

SSC Members Comments on
DS429
“EXTERNAL EXPERT SUPPORT ON SAFETY ISSUES”

CONTENTS

BELGIUM

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USNRC

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Benoit DE BOECK		Page1 of 1					
Country/Organization: Belgium/Bel V		Date: 05/11/2010					
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	General	We suggest that, when available, the outcome of the IAEA TSO Conference (Tokyo, 25-29/10/2010) be considered to further improve the draft.	Use the latest information	X	The outcome will be taking into account when available.		
2	1.10/2-5	The closing parenthesis should be put after "...mandated technical support organizations" instead of at the end of the paragraph.	typo	X			

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Country/Organization EC		Page Date: 10/10/2010					
Comment No.	Para/Line No.	Comments	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1.	General	The current draft describes many options but hardly gives some recommendations that have not been already included in the other IAEA Safety guides on the regulatory infrastructure. It contains a lot of repetitions and in some cases not very clear statements (examples are given below). It may be useful at this stage to publish this document as a TECDOC.	clarification		Most of repetitions are deleted following remarks made by reviewers	X	The purpose of this document is also to regroup recommendations spread in other Safety documents which will be revised and simplify at time. Most of the repetitions are now suppressed
2.	Para 1.1/ 1.4 & 1.7	It seems that the guide is prepared to serve mostly the regulatory bodies, however the relation of this guide to other possible users is not clearly defined. What is the added value of para 1.4?	clarification	X	Para 1.4 is added at the end of para 1.1 as an evidence of the necessity of technical support. The relation of this guide to other possible users is canceled from para 1.7		

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Country/Organization		EC	Page Date: 10/10/2010				
Comment No.	Para/Line No.	Comments	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
3.	Footnote 1	This footnote includes recognition of the external expert support person/organization within “the regulatory structure of a State”? How many States have this arrangement in place? This certainly is not required by the IAEA Requirements and it does not fit with the rest of the document (see 1.10) which assumes that sources for external expert support can come from universities, consultation organizations, international bodies, etc. that are not formally recognized within the regulatory structure.	It is important to make clear definition of “ external export support”.	X	A provider of external expert support, external expert advice or support provider, used here in the guide with the same meaning, is a person or organization that is not resident within a regulatory body but is recognized as having a specific role to support the regulatory body		
4.	Para 1.1, 1.2& 1.3	Certain repetition exists, text can benefit from shortening and streamlining.	clarity	X			

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Country/Organization EC		Page Date: 10/10/2010					
Comment No.	Para/Line No.	Comments	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
5.	Para 1.5	It is suggested to change the last sentence as follows: “It is fundamental that while using the information provided by the external expert support in its decision making process the regulatory authority retains responsibility for and makes the final decisions”	The current text suggests that the “external expert support may contribute to the regulatory decision- making” which is not clear and assumes some formal participation of the external expert support in the Regulatory Body work which is not currently supported by any of the other IAEA safety standards.	X			
6.	Para 1.7& 1.11	Certain repetition exists, text can benefit from shortening and streamlining	clarity	X			
7.	Para 2.2	Remove the 3 rd sentence and replace the 4 th sentence with: “ The expert advice should be properly justified, explained and documented.”	Text is not clear. The current text assumes some formal participation of the external expert support in the Regulatory Body work.	X	3 rd sentence is shorted. 4 th sentence is replaced as suggested.		
8.	Para 2.3	Remove “ however”	Simplicity	X			

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Country/Organization		Page EC	Date: 10/10/2010				
Comment No.	Para/Line No.	Comments	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
9.	Para 2.3, 4 th bullet	Replace with : “how the external expert advice provider and its advice are controlled and the degree to which the advice of the provider is considered in the regulatory decision making process, and,”	The current text assumes some formal participation of the external expert support in the Regulatory Body work and this can not be done at the level of this Guide. If this was the intention of the drafters, it has to be discussed and introduced in the guides for the regulatory body organization/ functioning.	X			
10.	Para 2.4	Second sentence sounds a bit naïve for a guide		X	Sentence is removed		
11.	Para 2.5	Consider rephrasing.	Two competing reasons are mentioned in the first part of the text but only one is explained later. In general the text is not very clear	X			

