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GENERAL COMMENTS								
RUSSIA	1			General comment In the draft of the standard there are no recommendations about the organization of work of resident- inspectors, especially on their interaction with the authorization party and with headquarters of regulator. It is necessary to provide the provisions reflecting tasks and work of the inspector -resident in different thematic areas of the draft standard			Y	It is true that there is no explicit reference to resident inspectors, but not all countries use this approach The guidance given in the safety guide is general and therefore applicable to all inspection activities, whether they are carried out by resident inspectors or not.
ENISS	1	General	The guide has improved since the NUSSC version of June 2015 and there are only some points left, where amendment would enhance the document. We provide them below. Two points we like to highlight here, where details can be found in the detailed comments: 1. The concept of licensing reference or generic facilities might lead to significant enhancements in the licensing process needs to taken into account. 2. International co-operation in licensing should be				Y	It is not the purpose of the IAEA Safety Guide to tell Member States how to conduct their business. Each Member State is a sovereign state and must make its

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			reflected more visible in the document, e.g. if facilities of the same or a similar kind have been authorised in other state. Additionally we still think that the current state of the document does not encourage its use due to its sheer size and the amount of repetitions in the text. We conducted an intensive review to find all double information in the document, which we provide for your courtesy as an appendix to this document.					own decisions on authorisation: authorisation elsewhere cannot be assumed to be acceptable and cannot be a substitute for the sovereign state's processes.
ENISS	A1	General Comment	The current state of the document does not encourage its use due to its sheer size and the amount of repetitions in the text. We conducted an intensive review to find all double information in the document as well as to other IAEA documents (e.g. GSR Part 7 or SSR 2/1). We also offer our support in a further review (e.g. in a dialog with the technical officer) – please contact ENISS via the know channels, if this is offer is appealing. One issue for the repetitions may also be the structure of the document: • In chapter 3 exists one chapter about "regulations and guide", which does not include all guidelines for topics to be included in the regulations. As example the chapter on "Notification and Authorization" contains a lot of guidelines for regulations – this could be combined. • Furthermore it is questioned, why there is a subchapter on "*Review and assessment of documents produced by the*			Original para 3.89 moved to R&G, see para 3.16. The others remain where they were.		Accepted the comment in principle and combined several paras to reduce repetition.

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			authorized party in the authorization process" in the "notification and Authorisation" chapter is needed, when there is a special chapter called "review and assessment of facilities and activities". This could be combined to avoid repetition.					
FINLAND	1	Main	The whole document should be in line with new GSR Part 2 (DS456).	DS456 has been enhanced after the DS472 was submitted to member states comments. The results from NUSSC 40 meeting in December 2015 (submitting also comments from WASSC and RASSC) should be considered.		DS473 will be reviewed when DS456 is published.		Waiting for DS456 to be published.
FINLAND	2	General	The terminology in the whole document should be checked.	For consistency Especially the terminology in chapter 5 Management System is not in line with DS456 as an example use of leadership differs.		DS473 will be reviewed when DS456 is published.		Waiting for DS456 to be published. However, as DS473 does not have a "Chapter 5 on Management System", this comment appears to be on the content in DS472.
FINLAND	3	General	Consider cross checking terminology used in the document, e.g. for radiation	For consistency	Y			Adopted reference to "radiation risk" to be consistent with its

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			and radiological risk.					use in GSR Part 1 (Rev 1). Note, no ref to "radiological risk" in GSR Part 1 (Rev 1).
FINLAND	4	General	The name of the document Functions and Processes of the Regulatory Body for Safety	The addition 'for safety' should be removed to be consistent with GSR Part 1 which uses the term 'Regulatory Body ' .			Y	Reference to "Safety" was originally added by the Security Division to distinguish between safety and security documents.
FINLAND	5	General	In the whole document the roles of the government and regulatory body discussed. Justification is needed for the presenting governments activities.	Clarification		The following original paras were modified: 1.13, 3.78 (now 3.81) and 3.124.		Originally there were 39 references to "government" in DS473. All were reviewed with the objective of removing what was considered to be inappropriate references to "government."
FINLAND	6	General	Interface with DS472 need to be clarified	Clarification Much repetition regarding functions. See also comments to DS472.			Y	DS473 "Background" provides a cross ref to DS472 and

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								explains what DS472 will address.
FINLAND	7	General	Interface with DS460 need to be clarified	Much repetition regarding communication with interested parties.			Y	The current position regarding the relationship between DS473 and DS460 is: The minutes of CSS (34), held November 2013, specifically items 4.5 and 4.6, state that the Commission agreed that: "…for the time being, DS460 would be developed as a standalone Safety Guide, but the option would be maintained of integrating it later into DS472 and DS473." The secretariat is still awaiting a decision. Consequently, this position is reflected

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								in Footnote 8 of DS473.
FINLAND	8	General	General guidance on processes is missing and it is not included in DS472 either	For clarity there is need to include generic guidance how to develop processes. Also DS472 should be improved in this respect.			Y	This topic is already addressed in DS472. Note that DS473 and DS472 are complementary safety guides and should be read together.
FINLAND	9	General	It is not clear how functions and processes differ from each other	Clarification			Y	Functions are what you do and processes are how you do them.
FINLAND	10	From 11.- to xx	Some but not all detailed comments to DS473	This document provides an overall picture on regulatory body's functions. However, specific guidance is needed how to develop processes within RB's Management System.			Y	DS472 covers the development of the regulatory body's management system.
ISRAEL	1	General Comment	**The position of the Regulatory Body versus the**			Appropriate references to		In addition, emergency

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			<u>Government</u> In some parts of the Guide, in the context of responsibilities of different organs, the "Government" and the "Regulatory Body" are related by the term "AND" (mutual responsibility?), in some other sections the term "OR" is used (so: who is the prime responsible body?). As another example: Paragraph 3.323 is quoting various requirements calling: "Within these requirements, the Government is required to clearly specify and assign the roles and responsibilities in emergency preparedness and response, including those of the regulatory body" and then, in the next paragraph (3.324), GSR Part 7 is quoted: "The regulatory body shall require that arrangements for preparedness and response for	Clarity		government and regulatory body were addressed in resolving Finland #5, see above.		preparedness covers both on-site and off-site activities and it is the responsibility of government to organise and assign responsibilities. However, on-site, the regulatory body must ensure that provisions are made for dealing with on-site emergencies.

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			a nuclear or radiological emergency be in place for the on-site area for any regulated facility or activity that could necessitate emergency response actions." Such demand is not any more based on the roles of the Government, as mentioned in the previous paragraph and the Regulatory Body is presented as responsible for the existence of arrangements for preparedness and response, almost irrespective of the Government position. It is proposed to clearly define the responsibilities of all involved parties in order to avoid misunderstandings and also to keep the hierarchical structure of Government versus Regulatory Body.					
ISRAEL	2	General Comment	**<u>The title of the Guide</u>** Although the title of the Guide is still "Functions and	Clarity			Y	The title was discussed and approved by the Safety and Security

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			Processes of the Regulatory Body for Safety", while on the DPP473 Ver7 the proposed title is: " Regulatory Body Functions and Processes", it is proposed to reflect in the title of this key-document the **responsibilities** of the Regulatory Body and then the activities which are considered as supporting the fulfillment of such activities. Par. 3.223 in the Guide does list the responsibilities of the Regulatory Body. On the other hand the Guide includes definitions on the responsibilities of "others" (The Government, the Authorized Party). The text of Paragraph 1.5 which also focuses on the "technical aspects of the regulatory body's functions" may create the feeling that responsibilities are not the core issue.					Committees and Comission at the DPP stage.

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			It is proposed to consider the terminology used in GSR Part 1: "**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**" as a more suitable title of this Guide.					
ISRAEL	3	General Comment	**The relative location of the "Regulations and Guides" on the list of the Main Regulatory Functions and Processes (Section 3 of the Guide).** When starting with the description of activities around the "development" of Regulations and Guides as part of the Main Regulatory Functions and Processes one can get the "feeling" that such activities are simply on the "top-of-the-list" of the major Functions and Processes. The focus on regulations and	Repetitions and clarity		The following paras were modified: 3.19 (now 3.23), 3.35 (now 3.38), and 3.36(b), 3.43 and 3.185, deleted.		The order of the regulatory functions presented in the safety guide does not imply anything about importance, but was decided to make the document more readable. A review of the repetition of the use of "internal guidance" in the paragraphs mentioned was conducted.

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			guides before focusing on activities like review and assessment and regulatory inspections are detailed - could be reconsidered. Whether the location of the Regulation and Guides at the front of this Guide is the correct approach or not, it seems that the text contains many repetitions of similar or even identical "requests'" distributed over its 352 paragraphs, in section 3. Just to demonstrate this repetition one can look at the issue of "internal guidance": The "internal guidance" is mentioned about 7 times (see 3.6, 3.19, 3.35, 3.36(b), 3.43, 3.185, 3.314) in the text, in some cases using the same language but seemingly not necessarily providing real guiding. It is suggested to examine the					Note, para 3.185 is deleted due to ENISS #44.

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			text and to consider avoiding repetitive paragraphs.					
ISRAEL	4	General Comment	**The extent of Linkage between the guides and procedures and the decisions of the Regulatory Body** In various parts of the text there are different statements expressing the expectations from the guides and procedures that should be developed by the Regulatory Body. Par. 3.37 seems to be unique in respect to such demands, saying that "Where there are no such requirements, regulations, guides or industrial standards in force, the regulatory body should consider developing them." Nevertheless, the text contains additional sentences which we propose to examine thoroughly: decisions of the Regulatory Body are expected	Clarity			Y	GSR Part 1, R32, clearly requires the regulatory body to specify its requirements (in regulations and guides) upon which its judgements, decisions and actions are to be based.

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			to be taken as <u>supported</u> (justified) by such guides and regulations. See, for example, Par. 3.284 or Par. 3.313, where the reports of the Regulatory Body "should be reviewed and approved according to established internal procedures" or the decisions (like significant enforcement actions) "should be approved by the regulatory body through its established procedures". Such "conditioning" may create significant problems: 1. The existence of detailed regulations and guides, as developed by the Regulatory Body should be still taken as an "ideal situation" and therefore the actual lack of such regulations may create a "logic catch" and challenging the "legality" of Regulatory Body decisions which can't be based on such regulations.					

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			2. There might be a potential "climate" encouraging "formalism" or "bureaucracy" in which the freedom of the Regulatory Body is reduced and on the other hand an unjustified "protective means", are given to the authorized party. It is suggested to consider amending the text with a statement which gives full power to the decisions of the Regulatory Body also where there is no direct link to internal or external regulations and guides, if so stated by the Regulatory Body.					
ISRAEL	5	General Comment	**<u>Notification format</u>** The Authorization is defined as a written permission, issued by the Regulatory Body (see 3.102). At the same time, conditions that should apply in case of	Clarity		Para 3.83 (now 3.86). modified as shown: "The objective of notification is to provide initial information to		Accept the comment in principle, but not recommend a regulatory response on receipt of every notification. The para, as modified, now recommends

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			notification are detailed as well (See 3.73, 3.74) and it is clearly indicated that the applicant making notification, should submit a (notification) document to the Regulatory Body. The description of the expected "reaction" of the Regulatory Body in such case is quite clear, however it will be probably useful to clarify whether a "written permission" approving the "notification" should be issued by the Regulatory Body. It is proposed to include a clear request for a written permission that should be issued, in case that the notification is accepted by the Regulatory Body.			the regulatory body that a person or organization is intending to operate a facility or conduct an activity. The regulatory body should utilize the information received in the notification process to update the register of sources, facilities and activities and to decide on the level of regulatory control to be applied. The notification should be reviewed and		that the regulatory body review the notification and, if necessary, inform the person or organization of any further regulatory interactions.

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						the regulatory body, if necessary, should inform the person or organization what further regulatory interactions will be required."		
ISRAEL	6	General Comment	**Changes (mainly to the design) of the facility or activity which was granted with an authorization or which was accepted by the Regulatory Body through Notification** We suggest to analyze the consistency of statements relevant to such situations: Par. 3.91:"…Modifications that are categorized as significant to safety should be submitted to the Regulatory Body for review and approval or agreement."	Consistency		The following paras were modified: 3.112 (now 3.113), 3.131 and 3.146 (now 3.143) Para 3.147 deleted. Para 3.91 deleted and combined with 3.131.		The paras listed in the comment were reviewed with the objective of reducing the repetition of references to modification control.

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			Par. 3.131:"….Where these affect safety they must be subjected to proper consideration by the Authorized Party and may require approval by the Regulatory Body." Par. 3.112:" ….notifying the Regulatory Body of any modification to safety related aspects." Par. 3.146:" The regulatory Body should require notification by the authorized party of any significant changes to safety of the facility or activity and apply, where necessary, for an amendment to, or a renewal of, the authorization." And in the same paragraph: "Any modification to safety of a facility or an activity should be subject to an assessment by					

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			the authorized party, with account taken of the possible magnitude and nature of the associated risk." For consistency purposes, it is proposed to use simple and conservative approach: Any proposed or planned modification to safety related aspect should be submitted by the Authorized Party to the Regulatory Body, except specific modifications that the Authorized Part could justify and prove as totally insignificant to safety by exercising comprehensive analysis and supported by clear evidences, and it is the responsibility of the Regulatory Body to review any such modification and consider whether modifications to the existing Authorization or Notification are needed.					
ISRAEL	7	General	**The use of the term**			The following		Originally, 61

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		Comment	**"Notification"** The "Notification" is a specific mechanism in the regulation process (See Par. 3.73, 3.94). It seems the same term (notification) is used through the text where it is not anymore related to this specific mechanism (See for example 3.146 - just mentioned in the previous comment, and 3.298, 3.305, and 3.330). We propose to edit the text in order to use the term "notification" only in context of the regulation mechanism.	Clarity		paras were modified: 3.94 (now 3.95), 3.101 (now 3.102), 3.298 (now 3.286), sub-title above 3.303 (now 3.291) and A.4.38.		instances of the use of "notification". All uses were checked for correct use.
ISRAEL	8	General Comment	**Appendix 3** Appendix 3 is supposed to provide a listing "of the topics that should be considered in the review and assessment process throughout the lifetime of a facility", see Par. 3.163. Regarding the aspects of	Clarity		Following a review the following paras in Appendix 3 were modified: A3.5 and A3.11.		Appendix 3 was reviewed to ensure appropriate coverage from expectations in main text.

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			"Verification of the Safety Analysis" Par. 3.197 is saying: "further details of topics for these aspects are set out in the Appendix 3". The following representative and partial list of "Safety Terms", contains such terms that are mentioned in the text (in the section "Review and Assessment Process, Par. 3.162-3.184) but it seems that they are not mentioned or included in Appendix 3: "Safety goals" "Safety objectives" "Safety requirements" "Safety standards" "Safety assessment" "Safety documentation" It is suggested to review and improve the Appendix 3 and ensure that this appendix is really fulfilling the goals that the text is specifying for this Appendix.					

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ISRAEL	9	General comment	**The responsibilities of the Regulatory Body as related to "off-site" in the context of Emergency Preparedness and Response.** The responsibilities of the Government in the area of emergency preparedness and response are well referenced in Par. 3.323 and the rationale is that the Government is required to clearly specify and assign the roles and responsibilities, including those of the regulatory body. Almost regardless the of roles and responsibilities as (and if) specified by Government, the text seems to repeat (see Par 3.324) the demand that "The regulatory body shall require that arrangements for	Clarity of responsibi-lities			Y	The difficulty of defining the regulatory body role off-site is that it varies so greatly between Member States. Please note that paras 3.323 (now 3.310) and 3.324 (now 3.311) are only quoting the requirements from GSR Part 7. Para 3.340 (now 3.327) is elaborating on the regulatory body requirement to interface with all other organizations involved in exercising EPR, as required in GSR Part, R25.

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			preparedness and response for a nuclear or radiological emergency be in place for the on-site area for any regulated facility or activity that could necessitate emergency response actions." Of course, this demand is a very "natural and logical", as far as the on-site regulatory body responsibilities are considered. The regulatory body is the "main and leading actor". When the responsibilities of the regulatory body are mentioned in the text for off-site, in context of emergency preparedness and response and also other situations – the definitions seem to be not as clear and defined, and they are					

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			also expanding the scope of such responsibilities beyond the requirements of the corresponding GSR's. Par. 3.340 includes expectation that the regulatory body will assess the interface between the authorized party, off-site response organization and itself in case of national exercises. Par. 3.333 is expressing similar expectations: the regulatory body "should assess the adequacy of coordination and integration of the on-site emergency arrangements with those off-site. "It is suggested to seek a clear definition of the responsibilities of the regulatory body in the area of off-site emergency preparedness and response (see					

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			also Par. 3.348), and "leaving" the Government with the responsibility to specify and assign responsibilities – in general – and regarding the assessment of the quality of the interface between all involved parties – in particular.					
JAPAN	6	Paras.3.50, 3.60(g), 3.105, 3.110, 3.122, 3.151(c), 3.165, 3.278, 3.289, 3.309, 3.348, A4.6	Delete descriptions regarding the member states practices, e.g. "In some States, for example, detailed guidance would be preferred to prescriptive regulations." in the para 3.50.	The member states practices are NOT universally recognized practices therefore it should be deleted.		Reference to "In some States" reviewed and the following paras modified: 3.309 (now 3.297) and 3.348 (now 3.335).		The text is not saying, or implying, that these are the practices that should be used, merely reflecting the differences in different member states.
UK	9. EDF	General	N/A – Comment concerns an inconsistency between the IAEA document Specific Safety Requirements (SSR-2/1) and DS473 (and new GSR	SSR-2/1 paras 2.11, 4.3, 5.27 and 5.31 all state that: "plant event sequences that could result in high radiation doses or radioactive releases must be			Y	The design provisions of NPP are already covered with reference to SSR-2/1, see DS473

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			Part 7)	practically eliminated and plant event sequences with a significant frequency of occurrence must have no or only minor potential radiological consequences". "Practically eliminated" is defined as: "The possibility of certain conditions occurring is considered to have been practically eliminated if it is physically impossible for the conditions to occur or if the conditions can be considered with a high level of confidence to be extremely unlikely to arise." This important requirement should be reflected in DS473 (and also in the new GSR Part 7). Clearly, if the goal of practically eliminating severe radiation doses can be met by a design, this should be taken into account by those applying				Ref [31].

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				a "graded approach" to safety (including emergency preparedness).				
IAEA CC Secretary	1	General comment	Chance all reference to "Main regulatory functions" etc., back to "Core regulatory functions."	To maintain consistency with DS472.				

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1. INTRODUCTION - BACKGROUND (1.1-1.7)								
GERMANY	1	1.3	Please specify which parts of GS-G-1.5 and SSG-12 is superseded by this Safety Guide.			Accepted, note para 1.3 does comment on which part of WG-G-1.5 is superseded		The text follows the DPP. Essentially most of the documents referred to are either directly carried over or paraphrased to make them more general, i.e. relate to facilities and activities.
GERMANY	2	1.7	"The information in these Safety Guides is intended to be mainly used by Regulatory Bodies but can be also useful for governments who are developing a regulatory framework for radiation and nuclear safety. It will also assist authorized parties and others dealing with ~~radioactive materials~~ radiation sources in understanding regulatory procedures, processes and expectations."				Y	"materials" include "sources" and is a wider term. See IAEA Safety Glossary.

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1. INTRODUCTION - BACKGROUND (1.1-1.7)								
JAPAN	1	Footnote2 (p.5) References	[2] Facilities and activities, …radiation from naturally occurring or artificial sources.[X] [X] INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA Safety Glossary: Terminology Used in Nuclear Safety and Radiation Protection, 2007 Edition, IAEA, Vienna (2007).	IAEA Safety Glossary should be added as a reference just like the other IAEA Safety Standards.	Y			

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1. INTRODUCTION - OBJECTIVE (1.8-1.10)								
ISRAEL	10	1.8	"1.8….– ~~development~~ provision of regulations and guides;…" Propose to use the term "provision" instead of "development" through all text of the Guide, like in paragraphs 1.9, 3.11, 3.14, 3.49, 3.54, 3.60, 3.64 **Regulations and guides might be provided by various alternative processes and not necessarily by "Development" activity**	See text in **bold**		Accepted but suggest "development and/or provision"		Both provision and development may be required in different situations.
ISRAEL	11	1.8	The "communication and consultation with interested parties" is not covered by this guide and probably is supposed to be covered by DS460. It is proposed to consider integrating relevant parts of content of DS460 into this guide as well.	With the goal to provide one comprehensive guide		To be advised by the Safety Committees		See Finland #7
ISRAEL	12	1.10	It seems that the text overlaps	Preventing repetition			Y	There is no overlap

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1. INTRODUCTION - OBJECTIVE (1.8-1.10)								
			partially Par. 1.6. It is proposed to combine both paragraphs into one.					as such and 1.10 serves to expand on 1.6
USA	1	p. 7 1.11	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 **review , or pre-licensing reviews**, through to the release from regulatory control by means of processes	Clarity, to emphasize the regulatory function of design review, rather than (commercial) design of facilities.		Accepted in principle, but it is suggested that a separate sentence is used to cover pre-licensing. "Whilst the SG is based on the regulation of licensed activities, many of the functions and process also apply during any pre-licensing phases".		The reason is that some of the functions do not apply to pre-licensing situations.

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1. INTRODUCTION - SCOPE (1.11-1.12)								
ISRAEL	13	1.11	"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 processes."~~	Not limiting the scope of the statement			Y	First use of lifecycle in the document. Also see resolution of USA #1 above.

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1. INTRODUCTION - TERMINOLOGY (1.13)								
ISRAEL	14	1.13	We suggest not to present the "license" in this paragraph as synonym to "authorization": "authorization" in the text is in the form of "License" or "Registration".	Preventing misunderstanding			Y	The context is clear
ISRAEL	15	1.13	"Lifecycle" is used to cover the stages of site evaluation, design, design changes, revamps, technology changes, construction, installation, commissioning, operation, decommissioning and removal from regulatory control…."	More comprehensive			Y	The term "lifecycle" is defined in DS473. The additional terms suggested are just aspects of the design approval process.
USA	2	p. 7 / 1.13 and p. 120	At the end of Para 1.13 add IAEA Glossary as a reference.	Completeness to address terminology in a consistent fashion.	Y			
GERMANY	3	1.13	Last sentence: " "Lifecycle" is used to cover the stages of site evaluation, design, construction, installation, commissioning, operation, decommissioning (or closure) and removal from	For radioactive waste disposal facilities, the term 'closure' instead of 'decommissioning' is used.	Y			

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1. INTRODUCTION - TERMINOLOGY (1.13)								
			regulatory control, though it is noted that whilst these stages apply for all facilities, they may not do so for all activities."					
UK	2. EA	1.13	It should be made explicit that safety includes environmental protection/safety in addition to RP and nuclear safety. This would be in line with para 1.1 which states that risks to the environment are within scope.				Y	The objective of the Safety Guide is clearly stated, which is to provide guidance and recommendations on the regulatory body's main functions and, as noted in the comment, covers the safety of facilities and activities that give rise to radiation risks for people and the environment. Consequently, there is no need to repeat this scope. Note that environmental

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1. INTRODUCTION - TERMINOLOGY (1.13)								
								protection is covered within many of the Sections covering the regulatory functions, e.g. in para 3.16(h) on assessment of EIA, in para 3.30 for regulations and guides to specify requirements for environmental protection, and in paras 3.88 & 3.97 on the need for a demonstration and subsequent assessment that facilities and activities do not pose an unacceptable risk to the environment etc.
JAPAN	2	1.13	Add the following text to the end of this paragraph. Terms in this publication are to be understood as defined and	Amendment to make the description consistent with other Safety Standards. This description is a common		Reference to IAEA Safety Glossary added to end of par		

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1. INTRODUCTION - TERMINOLOGY (1.13)								
			explained in the IAEA Safety Glossary (Ref. [X]), unless otherwise stated.	statement in IAEA Safety Standards. (Also see comment No.1.)		1.13.		

