recognized (noted) that some facilities where complex activities are conducted may have inspectors permanently assigned to the facility.	Completeness.		Noted. The use of resident inspectors is referred to in paras 3.264 and 3.290.		

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42	3.248	Add new bullets: - misadministration of radiopharmaceuticals to patients; - theft or diversion of radioactive material;	Completeness.		Bullets added to para 3.222 as, in reconciling France comment No 127, the bullet list in para 3.248 was deleted.		
43	Page 74/ S 3.249 & 3.250	Combine Sections 249 and 250 into one section	Section 250 is a carryover of the thought process from Section 249	Y			
44	Page 75/ S 3.254	The advantage of unannounced inspections is that the actual state of the facility and the way in which it is being operated can be observed. Inspections may be carried out at any time of the day or night so as to provide a more complete picture of the situation at the facility or activity. ~~In order to be able to carry out unannounced inspections, it is necessary that the regulatory body should have unfettered access at all times.~~ However, the regulatory body should be sensitive to activities on-going at the site.	Legislative and regulatory framework per Section 3.91 of this document requires unfettered access irrespective of unannounced inspection	Y			
45	75/	3.254. Unannounced inspections may	In some cases it may not be	Y			

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	3.254	not always be feasible, but they have their benefits. The advantage of unannounced inspections is that the actual state of the facility and the way in which it is being operated can be observed. Inspections may be carried out at any time of the day or night so as to provide a more complete picture of the situation at the facility or activity. In order to be able to carry out unannounced inspections, it is necessary that the regulatory body should have unfettered access at all times. However, the regulatory body should be sensitive to activities on-going at the site.	possible to conduct an unannounced inspection. If the regulatory inspectors require security clearance to access the site, then prior approval may need to be established with the authorized party. Thus, the regulatory body will only be able to conduct announced inspections at these sites.				
46	Page 75/ S 3.257	Insert a reference to Appendix 1," AUTHORIZATION FOR THE SUPPLY OF CONSUMER PRODUCTS"	Directs the reader to more information regarding the section topic. Also, is "Inspection for the Supply of Consumer Products" a "Type [planned or reactive, announced or unannounced, and team] of Regulatory Inspection? If not, may		Para moved to Appendix 1 and new para including a cross reference to Appendix 1 added at beginning of the Inspection Chapter. Appendix 1 title		

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			need to relocate out of this section		modified to make it more general so as to accommodate text on both authorization and inspection of consumer products.		
47	Page 76/ S 3.259	Expand section to include where the aforementioned factors are located such as: "aforementioned factors listed in Reference 4 and the Safety Guide" or list factors out individually	If this is where the factors are listed, referencing the location of the factors or listing them individually, since they are not listed enhances clarity.		The said factors were actually included in para 3.264. This para has been moved and placed just before para 3.257.		
48	Page 77/ S 3.266	…degrees of emphasis throughout the lifetime lifecycle of the facility or activity.	Lifecycle has been defined and used throughout this document. Authors should ensure consistency with the Safety Glossary.			Y	The use of lifetime here is consistent with the usage as defined in para 1.12.
49	Page 77 /S 3.268	"Whenever the authorized party makes use of the services or products of a contractor, the regulatory body should include the contractor's activities in its inspection programme in all lifecycle	If "all stages" means "life of the plant," this recommended change clarifies the stages	Y			

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		stages of the authorization process."					
50	3.269	Comment: Should the regulatory body establish a qualification program for their inspectors?			Yes. Competence of staff is covered in DS472.		
51	Page 78/ S 3.271	The type of preparation will depend on the type (planned or reactive, announced or unannounced, and team) and method (see Section 3.273 below) of inspection. Preparation may include a review of the following:	Clarity since method of inspection is described after this section. Adding examples of type inspections is a suggestion.	Y			
52	Page 78/S 3.272	Furthermore, it may be useful to establish a special plan for the inspection by compiling a ~~and to compile a~~ questionnaire and a list of the documents to be reviewed with the authorized party."	Not sure what a "special plan" is. This terminology is not used anywhere in this document. I assumed a "special plan" was a questionnaire and made the change to align with that assumption		Furthermore, it may be useful to establish a specific ~~special~~ plan for the inspection by ~~and to~~ compiling a questionnaire and a list of the documents to be reviewed with the authorized party.		
53	Page 78/ S 3.273	- Confirmatory tests and measurements	RB does not establish results from tests and measurements, rather RB confirms the authorized	Y			