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Reviewer: Country/Organization EC		Page Date: 10/10/2010					
Comment No.	Para/Line No.	Comments	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
12.	Para 2.6	This para lists any possible organization that can provide additional information to the regulatory authority, however many of these organizations will not have the characteristics of external expert support as described in chapter 3, nor will the Regulatory Body be able to examine their competence, prior experience, management systems, etc. External international organizations as IAEA, NEA, ISO for example can provide assistance for review services, but can they provide external expert support for the daily regulatory decision making?? It seems that there is significant difference between the advice provided by the IAEA missions for example and expert organizations which have to do detailed analyses/ assessment/ research on given safety issues?? Somehow the current guide does not make any difference on this subject??	It might be useful to specify more precisely the nature of the external expert support organizations covered by this guide, otherwise the document becomes very, very general			X	This point will be reconsidered in a future step

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Reviewer: Country/Organization		EC	Page Date: 10/10/2010				
Comment No.	Para/Line No.	Comments	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
13.	Para 2.8	Para 2.8 seems shorten version of para 2.6	Simplification of the document			X	This point will be reconsidered in a future step
14.	Para 3.5	Second sentence could be rephrase: "Technical competence and well developed safety culture usually help to understand the importance of and ensure independence of the technical advice"	Clarity	X	Technical competency ¹ and developed safety culture in the provider of external expert support contribute to the independence of the technical advice.		
15.	Para 3.9 and 3.10		What is the logic behind paragraphs numbering. Text under 3.10 is continuation of 3.9 and can not be understand in an isolated manner?	X	Para 3.10 is canceled. Sentences are added at the end of para 3.9		
16.	Para 3.10 last bullet	Delete the bullet	Para 3.9 refers to cases where no <u>independent</u> provider is available. How then the work can be checked by <u>second independent</u> provider??	X	Bullet deleted.		
17.	Para 3.25	The text under this para should be simplified	3.25 repeats a lot of the text under 3.14, 2.1 and 2.2	X			

¹ The technical competency represents the ability of the provider of external expert support to develop its own research assists in the development of state-of-the-art knowledge and techniques, and foster independent judgment.

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Reviewer: Country/Organization EC		Page Date: 10/10/2010					
Comment No.	Para/Line No.	Comments	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
18.	Chapter 4	The text under this chapter should be focused on the selection process and use of the external expert support Note wrong numbering of chapter 4 paragraphs	The text under 4.1; 4.2; 4.3; 4.9 has very little to do with the process to select and use external expert organization and repeats a lot the text from 2.1; 2.2, 1.3. Para 4.8 repeats a lot the guide on DS 424 “Establishing the Safety Infrastructure for a Nuclear Power Programme	X	Changes are introduced in the document.		
19.	Para 4.11	This chapter shall be one of the most important in this guide. It deserves more recommendations to be included rather than listing just some “useful questions”	Currently it seems that all principles are addressed in reference [6]. What is the added value of the current guide?	X	Statements are now recommendations		
20.	4.13 and 4.14 first bullet	Text might be simplified	Repetition	X	1 st sentence is deleted		
21.	4.14 bullets 2-6	Place this text somewhere else in the document, or delete if it is repetition of some other text	The text under these bullets is not related to the Title “Evaluation of the work performed”	X	Bullets are removed in para 2		

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Reviewer: Country/Organization		EC	Page Date: 10/10/2010				
Comment No.	Para/Line No.	Comments	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
22.	Para 51.	This para shall be rephrase	So far there is no international consensus that external export providers can be viewed (what does in mean in legal terms?) as <u>an extension</u> of the regulatory body. If anything like this is accepted it has to be defined properly and reflected in the Requirements and can not be introduced in the IAEA safety standards at a level of a guide for external export support	X	The external support provider do not replace the regulatory body when providing support.		
23.	Para 5.6	Why “ Independence” is addressed here? (see “Independence” under chapter 3)	Clarification	X	Canceled from here and added in para 3.7		
24.	Para 5.21	It is regulatory responsibility to ensure transparency in its decision making process and decide on the information to be disclosed to the public. Recommending any(but confidential) external advice to be published seems a bit excessive??	Clarification	X	The two last sentences are removed		

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Reviewer: Country/Organization EC		Page Date: 10/10/2010					
Comment No.	Para/Line No.	Comments	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
25.	Para 5.23	Delete	The text is not clear: for the first time in the document “ the organization set up by the State to perform research in the field of safety” is mentioned and it is not clear what kind of organization is this??	X			

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Page.... of.... Country/Organization: Date:		Moustafa Atomic Energy Authority of Egypt		Aziz			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	Page 16 para 3.23	The regulatory body should inform the owner of the IPR its intention to pass information to a third party	IPR should be defined	X	Intellectual Property Rights (IPR)		