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1. INTRODUCTION - STRUCTURE (1.14)								

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2. GRADED APPROACH (2.1-2.7)								
USA	3	p. 9 Section 2	The graded approach should refer early in this section to safety limits, exemption and clearance, as well as the optimization process, considering three exposure situations (planned, existing, and emergency) in order to evaluate actions based on risk significance for these exposure situations. In addition, socio-economic factors and stakeholders' inputs must be considered when using the graded approach concept. In other words, without having safety/risk limits to compare the graded approach with, and without using the concept of optimization for safety, considering multiple socio-economic factors, the implementation of the graded	We recommend addressing risk/safety limits early in order to compare options during the graded approach process.			Y	This is expanding the use of and definition of the graded approach. It has never been an approach that can be put on a numerical basis as seems to be suggested in the comment. Also it is not clear how socio-economic aspects would be used, but are already part of ALARA. Risk/safety limits are difficult to define in an international context, approach, but these are not the only factors

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2. GRADED APPROACH (2.1-2.7)								
			approach concept would be ambiguous, and decisions for actions could be controversial and confusing.					that need to be considered. It has to be accepted that applying the graded approach requires judgement so the decision may be not exact.
GERMANY	4	2.1	1st sentence: "Principle 5 of the Fundamental Safety Principles [1], states that: "The resources devoted to safety by the [licensee] authorized party, and the scope and stringency of regulations and their application, have to be commensurate with the magnitude of the ~~possible~~ radiation risks[3] and their amenability to control." To apply …"	Wrong citation of Para. 3.24 SF-1.		Citation corrected to GSR Part 4.		
ISRAEL	16	2.1	It is suggested to have footnote 3 referring to the specific Par. 4.19 of [9] instead of providing an independent and different			See resolution of Germany #4, which now includes a		

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2. GRADED APPROACH (2.1-2.7)								
			definition.			reference to Requirement 1 of GSR Part 4.		
JAPAN	3	2.1/1	Principle 5 (paragraph 3.24) of the Fundamental Safety Principles [1], states that:…	Clarification.		See resolution of Germany #4 and Israel #16 above.		
UK	4. EDF	2.3	N/A – Comment questions whether statement on GSR Part 7 is consistent with (a) the remainder of DS473 Section 2 and (b) with the IAEA Safety Fundamentals (SF-1). I appreciate that GSR Part 7 is due to be published imminetly but DS473 may provide an opportunity to correct these important inconsistencies.	Section 2 of DS473 explains that a "Graded Approach" means an approach that reflects "radiation risks". IE it is an approach that is commensurate with both the likelihood and the consequences of events. Yet the last part of para 2.3 referring to GSR Part 7 does not refer to radiation risk but instead requires a hazard assessment. "Hazard Assessment" does not normally include the likelihood of the hazard occurring. GSR Part 7 therefore seems to be inconsistent with this		Added reference to likelihood and possible consequences (i.e. risk) by quoting Principle 9 in SF-1.Also removed explicit reference to "hazard assessment," but retained the general cross reference to GSR Part 7.		

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2. GRADED APPROACH (2.1-2.7)								
				Section of DS473. In addition IAEA's SF-1 Principle 9 states that emergency preparedness should reflect "The likelihood and the possible consequences of a nuclear or radiation emergency"; and refers to "reasonably foreseeable" incidents in its goals. So, it would appear that this statement on GSR Part 7 is also not consistent with SF-1.				
GERMANY	5	2.5	The main factor that should be taken into consideration in the application of a graded approach is that the application of the regulatory functions has to be consistent with the magnitude of the ~~possible~~ <u>immanent</u> radiation risks arising from the facility or activity.	It is important, that the immanent radiological risk of a facility or activity should be taken into account for grading. This should not include the risk reduction e.g. due to safety features. The graded approach will adjust the stringency of requirements for such features.			Y	This is a direct quote from GSR Part 4 see above. The "magnitude of the possible radiation risk" covers the point in the comment.
GERMANY	6	2.6	Other relevant factors, such as the maturity or complexity of the facility or activity ~~and the~~	Grading relies on the risk of the facility or activity. Knowledge and expertise is			Y	In determining how often inspection is

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2. GRADED APPROACH (2.1-2.7)								
			~~knowledge and expertise of the authorized party,~~ should also be taken into account in a graded approach to regulatory activities.	not considered as appropriate factors for grading.				required, for example, these factors are important.
ISRAEL	17	2.6	"2.6… Complexity relates to the extent and difficulty of the effort required to construct and operate a facility or to implement an activity, the number of related processes for which control is necessary, the extent to which radioactive material has to be handled, the longevity of the radioactive material, and the reliability and ~~complexity~~ complication of systems and components…"	'complexity' as a term is used in the second part of the sentence to explain (the term 'complexity'			Y	The text is a direct quote from par 3.4 of GSR Part 4.
USA	4	p. 10 2.6	There is a lot of good information in this section, but the last sentence places too much emphasis on decommissioning (a relatively low risk activity compared to operating reactors). Consider separating this section into more than one section and/or				Y	The document is not just about NPP. In some situations clean-up and decommissioning may be more risky than operation

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2. GRADED APPROACH (2.1-2.7)								
			placing the decommissioning comment in a footnote as an example of an activity that would warrant additional focus.					

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.1)								
GERMANY	7	3.1	Finally, Communication and Consultation with interested parties is important throughout ~~all~~ the ~~whole~~ lifetime of the facility or activity to inform and obtain the views of the public.	Lifetime already defines all the phases of the plants "life", seems sufficient enough. See also definition in 1.13.	Y			
USA	5	p. 12 General	Consider adding that the Regulatory Body should designate ownership/responsibility of a regulatory process for final decisions in the course of resolution of an identified concern/issue at a facility, an application by a facility, or other unusual condition at a facility involving the regulatory body (e.g., licensing, inspection, etc.). This should also apply to technical areas covered during the review of a facility application or change to authorization.	To ensure thorough, efficient, and repeatable review results by the Regulatory Body.			Y	This topic is already addressed in DS472 in Chapter 5, Section "Responsibilities and Resources for the IMS". Reference to process owners is specifically addressed in paras 5.13-5.15 Note that DS473 and DS472 are complementary safety guides and should be read together.
USA	6	p. 12	While the difference between	Guides provide assistance on			Y	The text in this para

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.1)								
		3.1	Regulations and Guides is defined more clearly later in the chapter, these initial sections are contradictory and confusing because they refer to "Regulations and Guides" as providing safety *requirements*.	appropriate ways to conduct activities but do not have the force of law. This distinction is important, especially in clear and consistent regulation. These terms are used interchangeably in later sections as well. It is recommended that these terms not be used interchangeably and/or that the word *requirement* be used very specifically when referring to regulations and laws.				also includes reference to requirements, procedures and processes.

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
GERMANY	8	3.4	The provision of regulations and guides should be a means for the regulatory body to ensure that regulatory control is stable, unambiguous and consistent, to emphasize the continuous enhancement of safety as its general objective and to build confidence among interested parties [2].	It is important that regulations are unambiguous; consistent does not necessarily include that.	Y			
USA	7	p. 12 3.5	"When regulations are not issued by the regulatory body…"	Regulations should be so issued, not by government. The regulatory body could be the Government, but not necessarily.	Y			
ISRAEL	18	3.6	"3.6…authorized parties or by the regulatory body (internal guidance) and other ~~advisory~~ supporting documents…"	Clarity		3.6…authorized parties or by the regulatory body (internal guidance) and other relevant documents…		
SPAIN	1	3.6	The regulatory body should specify the purposes of the various regulatory documents necessary to perform its	Laws are not "regulatory documents".		The regulatory body should specify the purposes of the		Legislation provides the necessary powers for the regulatory body to fulfil its

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
			functions. 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.			various documents necessary to perform its functions. The documents may be categorized as comprising legislation and regulations (mandatory by law), supporting guides (not mandatory by law) to be used either……		responsibilities.
RUSSIA	2	3.8	Other technical and international standards can be applied by the authorized parties to the extent e not contradicting mandatory requirements of regulatory body.	To add this item with the sentence as proposed.			Y	This document concerns the functions of the regulatory body and as such the existing wording is adequate.
ISRAEL	19	3.9	"3.9. The regulatory body should establish a system to ensure the implementation of regulations and guides based	Accurate reflection of [2], Par. 4.62.	Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
			on a graded approach, such that the application of regulatory requirements is commensurate with the radiation risks associated with the types of facilities and activities ~~and the exposure situations.~~ in accordance with a graded approach…"					
ISRAEL	20	3.11	"3.11. As part of its integrated management system, the regulatory body should establish a process for the ~~development~~ provision of regulations and guides. This process should ensure that regulations and guides are available to the interested parties and: • provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization; • establish principles,	More general meaning.		3.11. As part of its integrated management system, the regulatory body should establish a process for the development of regulations and guides. This process should ensure that regulations and guides are made available to the interested parties and:		Within DS473, the regulatory body should develop regulations and not provide for their development.

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
			requirements and the criteria be used for assessing compliance; •reviewed and revised and ensure that they are kept up-to-date; • are consistent and comprehensive; • provide adequate coverage commensurate with the radiation risks associated with the facilities and activities; • involve consultations with interested parties. • consider internationally agreed standards and the feedback from related experience gained…."			• provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization; • establish principles, requirements and the criteria be used for assessing compliance; •reviewed and revised and ensure that these are kept up-to-date; • are consistent and comprehensive;		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
						• provide adequate coverage commensurate with the radiation risks associated with the facilities and activities; • involve consultations with interested parties. • consider internationally agreed standards and the feedback from related experience gained….		
ISRAEL	21	3.14	"3.14… the regulatory body should give consideration to supplementing its regulations~~,~~ with supporting guides of …."	Typo?	Y			
USA	8	p. 14 3.18	Consider adding that these professional bodies should be	There could be a conflict of interest (e.g., is the facility		3.18 (now 3.22) …..regarding		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
			independent from the facility, or the Regulatory body should give due consideration to the purpose of those bodies.	paying for all or part of the professional body's existence? Is it a professional industry-supported organization?).		safety, free from any undue influence that may compromise regulatory independence.		
GERMANY	9	3.19	1st sentence: "The regulatory body should provide internal guidance, to be used by its own staff, on the procedures to be followed for the completion of its tasks (e.g. notification, authorization, review and assessment, inspection, enforcement) as well as on the safety objectives to be met <u>inter alia in order to ensure uniform processing of the task irrespectively of the processor</u>. Detailed guidance …"	Motivation of the statement.			Y	The paragraph is considered as sufficiently explanatory as it stands. See also paras 3.7 and 3.10.
ISRAEL	22	3.19	"3.19. The regulatory body should ~~provide~~ consider provision of internal guidance, to be used by its own staff…"	We suggest to leave this to decision of the Regulatory Body			Y	According to the GSR 3, the regulatory body should provide for ….

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
RUSSIA	3	3.21	Existence or absence of alternative decisions has to be the main criterion of rating: of this or that topic as mandatory requirements or as recommendations. If those are not present, it has to be attributed as requirements. And if it is that as recommendations. In this case the concerned problem has to be reflected in regulation in a generalized form. Other requirements, such as those applicable for only a short duration or relating to individual characteristics, of facilities or activities, should be specified in any conditions attached to the authorization (authorization conditions, see para 3.110) and thus become mandatory.	In this item the criterion of attributing one or another topic to requirements or to recommendation is given. This criterion suggests to accept commonality of the topic for particular type of facility and activity. At the same time it is proposed to reflect more specific topics in authorization conditions that also makes them mandatory to execution. Such approach seems to be unsatisfactory. Existence or absence of alternative decisions has to be the main criterion of rating of this or that topic as mandatory requirements or as recommendations. If those are not present, it has to be attributed to requirement. And if it is to recommendations. Herewith, in requirements this problem has to be reflected in a generalized form. The first sentence of the considered			Y	The paragraph is considered as sufficiently explanatory as it stands. "Particular" is considered more appropriate for the specific sentence.

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
				item is to be replaced as it is proposed, and in the second sentence to replace the word "particular" with the word "individual" which is more correct.				
ISRAEL	23	3.22	Suggested to rearrange the text in form of listed sub-paragraphs for requirement, like: (a) technical limits and conditions; (b) a system for reporting events, modifications and incidents to the regulatory body; etc.	Clarity			Y	See next comment. The paragraph is deleted.
ENISS	A2	3.22	~~The authorization conditions should, where appropriate, include or refer to: technical limits and conditions; a system for reporting events, modifications and incidents to the regulatory body; and other requirements, depending on the magnitude of the radiation risk, the nature of the facility~~	Delete this para as relevant content for "Relationships between regulations, guides and authorization conditions" (chapter heading) is described in 3.21 and details for conditions are described in 3.110ff	Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
			~~or activity, and the stage in the lifecycle of the facility or activity. More information regarding authorization conditions are given in the sub-section dealing with authorization (see para 3.69).~~					
JAPAN	4	3.23/1,2	According to GSR Part 3, para 2.30 [3], the government and regulatory body are required to establish a regulatory system for safety that includes ~~(GSR Part 3, para 2.30 [3])~~:	To make the citation of GSR part 3 and its additional guidance clear (i.e. "should" statement). (Section 3 of SSG-23 would be a good example to cite Safety Requirements.)			Y	Based on the common practise followed by IAEA standards.
GERMANY	10	3.24 (f)	"Requirements for occupational radiation exposure, public radiation exposure, dose limits, medical exposure, safe construction, commissioning, operation and decommissioning (or closure) of facilities, management of radioactive waste, transport of radioactive material and emergency exposure situations;"	Clarification. Please add the further stages of the facility. For radioactive waste disposal facilities, the term 'closure' instead of 'decommissioning' is used.	Y			
JAPAN	5	3.24(j)/1	Safety criteria and planning for	This sentence should be	Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
			~~predisposal~~ radioactive waste management and discharge monitoring,…	intended to describe about not only predisposal but also disposal.				
ENISS	2	3.29.	The main content of an authorization, as well as the objectives of possible authorization conditions, should be specified within regulations and guides. Details regarding the content of authorization are given in the sub-section dealing with Notification and Authorization.	For clarification, as the conditions in person are not described in regulations, only objectives and way of issuing them.	Y			
ENISS	A3	3.30, 3.31	3.30. Regulations and guides covering the authorization process should identify the essential documents to be prepared and submitted by the authorized party in the authorization process. Additional documents may be requested as needed depending on the type of the facility or the activity in accordance with a graded approach and on the specific stage of the	Move last sentence of 3.31 to 3.30, as 3.30 deals with the authorization process. The other documents mentioned in para 3.31 are covered by 3.34 from our point of view – otherwise it needs to be specified, what is meant by 3.31 and not covered by the above mentioned paras.		3.30 (now 3.33). Regulations and guides covering the authorization process should identify the essential documents to be prepared and submitted by the authorized party in the authorization		Para 3.34 (now 3.37) deals with the records that should be kept, whereas para 3.31 (now 3.34) deals with the documents that should be submitted.

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
			authorization process. Details regarding the documentation to be submitted by the authorized party are given in the sub-section dealing with Notification and Authorization. ~~3.31. Regulations and guides should indicate other documents that should be submitted to the regulatory body to confirm that the requirements established in the regulations and authorization conditions have been satisfied. Details regarding the documentation to be submitted by the authorized party are given in the sub-section dealing with Notification and Authorization.~~			process. Additional documents may be requested as needed depending on the type of the facility or the activity in accordance with a graded approach and on the specific stage of the authorization process. Details regarding the documentation to be submitted by the authorized party are given in the sub-section dealing with Notification and Authorization.		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
						3.31 (now 3.34). Regulations and guides should indicate other documents that should be submitted to the regulatory body to confirm that the requirements established in the regulations and authorization conditions have been satisfied.		
GERMANY	11	3.35	1st bullet: Registers of ~~sealed~~ radioactive sources and radiation generators;	There is no obvious reason that this should not also apply for unsealed sources as well. Especially unsealed sources have a high risk for contamination and incorporation of radionuclides.		3.38. ……Registers of sealed radiation sources and radiation generators as well as records of the unsealed sources.		
GERMANY	12	3.35	4th bullet:	The term ‘permanent			Y	The word

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
			"Records that might be necessary for the <u>permanent</u> shutdown and decommissioning (or closure) of facilities;"	shutdown', as used in the General Safety Requirements GSR Part 6 "Decommissioning of Facilities", means that the facility has ceased its operations and operation will not be recommenced (in contrast to a planned or unplanned shutdown).				"permanent" is not consistent with IAEA safety standard GSR Part 1.
GERMANY	13	3.35	5th bullet: "Records of events, including non-routine releases of radioactive material to the environment, damage<u>,</u> ~~or~~ loss <u>or finding</u> of a <u>radioactive</u> source or malfunction of a device;	Any findings of orphan sources should be recorded by the regulatory body as well. A review of National Reports for the 5th Review Meeting of the Joint Convention revealed that many States undertake search and recovery campaigns for undetected orphan sources within their territory.	Y			
GERMANY	14	3.35	<u>Add an additional bullet: Records of airborne and liquid releases during normal operation</u>	Usually, allowed releases are regulated e.g. by licence conditions. To verify that the facility is operated according to their licence, the releases have to be monitored by the licensee and reported to the regulator.	Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
IAEA CC-SAS	2	3.39 (V5), was 3.36 (V3)	….In order to fulfil these requirements, the regulatory body should issue regulations for safety assessments to be performed by the authorized party to the facility or activity, which should be <u>submitted and reviewed by the regulatory body</u> prior to the granting of the authorization……					
ENISS	3	3.37.	The regulatory body should determine which requirements, regulations, guides ~~and industrial standards~~ are applicable to each type of facility or activity, and should determine the requirements to be placed on the authorized party for each type of facility or activity. Where there are no such requirements, regulations, guides ~~or industrial standards~~ in force, the regulatory body should consider developing them. In carrying out its review and assessment, the regulatory body should use the	Industrial standards are not legally binding and need to be deleted here. Text is also not in line with GSR Part 1 as cited in para 3.36.		3.40. The regulatory body should determine which requirements, regulations, guides and industrial standards are applicable to each type of facility or activity, and should determine the requirements to be placed on the		The responsibility for determining the requirements, regulations, guides and industrial standards to be used lies within the regulatory body

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
			applicable requirements as a reference for deciding on the acceptability of an authorized party's submission. The regulatory body should issue guidance on reporting on its review and assessment activities and how it reaches its regulatory decisions. It is considered good practice that there view and assessment procedural and technical guidance documents should be made available to regulatory bodies worldwide.			authorized party for each type of facility or activity. Where there are no such requirements, regulations, guides in force, the regulatory body should consider……		
RUSSIA	4	3.37	The regulatory body should determine which requirements, regulations, guides and industrial standards were used by authorized party to each type of facility or activity and assess its applicability.	To replace the first two sentences of the item 3.37 as it is proposed because it is an obligation of the authorized party to determine what requirements, regulations, guides and industrial standards are applicable for its facility or activity and to prove it in the submitted information. The task of regulator is to check it and to confirm. When there are			Y	The responsibility for determining the requirements, regulations, guides and industrial standards to be used lies within the regulatory body.

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
				no necessary rules and regulations, achievements of science and technology, i.e. results of scientific researches, the approved engineering practice, etc. have to be used. The regulator can develop the new regulations only after accumulation of necessary experience.				
USA	9	p. 20 3.41	"Regulations and guides governing the use and implementation of enforcement actions should be issued by the Government and regulatory body…"	Such regulations should be issued by the regulatory body. The regulatory body could be the Government, but not necessarily.			Y	No modification was proposed
USA	10	p. 22, 3.47, line 2	Change "asses" to "assess"	editorial	Y			
UK	3. EA	3.47	should be "assess" not asses		Y			
USA	11	p. 23 3.57	3.57. The regulatory body may find it useful to set up advisory committees to advise on the need for regulations and on their technical content. <u>The advisory committee members should be independent from</u>	Ensure independence, openness and transparency	Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
			the regulatory body to ensure separate and unbiased safety reviews. A well founded committee can provide a valuable service to the regulatory body by helping to ensure that policies and regulations are clear, practicable and complete.					
ENISS	4	3.58.	The regulatory body should follow a general and consistent process for establishing, reviewing and revising regulations and guides. It should be well documented, comprehensive, covering all regulated activities and facilities, with clear allocation of responsibilities. When establishing new regulation as well revising existing ones, care should be taken to the cumulative effect of these changes on nuclear safety.	To take into account the fact, that changes in the regulatory requirements and guides may impact similar parts of the plant and induce special difficulties.		3.60. The regulatory body should follow a general and consistent process for establishing, reviewing and revising regulations and guides. It should be well documented, comprehensive, covering all regulated activities and facilities, with		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
						clear allocation of responsibilities. When establishing new regulation as well revising existing ones, care should be taken to the cumulative effect of these changes on safety.		
GERMANY	15	3.59	The process should be based on clear procedures and should be flexible enough to take account of changing technological, legal and practical.	There is something missing at the end of the sentence, it makes no sense in its current form.	Yes	The process should be based on clear procedures and should be flexible enough to permit revisions to be made to take account of changing technological, legal and		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
						practical conditions.		
GERMANY	16	3.60	(b) *Setting the priority for the development of regulations and guides*. The regulatory body should consider the advantages and disadvantages of the proposed regulations and guides, including such matters as: the risk associated with the facility or activity; the need ~~and associated costs~~ for improvements in safety; the number of authorized parties to be affected; the effects on the efficiency of the authorization process; and the feedback of information and experience from review and assessments, inspections, investigations and enforcement activities;	The need for improvements is seen as the important aspect and strengthens the idea of continuous improvement. If there are safety reasons for improvements, they shall be required in the regulations. The associated costs should not be part of this consideration. This is an economic reason and is usually taken into account in the decision making of the licensee.			Y	In accordance with ALARA principle.
GERMANY	17	3.60	(e) *Collection of information*. The information necessary to prepare the proposed regulations and guides should be collected. In particular the state of the art in science and	Regulations on nuclear safety shall take into account the latest insights from science and technology to ensure a high level of safety.	Y	3.63. e) *Collection of information*. The information necessary to prepare the		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
			technology should be determined;			proposed regulations and guides should be collected. In particular the state of the art in science and technology should be taken into account;		
SPAIN	2	3.60	It is suggested to include an additional step to the "Process for developing regulations and guides" Regulations and guides development and updating plan	Conclusions of steps a) to c) should be recorded and communicated to interested parties.			Y	Consultation with interested parties is included in step (g). DS472 also addresses this topic in Annex II "Process Descriptions", specifically under Process Step 6 of II-12 "Development of Regulations and Guides." Note that DS473 and DS472 are complementary

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
								safety guides and should be read together.
RUSSIA	5	3.60	(a) Determination of the need for the regulations and guides. GSR Part 1 Requirement 32 [3] 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 judgements, decisions and actions are based.	Before the first sentence of subsection (a) it is necessary to provide the Requirement 32 of IAEA standard GSR Part 1 as it defines need for development of rules, regulations and guides. These documents are developed to establish the principles, requirements and the related safety criteria on the basis of which the regulator will base its work.			Y	Req. 32 is covered at para 3.2
RUSSIA	6	3.60 subsectio n (f)	(f) Drafting of the regulations and guides. The staff of the regulatory body, technical support organization, consultants,	After the regulator's staff the first among possible developers of the draft of the regulation or guide should be specified the technical support organization (TSO).	Y			
USA	12	p. 25 3.61	"3.61. Consideration should be given to grouping the guides into several broad categories as follows, but not limited to:" Add under this Para the				Y	Para 3.61(e) (now 3.64(e)) clearly mentions the safety assessment plans.

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
			following categories of guides: • Standard Review Plan (SRP): regulators should develop standard review plan as guidance to licensees to show areas of review to grant a generic licenses for certain common activities. The SRP would provide consistency and clarity to grant an authorization or a license. • Technical Positions and Technical Support Documents: regulators should develop and provide technical positions and technical support documents on					This documents doesn't concern only NPPs.