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			party's results				
54	Page 78/ S 3.274	The inspection programme of the regulatory body should include provision for direct monitoring of items, such as: human factors significant to safety (performance of personnel, managerial attitudes), tests and other safety related activities carried out by the authorized party.	Clarifies what items are being monitored.	Y			
55	Page 79/ S 3.275	See comment on 3.266 above regarding "over the lifetime of the facility"	See comment on 3.266		See comment on 3.266		
56	Page 79/ Footnote 5	"Note that the word "interview" does not necessarily imply a formal, pre-arranged, process, but should include less formal discussions with appropriate mangers ~~a t~~ [at] higher levels[.]"	Correct "a t" to at and add a period at end of footnote (editorial).	Y			
57	Page 80/ S 3.282	Specify which headquarter (RB's or Authorized Party or both): "The examination of documentation by regulatory inspectors may in some cases take place in part off the site, for example at the regulatory body's or Authorized party's headquarters, and can contribute towards their preparation for inspection of the facility or	Section 3.267 states Authorized Party's This recommended change clarifies location and allows review to be done both places	Y			

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		activity."					
58	Page 80/ S 3.283	"The extent to which the regulatory body does its own confirmatory testing and measurement work independently of the authorized party varies greatly between States…" …However, the regulatory body should not engage in the conduct of confirmatory tests or measurements which would necessitate it assuming direct operational control of the facility or activity or any of its systems.	See comment on S 3.273 above	Y			
59	Page 81/ S 3.284	"In some States, the inspection staff of the regulatory body conducts confirmatory tests and measurements as part of the inspection programme. … In most instances, these confirmatory tests and measurements replicate and serve as an independent verification of tests and measurements performed by the authorized party. The conduct of these confirmatory tests and measurements by the regulatory body shall not relieve the authorized party of its prime responsibility for safety."	Grammar: Change conduct to conducts. Consistency: Delete "physical" since physical tests is not used previously. Inserted "confirmatory" – see Comment on S 3.273 above	Y			

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60	Page 81/ S 3.285	Insert "confirmatory" in front of "test"	see Comment on S 3.273 above	Y			
61	Page 81/ S 3.286	Insert "confirmatory" in front of "test"	see Comment on S 3.273 above	Y			
62	3.288/2	"completion of the inspection, the inspectors should conduct an exit briefing with senior managers and share the details about the inspection activities, …"	To ensure senior management is informed.	Y			
63	Page 82 / S 3.290	type of the inspection, whether planned or reactive, announced or unannounced, team or Supply of Consumer Products	Recommended change clarifies the scope of all types of inspections beyond planned or reactive.	Y			
64	85/ 3.307	The principal objectives of enforcement should be to provide a high level of assurance that the authorized party at all stages of the authorization process and all stages during the lifetime of a facility or activity complies with all ~~safely~~ safety requirements and meets the safety objectives and authorization conditions, and promptly identifies and corrects non-compliances with safety requirements.	Safety requirements instead of safely requirements. Recommended wording for completeness	Y			
65	86/ 3.309/1-	As the main purpose of enforcement is	Improved language	Y			

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	2	to improve safety by deterring noncompliance and encouraging prompt identification and correction, ~~and not to punish~~, enforcement actions should be chosen to achieve this end.					
66	86/ 3.312	Deviations from, or violations of, requirements [of the authorization], or unsatisfactory situations which have more than minor safety significance, may be identified at facilities or in the conduct of activities. In such circumstances, the regulatory body should issue a written warning or directive to the authorized party which should identify the nature and regulatory basis of each violation, and may specify the period of time permitted for taking remedial action, and may provide guidance on the nature of the corrective action.	Language changed to reflect written warnings for more-than-minor violations.		"More than" added. However, not able to add "may specify" relating to the period of time as this would not be consistent with the requirement in GSR Part 1 Rev1 for the regulatory body to identify the period of time allowed for corrective action, consequently, there is no scope to incorporate the proposed modification.		
67	87/ 3.316/	(e) ~~The identity of the person or~~	Language changed to focus	Y			

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	(e)	~~organization who noted and reported the non-conformance,~~ Whether or not the authorized party identified and/or reported the non-compliance.	on whether the authorized party reported the non-compliance				
68	87/ 3.316	Add: (h) Whether the violation impacted the ability of the regulatory body to perform its regulatory oversight function	Example added to be consistent for completeness.	Y			
69	88/ 3.324/ (b)	(b) Check that corrective actions in response to enforcement measures intended to protect the workers, patients, the public, and the environment against an imminent radiological hazard have been taken by the authorized party, even though the authorized party may intend to appeal against the decision of the regulatory body.	Inspections may follow-up on the licensee's corrective actions in response to enforcement action.	Y			
70	89/ 3.325	It is required that, at each significant step in the enforcement process, the regulatory body identifies and documents the nature of any non-compliances. The regulatory body may	Depending on the significance of the noncompliance, the regulator may or may not specify a timeframe for the			Y	As this paragraph is paraphrasing the requirement in GSR Part 1