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Country/Organization: 29.10.2010		STUK, Finland		Page.... of.... Date:			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	2.2 /3-5	"This means that the regulatory body should... <i>have an adequate core competence on the subject as a minimum to ...retain the ability....</i> "	Addition gives a minimum reference level and makes the sentence to comply with the requirement of GSR-1 para 4.22.	X			
	2.2 / 5-7	Comment to the following sentence "In some cases, there may be value on allowing the ...decision making process".	This may be true but clarify the sentence, there are several possibilities to interpret it (e.g. in what phases of the decision making process the external experts might be used and what would be consequences of this; what kind of material the external experts produce: some background material vs. official documents)	X	In some cases, there may be value in allowing the provider of external support to take part in the decision-making process.		

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer:		F. Féron		Page			
Country/Organization:		France/ASN		Date: 26 October 2010			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1.	1.1/3	Delete “The increasing number ... external to their State”	Superfluous. This topic is not a new issue event if it may be more acute for new comers in nuclear safety.... (Some duplication with §1.6)	X	Part of the sentence is canceled		
2.	1.2	Delete 1.2 and transfer last sentence to 1.3	Superfluous (Some duplication with 2.1)	X			
3.	1.3/4	After “dedicated task.” Add the last sentence of 1.2 (“Depending on the type of the regulatory body, State legal system and traditions, different structures and arrangements may exist”).	This gives reason for various situations.	X			
4.	1.6/5	Replace “are likely to” by “may be”	Alternate wording	X			
5.	1.9	Merge 1.9 with 1.8	1.9 is explaining why external expert advice on security issues is not developed within the guide.	X			
6.	1.11	Locate 1.11 after 1.7	Same topic	X			
7.	2.2/4	Delete “This is the “intelligent customer” requirement (Ref. [9])”.	Superfluous as it is more clearly stated in the previous sentence.	X			

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Country/Organization:		France/ASN		Date: 26 October 2010			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
8.	2.5/2	Replace “The use of advice from other States may be a major factor for at least two competing reasons: the other State may have considerable experience with the particular issue; however,” by “If the use of advice from other States is considered, it should be kept in mind that although the other State may have considerable experience with the particular issue,”	More neutral wording.	X			
9.	2.6/2 nd bullet	After “embarking States” add “in nuclear energy programs”	Clarification.	X			
10.	2.9/5	After “and the organization” add “and needs”	Organization of the regulatory body is not the only factors....	X			
11.	3.2/2	Delete “should apply to the provider of external expert support, and”	The second requirement in 3.1 (regulator responsibility) does not apply to the provider of external support.	X			
12.	3.2/end	At the end of 3.2, add “Furthermore, when selecting a provider of external expert support, the regulatory body should ensure it will not compromise its independence.”	This is a more appropriate way to recall the independence requirement and its consequence on the use of external expert support.	X			
13.	3.4/3	Delete “need for independent advice and the”	The requirement does not call for independent advice, but for “independent” decision by the regulatory body.	X			

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Country/Organization:		France/ASN		Date: 26 October 2010			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
14.	3.5/2	Replace “independent of external influence” by “free from undue pressure from interested parties”	The proposed wording is more consistent with the one on independence of the regulatory body (see §3.1).	X			
15.	3.5/4	Transfer “The ability of the provider of external expert support to develop its own research assists in the development of state-of-the-art knowledge and techniques, and foster independent judgement” as a footnote to “technical competency” (previous sentence)	Clarification. Performing research is more on the competency side than the independence side (although choosing what research to perform is more a characteristic of independence).	X			
16.	3.8/4	Delete “which typically have no conflicts of interest”	May not always be true (part of IAEA promotes nuclear energy...)	X	All the para is removed		
17.	3.10	Merge 3.10 with 3.9	3.10 and 3.9 are on the same topic and 3.9 is actually giving examples where 3.10 would apply.	X			
18.	3.10/2	Before “conflicts of interest”, add “bias generated by”	More appropriate wording	X			
19.	3.14/1	Replace “demonstrates” by “expresses”	Alternate wording	X			
20.	3.16/2 nd bullet	Locate 2 nd bullet (quality management) to the management system section, after 3.19	Having a quality management system is not by itself an argument for competency...	X			