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
			approaches to achieve safety requirements for complex or controversial matters to avoid litigations and reduce ambiguities in licensing activities.					
ENISS	5	3.63.	Experience in implementing the regulations should be examined and any problems or difficulties that may arise should be duly considered. The status of applicable requirements should also be examined in the light of new safety related developments. The possible effects of frequent changes in regulations and guides on the stability of the regulatory system should be taken into account. ~~However, events may occasionally occur that necessitate more frequent revisions.~~ The reasons for	Delete sentence, as the impression should be avoided, that for certain events changes are needed in regulations to prevent exactly these events. Regulations should be general in its context and the experience feedback from events is covered sufficiently by the next sentence ("…experience from events, incidents and accidents…"	Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
			revising regulations may include: changes in legislation; changes in the organization, responsibilities, policies or procedures of the regulatory body; experience gained by the regulatory body in the authorization process; feedback of information and experience from events, incidents and accidents, as well as from relevant national and international good practices; technological advances; and the need to improve or eliminate any impractical, misleading, unenforceable or otherwise inadequate regulations.					
USA	13	p. 26 3.65	3.65. Nothing (e.g., tThe process and procedures established for the revision of regulations and guides) should not diminish the authority of the regulatory body to take immediate action if required for reasons of safety.	Clarity		3.68. Nothing should diminish the authority of the regulatory body to take immediate action if required for		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REGULATIONS AND GUIDES (3.2-3.68)								
						reasons of safety (e.g. the process and procedures established for the revision of regulations and guides).		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
ENISS	A4	3.70.	~~The authorization process is the principal mechanism connecting the legal framework of the regulatory system (laws and regulations) with the responsibilities of the principal parties concerned with the regulatory system (the regulatory body, applicant and the authorized party).~~	Para is misleading, as the responsibilities of the parties are established in laws and regulation and not in authorizations. Context fully included in para 3.84.			Y	The authorization process does not introduce additional laws and regulations
FINLAND	11	3.71	Consider replacing "complexity" with "potential negative consequence on safety or security".	For clarity		Partially accepted. As a consequence the text in para. 3.71 (now 3.74) was modified		
ISRAEL	24	3.74	The statement "An application for authorization may also serve as notification." is not clear: does it means that the Regulatory Body, to whom an application for authorization was submitted by the Authorized Party is in position to consider this application as an application for notification?	Clarity and consistency			Y	It is believed that the text is clear.

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
GERMANY	18	3.78	"Authorizations … should cover all stages of the lifetime of a facility or activity, for example, for a nuclear facility, site evaluation, design, manufacturing, construction, installation, commissioning, operation, decommissioning (or closure) and subsequent release of the site from regulatory control."	For radioactive waste disposal facilities, the term 'closure' instead of 'decommissioning' is used.	Y			
ENISS	A5	3.80.	An applicant is a legal person or organization who applies to a regulatory body for authorization. It is required that the applicant should refrain from carrying out any actions covered by the applications requiring authorizations until the authorization has been granted (GSR Part 3, para 3.9 [3]). The holder of a current and valid authorization is termed an authorized party. ~~The authorized party is the legal person or organization having~~	Move last sentence forward for clarification and add "requiring authorization", because the national legislation of some member states may allow some non-safety-related actions (e.g. excavation) prior to granting of authorization. Second last sentence is fully included in para 3.81 and can be deleted here as well.		Accepted as reported in the text. The text in para. 3.81 (now 3.84) has been modified as in the text		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~overall responsibility for a facility or activity. It is required that the applicant should refrain from carrying out any actions covered by the applications until the authorization has been granted, (GSR Part 3, para 3.9 [3]).~~					
ENISS	6	3.84.	The objective of granting authorizations is for the regulatory body to establish effective regulatory control throughout the lifetime of a facility or activity in relation to safety. The authorization process should require assurance that the applicant can fulfill ~~it's the~~ applicable safety ~~obligations~~ requirements~~; demonstrate sufficient competence in its staff, where appropriate; and demonstrate adequate safety~~. ~~These aspects should be subject to suitable review and assessment by the regulatory body before the authorization~~	For clarification. It is required to fulfill the applicable requirements. Sufficient competent Staff is only one part and does not need to be separately stated here. Included also in para 3.85a. Review and assessment is stated in later chapters, as well as the conditions. For clarification and for not repeating topics we suggest deleting them here.		Accepted with minor modification as reported in the text in para.3.84 (now 3.87)		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~is issued. In the granting of an authorization for a facility or an activity, the regulatory body should consider whether to impose limits, conditions and controls on the authorized party's subsequent activities.~~					
USA	14	p. 28 Chapter: *General principles of an authoriza-tion*	Consider adding that other regulatory bodies may need to be consulted as part of the authorization process by both the regulatory body and/or the facility/applicant (e.g., environmental and emergency response organizations).	Completeness		Accepted as reported in the text with the modification of para. 3.79 (now 3.82)		
ISRAEL	25	3.85(a)	"…(a) A facility and/or activity should be authorized only when the regulatory body was provided with evidences, in form of documents, and was confirmed that the facility or activity is going to be used or conducted in a manner that does not pose an unacceptable radiological risk to people or the environment. This should include documented evidences	Provision of "evidences" is the needed for confirma-tion		Accepted with minor modification to para 3.85(a) (now 3.88(a)) as reported in the text. The set of documentation is indicated in para 3.96 (now		

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			and confirmation that the applicant has the organizational capability, organizational structures, adequacy of resources, competence of managers and staff, and appropriateness of management arrangements to fulfill its safety obligations as an authorized party;…"			3.97) and following paras.		
ISRAEL	26	3.85(b)	"…The regulatory framework for dealing with authorization requests should be clear~~,~~ ~~especially the process for applying for authorization; …~~"	The regulatory framework should be always clear			Y	The text is taken from SSG-12 para.2.19(b)
ENISS	7	3.85(d)	Scope of Information that need to be submitted to the regulatory body for ~~T~~the authorization of a facility or activity ~~should be based on predefined documents that are submitted to the regulatory body~~ by the person or organization responsible for the facility or activity should be predefined. ~~These documents should be reviewed~~	Text seems to be written for one special authorization - it should be emphasized, that the scope of information to be submitted should be defined, not so much the type of documents to be submitted. Review and update of documents already included in other chapters, so no need for repetition.			Y	The text is taken from SSG-12 para 2.19(d)

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~by the regulatory body and, where required, should be updated regularly by the authorized party, as indicated in authorization conditions or regulations;~~					
ENISS	A7	3.85 (g)	A graded approach should be taken by the regulatory body when performing reviews, assessments or inspections throughout the authorization process. ~~Such an approach should be reflected in regulations and guides, and the extent of reviews, assessments or inspections should be commensurate with the magnitude of the possible radiation risks posed by the facility or the activity;~~	Delete repetition of detail of chapter 2 and subchapter "regulations and guides" of chapter 3.	Y	3.85(g) now 3.85(e)		The text is from SSG-12 para 2.19(h)
ENISS	8	3.85 (j)	(j) The ~~scope~~ coverage of allowed ~~the~~ authorizations (e.g. a site authorization, a facility, parts of a facility and activity~~ies~~ authorization, or a series of authorizations), ~~its~~ allowed validity periods and	Text seems to be written for one special authorization - rewritten to comply with the text of 3.85 "Authorization principles should be established in the regulatory and legal framework.			Y	The proposal was rejected because the text is in line with the heading "General principle of an

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			~~any~~ the possibility to incorporate~~d~~ conditions should be clearly defined by the regulatory body;	Examples of authorization principles are the following"				authorization", but some minor changes in para 3.85(j) (now 3.88(j)) were made.
ENISS	A8	3.85 (k)	~~The regulatory body should include conditions in the authorization, as appropriate;~~	Already included in 3.85 (j), also see amendment			Y	3.85(k) and 3.85(j) address different uses of "authorization conditions," i.e. one deals with conditions in general, the other deals with conditions when transferring an authorization.
ENISS	9	3.85 (m) to (o)	~~(m) The applicant and the regulatory body should take into account international good practices, as appropriate, throughout the authorization process;~~	The Listing (m) to (o) are not authorization principles and therefore should not be listed under 3.85 "Authorization principles should be established in the regulatory			Y	The text is taken from SSG-12 para. 2.19 (m) and (o)

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~(n) The analysis approach to safety should be clearly defined, including the use of deterministic and probabilistic methodologies and analytical tools as appropriate;~~ ~~(o) Safety reviews should be carried out by the authorized party either on a periodic basis or as required by the regulatory body, and the results should be submitted to the regulatory body for review and assessment. Appropriate regulatory decisions may then follow, including a decision to suspend operation, if doing so is deemed necessary;~~	and legal framework. Examples of authorization principles are the following"				
IAEA CC-SAS	3	3.88(n) in (V5), was 3.85 (n) in (V3)	The analysis approach to <u>demonstrate</u> safety should be clearly defined, including the use of deterministic and probabilistic methodologies and analytical tools as appropriate;					
ENISS	A9	3.85 (p)	~~The prime responsibility for safety is assigned to and~~				Y	The text of para.3.85(p) is in

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~assumed by the person or organization responsible for any facilities and activities that give rise to radiation risks. Compliance with regulations and requirements imposed by the regulatory body does not relieve the person or organization responsible for any facility and their activities of the prime responsibility for safety. The person or organization responsible for any facilities and their activities should demonstrate to the satisfaction of the regulatory body that this prime responsibility has been and will continue to be fulfilled~~;					SSG-12 2.19(p) and reflects GSR Part1 Requirement 6
ENISS	10	3.86	~~The legislative and regulatory framework should require unfettered access for designated regulatory staff at any time, to any authorized facility or activity and any documents related to safety and considered necessary for~~	Circular reference in this para "access at any time … to any authorized facility … for granting authorizations." We suggest deletion, as for issuing authorizations normally nothing exists yet – access is needed at any time for		3.89. The legislative and regulatory framework should require unfettered access for designated		The text of para.3.85(p) is in SSG-12 2.19(p) and reflects GSR Part1 Requirement 6

COMMENTS BY MEMBER STATES					RESOLUTION			
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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~granting authorizations.~~	checking compliance with authorization, but that's not part of this chapter.		regulatory staff, at any time, to: the premises of an applicant or authorized party; any facility or activity already authorized or proposed; and any documents related to safety and considered necessary for the authorization process.		
ISRAEL	27	3.87	"3.87.Nuclear security and nuclear safety should be viewed as being complementary, and the regulatory body with responsibility for nuclear	Some explanation or examples of **interface** could be very helpful			Y	The IAEA Standard approach is to highlight the interfaces between safety and security and not to give

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			safety should ensure that <u>any interface</u> between nuclear safety and nuclear security measures are addressed by the authorized party or the applicant for an authorization and are appropriately considered in conjunction with the regulatory body with responsibility for nuclear security…." This <u>extremely important</u> paragraph should be better explained : what is considered as "**interface**"? Is it a <u>mutual</u> responsibility of both regulators and not just a question of "interface"?					examples.
ENISS	A10	3.88.	It is required that authorization should take the form of either registration or licensing, (GSR Part 3, par. 3.8 [3]). ~~The regulatory body should determine which facilities and activities require only registration or to be subject to~~	Repetition of content already included 3.26.			Y	The para. 3.88 (now 3.91) reflects GSR Part 3 para.3.8 and deals with forms of authorization. Para 3.26 (now 2.29)

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~a licensing process.~~					distinguishes notification and authorization.
GERMANY	19	3.89	Bullet (i) i: "adequate financial resources for construction, operation and maintenance of facilities and/or activities as well as for the timely decommissioning <u>(or closure)</u> of facilities or termination of activities and the management of radioactive waste and/or spent ~~radiation~~ <u>radioactive</u> sources, including disposal;"			Note, original 3.89 moved to 3.16 (see ENISS #A1). Accept the adding of "closure", but maintain radiation because is more general (see IAEA Glossary)		
GERMANY	20	3.89	Bullet (i) ii.: "adequate human resources (quantity and qualification) to safely construct, maintain, operate …"				Y	"Adequate" cover quantity and qualification
ENISS	A11	3.89.	~~In the regulations and guides, the regulatory body should explicitly state the obligations,~~	Repetition of content already included in 3.27ff – graded approach should be mentioned		Note, original 3.89 moved to 3.16 (see		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~roles and responsibilities of the applicant or authorized party. In this respect,~~ the regulatory body should include in regulations, that the applicant or authorized party should accomplish the following, or part of, depending on the facility or activity, taking into account the graded approach:	here, as not all topics listed are applicable to all facilities or activities (e.g. x-ray unit).		ENISS #A1). Accepted, comment addressed by modifications of the text of original para. 3.27 (now 3.30).		
ISRAEL	28	3.89(a)	"…(a) Prepare and submit a comprehensive application to the regulatory body that demonstrates that highest priority is given to safety; that is, that the level of safety is as high as reasonably achievable and that safety will be maintained for the entire lifetime of the facility or activity, until this is released from regulatory control by the regulatory body;…"	Focus on highest priority	Y	Note, original 3.89 moved to 3.16 (see ENISS #A1).		
ISRAEL	29	3.89(e)	"… (e) Have a design capability and a formal and effective external relationship	Explanation for meaning of 'external relationship' could help			Y	Text in bullet consistent with SSG-12 para

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			with the original design organization;… "					2.38(f)
ISRAEL	30	3.89(i)ii	"…ii. Adequate human resources to safely manage, construct, maintain, operate and…."	More focus on managing resources.			Y	See Germany #20
FINLAND	12	3.89 h	Have an appropriate ~~prospective~~ assessment made for radiological environmental impacts, commensurate with the radiation risks associated with the facility or activity.	For clarity Consider reformatting this sentence.			Y	The text reflects the GSR Part.3 para 3.9(e)
UK	6. EA	3.89 (h)	(+Paras 3.192, 3.206)– should be clear here or somewhere else in the document what "radiological environmental impact" means either by referencing the new safety guide or by explaining that it means doses to the public and to non-human species, and any impacts on sensitive/specially protected habitats (e.g. under EU Habitats Directive etc)			Note, original 3.89 moved to 3.16 (see ENISS #A1). Comment accepted putting a reference to GSR Part.3 para 3.9(e).		
ENISS	11	3.90.	An additional requirement to be included in the regulations	Separate guide for management systems exist –		Accept the comment;		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			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 and the authorization;~~ ~~(b) For managing incidents and accidents and responding to a nuclear or radiological emergency.~~ Procedures should be periodically assessed, reviewed and revised, as appropriate, to take into account operating experience,	the mentioned points do not represent all parts of an integrated management system, which might lead to confusion. There are other procedures needed, e.g. for modification etc. Also covered by para 3.100. We suggest deletion.		DS473 should be review when DS456 (to be GSR Part 2) will be published		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			modifications, and national and international best practices.					
ENISS	12	3.91.	~~Throughout the authorization process,~~ the regulatory body should ensure that proposed modifications are categorized by the authorized party according to their safety significance. This categorization should follow an established procedure, which should be subject to agreement or approval by the regulatory body. Modifications that are categorized as significant to safety should be submitted to the regulatory body for review and approval or agreement. The regulatory body should inspect compliance with categorization procedures on a regular basis. Further information on modification control at Nuclear Power Plants is provided in [30].	This does not only apply to the authorization process but also to operation.		The authorization process covers the lifetime of the facility. Note, para 3.91 deleted and incorporated into para 3.131.		

RESOLUTION OF
MEMBER STATES COMMENTS on DS473 Version 3 (STEP 8)
&
IAEA COORDINATION COMMITTEE COMMENTS on DS473 Version 5 (STEP 10)

COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
ENISS	A12	3.92.	~~In the regulations it should be clearly stated that even if authorization expiry dates are established, on expiry they do not relieve the person or organization in charge of the facility or activity of the prime responsibility for safety until the regulatory body so decides.~~	Combine with same content of 3.81 and delete here.			Y	Para 3.81 (now para 3.84) is located in the General section of the "Notification and Authorization" Chapter and provides general information by paraphrasing the requirement in GSR Part 1 on the prime responsibility for safety. However, para 3.92 (now 3.94), which is located in the Section "Objective of Notification and Authorization" provides a specific recommendation that the regulations and guides should address this prime responsibility.
ENISS	A13	3.93.	~~Requirement 7 of GSR Part 3[3] requires that: "Any person~~	Fully covered by para 3.89 and 3.85		Accepted with modification of		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~or organization intending to operate a facility or to conduct an activity shall submit to the regulatory body, as appropriate a notification or an application for authorization". The application should be submitted in a form prescribed by the regulatory body with the information that is commensurate with the level of radiation risk in operating the facility or conducting the activity. Requirement 23 of GSR Part 1 (Rev.1) [2] requires that "Authorization by the regulatory body … shall be a prerequisite for all facilities and activities that are not either explicitly exempted or approved by means of a notification".~~			the text of para.3.69 (now 3.72)		
ISRAEL	31	3.94(c)	"…(c) Specification of the system to be used **for source management:… "** Why this specific paragraph is	Explanation needed for: '"source manage- ment" could be very useful		Accepted with modification of the text in para 3.94 (now 3.95). The		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			restricted to radiation sources, while the issues discussed are facilities and activities in general?			para. 3.94 (now 3.95) referring to notification that applies for radiation sources used to operate a facility or conducting an activity		
ENISS	A14	3.96.	~~The applicant should provide all relevant information describing the approach to safety in order to demonstrate that the facility or the activity will not present unacceptable radiological risks to people and the environment. This should include proposed objectives, principles, criteria, standards and analyses in relation to safety for all stages of the authorization process. The aim should be to provide the relevant information such that~~	Fully covered by para 3.89 and 3.85			Y	This para 3.96 is focused to the applicant

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~the regulatory body can conduct its review and assessment process without needing to seek further information or clarification.~~					
ENISS	A15	3.97.	The documents submitted to the regulatory body in the framework of the licensing process should be updated, as appropriate, during the lifetime of facility or activity, to ensure they cover relevant aspects. The documents submitted to the regulatory body (which may be divided or combined into different documents, as appropriate) should be incorporated as part of the authorization, if required by national regulations, regulatory regimes and practices.	Fully covered by para 3.85 (d)		Accepted. As a consequence para. 3.85(d) (now 3.88(d)) has been modified to avoid repetition.		
ISRAEL	32	3.98	"3.98~~… During this phase, the staff of the regulatory body should be trained so they have sufficient knowledge of the designs of facilities or of the phases of the activities that~~				Y	This is an important part of the authorization process.

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~may be proposed….~~" **The expectations from the regulatory staff as to their knowledge, is probably not in the scope of this guide**					
USA	15	p. 33 3.99	3.99. Early assessment of the competence… give consideration to how and from where it will recruit such staff. Any information provided to the applicant by outside organizations (e.g., contractors) for use during facility activities will be the responsibility of the applicant to ensure technical adequacy. Procedures developed by the regulatory body should include guidance on applicant/authorized body certification of adequate/complete information (e.g., statements under oath and affirmation).	Completeness, openness		Accepted as reported in the text with adding of a new bullet (h) in para 3.100 (now 3.101). The last sentence is not accepted because is covered by 3.89(c) (now 3.16(c)).		
ISRAEL	33	3.100(a) Legal	"…Details of any relevant existing authorizations	Authorization is not limited to licensing only	Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
		inform.	~~(licences)~~;.."					
JAPAN	7	3.100, Applicant 's Organizat ion, (c)/3 (p.34)	…and funding decommissioning or radioactive waste management, as	Clarification.	Y			
GERMANY	21	3.100	Bullet "Applicant's Organization" (d): "Evidence that the applicant has adequate human resources (quantity and qualification) to ensure that …"	See our related comment on Para 3.89.			Y	See Germany #20
GERMANY	22	3.100	Bullet "Management System": (d) Procedures for reporting on and learning from accidents and other incidents; (e) Procedures for learning from national and international good practices;	The internationally used term of "operational experience" should be added to either (d) or (e).		Accepted to include "operational experience" in para 3.100 (d) (now 3.101(d)) under "Management System"		
ISRAEL	34	3.100 -Safety activities	The list should include also: backup means, redundancy means, emergency procedures, analyses of flooding, winds,	More detailed description			Y	This comment is covered in Appendix 3

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			earthquakes, and other weather induced risks, aircraft crashes, transportation accidents, explosions, external fires, sabotage, etc.					
UK	7. EA	3.100	safety activities, (k)+(l), A.4.27 – needs to be some reference to the application of the best available techniques (BAT) to avoid and minimise effluents, which is how ALARA doses for the public are achieved.				Y	The concept is covered by para 3.100 "safety activities" bullet (o)(i), (now 3.101(o)(i))
JAPAN	8	3.100, Safety activities, (l)/2,4 (p.36)	The results of an analysis of the normal operation of the facilities and activities, and for a radioactive waste disposal facility, of the long term period after closure should be provided to demonstrate the acceptability of the design, including a demonstration that radiation protection criteria, radioactive waste management requirements	Clarification.	Y			
GERMANY	23	3.100	Bullet "Safety activities" (l): "The results of an analysis of	Ensuring consistency with the terminology used in the IAEA			Y	The para. deals with "normal

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			the normal operation of the facilities and activities, and for a waste disposal facility, of the long term period after closure should be provided to demonstrate the acceptability of the design, including a demonstration that radiation protection criteria, waste management requirements and dis-charge effluent limits are met by the design;"	Safety Guide WS-G-2.3 "Regulatory Control of Radioactive Discharges to the Environment" and its successor document DS442. According to the definition in the Safety Glossary (2007 Edition), a discharge is "*a planned and controlled release to the environment, as a legitimate practice, within limits authorized by the regulatory body, of liquid or gaseous radioactive material that originate from regulated nuclear facilities during normal operation.*"				operation"
GERMANY	24	3.100	Bullet "Safety activities" (n): "Additional recommendations and guidance on deterministic safety analysis for Nuclear Power Plants are provided in [28]; "	Use of qualifier 'deterministic' is recommended because the Safety Guide SSG-2 [28] deals with DSA only, while Level 1 and Level 2 PSA are covered by the Safety Guides SSG-3 and SSG-4, respectively.		Accepted in principle by adding references to SSG-3 and SSG-4		
ENISS	13	3.100 (b)	~~Information on whether the facility or activity is fully or primarily owned or controlled~~	Depends on legal system of the state and is not relevant for safety. Delete.			Y	It is important for the authorization process

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~by a person from another State or by a foreign corporation, and, if so, details of the ownership structure.~~					
FINLAND	13	3.100 man.sys. (e)	Good that Management system (e) also international good practices have been included!		Y			
ENISS	A16	3.100 (l)	~~The results of an analysis of the normal operation of the facilities and activities, and for a waste disposal facility, of the long term period after closure should be provided to demonstrate the acceptability of the design, including a demonstration that radiation protection criteria, waste management requirements and effluent limits are met by the design;~~	Fully covered by point i, j, k and m.			Y	Each point cover a different aspect; 3.100(l) (now 3.101(i)) cover analysis
ENISS	14	3.100 (m)	The results of a safety analysis should be provided to demonstrate how the design and related operational procedures of the facility or activity will contribute to the prevention of accidents and to	Wording	Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			the mitigation of the consequences of accidents if they do occur. The analysis should describe and evaluate the predicted response of the facility or activity to events, both internal and external, which could lead to abnormal and accident conditions. The analysis should ~~be extended to~~ include relevant combinations of such disturbances, malfunctions, failures, errors and events. Consideration should be given to aspects such as the initial conditions assumed, the physical or mathematical models used and their correlation with experiments, and the method of presenting the results;					
ENISS	15	3.100 (n)	~~A safety analyses that should show the extent to which the authorized party can control or accommodate situations at the facility or in conducting the activity relating to various~~	Split m for clarity and delete first part, as it gives wrong impressions (safety analysis added in second sentence).			Y	No need to split, the original para. 3.100(n) deals with safety analysis. However some

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~events and abnormal and accident conditions.~~ The limits and conditions for safe operation should be defined, based on the safety analysis report. (m2) If any part of the safety analysis has been independently reviewed by another organization, the results of this review should also be presented. Additional recommendations and guidance on safety analysis for Nuclear Power Plant are provided in [28];					modifications were made in the text for para. 3.100(n) (now 3.101(n). Added additional references to SSG-3 and SSG-4
ENISS	A17	3.100 (o)	Information on other plans and programmes that are established by the authorized party in support of its safety activities. This includes areas such as: ~~i. the radiation protection programme (including how to~~	Delete topics already mentioned in other points of 3.100. Research cannot be part of an operational application and should be deleted here, especially as it is a guide for all activities and facilities.		Accepted in part to cancel items (iii) and (v). It is believed that research is consistent with the operation.		