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		specify ~~and~~ the period of time allowed for correcting them, and should communicate this information in writing to the authorized party, (GSR Part 1, para 4.56 [2]).	licensee's corrective actions.				Rev 1, which requires the regulatory body to identify the period of time allowed for corrective action, there is no scope to incorporate the proposed modification.
71	3.334/2	"adequate on-site arrangements to prepare for and respond to a nuclear or radiological emergency or abnormal event."	The authorized party more likely will need to deal with abnormal events like a damaged guide tube preventing source return, shutters on gauges failing to close, moisture density gauges being run over by heavy construction equipment, brachytherapy sources being misplaced, etc.			Y	Advised by the ISSC that the current terminology, based on the definitions in the newly published GSR Part 7, is adequate and all encompassing.
72	91/	3.338. The review and assessment	Grammatical correction	Y			

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	3.338	should consider, but it is not limited to that of the on-site emergency arrangements:					
73	3.338	Replace "reasonably foreseeable" with "postulated"	Consistency with subsequent text.	Y			
74	92/ 3.345	3.345 ….. The results of the self-evaluation should be used to identify where and what further improvements are needed on its emergency arrangements.	Grammatical correction	Y			
75	95/ A1.2 (i)	Information about any advice to be provided to customers on the correct use, installation, maintenance, servicing, ~~and~~ repair, and disposal of the product.	Additional technical point	Y			
76	A3.12	Add a new item as provided below: (l) In selection of equipment, the minimum detection limit (MDL) should be commensurate with the compliance level such that the MDL should be around 10% of the level to be measured for demonstration of compliance.	Accuracy and precision to avoid conflict in measurement uncertainties. Therefore, it is imperative to consider MDL in selection of instruments to commensurate with the compliance level to be measured.	Y			
77	Page	The management's ability to create an	The use of the word,		The management's		

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	119/A4.40	environment in which problems are openly identified and discussed, and self-assessment programmes are effectively supported, helps to foster ~~an appropriate~~ a positive safety culture ~~for operation~~.	"appropriate" as an adjective for safety culture is not the norm in IAEA documents or in industry documents. There is also no need to qualify the "safety culture for operations" as an organization's safety culture will affect all activities within that organization.		ability to create an environment in which problems are openly identified and discussed and self-assessment programmes are effectively supported helps to foster a strong ~~appropriate~~ safety culture ~~for operation~~		
78	General	There are significant overlap and repetition between **DS473** *"Functions and Processes of the Regulatory Body for Safety"* and **DS472 "***Organization, Management, and Staffing of a Regulatory Body for Safety."* For example, main area of overlap and repetition is "Regulatory Functions and Organization" presented in detail Chapter 4 of DS472 and in Chapter 3 of DS473. We also note overlap between DS473 and DS460, **"**Communication	Harmonization between IAEA standards to minimize overlaps, repetitions, and redundancies particularly between DS472 and DS473.		Noted. S472 and DS473 provide complementary guidance (see para 1.6 in both DS472 and DS473). The inclusion of Chapter 4 in DS472 is for		

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		and Consultation with Interested Parties by the Regulatory Body," particularly in Sections on Emergency Preparedness and on Communications and Consultations with Interested Parties." Since DS472 and DS473 are at the same stage of development (e.g.; Both are at Step #7); we suggest these two documents be reconciled and harmonized to minimize repetitions and redundancies. Other option to consider is to combine these documents in one integrated safety guide. In addition, since DS460 is in an advanced stage of development (Step #11) we recommend DS473 refer to DS460 (e.g.; as reference) rather than repeating a portion of its text.			completeness only and to acknowledge the main regulatory functions and to provide a brief description. This provides a link between the documents and as stated in DS472 para 4.1, the detail is provided in DS473. Regarding the inclusion of text on communication and the reference to DS460. As stated in the footnote, the authors are awaiting a decision by the safety committees on the		

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					future of DS460. See the minutes of the 35th WASSC meeting.		
79	General Comment	The regulatory body might consider creating a nuclear material event database to catalog abnormal events such as damage or loss of a source, malfunction of a device. The regulatory body could conduct trend analyses of types of events and develop new regulations, regulatory guidance, or inspection guidance.					