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Country/Organization:		France/ASN		Date: 26 October 2010			
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21.	3.16/2 nd bullet	In the first sub-bullet, after “technical competency of the organization”, add “for example through the processes of assigning qualified people to a specific task or of reviewing advice before finalizing it.”	Clarify what aspects of the management system are related to a technically sound advice.	X			
22.	3.20	Locate 3.20 in the technical competency section, after 3.16	3.20 deals with competence of the advisor...	X			
23.	3.22	Delete 3.22	The scope of the guide, as expressed in 1.8 and 1.9 does not include security. The need for specific measures is already stated in 1.9.			X	3.22 gives elements to preserve security and confidentiality of the information
24.	3.23/6		What means “IPR”?	X	Intellectual Property Rights (IPR)		
25.	3.25/5	Delete “The provider of external support should also display ... safety culture policy”	Superfluous. The first sentence deals with competency (see 3.14 to 3.16). The second sentence deals with the regulator (this section is on the external support provider).	X	3.25/7: “While the external... regulatory body’s decision” is deleted. “indue pressure” is added at the end of para		
26.	3.25/14	Delete “It should be clear ... decision making process.”	Duplicate an idea already expressed in this paragraph (lines 7 and 8).	X			
27.	4.8/4	Replace “will be used will be based” by “may be used depends”	Use of external experts is not mandatory...	X			

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Country/Organization: France/ASN		Date: 26 October 2010					
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28.	4.8		Is this paragraph, especially the part of the general contractor helping a new comer, not inconsistent with the requirements on the regulatory body (see 1.5, 2.1, 4.1)? This should be discussed at NUSSC.	X	Para is changed and introduced TSO.		
29.	4.13/1	Determine	Typo	X			
30.	4.13/6	Replace “activity authorized” by “decision”	Clarification				
31.	4.14/1 st bullet	Replace “and to determine whether and how it is adopted” by “and determine how it will be used in its decision making process”	Clarification	X	Deleted		
32.	4.14/4 th bullet	Replace “contractors” by “external expert support providers”	To use consistent wording across the guide	X	Now para 2.3		
33.	4.14/4 th bullet	Replace “The process should be informed by” by “The process should be consistent with”	The word “informed” is quite unclear...	X	Now para 2.3		
34.	4.14/4 th bullet	Replace “nuclear safety” by “safety”	To be consistent with IAEA standards usual wording.		Now para 2.3		
35.	4.14/5 th bullet	Replace “nuclear safety” by “safety”	To be consistent with IAEA standards usual wording.	X	Now para 2.3		
36.	4.14/6 th bullet	Replace “contractors” by “external expert support providers”	To use consistent wording across the guide		Now para 2.3		
37.	4.14/6 th bullet	Replace “nuclear safety” by “safety”	To be consistent with IAEA standards usual wording.	X	Now para 2.3		

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Country/Organization:		France/ASN		Date: 26 October 2010			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
38.	5.2/3	Delete “,inspecting plants”	Inspecting is a prerogative of formally designated inspectors. The idea of being on-site or consulting documents is already covered by the other example given in the sentence.				
39.	5.2/7	After “be led”, add “or framed”	To be consistent with 5.3	X			
40.	5.3/4	After “external expert support”, add “and the licensees should be made aware by the regulatory body of such potential direct contacts by the external expert support provider”	To be sure that the licensee is aware that such direct contact might occur.	X			
41.	5.3/6	Delete “The instances where this situation occurs should be minimized”.	Such contacts should be as numerous as needed for the establishment of the advice, taken into account the framework defined by the regulator and the external expert support provider and arrangements defined for direct contacts.	X			
42.	5.21	Split 5.21 in two : <ul style="list-style-type: none"> - the first part, dealing with documenting the advice and eventually having it forwarded to the licensee; - the second part, dealing with the publication of the advice. This second part should be located after 5.22 	Clarification	X			

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Reviewer:		F. Féron		Page			
Country/Organization:		France/ASN		Date: 26 October 2010			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
43.	5.21/5	Replace “the basis” by “this input”	The external advice may not be the only basis for the regulatory decision.	X			
44.	5.21/7	Replace “all external advices should be published”, add “external advices should generally be published”	Whether advice is rendered public or not is to be established by the regulator. Not all advices may become public.... The proposed wording is also more consistent with §5.22				
45.	5.21/9	Delete “, and demonstration on how it was used in the arriving at the regulatory decision”	If the advice is not this only input in the regulatory decision, this may be challenging. Furthermore, it also depends on who publish the advice (the regulator or the external support provider)...	X			
46.	5.22	At the end of 5.22, add the 2 nd part of 5.21	See above comment 42				
47.	5.23	Delete 5.23	Although true, this paragraph seems to be out of the scope of this guide. Furthermore, the recommendation is directed at Government, not the regulatory body.	X			
48.	5.24/2	After “to the public,” add “,taking into the national legal framework governing public access to documents established or possessed by public bodies”.	National legal framework on such topic should also be considered. For example, documents may not be communicated until a decision as been made...	X			