COMMENTS BY MEMBER STATES					RESOLUTION			
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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~apply the 'as low as reasonably achievable' (ALARA) principle);~~ ii. the environmental monitoring programme; ~~iii. emergency preparedness and response;~~ iv. fire protection; ~~v. radioactive waste management;~~ ~~vi. research and development in relation to the safe design, operation, decommissioning or closure of the facility or the activity in the extent required by the national legislation;~~ vii. feedback of operating			Note, 3.100 now 3.101.		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			experience; viii. the decommissioning (or closure) strategy.					
ENISS	16	3.100 (p)	Arrangements to ensure safety ~~and nuclear security~~ of sources in order to prevent ~~loss of control due to theft, diversion or~~ severe environmental conditions.	Guide only deals with safety, not security			Y	Security at this level should be addressed. Minor modifications were made in the text of para. 3.100(p) (now 3.101(p)).
ENISS	17	New para 3.100 (q)	Information on authorizations issued for a reference or generic facility and information on authorizations for the same or similar facilities or activities issued by other states, if the authorization process could benefit from these processes.	In order to enhance the authorization processes the suggested para should be added.		Accepted the concept. As a consequence an additional bullet is added in para 3.85 (m) (now 3.88(m)).		
IAEA CC-IEC	4	3.101 (a) Emergency arrangements in	Emergency arrangements, including an emergency plan, and financial arrangements for preparedness and response for a nuclear or radiological					

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
		(V5), was 3.100 (a) Emergency arrangements in (V3)	emergency where appropriate, that address the general, ~~and~~ functional and infrastructural requirements as specified in GSR Part 7 [11].					
GERMANY	25	3.101	1st sentence: "An application to inform the regulatory body of the intention to operate a facility or conduct an activity for which normal exposures are expected to be very small and the likelihood and magnitudes of potential exposures are negligible (e.g. consumer products), but which are not suitable for exemption for some reason (e.g. to prevent uncontrolled waste disposal) should be made in the form of a notification."	To provide a typical example for which an application is made in the form of a notification. In this context, Para 3.7 of GSR Part 3 states: "*Notification is required for consumer products only with respect to manufacture, maintenance, import, export, provision, distribution and, in some cases, disposal.*" This requirement recognizes that the use of consumer products by members of the public is effectively beyond regulatory control and no notification of use is required. However, any person or organization intending to carry out any of the practices			Y	Notification can be required also for activities that are suitable for exemption

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				specified in the requirement should notify the regulatory body of its intention to do so.				
ENISS	A18	3.101.	~~An application to inform the regulatory body of the intention to operate a facility or conduct an activity for which normal exposures are expected to be very small and the likelihood and magnitudes of potential exposures are negligible, but which are not suitable for exemption for some reason (e.g. to prevent uncontrolled waste disposal) should be made in the form of a notification.~~ The regulatory body should set out what information is required which may be described in a notification form. The notification form should be available so that an applicant is able to give information in the respect of the provisions for justification of the activity and demonstrate that notification is	Repetition of 3.73	Y	Minor modifications were made in para 3.73 (now 3.76)		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			sufficient to allow operation of the facility or conduct of the activity. Depending on national requirements, the regulatory body might prefer to have separate notification forms for radioactive materials and other radiation sources. The regulatory body should acknowledge the notification, within a specified period, and, if appropriate, set out what regulatory actions it will put in place.					
ENISS	18	3.102.	An authorization is a written permission for an authorized party to operate a facility or to conduct an activity or a set of activities dealing with the siting, design, construction, commissioning, operation, decommissioning or closure of a facility. It also establishes, directly or by reference, conditions governing the safe performance of these activities.	To include the concept of reference and generic facility here, where the basic requirements for authorizations are stated and to introduce different licensees (Vendors and operators).			Y	It is covered by paras. 3.116 and 3.118

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			An Authorization could also be issued for a reference or generic facility or a design, which could be issued to a vendor as e.g. a design certification. (see also §3.118ff). Experience shows, that licensing processes can be significantly accelerated and made more resource efficient for all involved parties (e.g. vendor, operator, authority) by using this approach.					
ENISS	A19	3.102.	~~An authorization is a written permission for an authorized party to operate a facility or to conduct an activity or a set of activities dealing with the siting, design, construction, commissioning, operation, decommissioning or closure of a facility. It also establishes, directly or by reference, conditions governing the safe performance of these activities.~~	Repetition of 3.78 ff			Y	Para. 3.78 does not cover for a written permission
ENISS	A20	3.103 (a)	For a specific time period (e.g. 10 years, 40 years) or for a	Repetition of para 3.92			Y	It is not a repetition because para

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			specific stage in the lifetime of the facility (e.g. construction, operation) or activity. ~~In such a case, a mechanism should be put in place to ensure that the authorized party responsible for the facility and its activities remains responsible for safety and nuclear security at the facility, even if the authorization has expired, unless the site has been removed from regulatory control;~~					3.103(a) deals with the mechanism to ensure that the authorized party remains responsible of the authorization after the expiry of the authorization
ISRAEL	35	3.103(b)	"… (b) For an indefinite period of time ~~(a permanent authorization)~~… "	An indefinite period does not necessarily means permanent			Y	It is from SSG-12 para 2.7
GERMANY	26	3.103 (c)	"For a specific activity or a specific condition of the facility (e.g. ~~temporary~~ storage of spent fuel)."	Storage is, by definition, a temporary measure, but it can last for several decades if a disposal option is not avail-able. Consequently, the term 'temporary storage' would be appropriate only to refer to short term storage when contrasting this with longer term storage. Storage as			Y	See Israel 35

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
				defined in the IAEA Safety Glossary should not be designated as temporary storage.				
GERMANY	27	3.104	Bullet "Authorized activity.": "The authorization should clearly describe in sufficient detail the purpose, the mode of operation, the workload and the design of the facility, its location and the activities or inventory of sources, including …"	Clarification.		Accepted the concept. As a consequence the text in para. 3.104 (now 3/105) "Authorized activity" was modified.		
ISRAEL	36	3.104	"3.104…Thus, the format of an authorization ~~will~~ may vary not only among States…"	Clarity			Y	Reference to "will" is judged to be more appropriate
ISRAEL	37	3.104 Autho-rized Activity	"…site boundaries, and other ~~drawings~~ documents, as appropriate…"	More general definition		Accepted in principle. Reference to "other relevant information, as appropriate" added. See also response to Germany #27.		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
ENISS	A21	3.104	… ~~*The authorized party's responsibility for compliance.* The authorization should contain:~~ ~~• an appropriate declaration that the authorized party has the responsibility for compliance with the legal requirements, regulations and conditions referenced or contained in the authorization or in other references, if applicable;~~ ~~• a statement that establishes that the authorization may be transferred to a different authorized party, with the approval of the regulatory body.~~	This is contained in regulations, as stated in para 3.81 and does not need to be restated here			Y	It is not a repetition of how reported in para 3.81 (now 3.84), but this should be part of the form of the authorization.
ENISS	A22	3.111.	Authorization conditions should cover, as appropriate,	Deleted part included in first sentence "safety aspects" and			Y	See ENISS A21 with reference to

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			safety aspects affecting the facility or activity throughout its lifecycle encompassing site evaluation, design, construction, installation, commissioning, operation and decommissioning of the facility or activity and its subsequent release from regulatory control so as to enable effective regulatory control at all stages. ~~These requirements should cover, among other things, important aspects such as design, radiation protection, maintenance programmes, emergency plans and procedures, modifications, the management system, operational limits and conditions, procedures and authorization of personnel.~~ Furthermore, authorization conditions may refer to, but should not duplicate, regulations, to avoid	already named in 3.78.				the principle established in addressing para 3.81 (now 3.84).

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			discrepancies or inconsistencies when the regulations are amended.					
ISRAEL	38	3.112 Authorization conditions pertaining ..	".. procedures for, information about and identification of the legal framework for challenging the authorization or part of the authorization…. " **It might be helpful to explain the meaning of "challenging the authorization"…**	Explanation needed. + see text in **bold**		Accepted the concept. As consequence the text in para 3.112 (now 3.113) "Authorization conditions" last bullet was modified as follows: "procedures for, information about and identification of the legal framework for challenging the conditions in the		

COMMENTS BY MEMBER STATES					RESOLUTION			
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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
						authorization or part of it."		
JAPAN	9	3.112, Authorization conditions that specify procedures and modes of operation: , 2nd bullet	conditioning criteria for radioactive waste processing for existing or foreseen radioactive waste management facilities; encouragement for radioactive waste minimization should be addressed;	Clarification.	Y			
ENISS	19	3.112	- *Authorization conditions pertaining to administrative matters such as:* • … • ~~any additional separate authorizations that the authorized party should obtain from the regulatory body;~~ • … • ~~procedures for, information about and identification of the~~	Requirements for obtaining authorizations are stated in Regulations – in an authorization there is normally indication, that the authorization is issued without anticipation of other authorizations needed. Point should be deleted here. Same for the last point, this is not a condition for an authorization but a legal requirement.			Y	Retaining existing text from an already established safety guide, specifically SSG-12, para 2.40(q).

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			~~legal framework for challenging the authorization or part of the authorization.~~					
GERMANY	28	3.112	2nd sentence: *- Authorization conditions that specify procedures and modes of operation:* … • ~~conditioning~~ criteria for radioactive waste processing for existing or foreseen waste management facilities; encouragement for waste minimization should be addressed; …"	Clarification. 'Conditioning criteria' for the processing of radioactive waste do not exist.			Y	Retaining text from an already established safety guide, GS-G-1.5 para 3.44(e). For conditioning see the IAEA Safety Glossary under "waste management."
GERMANY	29	3.112	3rd sentence: *- Authorization conditions relating to human resources:* • the number, qualification, competences and trustworthiness of the staff or parts of the	Completion. Please add the bullet "Authorization conditions relating to human resources."			Y	Covered by the first bullet of "Authorization conditions that specify procedures and modes of operation."

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			staff.					
GERMANY	30	3.112	3rd sentence: *- Authorization conditions relating to equipment:* • the provision of adequate equipment.	Completion. Please add the bullet "Authorization conditions relating to equipment."			Y	Covered by the first bullet of "Authorization conditions that specify procedures and modes of operation."
GERMANY	31	3.112	3rd sentence: *- Authorization conditions relating to the public:* • the provision of information regarding justification of the facility or activity and its impact on the environment.	Completion. Please add the bullet "Authorization conditions relating to the public."			Y	Justification is not part of the authorization. First bullet of "*Authorization conditions that set technical limit and threshold such as*" covers the comment.
ENISS	A23	3.113	~~*General authorization conditions*~~ ~~3.113. General authorization conditions should include the following provisions:~~ ~~(a) The authorized party~~	The way of issuing conditions is very specific to the legal system of a member state. The topics listed here are in the form of laws or regulations (e.g as described in 3.32 for reporting of events, or 3.33 for	Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~should provide the authorized representatives of the regulatory body with full access to personnel, facilities and records that are under the authorized party's control, when such access is deemed necessary by the regulatory body to verify compliance and to assess safety;~~ ~~(b) The authorized party should keep the regulatory body fully and continuously informed of any significant or potentially significant events or changes in the considerations, information, assumptions and expectations upon~~	modifications), so there is no need to put these issues into a license condition. As all topics listed here are mentioned in the guide at other paras, we suggest deleting the whole paragraph, as it might be misleading.				

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			~~which the issue of the authorization was based;~~ ~~(c) The authorized party should take such corrective actions or measures as the regulatory body may require in the interests of safety;~~ ~~(d) The authorized party should not extend its activities beyond those specifically authorized in the authorization without the prior approval of the regulatory body;~~ ~~(e) The authorized party should develop, preserve, update and maintain a complete set of records relating to the safety of the facility or the activity including~~					

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			~~those referenced in the applications and those required by law, regulations and the authorization, and should dispose of them only as authorized by the regulatory body;~~ ~~(f) The authorized party should carry out its activities in accordance with an approved management system programme covering all stages of the authorization process, so as to provide a basic framework for ensuring that all activities are carried out with due regard for safety;~~ ~~(g) The authorized party~~					

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			~~should report on modifications to operate the facility or conduct the activity in accordance with the requirements established by the regulatory body;~~ ~~(h) The authorized party should report on all accidents, incidents and events relating to safety as required by the regulatory body;~~					
ISRAEL	39	3.113(b)	"… The authorized party should keep the regulatory body fully and continuously informed of any ~~significant or potentially significant~~ events or changes…" **The terminology "significant or potentially significant" leaves too broad "grey area" and probably the best way to prevent it is by using the**	See text in **bold**			Y	Para 3.113 was deleted according with comment ENISS A23.

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			term "any".					
ISRAEL	40	3.115	"3.115. The authorization process should be understood by the parties concerned and should be ~~predictable~~ ~~(i.e.~~ well defined, clear, transparent and traceable~~)~~…" **The term 'predictable' is different and wider than the content within parenthesis and therefore it is recommended to be removed**.	See text in **bold**			Y	Retaining text from an already established safety guide. Para 3.115 is taken from SSG-12 para 2.6.
ENISS	A24	3.115.	~~The authorization process should be understood by the parties concerned and should be predictable (i.e. well defined, clear, transparent and traceable). The authorization process should be established in a systemic way to facilitate efficient progression of regulatory activities. The steps of the authorization process should be discrete and should follow a logical order.~~	Content included in 3.85b and 3.98.			Y	See Israel #40

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
ENISS	A25	3.117.	~~The authorization process, and in particular an authorization (licence) renewal process, should be carried out in a very transparent manner, providing opportunities for communication with the public and their involvement.~~ 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.	Content fully included in 3.1, 3.4, 3.23 (f)			Y	It is not considered to be a repetition.
JAPAN	10	3.117	The authorization process, and in particular an authorization (licens<u>e</u>) renewal process, should be carried out in a very transparent manner providing opportunities for communication with <u>interested parties. Details of communication are provided in DS 460 [ref. _].</u> ~~the public and their involvement. In some~~	- The member states practices are NOT universally recognized practices therefore it should be deleted. - Duplicated description should be deleted.		Accepted in part with some modifications of the text of para. 3.117		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~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~~.					
GERMANY	32	3.118	Whenever submissions for a particular type of facility (or parts thereof) may be repeated many times, it may be appropriate for an authorized party to provide a submission for a 'reference facility', ~~or~~ a 'generic facility' or a 'generic design'. A reference facility is a designated existing facility of a type that is to be constructed in various other locations as well, whereas a generic facility or a generic design is a type of facility or a design concept which is to be constructed with relatively minor modifications in various locations. (…)	In 3.118 the terms "generic facility" and "reference facility" are discussed. In 3.119 also design is added. Thus it would be useful to add and explain the term "generic design" in 3.118		Accepted the comment partially. As a consequence, the text of para 3.118 and para 3.119 was modified.		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
GERMANY	33	3.120	Penultimate bullet: "decommissioning (or closure);"	For radioactive waste disposal facilities, the term 'closure' instead of 'decommissioning' is used.	Y			
ENISS	A26	3.120.	~~The authorization process for a complex facility or activity should be considered to consist of a series of lifecycle stages each subject to the need for regulatory input to allow progress from one stage to the next. These stages may depend on national legislation but are normally labelled as follows:~~ ~~•siting and site evaluation (which may include the environmental impact assessment);~~ ~~•design;~~ ~~•construction;~~ ~~•commissioning;~~ ~~•operation;~~ ~~•decommissioning;~~ ~~•release from regulatory~~	Deleted content included in 3.78 and 3.114		Accepted partially. The first part of the comment is rejected. The second part is accepted and the text deleted.		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~control.~~ Each stage of the licensing process may be divided into several sub-stages or may be merged or combined as appropriate to facilitate the regulatory process. Combining the authorizations (e.g. for construction and operation) may also give more predictability to the process for the authorized party. ~~At each hold point set down by the regulatory body or in the licensing process, different authorizations from the regulatory body may be required. Conditions may be attached to authorizations granted at each step and may require that the authorized party obtain further, more specific, authorizations or approvals before carrying out particular activities.~~					
JAPAN	11	3.120, 6th bullet	decommissioning or closure;	Clarification.	Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
ENISS	20	3.122.	Once an ~~application has been accepted and the~~ initial authorization has been issued, subsequent licensing process activities and arrangements should be undertaken between the authorized party and the regulatory body. These will include requests for carrying out further activities, including, in some States, the construction of additional facilities on the site.	It is unclear what is meant by "application has been accepted" – there is not description of that process in the para before.	Y			
ISRAEL	41	3.123	"3.123… Where there are different authorized parties on the same site, or on neighboring sites, the regulatory body should ~~ensure~~ use its best efforts to establish co-operation between the authorized parties…" **The Regulatory Body may not be able to achieve such goal.**	See text in **bold**			Y	Cooperation is essential in this situation.
JAPAN	12	3.124/4, Reference	For radioactive waste disposal sites, geological and	- Clarification. - SSG-1, [26] and [27] are	Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			hydrogeological considerations…in site evaluation.[Y, 26, 27] [Y]SSG-1	relevant document so it should be added as reference.				
USA	16	p. 45 3.124	3.124. Site evaluation for many facilities or activities is initially determined by processes not greatly influenced by highly prescriptive technical criteria. However, general requirements concerning remoteness, environmental concerns, local population density and transport arrangements will apply, usually at a governmental level. For waste disposal sites, geological and hydrogeological considerations should be major factors in site evaluation. For such sites The regulatory body should consider being involved in the formulation of site selection criteria and in the process of determining the general	Specifically calling out 'waste disposal sites' seems to imply that geological and hydrogeological considerations are *not* also major factors for operating power reactors and other production facilities.		Accepted with the modifications of the text of para 3.124		

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			suitability of a site. Further guidance on site evaluation is given in [18–25].					
ENISS	21	3.124.	~~Site evaluation for many facilities or activities is initially determined by processes not greatly influenced by highly prescriptive technical criteria. However, general requirements concerning remoteness, environmental concerns, local population density and transport arrangements will apply, usually at a governmental level. For waste disposal sites, geological and hydrogeological considerations should be major factors in site evaluation. For such sites the regulatory body should consider being involved in the formulation of site selection criteria and in the process of determining the general~~	The guide should be restricted to functions and processes not to details for site evaluation, as there are other guides available.			Y	Para.3.124 is important to highlight the importance of site evaluation

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~suitability of a site.~~ Further guidance on site evaluation is given in [18–25].					
GERMANY	34	3.126	Please insert new sentence: "… Further information on the design requirements for nuclear power plants is provided in [31]. Guidance on the construction of nuclear installations consistent with the design requirements can be found in [39]." Please add the Draft Safety Guide DS441 to the list of references: "[39] INTERNATIONAL ATOMIC ENERGY AGENCY, Construction for Nuclear Installations, IAEA Safety Standards Series, Draft Safety Guide DS441, IAEA, Vienna (in preparation)."	The related subsection is entitled "Design, construction, manufacture and installation". Specific recommendations and guidance on construction of nuclear installations are provided in the Draft Safety Guide DS441 (currently in SPESS Step 14). A reference [39] to this publication should be added.	Y			
GERMANY	35	3.127	Last sentence: "Further recommendations on commissioning of nuclear power plants and research	Clarification and completion.	Y			

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			reactors are provided in Refs [35, 36]."					
ENISS	22	3.127.	There is some overlap between the construction and commissioning stages in that individual structures, systems and components may be commissioned before completion of the entire facility or start of an activity ~~systems~~. There are several steps in the commissioning process for which the regulatory body may require the authorized party to obtain prior approval and at which regulatory decisions may be made. However, the introduction of fissile and/or radioactive material into the facility or activity marks a significant step in the commissioning procedure and is often considered the main point at which regulatory decisions are made ~~at this stage~~. Introduction of fissile	For clarification, as it is unclear, what "activity systems" are. Second deletion for clarification		Accepted with minor modifications of the text of para. 3.127		

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			and radioactive material should not be authorized until the proposed commissioning programme has been reviewed and assessed, preliminary operational limits and conditions have been established, the final design has been assessed and conformity of the construction with the design of related systems has been verified. Further recommendations on commissioning are provided in Refs [35, 36].					
ENISS	23	3.129.	Over the full operational lifetime of the facility or activity, the regulatory body should require the authorized party to provide evidence at appropriate intervals, in the form of a comprehensive safety review, such as a periodic safety review [8], that the facility or the activity is still fit to continue in operation. In many States, this	For clarification.	Y			

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			reassessment period is around ten years for a major nuclear installation. In the comprehensive safety review, account should be taken of significant changes in ~~the~~ potential nature and magnitude of the associated hazards, operating experience, significant changes to safety standards, technical developments, and new safety related information from relevant sources. Depending on the national laws and regulations and the outcome of the comprehensive safety review, the regulatory body may renew the authorization of the authorized party at this stage.					
USA	17	p. 46 3.131	During the lifetime of the facility or activity modifications will be made to both equipment and management and operational procedures. Where these affect			Para 3.131 modified to refer to the potential of a modification to		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			safety they must be subjected to proper consideration by the authorized party and may require approval by the regulatory body. Clear standards need to be set for when review and approval by the regulatory body is required. Significant modifications should result in changes to the safety assessment and safety documentation so that it properly reflects the actual situation [30].			affect safety and also to its safety significance.		
ISRAEL	42	3.131	"3.131. During the lifetime of the facility or activity modifications ~~will~~ are expected to be made to equipment, management or operational procedures. Where these affect safety they must be subjected to proper consideration by the authorized party and ~~may~~ must require approval by the regulatory body. ~~Significant~~	Clarity.		Partially accepted. As a consequence the text of para 3.131 was modified with reference to the "safety significance" of the modification.		

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			Any modifications that ~~should~~ may result in changes to the safety should be well represented in the assessment and safety documentation so that it properly reflects the actual situation [30]…."					
JAPAN	13	3.132/3	…[16, 33, 37, 38].	GSR Part6 is also relevant document so it should be added as reference.			Y	Para 3.132 is referring to operation and not decommissioning. Para 3.134, under decommissioning, already includes the reference to GSR Part 6, i.e. [16].
GERMANY	36	3.132	"Plans for radioactive waste management and decommissioning (including technical solutions, waste streams, the ~~policy~~ regulatory framework for disposal and funding) should be reviewed and updated periodically during operation [~~33,~~ 16, 37,	In order to be in the hierarchy of Safety Standards at the same level as GSR Part 5 [37] and SSR-5 [38], the guidance should refer to the General Safety Requirements GSR Part 6 [16], not to a facility-specific Safety Guide such as WS-G-2.1 [33]. When using [33], one		Accept the comment with modification of the text of para. 3.132. The additional references have been		The word government was add because waste disposal is a governmental responsibility.

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			38].”	could ask why other relevant Safety Guides such as WS-G-2.4 [34], WS-G-2.5 and WS-G-2.6 are omitted.		added to para 3.134.		
SPAIN	3	3.133	Decommissioning or closure should only be authorized once the ~~detailed~~ relevant plans and procedures to be used, the conditions to be observed during decommissioning or closure, and the proposed final state of the facility, including the radiological status, have been inspected, reviewed and assessed by the regulatory body.	3.134 refers to “relevant documents” Requirement 25 of GSR part 1 refers to “information relevant to safety”	Y			
ENISS	24	3.134.	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, (GSR Part 6 para 7.7 [16]). ~~In addition, the regulatory body should ensure that an effective record system~~	Move deleted part to next chapter “release from regulatory control”.	Y			

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~for the released sites is in place and is maintained for future users of the sites. The responsibilities for maintaining site release records should be clearly assigned, with account taken of the fact that these records could be maintained by a specific organization.~~ Further Requirements for decommissioning are established in [16]; further recommendations are provided in [33, 34, 37 and 38].					
ENISS	A27	3.138.	~~Essential documents to be prepared by the authorized party in the authorization process should be identified in the regulations and guides issued by the regulatory body. Additional documents may be requested as needed, depending on the type of facility or activity concerned as well as on the specific stage of the authorization process.~~	Content fully included in other paras, e.g. 3.85(d) and 3.31– no added value here.			Y	The content of para. 3.138 is not covered by the other paras indicated in the reason.
ENISS	A28	3.139.	~~Documents of different types~~	Content fully included in other	Y			

COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~are required to be prepared by the authorized party in discharging its responsibilities with respect to the safety of the facility or the activity. Some of these documents are required to be submitted formally to the regulatory body for review and assessment in the course of the authorization process. Other documents are reports that should be submitted to the regulatory body periodically, or event, incident or accident reports to keep the regulatory body fully informed of the conditions prevailing at the facility or for the activity. A third type of document is for internal use by the authorized party but should be made available upon request to the regulatory body to ensure its complete understanding of the design and operation of the facility or the activity, so that it can confirm that the~~	paras, e.g. 3.85(d) and 3.31 – no added value here.				

COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~requirements established in the regulations and authorization conditions have been fulfilled.~~					
ISRAEL	43	3.140	"3.140… international industry standards ~~(of the IEC and the ISO)….~~" **Unclear why IEC and ISO standards are explicitly specified here (Other standards could be added)**	See text in **bold**		Para 3.140 deleted.		
ENISS	A29	3.141.	~~The regulatory body should not issue an authorization solely because a model of equipment was 'type approved' or carried a certificate of compliance, in accordance with IEC standards or nationally recognized equivalent standards in the State of use. The safety of each facility or activity will depend on many factors in addition to the design and manufacture of the structures, systems and components which are required for safety, such as the~~	The requirements for an authorization have been stated before, e.g. 3.100, 3.61.	Y			

COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~qualification and training of the staff, and managerial and operational procedures and processes.~~					
ENISS	A30	3.142.	~~A fundamental feature of the process of review and assessment of an application for authorization by the regulatory body is its consideration of the documentation submitted by the applicant.~~ For significant radiation risks or unusual or complex facilities or 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. These inspections will also allow the regulatory body to supplement the information and data needed for review and assessment. Additionally, the regulatory body will be able to extend its practical	No need for repetition of content from other paras.		Para 3.142 deleted.		

COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			understanding of the managerial, engineering and operational aspects of the application for authorization and to foster links with specialists of the operating organization.					
ENISS	A31	3.143.	The granting of an authorization should not restrict or preclude subsequent amendment, suspension or revocation of that authorization by the regulatory body within the period of its validity. ~~Once it has been issued, however, the terms of the authorization, including any conditions attached to it should be binding on the authorized party unless and until amended, suspended or revoked by the regulatory body.~~ A request for an amendment may be initiated by the authorized party, or an amendment may be imposed by the regulatory body in the	Content has been stated before and is not needed for understanding here.	Y			

COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			interest of safety. A modification of the authorization may be desirable or necessary as a result of proposed changes relating to the facility or activity, experience from the facility itself or elsewhere, or technological advances, or as a consequence of research and development relating to nuclear or radiation safety.					
ISRAEL	44	3.144	"3.144… of applications for renewal or amendment of authorization**s**…."	Typo?	Y			
ENISS	A32	3.145.	~~The regulatory body may require the renewal of an authorization after a set time interval, depending on national legislation. In such instances, a review would usually be made of the findings of inspections and of other information on performance, and its results would be documented as part of the revalidation process. Authorization details should be~~	First sentence fully covered by 3.129. A review includes more than a review of findings and performance – additionally reviews covered fully by separate chapter (paras 3.149ff). Last sentence not needed, as this is fully described in all		Partially accepted with modifications of the text of para. 3.145 (now 3.142).		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~kept up to date.~~	other para of that chapter.				
ENISS	A33	3.146.	The regulatory body should require notification by the authorized party of any significant changes to safety of the facility or activity and to apply, where necessary, for an amendment to~~, or a renewal of,~~ the authorization. Any modification to safety of a facility or an activity should be subject to an assessment by the authorized party, with account taken of the possible magnitude and nature of the associated risk.	Deletion sufficiently covered by 3.129.	Y			
ENISS	A34	3.147.	~~At any stage of the lifetime of the facility or activity, proposals to change or modify the site, the facility, the activity, the organizational structure of the authorized party, and associated managerial and operational procedures, processes including plans for future activities (e.g.~~	Content fully covered by para 3.131	Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~decommissioning) may be made. These proposals should (depending on factors such as the nature of the changes and the magnitude of the risks involved) be subject to prior review, assessment and approval by the regulatory body and revision of the authorization as appropriate.~~					
GERMANY	37	3.148	2nd to 4th sentence: "The regulatory body should ensure that the radiation sources are transferred to an authorized party that possesses a valid authorization [3] or are disposed of ~~to~~ in an authorized waste disposal ~~management~~ facility. The regulatory body should provide guidance on radiological criteria for the removal of regulatory control from materials, facilities and sites. Further information is provided in ~~[33]~~ [40]." Please add the Safety Guide	The last part of the second sentence is referring to disposal. Specific guidance on removal of regulatory control is provided in the Safety Guide WS-G-5.1. A reference [40] to this publication should be added and the existing one to the Safety Guide WS-G-2.1 should be deleted.		Accepted to add reference, but in para. 3.135.		

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			WS-G-5.1 to the list of references: "[40] INTERNATIONAL ATOMIC ENERGY AGENCY, Release of Sites from Regulatory Control on Termination of Practices, IAEA Safety Standards Series No. WS-G-5.1, IAEA, Vienna (2006)."					
JAPAN	14	3.148/4	or are disposed of to an authorized radioactive waste management facility.	Clarification.	Y			
ENISS	A35	3.148.	An authorization for an activity involving the use of radiation sources may be cancelled because the radiation sources are no longer required or because the regulatory body has taken an enforcement action. The regulatory body should ensure that the radiation sources are transferred to an authorized party that possesses a valid authorization [3] or are disposed of to an authorized waste management facility.	Fully covered by 3.46 and 3.135	Y			

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – NOTIFICATION AND AUTHORIZATION (3.69-3.148)								
			~~The regulatory body should provide guidance on radiological criteria for the removal of regulatory control from materials, facilities and sites. Further information is provided in [33].~~					

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COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
USA	18	p. 49 3.149	Following the quote from GSR Part 1, insert: The authorized party is fully responsible for the work performed on its behalf by vendors or contractors.	There is a need to ensure that the authorized facility takes full responsibility for the work performed on its behalf by a vendor or contractor			Y	In this para the responsibilities of the regulatory body are discussed, not those of the authorised party.
USA	19	p. 50 3.150/ Line 12	Add the following sentence: **Regulatory bodies should participate in international convention and peer reviews as necessary such as: Convention on Nuclear Safety (CNS); Joint Convention on the safety of Nuclear Fuel and the Safety of Radioactive Waste management (Joint Convention); and Integrated Regulatory Review for Safety (IRRS). In addition**, the review and assessment process should include checks on the site and elsewhere to verify the claims made in the submissions. For facilities or activities with significant risk,	Completeness to encourage participation in international conventions and peer reviews for safety.			Y	Req. 14 of GSR Part 1: requires this for the government.

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			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.					
ENISS	A36	3.150.	The review and assessment process is a critical appraisal, performed by the regulatory body, of information submitted by the authorized party or which comes from inspection, information on events, relevant operational experience at national and international level or other specified reports (e.g. records, comprehensive safety reviews, dose records) to demonstrate the safety of the facility or activity. Review and assessment are undertaken in order to enable the regulatory body to make a decision or	First deletion included in the sentence before and also in the regulations chapter. Deletion of start of second sentence for clarification. “Elsewere” is unspecific and should be avoided in a guiding document, as it does not give guidance. On-site is sufficient. Last sentence covered fully by 3.100 (n), repetition not needed here.	Y			

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			series of decisions on the acceptability of the facility or activity in terms of safety. The process consists of examining the authorized party`s submissions, and other information as described above, on all aspects relating to the safety of the facility or activity. ~~It should include consideration of normal, abnormal and accident conditions, including human errors that have the potential for causing the exposure of workers or the public or radiological hazards to the environment. This safety analysis should be as complete as possible, and o~~One of the initial tasks of the review and assessment is to confirm its completeness. The review and assessment process should include checks on ~~the~~ site ~~and elsewhere~~ to verify the claims made in the submissions. ~~For~~					

COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			~~facilities or activities with significant risk, 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.~~					
ENISS	A37	3.151.	~~A primary basis for review and assessment activities is the information submitted by the authorized party. A thorough review and assessment of the authorized party's technical submission should be performed by the regulatory body in order to determine whether the facility or activity complies with the relevant safety objectives, principles and criteria. In doing this,~~ the regulatory body should acquire an understanding of the design of the facility or equipment,	Stated in the para before and many other paras.	Y			

COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			the safety concepts on which the design is based and the operating principles proposed by the authorized party, to satisfy itself that:					
ENISS	25	3.151.	A primary basis for review and assessment activities is the information submitted by the authorized party. A thorough review and assessment of the authorized party's technical submission should be performed by the regulatory body in order to determine whether the facility or activity complies with the relevant safety objectives, principles and criteria. The regulatory body should take into account assessments done in the past as well as assessments by other states for the same or similar facilities or activities. Through the assessments ~~In doing this,~~ the regulatory body should acquire an understanding of the design of the facility or	To avoid unnecessary work and to speed up the licensing process, we consider it as necessary to take into account other assessments.		Comment accepted. Note that the first part of 3.151 (now 3.149) was deleted, see ENISS #37.		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			equipment, the safety concepts on which the design is based and the operating principles proposed by the authorized party, to satisfy itself that: …					
ENISS	26	New para between 3.151 and 3.152	If a vendor has applied for an authorization for the same design in two or more countries, the regulatory bodies of the concerned countries could join their effort and set up a joint team for review and assessment. The conclusion could be a joint statement with potentially different caveats for the counties concerned.	To introduce the idea of assessing one design by different reg. body, as e.g. done for some topics of the EPR in Europe.			Y	It is the responsibility of the regulatory body.
RUSSIA	7	3.152	Accordingly, the regulatory body should have a fu11 time staff capable of either performing regulatory reviews and assessments, or evaluating any assessments performed for it by consultants or technical support organization.	To add this item with words: "or technical support organization".	Y			
FINLAND	14	3.154 b	Consider adding:	It is important to analyse the operational procedures to		“To determine whether the		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			"To determine whether the operational limits and conditions are consistent with the regulatory body's requirements, the operational characteristics of the facility or activity, and the state of knowledge and operational procedures and experience; and to determine whether an adequate level of safety is being maintained and improved;…"	assess that they are fulfilling the regulatory requirements. It is important to maintain an adequate safety level but according to good culture also continuous improvement should be practiced.		operational limits and conditions are consistent with the regulatory body's requirements, the operational characteristics of the facility or activity, and the state of the art and operational procedures and experience; and to determine whether an adequate level of safety is being maintained and improved;…"		
FINLAND	15	3.154 c	Consider adding: "Special consideration should be given to management commitment to safety and	Management commitment is an essential success factor, setting the scene for organizational culture.			Y	Included in 3.154 (a)

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			security.”					
ISRAEL	45	3.154(c)	"…To determine whether the authorized party`s personnel meet the regulatory requirements, in terms of ~~both~~ availability, qualifications, ~~number~~, competence and any other specific requirements ~~reliability~~ demanded by the regulatory body;…"	Requirements context.			Y	“availability” is covered in “numbers” and “qualification” is included in “competence”
ENISS	A38	3.154.	~~The specific objectives of the review and assessment will depend on the stage of the lifetime of the facility or activity. Examples of these specific objectives include but are not limited to the following:~~ ~~(a) …~~ ~~…~~ ~~(k)…~~	All points listed here have been stated before (e.g. 3.100) and are covered by 3.153. We suggest deletion for avoiding double information and shortening of the document.			Y	Para 3.100 (now 3.101) concerns authorisation, not review and assessment, whereas para 3.153 (now 3.151) doesn’t cover the content of 3.154 (now 3.152).
JAPAN	15	3.154 (g),(j)	a disposal facility → radioactive waste disposal facility waste disposal facilities →	Making the wording consistent through this document taking account the other comment such as No.7, 8, 9 and so on.	Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			radioactive waste disposal facilities					
ENISS	27	3.155.	Even if the same or a similar design or ~~a similar~~ facility has been authorized in another State, the regulatory body should still perform its own independent review and assessment. It may take into account the review and assessment made by the other State, and also new experience and knowledge that have been gained since that review and assessment. It should also take into account the differences in the regulatory environment ~~in safety objectives and requirements~~ between the States. The regulatory bodies of the States concerned should establish close contact in order to facilitate the review and assessment process.	Should also include same designs and facilities. The safety objectives should be in compliance with the IAEA SF and should not be different – with rewording it to regulatory environment differences in the legal system, the resulting regulatory system as well as in safety requirements can be covered.	Y			
ENISS	A39	3.156.	~~The requirements for periodic reporting and progress reporting and the general~~	Content fully included in other paras, e.g. 3.112/113 and 3.32 – no added value here.	Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			~~criteria for notifying the regulatory body of events, incidents or accidents should be specified in regulations or authorization conditions.~~					
ENISS	A40	3.157-3.160		These are guidelines for the chapter of regulations/guides or authorization conditions and not for review and assessment – suggestion move to there.			Y	The information provided in these paras is useful.
SPAIN	4	3.158	It is suggested to add the underlined text: During the stage of site evaluation and construction, reports should be prepared to keep the regulatory body informed of the progress of the project. The reports should cover, <u>at least</u>: - <u>Relevant construction and manufacturing events</u>			Incorporated into para 3.154		
SPAIN	5	3.159	It is suggested to add the underlined text:			Incorporated into para 3.154		

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			During commissioning and operation, reports should be prepared to demonstrate to the regulatory body the continuing safety of the facility. The reports should cover, at least: - Relevant operational safety and performance events					
GERMANY	38	3.160	1st sentence: "In order to enable the regulatory body to consider the release of any facility from regulatory control, or to require institutional controls for the post-closure phase of a radioactive waste disposal facility, reports should include details of, but not limited to: …"	Clarification and completion.	Y			
JAPAN	16	3.160/1	to consider the release of any facility or site from regulatory control,…	Clarification.	Y			
JAPAN	17	3.160/3rd hyphen (p.53)	results of environmental monitoring including final radiological survey and other	Making the description consistent with DS452, DS403 and WS-G-5.1.	Y			

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			performance confirmation programmes.					
EC	1	3.160	Revision proposed	"…reports or *safety case* should also include such details of:…" contains the term "safety case" for the first time in DS473 It should be defined or introduced before using.			Y	"Safety case" is defined in IAEA glossary.
ENISS	28	3.161	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 should be subjected to review and assessment by the regulatory body~~, in addition to any violations and non-compliances~~. Whilst this source of information may only represent a small part of the review and assessment, it is an essential part as it provides factual insights on how the authorized party complies with regulatory requirements.	Violations and non-compliances do not need to be stressed here.			Y	The review includes violations and non-compliances.

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
ENISS	A41	3.162.	~~Review and assessment should be carried out in a formalized approach.~~	Fully covered by 3.37			Y	It is an important statement necessary in this part of the text too.
ENISS	A42	3.164.	~~As a practical matter, review and assessment of each area may start at an earlier stage and continue into subsequent stages. Also, depending on the arrangements made at the national level and the nature of the facility or activity, review and assessment of some areas may be combined.~~ Since this Safety Guide covers a wide range of facilities and activities, it is not possible to provide details of specific areas that should be subject to review and assessment at each stage of the lifetime of facilities or activities of each type. However, this section provides a general overview of major areas for review and assessment; a graded approach should be used to determine	Fully covered by 3.121	Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			how the respective areas should be considered depending on the nature of the facility or activity and the risks associated with them.					
ENISS	A43	3.165-3.180	Delete all paras and include missing information in 3.124ff.	3.124ff give all needed guidance on site evaluation and the other topics – there is no need to restate it here and there is no added value here – suggestion, just state the areas for review, like: • Site evaluation • Design • etc.			Y	Detailed information about these elements should remain in this chapter.
ISRAEL	46	3.166	"3.166… The ~~process~~ period during which ~~of~~ review and assessment of the site characteristics have to be considered, could take many decades and indeed may last into a period of institutional control following closure of the facility…" **One might understand that the process itself (of**	Clarity See text in **bold**			Y	The existing text is clearer.

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			performing review and assessment) can be that long.					
JAPAN	18	3.166/1	For radioactive waste disposal facilities,…	Clarification.	Y			
ISRAEL	47	3.174	"3.174… The comprehensive safety review should enable the regulatory body to judge whether it is acceptable for the facility to continue to be operated and for how long. ~~until the next comprehensive safety review is carried out….~~"	Clarity			Y	Reference in GSR Part 1 Req. 26.
EC	2	3.174	…assessed and the regulatory body notified. Possible ways of meeting …	"When a review shows that the facility or activity does not meet current standards and operating practices, the significance of the shortcomings should be *assessed*…" Is it enough if only the authorized party assesses or should the regulatory body be involved in particular when safety is concerned?	Y			
JAPAN	19	3.176/1-2	…the initial ~~outline plan for~~	Making the description	Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			decommissioning plan should be updated by the authorized party…	consistent with DS452 and DS403.				
JAPAN	20	3.177/1-5	The first two ~~and the second texts~~ sentence in this should be changed to such texts as follows; Aspects of decommissioning typically include planning for decommissioning, conducting decommissioning actions and terminating the authorization for decommissioning.[16] Decommissioning actions involve decontamination, dismantling and removal of structures, systems and components (SSCs), including management of radioactive waste and radiation protection, as well as radiological surveys to support decommissioning.	Making the description consistent with GSR Part6 and relevant Safety Guides such as DS452.		Aspects of decommissioning typically include planning for decommissioning, conducting decommissioning actions and terminating the authorization for decommissioning.[16] Decommissioning actions are the procedures, processes and work activities (e.g. decontamination, dismantling and removal of structures, systems and		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
						components (SSCs)) as described in the approved final decommissionin g plan.		
UK	8. EA	3.177	"design for decommissioning" should be emphasized here or elsewhere in the document				Y	Recommendations covering the review and assessment of the decommissioning aspects of the design are addressed in original para 3.167 (now 3.161) with reference to the decommissioning plan. This para also includes a cross reference to the assessment of the design features covered in SSR-2/1, ref [31]. This would include SSR-2/1 Requirement 12, which covers the design features to

COMMENTS BY MEMBER STATES					RESOLUTION			
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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
								facilitate decommissioning.
JAPAN	21	3.178/1	*Closure of a radioactive waste disposal facility* 3.178. To enable a radioactive waste disposal facility to proceed beyond…	Clarification.	Y			
JAPAN	22	3.178/2-4	Safety case including d~~D~~etailed proposals for closure and for assessment of the safety of a disposal facility in the long term is required to ~~should~~ be reviewed ~~and assessed~~ by the regulatory body.	Making the description consistent with SSR-5 (e.g. See para.4.6 and Req.14).		Safety case including detailed proposals for closure and for assessment of the safety of a disposal facility in the long term is required to be reviewed and assessed by the regulatory body.		
JAPAN	23	3.178/8	…aspects of monitoring and surveillance, and irretrievability…	Term “monitoring and surveillance” is appropriate.			Y	The original text is clear enough.
JAPAN	24	3.180/5	…the remediated ~~rehabilitated~~	Amendment to use more	Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			site…	appropriate term which is used in used in GSR Part3 and so on.				
ENISS	A44	3.185.	~~The regulatory body should provide internal guidance on the procedures to be followed in the review and assessment process and guidance on the safety objectives to be met. Detailed guidance on specific topics for review and assessment should also be provided, as necessary.~~	Fully covered by 3.36b and also covered by 3.186	Y			
SPAIN	5	3.186	A final step should be added to the process: <u>6) Reporting and documentation</u>	Review and assessment analysis and conclusions should be recorded and reported.	Y			
ENISS	A45	3.187.	~~A major feature of the authorized party´s safety documentation will be its safety assessment, including the analysis of normal, abnormal and accident conditions. However, the importance of the other aspects of the safety documentation~~	Fully covered by 3.89 and 3.100	Y			

COMMENTS BY MEMBER STATES					RESOLUTION			
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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			~~should be recognized: the safety of a facility or activity is based on sound engineering and good management, and safety analysis is a confirmation of the adequacy of these and not a substitute for them.~~					
ENISS	A46	3.188.	~~At all stages of the authorization process, the regulatory body should have a clear understanding of the safety objectives and regulatory requirements that will be used in the review and assessment. The safety objectives and regulatory requirements should be communicated to the authorized party for guidance in preparing its documentation.~~	Fully covered by 3.10 and especially 3.28		At all stages of the authorization process, the regulatory body should have a clear understanding of the safety objectives and regulatory requirements that will be used in the review and assessment.		
ENISS	A47	3.189.	~~Safety objectives and regulatory requirements should specify safety goals for levels of performance of the safety structures, systems and~~	Fully covered by 3.12		Retaining important information and for completeness		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			~~components 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.~~			and understanding, moved to para 3.14.		
ENISS	A48	3.190.	~~The regulatory body may develop safety objectives and requirements itself or it may adopt objectives and requirements that have been developed and issued by international organizations or by regulatory bodies in other States. If these objectives and requirements are to be adopted, a good understanding of their basis, use and effectiveness in other States should be acquired by means of appropriate contact with the relevant bodies. They should be adopted as necessary for~~	Fully covered 3.53 and 3.54.		Retaining important information, completeness and understanding, moved to para 3.13.		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			~~specific purposes.~~					
ENISS	29	3.191.	~~In formulating the content and structure~~ When collecting and structuring ~~of~~ the applicable safety objectives and requirements to be used in its review and assessment process, the regulatory body should consider a broad range of sources, including:	For clarification, as all safety objectives and requirements are stated in national regulations, as stated in the chapter regulations and guides.	Y			
ENISS	A49	3.192.	~~The safety objectives and regulatory requirements should cover, among other things, as appropriate:~~ ~~– Prevention of, rather than mitigation of accidents;~~ ~~– 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~~	This is guidance for requirement development and not for review. Also this is stated in many other IAEA safety series documents, e.g. SSR 2-1 on requirement level. We suggest deletion here to avoid confusion of what should be developed in the preface of a review.		Retaining important information, completeness and understanding, moved to para 3.15. Note, text also modified due to comments by the IAEA Coordination Committee, i.e. reference to		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			~~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 generated, including the future decommissioning stage;~~ ~~– Emergency preparedness and response.~~			passive safety.		
IAEA CC-	5	3.15 (V5),	Careful consideration in the					

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
SAS		was 3.192 (V3)	case of using ~~Preference for the use of~~ passive systems ~~over an active or operator based safety systems~~					
ENISS	30	3.193.	The regulatory body might not have, in advance, detailed ~~safety objectives and~~ requirements covering all the areas that are subject to review and assessment since, even with a fairly comprehensive set of safety objectives and requirements, some aspects of safety may not be covered. The regulatory body should evaluate the acceptability of the proposals put forward by an authorized party or applicant on a case-by-case basis against general principles stated in laws and regulations. Consideration of the proposals may lead to the production of additional regulations and guides or in the modification of existing ones (see also para 3.49ff).	The safety objective is stated in SF-1 and is not detailed but an objectives. For clarification	Y			

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MEMBER STATES COMMENTS on DS473 Version 3 (STEP 8)
&
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COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
ENISS	A50	3.195.	~~*Comparison with regulations, guides and industrial standards*~~ ~~The regulatory body should establish which requirements, based on regulations, guides and industrial standards are applicable to the facility or activity in question and to be placed on the authorized party. Where no such requirements 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.~~	Fully covered by 3.37 – no added value here.	Y			
RUSSIA	8	3.195	Where no such requirements exist, the regulatory body should use in review current achievements of science and technology	To replace the second sentence of this item with the following: "Where no such requirements exist, the regulatory body should use current achievements of science and technology", i.e. results of		Par 3.195 deleted (see previous comment)		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
				scientific research, the approved engineering practice, etc. The regulator can develop the new rules and regulations only after accumulation of necessary experience.				
ISRAEL	48	3.196	"3.196. The regulatory body may decide to perform ~~a limited number of~~ confirmatory calculations to check that the authorized party has justified a particular aspect of safety correctly, for specific purposes. ~~However, in general it is not a resource-effective approach to carry out a significant amount of confirmatory calculations and~~ where additional analyses are deemed necessary, the regulatory body should require the applicant or authorized party to perform them…" **We suggest to leave to the decision of the Regulatory Body to perform any selected**	See text in **bold**	Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			amount of confirmatory calculations not using effectiveness as a limiting factor.					
JAPAN	25	3.196(a),(b)	the authorized party's safety case	Typo.	Y			
JAPAN	26	3.196(d)/2	particularly important for radioactive waste disposal facilities);	Clarification.	Y			
ENISS	A51	3.197.	~~The review and assessment process by the regulatory body 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. This safety analysis should cover both normal, abnormal and accidents conditions in order to demonstrate that the safety of the facility or activity meets the safety objectives and~~	First part fully covered by para 3.100 Second deletion because fully covered by 3.85p and other paras (e.g. 3.80). No need to restate here.		The review and assessment process by the regulatory body consists in examining the submissions from the authorized party on its managerial arrangements, engineered systems and operational procedures and		Important information retained.