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Reviewer: F. Féron		Page					
Country/Organization: France/ASN		Date: 26 October 2010					
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
49.	5.24/3	Replace “Provided that... always support openness and publication” by “The regulatory body should then reconsider whether such advice should be made public or sent to the person requesting it, taking into account confidentiality or security issues”	There may be good reasons for such advice not having been made public. See also comment 48	X			

COMMENTS BY REVIEWER ¹⁾				RESOLUTION			
Reviewer: Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) (with Comments by GRS)							
Country/Organization: Germany				Page 1 of 10 Date: Oct 26 th , 2010			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	General		We propose that the term “Independency of the external expert support” should be defined in the glossary because there is a legal background	X	Not added in the present document. The remark will remain as a feedback for a future revision of the glossary		
2	General		In the whole Draft Guide the words “expert support”, “expert advice” or “support provider’s advice” are used	X	Added in footnote 1		

COMMENTS BY REVIEWER ¹⁾				RESOLUTION			
Reviewer: Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) (with Comments by GRS) Country/Organization: Germany				Page 1 of 10 Date: Oct 26 th , 2010			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
			in different contexts but for the same subject. It should be stated that the words are used in the same meaning.				
3	1.7		The text of Para 1.7 should be replaced by or merged with the text of Para 1.11. Both Paras are very similar. Avoidance of redundancies.	X	Para 1.7: last sentence “but it can be usefull... as well.” Is deleted. Para 1.11 is placed below para 1.7		
4	2.2		Please clarify the 3 rd sentence “In some cases, there may be value in allowing the provider of external support to take some part in preparing for the decision making process.”	X	“In some cases, there may be value in allowing the provider of external support to take part in the decision making process.”		
5	2.3	1 st sentence: “ However, in using a provider ...”	Simplification without any loss of information.	X			
6	2.3	2 nd bullet: “the method to decide which providers have the capability, <u>independency</u> and knowledge to provide that advice,”	Independency of the external expert is an important aspect as pointed out many times in this document. It should also be mentioned here.	X			

COMMENTS BY REVIEWER ¹⁾				RESOLUTION			
Reviewer: Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) (with Comments by GRS) Country/Organization: Germany				Page 1 of 10 Date: Oct 26 th , 2010			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
7	2.5	Footnote 2: “... would not be allowed to disclose certain security or sensitive commercial information without agreement of the owner ...”	The aspect of commercial information is addressed in Footnote 3.	X			
8	2.6	2 nd bullet: „... contractual arrangements (Ref. [1], Requirement 14). †These organizations may be ...”	Editorial.	X			
9	2.8	In each bullet the text should start with either a small or a capital letter. 5 th bullet: “...training;” (add semicolon)	Editorial (uniformity). Editorial.	X			
10	2.9	1 st line: “... in the form <u>of</u> a fixed arrangement ...”	Editorial.	X			
11	Section 3 (general)		Editorial: Check numbering of Paras in Section 3: Paras 3.12 - 3.13 and 3.17 - 3.18 are missing.	X			
12	3.1		4 th line: Replace Ref. [2] by [1]. last line: Replace Ref. [2] by [1]. Text refers to GSR Part 1	X			

COMMENTS BY REVIEWER ¹⁾				RESOLUTION			
Reviewer: Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) (with Comments by GRS) Country/Organization: Germany				Page 1 of 10 Date: Oct 26 th , 2010			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
13	3.4		1 st line: Replace Ref. [2] by [1]. 4 th line: Replace Ref. [2] by [1]. Text refers to GSR Part 1	X			
14	3.9, 3.10		Text in Para 3.10 is direct continuation of text in Para 3.9 and can't be understood in an isolated manner. Combine both Paras.	X			
15	3.10		3 rd line: Replace Ref. [2] by [1]. Text refers to GSR Part 1	X			
16	3.16		2 nd line: Replace Ref. [2] by [1]. Text refers to GSR Part 1	X			
17	3.23	The regulatory body should inform the owner of the IPR (Intellectual Property Rights) its intention to pass information to a third party (e.g. an external expert) and give it sufficient time to agree to the arrangements or to raise objections.	Clarification.	X			