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			~~requirements of the regulatory body. It should be the responsibility of the regulatory body to determine whether these submissions have provided a sufficiently complete, detailed and accurate demonstration of this.~~ In carrying out the review and assessment, the regulatory body may find it useful to perform its own analyses or research. ~~Any input of this nature by the regulatory body should in no way compromise or diminish the authorized party´s responsibility for the safety of the facility or activity.~~ The following sections deal with major aspects of such verification; further details of topics for these aspects are set out in the Appendix 3.			on the safety analysis for the facilities or activities. This safety analysis should cover both normal, abnormal and accidents conditions in order to demonstrate that the safety of the facility or activity meets the safety objectives and requirements of the regulatory body. It should be the responsibility of the regulatory body to determine whether these submissions		

COMMENTS BY MEMBER STATES					RESOLUTION			
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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
						have provided a sufficiently complete, detailed and accurate demonstration of this. In carrying out the review and assessment, the regulatory body may find it useful to perform its own analyses or research. The following sections deal with major aspects of such verification; further details of topics for these aspects are set out in the Appendix 3.		
ENISS	A52	3.198.	~~In carrying out its review and~~				Y	No reasoning is

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			~~assessment, the regulatory body should determine, if applicable, whether the authorized party has defined criteria which meet the safety objectives and requirements relating to:~~ ~~(1) Engineering design;~~ ~~(2) Operational and managerial aspects;~~ ~~(3) Normal, abnormal and accident conditions.~~					provided. The information included in this para is considered useful.
ISRAEL	49	3.199	"3.199…-Prevention and mitigation of failure of the barrier itself and prevention and mitigation of failure of related systems in normal, abnormal and accident conditions;…" **We suggest to use "prevention and mitigation" (See GSR Part 3)**	See text in **bold**	Y			
ENISS	A53	3.199.	~~The general aim of the regulatory review of a safety analysis report [9], whether based on deterministic or~~		Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			~~probabilistic analyses, should be to verify that for each identified barrier to the release of radioactive material the safety measures are sufficient to provide adequate assurance at the following levels:~~ ~~– Prevention of failure of the barrier itself and prevention of failure of related systems in normal, abnormal and accident conditions;~~ ~~– Monitoring of any parameter significant to the integrity of the barrier, to allow the initiation of either manual or automatic actions in order to prevent any evolution towards an unsafe condition;~~ ~~– Safety action to prevent or limit the release of radioactive material~~					

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			~~if the barrier has failed;~~ ~~– For certain applications and depending on the associated risk, the mitigation of consequences.~~					
ENISS	A54	3.200.	~~The safety analysis should demonstrate that the safety functional requirements on the structures, systems and components and operations are sufficient to ensure adequate safety. The review and assessment by the regulatory body should ensure that the authorized party has performed a suitable and sufficient safety analysis to confirm the requirements on the structures, systems and components and has used the results to demonstrate that the requirements will be met by the equipment and in operational procedures. Specific features that should be~~	This is guidance for requirement development and not for the review. Also this is stated in many other IAEA safety series documents, e.g. SSR 2-1 on requirement level. We suggest deletion here to avoid confusion of what should be developed in the preface of a review.		The review and assessment by the regulatory body should ensure that the authorized party has performed a suitable and sufficient safety analysis to confirm the requirements on the structures, systems and components and has used the results to demonstrate that the requirements will be met by		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			~~subject to review and assessment include:~~ ~~(a) Definition and categorization of the Safety functions;~~ ~~(b) Identification and classification of structures, systems and components;~~ ~~(c) Ensuring the quality of engineered features in terms of good engineering practice or as set out in the regulatory requirements;~~ ~~(d) Demonstration of control of the facility or activity in normal, abnormal and accident conditions, with account taken of automatic systems, the human–machine interface and operating instructions;~~			the equipment and in operational procedures. Specific features that should be subject to review and assessment include: (a) Definition and categorization of the Safety functions; (b) Identification and classification of structures, systems and components; (c) Ensuring the quality of engineered features in terms of good		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			~~(e) Adequacy of the safety management system, covering structures, systems and components and operational aspects such as the training, qualification and experience of the authorized party´s personnel and quality assurance procedures.~~			engineering practice or as set out in the regulatory requirements; (d) Demonstration of control of the facility or activity in normal, abnormal and accident conditions, with account taken of automatic systems, the human–machine interface and operating instructions; (e) Adequacy of the safety management system, covering structures,		

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						systems and components and operational aspects such as the training, qualification and experience of the authorized party´s personnel and quality assurance procedures.		
RUSSIA	9	3.200 (c)	Ensuring the quality of engineered features as set out in the regulatory requirements or in terms of good engineering practices/	To write down this item as it is proposed, having put on the first place the regulation requirements, and on the second - good engineering practice.	Y			
ENISS	A55	3.201.	~~The regulatory body should review reports submitted periodically by the authorized party, in compliance with established requirements, so as to monitor the operational safety performance of the facility or activity.~~				Y	No reasoning provided.

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			~~Additionally, reports on safety significant events should be thoroughly reviewed by the regulatory body.~~					
ISRAEL	50	3.202	"3.202. The regulatory body should ensure that an effective system for the feedback of operational safety experience is in place, that ~~no~~ safety related events will be ~~go~~ undetected, ~~as an utmost important goal~~…" **We suggest to try to avoid unrealistic goals, in general, and specifically when and where the control of the Regulatory Body on those goals is limited.**	See text in **bold**			Y	This part of the para was deleted. See ENISS A56 below.
ENISS	A56	3.202.	~~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~~			The regulatory body should ensure that an effective system for the feedback of operational		

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			~~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, usually by a team with appropriately selected areas of expertise, to confirm that the event was adequately investigated, the root causes were correctly identified, and the corrective and remedial actions taken were adequate. 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~~			safety experience, including adverse events, is in place. If the severity of the event warrants it, the regulatory body may conduct or arrange for an independent investigation, usually by a team with appropriately selected areas of expertise, to confirm that the event was adequately investigated, the root causes were correctly identified, and the corrective and remedial		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			~~activities from which lessons may be learnt.~~			actions taken were adequate. The regulatory body's review should cover the identification of lessons to be learned and the sharing of safety related information. Operational experience feedback 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		

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						learnt.		
ENISS	A57	3.203.	~~A well-engineered facility or activity may not achieve the required level of safety if it is not operated or managed well. Review and assessment by the regulatory body should therefore include consideration of the authorized party´s organization, management, procedures and safety culture [10], which may affect the operation of the facility or conduct of the activity. The authorized party should be required to demonstrate by documentary means that there is an effective safety management system in place which gives safety the highest priority.~~	First sentence is not needed, all others are covered by 3.85 and 3.100			Y	3.100 (now 3.101) is about what information should be submitted and not what the regulatory body should review.
ENISS	A58	3.204		All topics mentioned there should be placed in the regulations and guides section – this is not something one expects in the review section.			Y	This text fits better in review and assessment and not in regulations and guides section.
ISRAEL	51	3.204(5)	"…(5) Whether the authorized	See text in **bold**			Y	The regulatory body

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			party ~~has systems in place to ensure that it acquires and~~ retains adequate capability within its organization to understand the nature, substance and detail of the advice given to it by contractors and is able to judge the soundness of that advice…." **This requirement seems to be too general and probably not realistic to be set as a goal for the Regulatory Body and therefore it is recommended to consider to present it in a limited scope.**					has to look at the system of the authorised party.
ENISS	A59	3.205.	~~The review and assessment by the regulatory body should cover all aspects of the authorized party´s managerial and organizational procedures and systems which have a bearing on safety, such as:~~	Content fully covered by 3.100.			Y	Par 3.100 (now 3.101) does not cover the content of 3.205 (now 3.194). The regulatory body has to look at the management system

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			~~feedback of operational safety experience; the development of operational limits and conditions; the planning and monitoring of maintenance, inspection and testing; the production and revision of safety documentation; and the control of contractors (see Appendix 3 for further details). The regulatory body should also review and assess the authorized party´s procedures for the control and justification of changes to the authorized party´s managerial and organizational procedures and systems which could have an impact on safety.~~					and organisational procedures of the authorised party. See comment ENISS A57 on 3.203.
ENISS	A60	3.206.	~~The assessment of routine operation is directed towards the determination of occupational radiation doses and radioactive discharges [3]. These consequences will be compared with those safety objectives, requirements and~~	Content fully covered by 3.24 and 3.100			Y	Paras 3.24 (now 3.27) and 3.100 (now 3.101) do not cover 3.206 (now 3.195). See comment ENISS A57 on 3.203 and ENISS A59 on 3.205 above.

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			~~limits approved by the regulatory body, including applying the 'as low as reasonably achievable' (ALARA) principle. In the regulatory review and assessment of the authorized party´s submission, it should be determined whether the submission meets these objectives and requirements. In the review and assessment, particular attention should be devoted to a number of factors that influence the potential radiological consequences for people and the environment in routine operation, which include:~~ ~~(1) Inventory of radiation sources;~~ ~~(2) The occupational radiation protection programme and other matters relating to radiation protection;~~ ~~(3) Radiation protection of the public, with all pathways of~~						

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			~~exposure taken into account;~~ ~~(4) Radioactive waste management;~~ ~~(5) Discharge, dilution and dispersion of radioactive effluents.~~					
ENISS	A61	3.207.	~~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. Specifically, review and assessment should ensure that:~~ ~~(1) The operational limits and conditions and the bases for these have been determined;~~ ~~(2) The potential radiological consequences at the upper limits of this range have been considered;~~ ~~(3) It has been demonstrated that arrangements (including operating~~	Content fully covered by 3.24 and 3.100			Y	Paras 3.24 (now 3.27) and 3.100 (now 3.101) do not cover 3.207 (now 3.196). See comment ENISS A57 on 3.203, ENISS A59 on 3.205 and ENISS A60 on 3.206 above.

COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			~~procedures) which apply the ALARA principle are in place.~~					
ENISS	A62	3.208.	~~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.~~	Para misplaced in the review section, should be placed in the regulations and guides section.			Y	This doesn't relate to R&G
ENISS	A63	3.209.	~~The consideration of abnormal and accident conditions strongly influences the design limits for the safety systems and for most structures, systems and components needed for the operation of the facility or activity [9, 28]. It will also strongly influence the operational instructions and procedures that operating personnel should follow. In addition, the potential radiological consequences for people and the environment of abnormal and accident~~	Shorten para, as explanation is already stated in other sections of the guide.	Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
			~~conditions may be much more severe than those in routine operation. For this reason,~~ the major part of the review and assessment effort should be directed to the safety analysis of the abnormal and accident conditions provided by the authorized party. It should be performed in accordance with the potential magnitude and nature of the risks associated with the particular facility or activity.					
JAPAN	27	3.210/3	A comprehensive ~~complete~~ list of features, events and processes should be developed…	Amendment for a more appropriate description. (See para.5.40 of SSG-23)	Y			
FINLAND	16	Chapter "REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVIT	Add a sub-chapter: **Information security of review and assessment** The regulatory body should establish measures to ensure information security of the licensees' information subject	The regulatory body collects, receives, stores, handles, transmits, archives and disposes of information from all licensees. It becomes a significant depository of information, some of which is classified and some of which is important for accident			Y	This topic is already addressed in DS472 in Chapter 5, Section "Documentation of the IMS", specifically in paras 5.68-5.70.

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – REVIEW AND ASSESSMENT OF FACILITIES AND ACTIVITIES (3.149-3.212)								
		IES", e.g. after 3.212	to review and assessment. It should have appropriate information security processes, procedures, instructions and training in place for its staff considering the entire life cycle of information. Graded approach to security measures should be applied according to the classification and level of sensitivity and criticality of information. IAEA NSS Implementation Guide *Security of Nuclear Information, 23-G* should be consulted for guidance on classification schemes and information security measures.	management. Thus management of information security (confidentiality, integrity, availability of information) by the regulatory body is essential for national nuclear security and safety.				Note that DS473 and DS472 are complementary safety guides and should be read together.

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
ENISS	A64	3.214.	~~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 supplement the information and data needed for review and assessment.~~	No need to repeat content here, fully included in 3.23c and 3.38ff – move para 3.219 forward to 3.214 and delete 3.214		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 supplement the information and data needed for review and assessment.		
ISRAEL	52	3.217	"3.217…These inspections may include, ~~within reason,~~ unannounced inspections…."	See text in **bold**	Y			

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			It is suggested not to restrict the option to perform unannounced inspections.					
ENISS	31	3.217.	GSR Part 1 (Rev.1), para 4.52 [2] requires that the regulatory inspections cover all areas of responsibility of the regulatory body, and the regulatory body has the authority to carry out independent inspections. It is also required that regulatory inspectors have free access to any facility or activity at any time, within the constraints of ensuring operational safety at all times and other constraints associated with the potential for harmful consequences. These inspections may include, within reason, unannounced inspections. Inspections should at no point have the potential to compromise the safety of a facility or activity or its safe operation.	For clarification that inspections should not be contrary to safety.			Y	Already covered in the existing text.

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
USA	20	p. 67 3.222 Inspection Objectives	Consider adding in the Inspection Section that efforts should be made in prevention of non-compliances or performance degradation ('look ahead') rather than identification of non-compliances or degradation that has already occurred and imposing consequences (reactionary).	Inspection programs fostering a questioning attitude and forward thinking, as well as attention to detail for current or past non-concurrences are expected to lead to better overall safety results.			Y	In line with Req. 27 of GSR Part 1, the purpose of the inspection is to verify compliance with the requirements.
USA	21	p. 68 3.222 (b)	The authorized party has in place an effective management system, a corrective action program, and a strong safety culture and self-assessment systems for ensuring the safety of the facility or activity and the radiation protection of people and the environment;	Completeness			Y	A corrective action programme is a part of the management system.
ENISS	32	3.222.	Regulatory inspection is performed to make an independent check on the authorized party and the state of the facility or activity, and to provide a high level of confidence that authorized	Regulatory inspections are not done to ensure compliance with safety objectives, but to ensure, that the party does complies with laws, regulations, licence conditions and other regulatory			Y	The text as it stands includes useful details that should be included in a safety guide.

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			parties are in compliance with the ~~safety objectives prescribed or approved by the regulatory body. This should be achieved by confirming that:~~ ~~(a) All~~ applicable laws, regulations, ~~and~~ license conditions and other regulatory requirements as well as ~~all~~ relevant codes, guides and , specifications ~~and practices are complied with;~~ ~~(b) The authorized party has in place an effective management system and a strong safety culture and self assessment systems for ensuring the safety of the facility or activity and the radiation protection of people and the environment;~~ ~~(c) The required quality and~~	requirements (also state in 3.230). Futhermore the other detailed points are stated in other para and stating them again, does not add guidance. They are also included in the first sentence.				

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			~~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 contractors) possess the necessary competence for the effective performance of their functions throughout the whole lifetime of the facility and activity;~~ ~~(e) Deficiencies and abnormal conditions are identified and promptly evaluated and remedied by the authorized party and duly reported to the regulatory body as required;~~					

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			~~(f) Any other safety issue that is neither specified in the authorization nor addressed in the regulation is identified and appropriately considered;~~ ~~(g) Any lessons learned are identified and propagated to other authorized parties and suppliers and to the regulatory body as appropriate.~~					
ENISS	A65	3.223.	Specific responsibilities of the regulatory body with respect to inspection should include: − conducting planned inspections at all stages of the authorization process; − carrying out reactive inspections, if appropriate, in response to events, incidents or accidents; − identifying and	The deleted parts are named before and are not part of "Organization of Regulatory Inspection Function", which is the title of the chapter. The last two points can be deleted as well, as they are covered by the guidance chapter and enforcement chapter Furthermore it is unclear, why		Specific responsibilities of the regulatory body with respect to inspection should include: − conducting planned inspections at all stages of the authorizati		

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			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~~	this section is needed, as guidance is made in 3.38ff regarding inspections.		on process; − carrying out reactive inspections, if appropriate, in response to events, incidents or accidents; − identifying and recommending necessary changes to the requirements approved by the regulatory body, specified in the authorizati		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			~~up to date;~~ ~~– tracking recurrent problems 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.~~			on or contained in the regulations; – preparing reports to document its inspection activities and their findings; – ensuring that the authorized party has adequate, comprehensive and up to date information on the status of the facility or activity and		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
						information for demonstrating its safety, and a procedure to maintain this information up to date; − tracking recurrent problems and non-compliance; − developing procedures and directives as necessary for the effective conduct		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
						and administration of the inspection programme; − determining and recommending suitable enforcement actions when non-conformance with requirements is encountered.		
ENISS	A66	3.227.	~~Regulatory inspection programmes should be comprehensive and consistent with the overall regulatory strategy. The inspection programmes should be thorough enough to ensure that the regulatory objectives and requirements are met thereby providing the regulatory body~~	Covered already by 3.38ff and other paras of the guide – added value not seen.			Y	The details provided are not covered in 3.38 (now 3.41) which is about procedures for inspectors.

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			~~with a high level of confidence that authorized parties are effectively maintaining the safety of their facility and activities. The inspection programme should also be developed so that the regulatory body can determine if the authorized party has an effective self-assessment process capable of prompt identification and correction of actual and potential problems and conducts activities in accordance with previously established high quality procedures.~~					
ENISS	A67	3.228.	~~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 investigation and~~	Stated in many para before, e.g. 3.223			Y	The details provided are not covered in 3.223 (now 3.212).

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			~~follow-up of events and deviations from normal operation;~~ ~~• the submission of information on key operational safety parameters by authorized parties.~~ On-site inspection[6] 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.					
ENISS	33	3.229.	The regulatory inspection programme should give due consideration to technology, human as well as organizational (leadership and management system) factors. Accordingly, the inspectors' training and qualification program should also be tailored to develop competencies of regulatory inspectors in these areas.	The appointment of specialists should be also mentioned in the guide, as it is common, that some inspections are done by other staff then regulatory staff.	Y			

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			Independent specialists (e.g. TSOs) might be also engaged for inspections as appropriate and allowed by the regulatory system.					
ENISS	34	3.230.	In addition to verifying compliance with all applicable regulatory requirements, the regulatory body's inspection programme should be such as to provide a general sense of~~-~~ ~~the 'safety' of operations. Perspectives on safety in general should be aided by the use of indicators of the potential for degraded~~ safety performance. The more common indicators ~~of degraded~~ for safety performance include, but not limited to: • ~~poor~~ housekeeping; • ~~poor~~ financial stability; • ~~insufficient~~ staffing situation; • ~~high~~ turnover of staff; • ~~poor~~ record retrieval	To stick to common understood terms and a more positive wording.	Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			systems; • ~~lack of~~ set investigation levels; • ~~lack of~~ procedures to be followed in the event that investigation levels are exceeded; • ~~inadequate~~ training situation, including ~~;~~ ~~• lack of~~ retraining of staff;~~-~~ • ~~higher than average~~ occupational exposures for the type of facility or activity; • Repetitive failures of important facility equipment (reliability); • ~~Frequent~~ unavailability of the facility; • ~~Increasing~~ frequency of safety allegations or other enforcement actions.					
ISRAEL	53	3.234	"3.234. The authorized party should be required to keep the regulatory body informed of its schedules for carrying out activities and tests of	Wider definition	Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			regulatory interest and should submit or make available to the regulatory body in a timely manner the procedures for these activities. To facilitate this process, the regulatory body should specify well in advance to the authorized party the activities and tests of which it wishes to be informed and possibly also to participate on-site…"					
ENISS	A68	3.237.	~~Regulatory inspection should include a range of planned and reactive inspections over the lifetime of a facility or activity and include inspections of other relevant parts of the authorized party's organization and contractors to ensure compliance with regulatory requirements.~~	Covered by 3.223			Y	In this section the types of inspections are described.
ENISS	A69	3.239.	~~Planned inspections, either announced or unannounced, are carried out in fulfilment of, and in conformity with, a~~	Stated before, e.g. 3.29 and others. No added guidance here.			Y	In this section the types of inspections are described.

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			~~structured and largely prearranged or 'baseline' inspection programme developed by the regulatory body. They may be linked to authorized party schedules for the performance or completion of certain activities at all stages of the authorization process.~~ Planned inspections differ from reactive inspections in that they are scheduled in advance by the regulatory body ~~and are not initiated because of unusual or unexpected circumstances~~. Planned inspections provide an opportunity for the examination of the authorized party's activities in order to confirm the authorized party's performance and to identify potential problems at an early stage.	Second deletion, as stated in 3.242				
SPAIN	6	3.239	Planned inspections, either announced or unannounced, are carried out in fulfilment of,				Y	Prefer to use authorization process.

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			and in conformity with, a structured and largely prearranged or 'baseline' inspection programme developed by the regulatory body. They may be linked to authorized party schedules for the performance or completion of certain activities at all stages of the ~~authorization process~~ lifecycle					
ENISS	A70	3.243.	~~Reactive inspections, by individuals or teams, are usually initiated by the regulatory body in response to an unexpected, unplanned situation or incident in order to assess its significance and implications and the adequacy of corrective actions. A reactive inspection may be occasioned by an isolated incident or a series of lesser events occurring at the particular facility or activity under consideration. Similarly, a reactive inspection may be~~	All deleted parts are logically fully included in 3.242 and don't need further guidance.			Y	3.243 (now 3.233) provides the explanation when to conduct the inspections that is not covered in 3.242 (now3.232).

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			~~made in response to a generic problem encountered at another facility or activity or identified by the review and assessment staff of the regulatory body. Unlike planned inspections, which are scheduled, reactive inspections are only partly subject to planning by the regulatory body and may disrupt regulatory programmes and schedules. The regulatory body should assume that there will be a need for reactive inspections and should plan to meet its needs for staff and external experts accordingly. 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					

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			appropriate level of resources for use in inspections.					
ENISS	A71	3.244		This is general guidance for inspection and should not be place in the chapter "*Reactive inspections*" – we suggest moving to first part of chapter "INSPECTION OF FACILITIES AND ACTIVITIES"	Y			
ISRAEL	54	3.245(1)	"Determination of the root-reasons why…"	focusing			Yes	The existence phrasing is broader and includes the root-reasons.
ENISS	A72	3.245.	T~~he inspection programme of the regulatory body should include provisions for investigation of incidents and accidents by leaving some inspection resources available for reactive inspections. As such,~~ for more serious accidents or potentially serious accidents, or when operational parameters (e.g. doses) exceed regulatory limits or are significantly elevated, an	Deleted parts covered by 3.232	Y			

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			independent investigation should be conducted by the regulatory body and in some cases by other governmental bodies, in addition to the investigation to be conducted by the authorized party. There are usually two main objectives in an investigation of a serious accident by the authorities, which are not completely separable but which need to be distinguished: (1) Determination of the reasons why the accident happened so as to take measures to prevent its recurrence; (2) Consideration of the legal aspects concerning liability for the accident.					
ISRAEL	55	3.249	"3.249…However, the regulatory body should be sensitive to activities on-going	Comprehen-sive statement			Y	The first sentence already mentions that unannounced

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			at the site and to the potential consequences of unreasonable frequency of performing unannounced inspections."					inspections may take place only when feasible.
SPAIN	7	3.251	Please, check underlined text for possible mistake: Different approaches should be used in planning team inspections. Some team inspections may be broad in focus and cover a wide subject area ('horizontal slice') in the programme area of interest. For example, during a team of inspectors may assess the performance			…. during operation a team of ….		
ENISS	A73	3.253.	~~The particular aspects that should be considered in determining the intervals between inspections in the various areas and the level of effort to be applied in the inspection include:~~ ~~– the safety significance of~~	All topics covered by 3.220 and 3.231			Y	Section 3.231 (now 3.220) doesn't cover all the aspects which are considered in determining the frequency of an inspection.

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			~~the issues;~~ ~~– the inspection methods and approaches used (for example, the use of resident inspectors may influence the intervals and the scope and depth of inspections);~~ ~~– the performance record of the authorized party and the facility, for example, the number of violations, deficiencies, incidents and problems and the number of reactive inspections;~~ ~~– the results of regulatory review and assessment;~~ ~~– the type of facility or activity;~~ ~~– the personnel and other resources that must be available to the~~					

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			~~regulatory body;~~ ~~– the results of previous inspections.~~					
ENISS	A74	3.254.	~~To facilitate management of the allocation of resources for inspections, the regulatory body should develop specific inspection plans in which the aforementioned factors are taken into account. The inspection plans should be recorded in such a way that they can easily be modified to take into account continuing activities, and they should be reviewed periodically and modified as necessary.~~	Covered fully by 3.226 and 3.227			Y	Inspection plan is one element of an inspection programme.
ENISS	A75	3.258.	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.~~	Covered by 3.226	Y			
ENISS	A76	3.259.	~~Inspections by the regulatory~~	Covered by 3.226 and other	Y			

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			~~body should be concentrated on areas of safety significance. These are those items and activities affecting safety or processes important to safety which are identified as such in the safety documentation submitted by the authorized party or in the findings of the regulatory body's review and assessment, or which are stipulated in the conditions attached to the authorization (or regulations as appropriate).~~	paras – not need for duplication.				
USA	22	p. 76 3.260	3.260. The regulatory body's attention to major inspection areas does not begin and end in a single stage but continues with varying degrees of emphasis throughout the lifetime <u>lifecycle</u> of the facility or activity.	Change lifetime to lifecycle because Lifecycle has been defined and used throughout this document.	Y			
ENISS	A77	3.260.	~~The regulatory body's attention to major inspection areas does not begin and end in a single stage but continues with varying degrees of~~	Deleted parts are covered by 3.224 and other paras.		Accepted deletion of first part of sentence. "This Safety		

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			~~emphasis throughout the lifetime of the facility or activity.~~ This Safety Guide covers a wide range of types of facilities and activities, and it is not possible to provide for each type details of specific areas that would be subject to inspection at each lifecycle stage. ~~The degree to which the areas should be considered will depend on the nature of the facility or activity and the risks associated with it.~~ Major inspection areas for nuclear facilities are listed in Appendix 4.			Guide covers a wide range of types of facilities and activities, and it is not possible to provide for each type details of specific areas that would be subject to inspection at each lifecycle stage. The degree to which the areas should be considered will depend on the nature of the facility or activity and the risks associated with it. Major inspection areas for nuclear facilities are listed in		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
						Appendix 4.”		
ENISS	35	3.261.	Inspection should not be limited to the facility or activity itself and should cover any safety relevant central services which may be supplied at an authorized party’s headquarters or other offices such as safety assessment development, outage planning or training.	For clarification, as only safety relevant function can be of concern.	Y			
ENISS	36	3.262.	Whenever the authorized party makes use of the safety relevant services or products of a contractor, the regulatory body should include the contractor’s activities in its inspection programme in all lifecycle stages of the authorization process. This may comprise inspection of the design and manufacturing of components, including, where appropriate, activities performed in other States. Inspection of the authorized party’s contractors should only	For clarification, as only safety relevant function can be of concern.		…safety related …		

COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			be performed in connection with the authorized party so that the authorized party is not relieved from the prime responsibility for safety.					
GERMANY	39	3.265	Last sentence: "Preparation may include a review of the following: − regulatory requirements relating to the authorized facility or activity, and conditions on the authorization issued to the authorized party; − experience feedback relating to the inspection area; − findings of previous inspections and enforcement actions relating to the inspection area, and any unresolved issues from previous inspections; <u>− the analysis of incidents and accidents in the past;</u> − past correspondence between the regulatory body and the authorized party relating to the inspection area;	Completion.	Y			

COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			− the safety documentation and operational limits and conditions; − documentation on operation and design for the facility or activity; − the authorized party's management system."					
GERMANY	40	3.265a	Preparation includes the identification of necessary equipment for the inspection. Depending on the particular circumstances and the nature of the facility or activity this may include: − relevant inspection procedures and checklists as well as other relevant documents; − personal dosimeters; − the accreditation of the inspector; − appropriate survey meters or other necessary measuring equipment; − safety flashes, safety shoes, hard-hat etc.;	Please add a para dealing the equipment of the inspector.	Y			

COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			− a camera for documentation.					
ENISS	A78	3.265.	Before an inspection is carried out, the inspection personnel should be thoroughly prepared for the task. The type of preparation will depend on the type (planned, reactive, announce or unannounced, and team) and method (see para 3.267) of inspection. ~~Preparation may include a review of the following:~~ ~~− regulatory requirements relating to the authorized facility or activity, and conditions on the authorization issued to the authorized party;~~ ~~− experience feedback relating to the inspection area;~~ ~~− findings of previous inspections and enforcement actions relating to the~~	Deleted parts are covered by 3.222 and 3.231 as well as other paras.			Y	The preparation for the inspection is not covered elsewhere.

COMMENTS BY MEMBER STATES					RESOLUTION			
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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			~~inspection area, and any unresolved issues from previous inspections;~~ ~~– past correspondence between the regulatory body and the authorized party relating to the inspection area;~~ ~~– the safety documentation and operational limits and conditions;~~ ~~– documentation on operation and design for the facility or activity;~~ ~~– the authorized party's management system.~~					
USA	23	p. 77 3.269	Monitoring is particularly useful during the commissioning stage, or as a means of verifying corrective action at any stage over the lifetime <u>lifecycle</u> of the facility or	Change lifetime to lifecycle because Lifecycle has been defined and used throughout this document.	Y			
ENISS	A79	3.270.	~~The regulatory inspection~~	Fully covered by 3.230 –			Y	Not covered in 3.230

COMMENTS BY MEMBER STATES					RESOLUTION			
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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			~~programme should provide time for general surveillance of the facility or activity site by regulatory inspectors. Such surveillance is aimed at gaining an overall impression of the authorized party's capabilities and performance and is not restricted to specifically designated components and systems or designated scheduled activities and tests.~~ ~~Examples of areas for observation include:~~ ~~– workplaces;~~ - ~~…~~	added value not given.				(now 3.219).
ENISS	37	3.272.	The authorized party's personnel should be kept appropriately informed of inspection activities. These considerations can be partly satisfied by means of discussions and interviews. Interviews[7] with workers, the facility or activity manager and, as appropriate, with other	For clarification, that inspection should be based generally on MTO aspects and not on individual guilt (see also 3.289 and statement for naming individuals).		The authorized party's personnel should be kept appropriately informed of inspection activities. These considerations can be partly		

COMMENTS BY MEMBER STATES					RESOLUTION			
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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			senior managers should be standard features of most inspection visits. In interacting with the authorized party's staff, the inspector should exercise mature judgment concerning the prerogatives and responsibilities of the facility's management. Generally the focus of interviews should be to gain insides about technical, human or organizational topics and processes and not to be able to blame individuals.			satisfied by means of discussions and interviews.[7] Interviews with workers, the facility or activity manager and, as appropriate, with other senior managers should be standard features of most inspection visits. In interacting with the authorized party's staff, the inspector should exercise mature judgment concerning the prerogatives and responsibilities of the facility's		

COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
						management. Generally the focus of interviews should be to gain insights about technical, human or organizational topics and processes.		
ENISS	A80	3.273.	~~The authorized party should be required to record all activities, results and considerations important to safety at all lifecycle stages of the facility or activity.~~	Fully covered by 3.35, 3.100, 3.112/113	Y			
GERMANY	41	3.274	Documentation examined by regulatory inspectors may include: − procedures and schedules for maintenance and testing; − quality assurance records; − test results and data; − operational and maintenance records; − records of deficiencies and	Completion. Shift schedules can provide important information for the inspector about the adequacy of the staff.	Y			

COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			incidents; − modification records including modifications to management and operating procedures; − training records; <u>− shift schedules;</u> − dose records.					
ENISS	A81	3.274.	Examination of the authorized party's documentation contributes to the regulatory body's verification of the authorized party's compliance without unduly disrupting work schedules or interfering with the authorized party's primary responsibility for safety during all lifecycle stages. ~~Documentation examined by regulatory inspectors may include:~~ ~~− procedures and schedules for maintenance and testing;~~ ~~− quality assurance records;~~ ~~− test results and data;~~ ~~− operational and maintenance records;~~	Details fully covered by 3.35, 3.100, 3.112/113			Y	For completeness the examples are needed.

COMMENTS BY MEMBER STATES					RESOLUTION			
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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			~~– records of deficiencies and incidents;~~ ~~– modification records including modifications to management and operating procedures;~~ ~~– training records;~~ ~~– dose records.~~					
ISRAEL	56	3.275	"3.275. The regulatory body should examine ~~samples of~~ the authorized party's documentation in a manner sufficient to satisfy itself that the authorized…" **No need to be so specific by saying "samples". It is suggested to let to the decision of the Regulatory Body to select sampling, as a selected process.**	See text in **bold**	Y			
ENISS	A82	3.275.	~~The regulatory body should examine samples of the authorized party's documentation sufficient to satisfy itself that the authorized~~	3.274 covers sufficiently the content 3.275, no further guidance necessary.			Y	3.275 (now 3.263) concerns the purpose of the examination and not the content as is the case in

COMMENTS BY MEMBER STATES					RESOLUTION			
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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			~~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.~~					3.274 (now 3.262).
ISRAEL	57	3.278	"3.278…The regulatory confirmatory test should not place the facility in an unsafe condition nor contribute to a potential risk of any kind…."	Wider definition	Y			
ENISS	A83	3.278.	~~In some States, the inspection staff of the regulatory body conduct confirmatory tests and measurements as part of the inspection programme.~~ Tests of components and systems of the facility should only be undertaken after consultation with the facility's management. In most instances, these confirmatory	Deleted part covered by 3.277	Y			

COMMENTS BY MEMBER STATES					RESOLUTION			
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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			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. The regulatory confirmatory test should not place the facility in an unsafe condition.					
SPAIN	8	3.282	It is suggested to add the underlined text: Inspectors should note down their observations while conducting the inspections. Upon completion of the inspection, the inspectors should conduct an exit briefing with <u>authorized party's</u> senior management		Y			
ENISS	A84	3.285.	The purposes of inspection	Deleted parts covered by the			Y	We should give the

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			reports are to: − 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~~	first bullet, further details are provided also in para 3.286				complete picture of the purpose of inspection reports in accordance with GSR Part 1 para 4.51.

COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			~~actions taken;~~ − ~~record any findings or conclusions reached by inspectors;~~ − ~~record any recommendations by inspectors for future actions by the authorized party or the regulatory body and to record progress on recommendations from previous inspections;~~ − inform other members of the regulatory body; − contribute to maintaining an organizational memory.					
ENISS	A85	3.287.	Inspection reports should be distributed, or made available electronically, according to established procedures in order to provide for the following: ~~= a basis for future regulatory action;~~	Deleted parts redundant and covered by the other bullets or 3.288			Y	We should give the complete picture of the utilisation of inspection reports.

COMMENTS BY MEMBER STATES					RESOLUTION			
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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			− 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 staff responsible for regulations and guides;					

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			− a basis for periodic reviews of inspection findings, including trends and root causes; ~~= information to regulatory staff responsible for the development of requirements for authorization or new regulations;~~ ~~= a means of sharing information with other inspectors;~~ − a means of passing information to interested parties or governmental bodies; ~~= self-assessment activities~~.					
SPAIN	9	3.287	It is suggested to add the underlined text: Inspection reports should be distributed <u>to the regulatory body staff</u> , or made available electronically,				Y	It is already covered in several bullets of 3.287 (now 3.275).
ENISS	A86	3.290.	~~Documents that are made~~	Fully covered by 3.285 and			Y	3.285 (now 3.273)

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			~~available to the inspector by the authorized party during an inspection should be referenced in the inspection report. Inspection reports and copies of documents received in connection with the inspection should be stored in a manner that permits ready retrieval and that follows the applicable classification procedures.~~	3.286				provides for the purpose of inspections report and 3.286 (now 3.274(provides for the content of the report.
SPAIN	10	3.290	It is suggested to add the underlined text: … Inspection reports and copies of <u>relevant</u> documents received in connection with the inspection should be stored		Y			
ENISS	38	3.295.	A programme to monitor and follow up inspection findings should also be in place~~. The programme should include provisions for regular/periodic review and surveillance of the follow up action~~s to verify that the applicant or authorized	Periodic review of inspection findings does not take place, as they are normally closed after completion (included in last sentence). We suggest to combine the first and the second sentence.			Y	The text provides for the follow up actions after the inspection.

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COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – INSPECTION OF FACILITIES AND ACTIVITIES (3.213-3.295)								
			party is taking necessary actions in response to inspection findings. Upon satisfactory completion of the actions, the inspection findings should be closed in writing and necessary documents and records maintained.					

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COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – ENFORCEMENT OF REGULATORY REQUIREMENTS (3.296-3.322)								
USA	24	p. 84 3.301	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 lifecycle of a facility	Change lifetime to lifecycle because Lifecycle has been defined and used throughout this document.	Y			
ENISS	A87	3.302.	Regulatory enforcement ~~actions are actions taken by the regulatory body to address 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 procedures and practices, or of a facility or activity's structures, systems and components, ~~or managerial or operational procedures and processes,~~ that are necessary to ensure safety. ~~Enforcement actions should also include the imposition or recommendation~~	First deleted part covered by 3.297. Second deleted part covered by "procedures and practices" of the same sentence. Last part covered by 3.298		Regulatory enforcement actions are actions taken by the regulatory body to address 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		Retained 1st sentence to provide the objective of enforcement, i.e. to address non-compliances and suggested deletions accepted.

COMMENTS BY MEMBER STATES					RESOLUTION			
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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – ENFORCEMENT OF REGULATORY REQUIREMENTS (3.296-3.322)								
			~~of civil penalties and other sanctions, as appropriate, depending on national legislation.~~			aspect of its procedures and practices, or of a facility or activity's structures, systems and components, ~~or managerial or operational procedures and processes,~~ that are necessary to ensure safety. ~~Enforcement actions should also include the imposition or recommendation of civil penalties and other sanctions, as appropriate, depending on national legislation.~~		
ENISS	A88	3.303.	~~As the main purpose of~~	Introduction not needed and			Y	It is correct that the

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – ENFORCEMENT OF REGULATORY REQUIREMENTS (3.296-3.322)								
			~~enforcement is to ensure safety by deterring noncompliance and encouraging prompt identification and correction, enforcement actions should be chosen to achieve this end. However, the method chosen should also be appropriate to the severity of the violation or non-conformance. The next paragraphs describe some of the main enforcement methods followed by a discussion of the factors affecting the choice of method.~~	content fully included in paras 3.296 to 3.298 and 3.301ff.				paragraphs cited do cover the content; however, the introductory text helps the document flow and notes that factors affecting the choice of method are addressed below.
GERMANY	42	3.309	<u>In case of criminal acts it may be necessary to inform the law enforcement authorities.</u>	Completion. Please add a sentence about informing law enforcement authorities.			Y	Paragraph 3.316 (now 3.304) notes that procedures should stipulate which other governmental bodies, if any, should be informed in the event of enforcement actions being made. The text in para 3.316

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – ENFORCEMENT OF REGULATORY REQUIREMENTS (3.296-3.322)								
								(now 3.304) is more general and includes reference to other governmental bodies as well as law enforcement.
ENISS	A89	3.314.	~~The regulatory body should adopt clear administrative procedures governing the taking of enforcement actions, which should be documented in internal guidance.~~ All inspectors and other staff of the regulatory body should be trained in, and knowledgeable about, the administrative procedures.	First part fully covered by 3.41ff			Y	First sentence of para 3.314 (now 3.302) not deleted as suggested. Paragraph 3.41 (now 3.44) notes that guides (i.e., documents that advise the authorized parties) should state the policy for the use of regulatory and enforcement measures, while paragraph 3.314 (now 3.302) is specific to procedures used by the regulatory body.
ENISS	39	3.315.	If there is no immediate risk to safety, the regulatory body	Term "seriousness" is not an established term and also other		The time period should reflect		Used the phrase "the safety significance"

COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – ENFORCEMENT OF REGULATORY REQUIREMENTS (3.296-3.322)								
			should allow the authorized party a reasonable period of time in which to complete a corrective action. The time period should reflect the ~~seriousness~~ importance of the issue for safety and the complexity of the corrective action required as well as other topics (e.g. energy supply situation). However, in an integrated approach to safety, the contribution of each deficiency requiring a corrective action to the total risk for the facility or activity should be considered.	factors might be important (commercial factors, energy supply, etc.)		the safety significance of the issue and the complexity of the corrective action required as well as other topics (e.g. the proximity to a maintenance outage).		to be consistent with use in the document.
ENISS	A6	3.316.	~~Procedures should stipulate which other governmental bodies, if any, should be informed in the event of enforcement actions being made.~~	Same content as 3.42			Y	Paragraph 3.42 (Now 3.45) notes that guides (i.e., documents that advise the authorized parties) should indicate which other governmental organizations should be informed of

COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – ENFORCEMENT OF REGULATORY REQUIREMENTS (3.296-3.322)								
								enforcement actions, while paragraph 3.316 (3.304) is specific to procedures used by the regulatory body.
USA	25	p. 87 3.317	Consider clearly stating that the public does not participate in regulatory body enforcement actions.	Due to safety considerations and time-critical protective actions, public participation is not warranted; however, documents associated with enforcement should be public to the extent practical.			Y	It is not necessary to make such a statement as the para clearly states that the public is only informed of about the enforcement process.
ENISS	A90	3.317.	~~To inform the public and interested parties about the enforcement process, a formal enforcement policy statement from the regulatory body should be developed and made available to the public.~~	Move to chapter on regulations and guides following para 3.42	Y			
ENISS	A91	3.318.	~~Regulatory procedures should state the circumstances under which it is appropriate to carry out further inspections to check whether the authorized party has responded to~~	Fully included in 3.295 – if a special para is needed for enforcements, work with a reference to the above para.		Regulatory procedures should state the circumstances under which it is appropriate to		Par 3.295 (now 3.283) is concerned with checking on inspection

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – ENFORCEMENT OF REGULATORY REQUIREMENTS (3.296-3.322)								
			~~regulatory and enforcement measures. The purpose of these inspections should be to:~~ ~~(a) Confirm that the authorized party has complied with the enforcement measures within the periods of time specified;~~ ~~(b) Check that corrective actions in response to enforcement measures intended to protect the people, patients 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.~~			carry out further inspections to check whether the authorized party has responded to regulatory and enforcement measures. The purpose of these inspections should be to confirm that the authorized party has complied with the enforcement measures within the periods of time specified.		findings, par 3.318 (now 3.305) is concerned with checking on enforcement actions.

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COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – EMERGENCY PREPARDENESS AND RESPONSE (3.323-3.349)								
ENISS	41	3.324.	Paragraph 4.13 of GSR Part 7 [11], states that: "The regulatory body shall require that arrangements for preparedness and response for a nuclear or radiological emergency be in place for the on-site area for any regulated facility or activity that could necessitate emergency response actions." These arrangements should address coordination and integration of on-site emergency arrangements with other relevant plans (such as those of other response organizations or ~~the nuclear security~~ plans of the authorized party).	Security plans are not the only ones to be concerned.		Minor modification to improve clarity.		The original text provided examples which did not infer that security was the only plans to be considered.
IAEA CC-IEC	6	3.313 (V5), was 3.326 (V3)	The functions and processes for which the regulatory body will have a role can be considered under the following four general headings: □ Ensuring on-site emergency arrangements <u>are in</u>					

COMMENTS BY MEMBER STATES					RESOLUTION			
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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – EMERGENCY PREPARDENESS AND RESPONSE (3.323-3.349)								
			place; □ Ensuring coordination with off-site response organizations; □ Establishing and maintaining internal arrangements; □ Discharging its assigned responsibilities in emergency response. Much of this is carried out through the functions and processes described in earlier sections but they may also require considering additional processes with the integrated management system [4].					
ENISS	40	3.327.	Whilst much of the efforts by the regulatory body and authorized parties in preparedness and response for nuclear and radiological emergencies will be devoted to incidents and accidents at facilities and activities within the State, some nuclear and radiological emergencies in	Normally a reg. body is not doing hazard assessment for facilities on foreign counties, but taking into account possible impacts.		True: Proposed change to read "……Such impacts should be considered in the hazard assessment carried out for these facilities and activities by		To improve clarity. Note, text also modified due to comments by the IAEA Coordination Committee.

COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – EMERGENCY PREPARDENESS AND RESPONSE (3.323-3.349)								
			other States may have an impact on these facilities and activities. Such impacts should be considered ~~in the hazard assessment carried out for these facilities and activities~~ and should be addressed, as appropriate, in the response planning.			the authorized party and should be addressed, as appropriate, in the emergency arrangements."		
IAEA CC-IEC	7	3.314 (V5), was 3.327 (V3)	…..Such impacts should be considered in the ~~risk~~ hazard assessment carried out for these facilities and activities by the authorized party and should be addressed, as appropriate, in the ~~response planning~~ emergency arrangements.					
IAEA CC-IEC	8	Title between 3.314-3.315 in (V5), was 3.327 & 3.328 in (V3)	Ensuring on-site emergency arrangements are in place					
IAEA CC-	9	3.315	The Regulatory body should					

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – EMERGENCY PREPARDENESS AND RESPONSE (3.323-3.349)								
IEC		(V5), was 3.328 (V3)	have the responsibility for ensuring that the authorized party has adequate on-site arrangements to prepare for and respond to a nuclear or radiological emergency in relation to the facility or the activity under its responsibility consistently with GSR Part 7 [11].					
USA	26	p. 89 3.330	"The regulations and guides…..assessment…**timely** notification and activation….**..use of an emergency classification level system for classifying emergency conditions, …"**	IAEA GSR Part 1, requirement 8, notes that provisions must be in place for a "timely and effective response". Most if not all existing member state regulations require a timely (e.g. within 15 minutes) emergency declaration and notification to offsite authorities, and require the use of an approved emergency classification level system for classifying emergency events in a graded manner.		Accepted need to add reference to 'Timely".		Emergency classification system not necessary as part of this document but is covered in GSR Part 7.
ENISS	A92	3.330.	~~The regulations and guides in emergency preparedness and response should cover~~	No need for detailed guidance here, as link to the much more comprehensive GRS Part 7 is			Y	Agree with the principle, but judge it is necessary to

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – EMERGENCY PREPARDENESS AND RESPONSE (3.323-3.349)								
			~~provisions for: performing a hazard assessment; notification and activation; obtaining off-site support and coordination with off-site authorities; taking necessary emergency response actions on-site and, as relevant, off-site; protecting emergency workers (including for health surveillance, medical follow-up, monitoring and controlling their exposure during the response); analysis of an emergency and emergency response; terminating the emergency; establishing and maintaining adequate infrastructure to support the performance of emergency response actions (e.g. plans, procedures, training and exercise programmes, staffing, equipment, tools, facilities, quality management programme and records keeping).~~	given.				retain this brief overview. This paragraph summarises the major features of such a system. Note this SG is about the RB whereas GSR Part 7 is more general on Emergencies. See next comment from the EC which is to keep the paragraph.
EC	3	3.330		The whole paragraph should	Y			

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – EMERGENCY PREPARDENESS AND RESPONSE (3.323-3.349)								
				be bulleted for better reading.				
IAEA CC-IEC	10	3.317 (V5), was 3.330 (V3)	The regulations and guides should cover, but are not limited to: • performing a ~~risk~~ hazard assessment; • timely notification of a nuclear or radiation emergency to appropriate ~~bodies~~ authorities; • timely activation of necessary emergency response actions on-site and, as relevant, off-site; • provisions for obtaining off-site support and coordination with off-site authorities; • ~~timely activation of necessary emergency response actions on-site and, as relevant, off-site;~~ • provisions for protecting emergency workers (including ~~for~~ health surveillance, medical follow up, monitoring and controlling					

COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – EMERGENCY PREPARDENESS AND RESPONSE (3.323-3.349)								
			their exposure during the response); • analysis of an emergency and emergency response; • provisions for terminating the emergency; and • provisions for establishing and maintaining adequate infrastructure to support the performance of emergency response actions (e.g. plans, procedures, training and exercise programmes, staffing, equipment, tools, facilities, quality management programme and records keeping).					
ENISS	A93	3.331.	The regulatory body should review and assess the on-site emergency arrangements developed by the authorized party to verify compliance with its requirements. For details see GRS Part 7 (e.g.	Duplication of information should be avoided – comprehensive work done in GRS Part 7.			Y	The retained text explains the purpose of the regulatory body's review and assessment. On-site emergency response is a specific area of

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – EMERGENCY PREPARDENESS AND RESPONSE (3.323-3.349)								
			para 4.25) ~~This review and assessment should ensure that on-site emergency arrangements provide, to the extent practicable, assurance of an effective response to a full range of postulated nuclear or radiological emergencies, including those of very low probability [19].~~					regulatory body responsibility.
IAEA CC-IEC	11	3.318 (V5), was 3.331 (V3)	…….or radiological emergencies, including those of very low probability ~~[19]~~ [11].					
ENISS	A94	3.332.	~~The review and assessment should consider that the on-site emergency arrangements:~~ ~~– Are based on a hazard assessment that identifies all postulated nuclear or radiological emergencies that might occur in relation to the facility or activity, including those of very low probability [19];~~ ~~– Include emergency~~	Duplication of information should be avoided – comprehensive work done in GRS Part 7 – link given in 3.331			Y	For reasons above, see ENISS A93.