COMMENTS BY REVIEWER ¹⁾				RESOLUTION			
Reviewer: Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) (with Comments by GRS) Country/Organization: Germany				Page 1 of 10 Date: Oct 26 th , 2010			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
18	3.25		Delete the 3 rd sentence “The provider of external expert support should also display competence (Ref. [1], Para. 2.35).” The sentence is dispensable at this place. Competence is not directly a matter of safety culture. In addition, the issue is already addressed in Paras 3.14 to 3.16.	X			
19	Section 4 (general)		Editorial: Check numbering of Paras in Section 4: Paras 4.4 - 4.7 are missing, Paras 4.8 and 4.9 in wrong order.	X			
20	4.2	“If a regulatory body does not have an adequate number of qualified personnel or an adequate diversity of technical skills, or if the workload does not justify the recruitment of full time staff, external experts <u>(individuals or organizations)</u> may be used to perform selected tasks. <u>For example, it may be decided to always</u>	The first sentences of Paras 4.2 and 4.3 are very similar. This is a proposal to combine both Paras in order to avoid or minimize doublings.	X			

COMMENTS BY REVIEWER ¹⁾				RESOLUTION			
Reviewer: Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) (with Comments by GRS) Country/Organization: Germany				Page 1 of 10 Date: Oct 26 th , 2010			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		<u>use external support for particular specialties as they may only be needed infrequently. In other cases, regulatory bodies rely heavily on dedicated support organizations, which provide all the functions that require expert input. However, even in these cases there may be situations where additional support is needed in specific areas. The technical qualifications and experience of such external experts should be at the same level as or greater than those of the staff of the regulatory body who are performing similar tasks.</u>					
21	4.3		Delete this Para and combine text with Para 4.2. See remark on Para 4.2.	X			
22	4.8		This Para should be formulated more clarified.	X			
23	4.8/ line 7	<u>“.advice contract manager”</u> instead of <u>“general contractor”</u> .	Also the organization of the advice in form of a “general contract” with a consortium team could make sense and could save resources. In that case the “general contractor” is part of a consortium of advice	X			

COMMENTS BY REVIEWER ¹⁾				RESOLUTION			
Reviewer: Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) (with Comments by GRS) Country/Organization: Germany				Page 1 of 10 Date: Oct 26 th , 2010			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
			providers and he becomes active as advice provider.				
24	4.12		In each bullet the text should start with either a small or a capital letter. Editorial (uniformity).	X			
25	4.13	1 st sentence: “... and determining whether and how it is utilized.”	Editorial	X			
26	4.14		This Para should be checked with regard to the question which parts of the current version really fit to the headline “Evaluation of the work performed”. Some aspects mentioned in Para 4.14 (e.g. the definition of the scope of work at the outset, the requirement to provide a detailed written report) play an important role during the <u>commissioning</u> of external experts and should therefore be dealt with at an <u>earlier</u> part of this document, e.g. in a separate Para after Para	X			

COMMENTS BY REVIEWER ¹⁾				RESOLUTION			
Reviewer: Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) (with Comments by GRS) Country/Organization: Germany				Page 1 of 10 Date: Oct 26 th , 2010			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
			4.11.				
27	Section 5 (general)		Check numbering of Paras in Section 5: Paras 5.7 - 5.20 are missing. Editorial.	X			
28	5.6	<p>“As noted above, when working for the regulatory body, the independence of the provider of external expert support from the organization(s) which are the subject of the regulatory activities should match that of the regulatory body itself, in relation to the specific issue for which the advice is being given. This recommendation applies to both an organization and the individuals carrying out the work within an organization. However, a provider of external expert supports may provide advice in their fields of expertise to different organizations, including other regulatory bodies, and may recruit their staff from the same range of organizations. Therefore, a support provider should make rigorous, demonstrable arrangements to maintain the required independence and clearly indicate to</p>	Clarification and simplification.	X			