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – EMERGENCY PREPARDENESS AND RESPONSE (3.323-3.349)								
			~~arrangements for managing the on-site emergency response and for coordination with off-site response;~~ ~~– Include, 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~~					

COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – EMERGENCY PREPARDENESS AND RESPONSE (3.323-3.349)								
			~~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;~~ ~~– Include a specific training programme (which includes drills) and instructions for all the authorized parties staff on how to respond to a nuclear or radiological emergency and on the discharge of their expected duties;~~ ~~– Include sufficient suitably qualified staff to be~~					

COMMENTS BY MEMBER STATES					RESOLUTION			
Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – EMERGENCY PREPARDENESS AND RESPONSE (3.323-3.349)								
			~~available at all times to implement the emergency plans and procedures;~~ ~~– Include arrangements for obtaining support from off-site response organizations and for coordination with relevant off-site response;~~ ~~– Describe the coordination with other plans such as plans for nuclear security and plans for fire fighting;~~ ~~– Include an exercise programme to ensure that all the emergency arrangements are tested satisfactorily within specific period.~~					
IAEA CC-IEC	12	3.319 (V5), was 3.332 (V3)	The review and assessment should consider, <u>inter alia</u>, that the on-site emergency arrangements: □ Are based on a ~~risk~~ <u>hazard</u> assessment that identifies all postulated					

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – EMERGENCY PREPARDENESS AND RESPONSE (3.323-3.349)								
			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; □ ~~Include~~ Address, as applicable, the operability and habitability of emergency……					
ENISS	A95	3.333.	As part of its inspection plan, the regulatory body should inspect the on-site emergency arrangements, including observing emergency exercises (see also GSR Part 7, paragraph 6.30 [11]), to ensure that they are effective and are in compliance with the regulatory body requirements. ~~It is required that the regulatory body evaluate some of the emergency exercises, (GSR Part 7, paragraph 6.30~~	Move link to GRS Part 7 up. Changes made for clarification of the role of the reg. body and the established requirements of GRS Part 7.		As part of its inspection plan, the regulatory body should inspect and evaluate the on-site emergency arrangements against pre-determined criteria and checklists. In addition, it is		To improve clarity and logic. Note, text also modified due to comments by the IAEA Coordination Committee – IEC, see comment below.

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – EMERGENCY PREPARDENESS AND RESPONSE (3.323-3.349)								
			~~[11]~~). To do so, the regulatory body should ~~take part in~~ be knowledgeable about the exercise- scenario resulting from preparation, take part at conduction ~~conducting~~ and obtain the results of the evaluations of ~~evaluating~~ some of the exercises ~~and should develop necessary evaluation guides and checklists~~. When appropriate, this evaluation should assess the adequacy of coordination and integration of the on-site emergency arrangements with those off-site.			required that the regulatory body evaluates some of the emergency exercises carried out by the authorized party (GSR Part 7, paragraph 6.30 [11]). To do so, the regulatory body should develop necessary evaluation guidelines and checklists. When appropriate, this evaluation should assess the adequacy of coordination and integration		

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – EMERGENCY PREPARDENESS AND RESPONSE (3.323-3.349)								
						of the on-site emergency arrangements with those off-site.		
SPAIN	11	3.333	It is suggested to reconsider underlined text, in order to avoid confusions. As part of its inspection plan, the regulatory body should inspect the on-site emergency arrangements, including observing emergency exercises, to ensure that they are effective and are in compliance with the regulatory body requirements. It is required that the regulatory body evaluate some of the emergency exercises, (GSR Part 7, paragraph 6.30 [11]). <u>To do so, the regulatory body should take part in preparation, conducting and evaluating</u>…	See 3.346 "The prime responsibility for safety remains with the authorized party during nuclear or radiological emergencies confined to the site of the facility or where the activity is taking place. The role of the regulatory body should observe the actions the authorized party takes."		Accepted , see new text from ENISS A95		Text in 3.333 (now 3.320) is referring to exercises, however, the text in 3.346 (now 3.333) is during an actual emergency.
IAEA CC-	13	3.320	As part of its inspection plan,					

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – EMERGENCY PREPARDENESS AND RESPONSE (3.323-3.349)								
IEC		(V5), was 3.333 (V3)	the regulatory body should inspect and evaluate the on-site emergency arrangements against pre-determined criteria and checklists. ~~To do so~~ In addition, ~~the regulatory body should take part in preparing, conducting and evaluating some of the exercise plans, which includes observing emergency exercises. I~~ it is required that the regulatory body evaluates some of the emergency exercises carried out by the authorized party, (GSR Part 7, paragraph 6.30 [11]), ~~to ensure that they are effective and are in compliance with the regulatory body requirements~~. To do so, the regulatory body ~~and~~ should develop necessary evaluation guidelines and checklists.					
ENISS	A96	3.334	~~The regulatory body should ensure that the authorized party demonstrates the effectiveness of the on-site~~	Fully included in GRS Part 7 Para 4.13/4.14 and 6.21. – no need to restate here.			Y	Cross referencing GSR Part 7 is insufficient on its own as there is a

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – EMERGENCY PREPARDENESS AND RESPONSE (3.323-3.349)								
			~~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.~~					need to place emphasis on the regulatory body's role and responsibilities. Therefore the text is being retained.
ENISS	A97	3.336.	~~As noted above, the various Safety Standards put the specific responsibility for emergency preparedness and response on the government e.g. Requirement 8 of GSR Part 1 (Rev.1) [2] states that "The government shall make provision for emergency preparedness to enable a timely and effective response in a nuclear or radiological emergency." Requirement 2 of GSR Part 7 [11] states that: "The government shall make provisions to ensure that roles and responsibilities for preparedness and response for a nuclear or radiological~~	Links provided just 13 paras before in 3.323 – delete repetition here.		Accepted in part and all specific references removed.		To avoid repetition.

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – EMERGENCY PREPARDENESS AND RESPONSE (3.323-3.349)								
			~~emergency are clearly specified and assigned.~~"					
IAEA CC-IEC	14	3,323 (V5), was 3.336 (V3)	As noted above, in paras 3.310 and 3.312, ~~the~~ various……..					
ISRAEL	58	3.337	"3.337. The regulatory body **is** part of the coordinating mechanism that is required to be established by the Government in accordance with GSR Part 7, paragraph 4.10 [11]…." **In accordance with GSR Part 7, paragraph 4.10 [11] the regulatory body is supposed to be part of the coordinating mechanism that is required to be established by the Government.** "	Consistency			Y	To maintain consistency with GSR Part 7
ENISS	A98	3.337.	The regulatory body is part of the coordinating mechanism that is required to be established by the Government	Req. 22 of GSR Part 7 would be the better link and more could be deleted by that.		Accepted comment on reference to Requirement 2,		Deleted text provides useful information for the regulatory body.

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – EMERGENCY PREPARDENESS AND RESPONSE (3.323-3.349)								
			in accordance with GSR Part 7, paragraph 4.10 and requirement 22 [11]. ~~The coordinating mechanism ensures that emergency arrangements are coordinated, consistent and are in place for all postulated nuclear or radiological emergencies, including those beyond borders.~~ In its capacity, the regulatory body should ensure that the authorized party provides the information necessary for establishing and maintaining adequate and coordinated off-site emergency arrangements at all levels, as appropriate.			However, not deleted proposed text.		
IAEA CC-IEC	15	3.325 (V5), was 3.338 (V3)	It is usual, ~~in most Member States~~, that the regulatory body will be either a source of advice during the preparation of the national radiation emergency response plan or a lead organization for its preparation.					

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – EMERGENCY PREPARDENESS AND RESPONSE (3.323-3.349)								
ENISS	A99	3.342.	~~The regulatory body, within its sphere of responsibility, should coordinate its emergency arrangements with those of the authorized parties, and also at the national and local level and with its related international agreements and obligations.~~	No added guidance to 3.337			Y	This paragraph is about the internal arrangements within the RB: para 3.337 (now 3.324) is about external arrangements.
ENISS	A100	3.345.	~~The roles and responsibilities of the regulatory body during a nuclear or radiological emergency can be considered under the headings of on-site and off-site below:~~	superfluous			Y	Need an introduction.
SPAIN	12	3.346	It is suggested to check underlined text for possible mistake: The role of the regulatory body should observe the actions the authorized party takes.		Y	should be to observe		
EC	4	3.346	The role of the regulatory body should *be to* observe the actions the authorized party takes.	Language. The 'role' cannot observe.	Y			
IAEA CC-IEC	16	3.333 (V5), was	The prime responsibility for safety remains with the					

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – EMERGENCY PREPARDENESS AND RESPONSE (3.323-3.349)								
		3.346 (V3)	authorized party during nuclear or radiological emergencies confined to the site of the facility or where the activity is taking place. The role of the regulatory body should be to observe the actions the authorized party takes; however, such a role should not impede the taking of necessary pre-planned emergency response actions on-site in a timely manner by the authorized parties (see para. 4.15 and 5.23 of GSR Part 7 [11]).					
ENISS	A101	3.348.	~~The regulatory body's responsibilities should have been set out in the government's provisions for dealing with nuclear or radiological emergencies. In most Member States, in the event of an emergency, the regulatory body's role will be to advise the government and competent authorities: in some~~	Superfluous, as stated clearly in GSR Part 7 and repetition of para 3.338			Y	3.338 (now 3.325) is about preparation and 3.348 (now 3.335) about doing.

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3. MAIN REGULATORY FUNCTIONS AND PROCESSES – EMERGENCY PREPARDENESS AND RESPONSE (3.323-3.349)								
			~~situations in some States, the regulatory body may provide expert services e.g. services for radiation monitoring.~~					
IAEA CC-IEC	17	3.335 (V5), was 3.348 (V3)	The regulatory body's responsibilities should have been set out in the government's provisions for dealing with nuclear or radiological emergencies. It is required that in preparing a radiation emergency response plan……..					
UK	5. ONR	2.24	In preparing an emergency response plan and in the event of an emergency, the regulatory body shall advise the government and competent authorities, and shall provide expert services (e.g. services for radiation monitoring and risk assessment for actual and expected	Thus, there is a requirement on regulatory bodies buried in amongst government requirements. In GSR 1. It would therefore seem appropriate to include some reference to this in the guidance for completeness. I therefore do not fully support the comments			Y	Not able to find para 2.24 in DS473. However, the role of the regulatory body is covered in the section "Emergency Preparedness and Response". Para 3.325 covers providing advice to government and the provision of services, as appropriate.

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3. MAIN REGULATORY FUNCTIONS AND PROCESSES – COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES (3.350-3.352)								
ENISS	A102	3.352.	The regulatory body should develop and implement a communication and consultation strategy and a culture of transparency and openness, and to involve 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 Part 1 (Rev.1) [2] for example.~~ Recommendations and guidance covering the communication and consultation with interested parties are covered in [13].	Superfluous.	Y			

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APPENDIX 1 SUPPLY OF CONSUMER PRODUCTS								
GERMANY	43	App. 1, A1.2	*Note:* *With regard to contents, an analogous but more comprehensive list is provided in Para 3.22 of the Safety Guide SSG-36 "Radiation Safety for Consumer Products" (previous DS458; currently in SPESS Step 14). To align SSG-36 with DS473, the following changes in A1.2 are proposed:* Bullet (b): "The activity and the chemical and physical forms of the radionuclide(s) contained in the product;"	Bullet (b): According to Para 3.22 (b) of SSG-36, the activity of the radionuclide(s) to be used in the consumer product should also be specified.			Y	It is covered by A1.1(b)
GERMANY	44	App. 1, A1.2	Bullet (g): "Safety ~~Dose~~ assessments, including individual doses and, if appropriate, collective doses arising from normal use, possible misuse and accidental damage and disposal and, if applicable, servicing and	SSG-36 explicitly recommends a safety assessment; see Paras 3.20, 3.22 (i) and 3.30 to 3.35 of SSG-36.	Y			

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
APPENDIX 1 SUPPLY OF CONSUMER PRODUCTS								
			repair;"					
GERMANY	45	App. 1, A1.2	Bullet (i): "Information about any advice to be provided to customers on the correct use, installation, maintenance, servicing, <u>and</u> repair ~~and disposal~~ of the product;" Please include a new bullet after (i): "<u>The provisions foreseen for recycling or disposal of the product at the end of its useful lifetime</u>;"	According to Para 3.22 (n) of SSG-36, any provisions for recycling or disposal of a consumer product should be addressed in a separate bullet (see our related proposal at the left). Many States place restrictions on the available disposal options for certain types of consumer product, in order to minimize the amount of radionuclides present in the environment and not under proper control, to encourage recycling or in response to other regulatory controls (see Paras 4.39 to 4.43 of SSG-36). If, after the end of its useful lifetime, a consumer product is to be collected for disposal, it may need to be treated as radioactive waste. In such circumstances, the Safety Requirements GSR Part 5 and SSR-5 will apply. If disused consumer products are to be		Partially accepted with modification of the text in A1.2(i)		

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
APPENDIX 1 SUPPLY OF CONSUMER PRODUCTS								
				recycled, this should be considered a practice and should be regulated accordingly.				
GERMANY	46	App. 1, A1.2	Bullet (j): "An analysis to demonstrate that the product is inherently safe (i.e. it will not give rise to significant doses to individuals in the event of foreseeable accidents);"	The proposed amendment for clarification purposes is consistent with Para 3.22 (l) of SSG-36.	Y			

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
APPENDIX 2 AUTHORIZATION CONDITIONS RELEVANT TO CERTAIN STAGES OF THE AUTHORIZATION PROCESS FOR COMPLEX FACILITIES AND ACTIVITIES								
SPAIN	13	A2.5	Penultimate sentence: "- Only changes given prior approval by the regulatory body should be made to the approved arrangements, schedules, procedures and rules;" Should be reworded: only changes important to safety are to be approved by regulatory body	Application of graded approach.			Y	Does not require the graded approach to be explicitly mentioned as this is covered in Chapter 2.
ENISS	A103	A2.6.	*Decommissioning*. ~~In authorizing the activity of decommissioning of a facility, the regulatory body should take particular care in specifying requirements to ensure compliance, since the sanction of shutting down the facility or revoking the authorization is unlikely to be effective at this stage~~. The regulatory body should	Compliance should always be in the focus of the reg. body – no need to state this here. Furthermore shutting down work or revoking the license must be effective, otherwise there would be a problem in the legal system. We suggest to delete this part.			Y	This is an important aspect of the authorization. Minor modification in the text in A2.6

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
APPENDIX 2 AUTHORIZATION CONDITIONS RELEVANT TO CERTAIN STAGES OF THE AUTHORIZATION PROCESS FOR COMPLEX FACILITIES AND ACTIVITIES								
			examine a final radiological survey conducted by the authorized party. The radiological survey should be conducted after the completion of decommissioning activities to ensure that regulatory requirements are met prior to terminating the authorization and releasing the site.					
GERMANY	47	App. 2, A2.7	"*Closure*. Following the closure of a waste disposal facility, continuing <u>institutional</u> control, including environmental monitoring, may be necessary. …"	Ensuring consistency with the terminology used in the Safety Requirements SSR-5 and all associated Safety Guides (GSG-1, SSG-14, SSG-23, SSG-29 and SSG-31).	Y			
SPAIN	14	A2.7	Closure. Following the closure of a ~~waste disposal~~ facility, continuing control, including environmental monitoring, may be necessary. Depending on national legislation, requirements may be specified in a post-closure authorization held by the authorized party or responsibilities may be taken	Sentence applies to any complex facility			Y	Closure is specific for waste disposal. See IAEA Safety Glossary.

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APPENDIX 2 AUTHORIZATION CONDITIONS RELEVANT TO CERTAIN STAGES OF THE AUTHORIZATION PROCESS FOR COMPLEX FACILITIES AND ACTIVITIES								
			by a relevant national authority prior to agreeing to closure of the facility.					

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Member State	Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
APPENDIX 3 TOPICS TO BE COVERED BY REVIEW AND ASSESSMENT								
ENISS	A104	Appendix 3		We suggest deletion of Appendix 3, as all topics are mentioned in other IAEA safety series documents and the lists are not exhaustive anyway. We do not see any added value in this guide, compared to the information stated in other IAEA documents, like SSR2/1, SSR 2/2, guides on Site evaluation, safety analysis, management systems and so on.			Y	The safety guide should be self-explanatory and complete.
GERMANY	48	App. 3, A3.3	"Throughout the lifetime of any facility or activity, the authorized party will have to propose and implement arrangements for waste management. The regulatory body should review and assess proposals for on-site processing (i.e. pretreatment, treatment and conditioning) and storage of radioactive waste to ensure that the characteristics of the processed	According to the IAEA Safety Glossary (2007 Edition), the term 'processing' is more comprehensive and includes 'pretreatment', 'treatment' and 'conditioning' of radioactive waste.	Y			

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APPENDIX 3 TOPICS TO BE COVERED BY REVIEW AND ASSESSMENT								
			waste and the waste packages are compatible with the national strategy for radioactive waste management, …"					
JAPAN	28	A.3.3/3 (p.101)	proposals for on-site treatment, conditioning and storage of radioactive waste in the safety case to ensure that…	Making the description consistent with GSR part5. (See A.4.29.)		….proposals for on-site processing (i.e. pre-treatment, treatment and conditioning) and storage of radioactive waste in the safety case to ensure that…		
JAPAN	29	A.3.3/3rd hyphen (p.101)	Can be retrieved for further steps in ~~predisposal~~ radioactive waste management…	Clarification.	Y			
GERMANY	49	App. 3, A3.5	Bullet (e): "Postulated initiating events (PIEs) for the safety analyses: …"	Please introduce abbreviations before using them for the first time in the document.	Y			
GERMANY	50	App. 3, A3.8	Bullet (2): "A demonstration of the adequacy of resources in terms of sufficient and appropriately	Completion.	Y			

COMMENTS BY MEMBER STATES					RESOLUTION			
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APPENDIX 3 TOPICS TO BE COVERED BY REVIEW AND ASSESSMENT								
			trained and experienced staff, ensuring in-house expertise;"					
SPAIN	15	A3.8 (7)	~~Any proposals~~ Provisions for the use of contractors.		Y			
GERMANY	51	A3.10	Bullet (m): "Sufficient ~~Q~~qualified staff available and on duty at all times;"	Completion.		"Sufficient and qualified staff available and on duty at all times;"		
EC	5	A3.10, (q)		The authorized party is required to demonstrate a long list of procedures and activities but in relation to feedback of operational experience this is limited to failures in human performance. Why?		(q) Programmes for the feedback of operational experience;		

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APPENDIX 4 INSPECTION AREAS FOR NUCLEAR FACILITIES								
ENISS	A105	Appendix 4		Appendix 4 contains a lot of information already stated in the guide – we suggest deletion of these parts, only stating areas not paraphrased in other parts of the guide. Also we questions the added value of this appendix, as other more comprehensive documents exist in the IAEA Safety Series (see also comments to App. 3) . E.g. A4.38, which is stated in the guide as well as in GSR Part 7.			Y	The safety guide should be self-explanatory and complete.
GERMANY	52	App. 4, A4.24	2nd sentence: "The area of radioactive waste management should cover processing (i.e. pretreatment, treatment and conditioning), storage and transport of waste, the release of effluents and the environmental monitoring programme [15]."	According to the IAEA Safety Glossary (2007 Edition), the term 'processing' is more comprehensive and includes 'pretreatment', 'treatment' and 'conditioning' of radioactive waste.	Y			
USA	27	p. 114 A4.24, line 2	Add a period after "public [14]"	editorial	Y			

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APPENDIX 4 INSPECTION AREAS FOR NUCLEAR FACILITIES								
JAPAN	30	A.4.29/1	*Radioactive w~~W~~aste management.*	Making the description consistent with the title of this subsection.	Y			
GERMANY	53	App. 4, A4.30	"Whenever unpackaged waste is stored or waste packages are stored or have been placed in a waste disposal facility ~~repository~~ pending a decision on closure of the facility, degradation of the waste with time may occur. The storage conditions for the waste and the waste packages should be inspected at appropriate intervals to provide confidence that the waste remains suitable for treatment/conditioning or that the waste packages will be suitable for retrieval, transport and further steps in radioactive waste management, as necessary."	Although defined in the IAEA Safety Glossary, the term 'repository' is meanwhile considered as outdated and should be replaced by 'disposal facility'. The Safety Requirements SSR-5 and all associated Safety Guides (GSG-1, SSG-14, SSG-23, SSG-29 and SSG-31) solely refer to disposal facilities. The unpackaged waste needs to remain suitable for further treatment and/or conditioning prior to disposal, depending on the preceding steps that have already been performed in predisposal management of this waste.	Y			
JAPAN	31	A.4.44/1st bullet	conformance with the overall radioactive waste inventory	Clarification.	Y			

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REFERENCES								
USA	28	p. 120, reference [1]	EUROPEAN ATOMIC ENERGY COMMUNITY, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, INTERNATIONAL MARITIME ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Fundamental Safety Principles, IAEA Safety Standards Series No. SF-1, IAEA, Vienna (2006).	Recognize all of the sponsors, and consistency with other safety guides.	Y			
USA	29	p. 120, reference [3]	EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE		Y			

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REFERENCES								
			UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).					
GERMANY	54	Ref. [8]	"INTERNATIONAL ATOMIC ENERGY AGENCY, Periodic Safety Review <u>for Nuclear Power Plants</u>, SSG-25 (2013)."	Citation of the full title of SSG-25.	Y			
IAEA CC-IEC	18	Ref. [11] in (V5), was also Ref. [11]	<u>FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC</u>					

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REFERENCES								
		in (V3).	ENERGY AGENCY, INTERNATIONAL CIVIL AVIATION ORGANIZATION, INTERNATIONAL LABOUR ORGANIZATION, INTERNATIONAL MARITIME ORGANIZATION, INTERPOL, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, PREPARATORY COMMISSION FOR THE COMPREHENSIVE NUCLEAR-TEST-BAN TREATY ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, UNITED NATIONS OFFICE FOR THE CO¬ORDINATION OF HUMANITARIAN AFFAIRS, WORLD HEALTH ORGANIZATION, WORLD METEOROLOGICAL				

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REFERENCES								
			ORGANIZATION, Preparedness and Response for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GSR Part 7, IAEA, Vienna (2015).~~INTERNATIONAL ATOMIC ENERGY AGENCY, Preparedness and Response for a Nuclear or Radiological Emergency, GSR Part 7 (2015).~~					
GERMANY	55	Ref. [30]	"INTERNATIONAL ATOMIC ENERGY AGENCY, Modification to Nuclear Power Plants, NS-G-2.3 (2001) ~~(will be replaced by DS485)~~."	Misleading revision notice. DS485 will supersede and replace NS-G-2.12 "Ageing Management for Nuclear Power Plants".	Y			