COMMENTS BY REVIEWER ¹⁾				RESOLUTION			
Reviewer: Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) (with Comments by GRS) Country/Organization: Germany				Page 1 of 10 Date: Oct 26 th , 2010			
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		the regulatory body any potential, actual or perceived conflicts of interest. Any changes of personnel in the advice provider , which might affect independence, should be discussed with the regulatory body before work continues.“					
29	5.23		It is not quite clear which is the relationship between the organization set up by the State to perform research and the provider of external expert support (who supports whom?) and why it is important to address the public concerns in the context of the research activities.	X	Para was deleted		
30	Ref. [1]	... IAEA Safety Standards Series No. GSR Part 1, IAEA, Vienna (2010) (in preparation) [DS415]	Published in October 2010.	X			
31	Ref. [9]	... T/AST/049, Issue 3 (2009). http://www.hse.gov.uk/foi/internalops/nsd/tech_asst_guides/tast049.htm	Completeness; the website of the NII document is incorrectly cited.	X			

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: T. Oshima, H. Tezuka Page....1 of.... Country/Organization: NISA, JNES Date: 29 Oct. 2010							
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	General	Roles and responsibilities of external experts vary according to the requests from their contracted regulatory bodies e.g. an advisory body such as a safety committee may not have the same level of responsibility in their advises as a technical support organization to the regulatory body has. In this regard, DS429 should distinguish the expert specific guidance from common ones in relation to their roles and level of responsibilities.	4.13 and 4.14 may not the same request for all external experts. For example, a regulatory body receives some advises of an advisory body and/or individual advisor to the regulatory body, and uses it as reference but dose not need to evaluate all of them. Therefore these paras do not fully applicable to all external expertise.	X	4.13 & 4.14 has been simplified. The purpose is to evaluate the work performed accordingly with the scope.		

2	4.13	The regulatory body should evaluate the advice of external experts and determining whether and how it is utilized. <u>The evaluation of the advice should be done appropriately based on the characteristics of external expert support.</u> The regulatory body should document the decisions made...	See General comment No.1.	X			
3	2.2	Modify as follows; In some cases, there may be value in allowing the provider of external support to take some part in preparing for the decision-making process. In this the case, <u>In the case that the external support would be required, the provider of external support should be clearly placed in regulatory process and its advice should be properly documented and clearly understood. It should be used, communicated, and documented correctly, and there should be no ambiguity or dilution in the responsibility of the regulatory body which will take the final decision.</u>	Seeking advice itself means adviser's involvement in regulatory process.	X	In some cases, there may be value in allowing the provider of external support to take part in the decision-making process		
4	2.3 4 th ballet	The fourth ballet should be included in first ballet as follows; how the need for external advice is determined, as well as the usage of external advice in regulatory activity,	When regulatory body seeks the external support, the regulatory body has to clearly show how to use the external support in his regulatory activity at the very beginning of	X			

			decision to depend on external support.				
5	2.5/ line 1	Modify as follows; 2.5 Regulatory bodies should consider the availability of expertise <u>and/or service</u> and consider which source is best suited to its needs.	The list of sources of expertise shown in para 2.6 involves service activity such as ninth ballet.	X			
	2.6/ line 1	2.6 Sources of the expertise <u>and/or service</u> range from large organizations to specific individual experts.		X			
6	2.6/ Fifth ballet	Add as follows; Vendor State regulatory bodies: advice related to the regulatory structure and its application in a State from where the reactor has been purchased. This can be extremely useful but care should be taken not to underestimate that fact that the influence of <u>regulatory conditions</u> in one State may not necessarily apply to another	Clarification	X			
7	2.7	Move after 2.3.	Para 2.7 should be described in “General”, as it describes the needs of external support.			X	Para 2.7 focus in sources of expert support for specific organizations.
8	3.6/ 3 rd line	Clarify meaning of “openly” This does not mean that external support provider cannot work on a particular issue for the regulatory body on one facility and an operator on another, but all such situations need to be openly discussed and managed carefully.	Clarification Meaning of "openly" is vague.	X	“openly” is replaced by “explicitly”		

9	3.9 and 3.10	Add some instructions in the case of individual. Sometimes competent providers are extremely limited in very few people.	Para 3.10 describe the case of legal parties or organizations. Then, this may not be applied in the case that competent provider is individual,			X	Even an individual belong to an organization or has at least a specific status. Para 3.10 is merged with 3.9
10	3.23/ 2 nd line	Add as follows; The provider of external expert support should also be made aware of the existence of any confidential proprietary information (<u>including</u> information of commercial value if disclosed), of its precise scope, restrictions on its use and the organizations to whom it may be disclosed.	Information to be closed should no be limited to "commercial value"	X			
11	4.11/ 3 rd ballet	Does the provider of external expert support have a potential, actual, or perceived conflict of interest? If this is the case, is this situation openly discussed and managed?	Clarification Meaning of "openly" is vague. same as article 3.6	X			
12	4.8/ line 7	What is "a general contractor"?	Clarification	X	Replaced with: "an advice contract manager"		

Reviewer: **M. Anwar Habib**

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Country/Organization: **Pakistan/PNRA**Date: **29-10-2010**

Comment No.	Para/Line No	Proposed new text	Reason	Accepted	Accepted but modified as follows	Rejected	Reason for modification/rejection
1.	2.6 Sources of expertise range	<p>QA Organizations: These Organizations which may be national or international can provide advice within their fields of expertise, however contacts with operators, designers etc may mean that the advice is not fully independent.</p> <p>Manufacturing/industrial organizations: These Organizations which may be national or international can provide advice within their fields of expertise, however contacts with operators, designers etc may mean that the advice is not fully independent;</p>	<p>Quality Assurance is an important area and is considered during all phases of Nuclear power plants design, construction/ manufacturing, installation, commissioning, operation, maintenance and decommissioning. Any technical issue may need technical support from TSOs.</p> <p>Manufacturing and industrial organizations play a leading role in performance of NPPs and any problem during operation may be properly addressed by the involvement of such organizations. Moreover, NPP components are manufactured following the codes which are formulated by manufacturing industries.</p>	X	Added in bullet 6		
2.	3.0 Characteristics of external expert support	Financial aspects and time commitment are also the characteristics which may also be included in the section.	This information will enhance the confidence of the customers before taking the services of technical support organizations or experts.			X	Need to be discussed. If agreed, it will be added in a further version
3.	2.8	a. Review & Assessment b. Inspection	Regarding Areas for External Expert Support please include the proposed new text. These	X			

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Country/Organisation: UK(NUSSC)/HSE(ND) comments for DS 429 Date: 21/10/2010							
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	General		This document provides a reasonable high-level overview of the relevant considerations, including procurement and security issues. The UK supports this document, although it might be worth noting that procurement arrangements may vary according to national laws.	X			

COMMENTS BY REVIEWER				RESOLUTION			
Country/Organization: United States of America Date: October 2010							
Comment No. / Reviewer	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	General	Realizing the importance of independent views and advice of the providers; the document obscures the relevance of effective independence from Ref [1]. In this context, "Independence [1]" is an issue between the regulatory body and the applicant or the licensee. The obligation is on the regulatory	Clarification of the mix up between independence of the regulators and independence of the external support provider. We suggest keeping independence of the provider, at best, as a	X	Will be discussed and take into account in a later step. Independence is one of the big issues of this guide...		

COMMENTS BY REVIEWER				RESOLUTION			
Country/Organization: United States of America		Date: October 2010					
Comment No. / Reviewer	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		<p>body to ascertain whether the advice or service can be used or taken without undue influence or conflict of interest. It seems unrealistic to impose <i>ex post facto</i> independence obligations on the external expert organizations. However, it is incumbent on the regulatory authority to ensure that there is no actual or perceived conflict-of-interest for the provider.</p> <p>This issue should require selective revisions of the text in paragraphs 2.6 and 3.1 - 3.11.</p>	<p>secondary consideration throughout the document. In other words, providers cannot be held to the same measure or pedigree of independence that is required by the regulatory body, unless the country delegates some or all of the functions of its regulatory body to an external organization.</p>				
2	General Definition P3, Footnote	<p>The Definition "Providers of External Support," presented in the footnote contemplates that the provider needs to be recognized or defined within the regulatory structure. In addition, it appears to exclude commercial entities, academic institutions, and other reliable providers of expert support. In many cases, the external support</p>	<p>Providers of external expert support may not always be identified within the structure of the organization but can be designated to provide technical support on <i>ad-hoc</i> basis as needed by the regulatory body or the concerned</p>	X			

COMMENTS BY REVIEWER				RESOLUTION			
Country/Organization: United States of America		Date: October 2010					
Comment No. / Reviewer	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		organization or persons cannot be identified within the structure of the organization as support can be provided through Ad-hoc working groups or contractors especially designated to address safety issue outside of the regulatory structure. Therefore, we suggest the footnote be modified to read: <i>“A provider of external expert support is a person or organization that is not resident within a regulatory body, but is recognized of its expertise and competency in safety and which can provide support to the mission of the regulatory.”</i>	organization.				
3	General Scope,	Under the scope of the SG, it was stated: “This guide covers all forms of support for safety issues that may be required by a regulatory body, whether technical, legal, analytical or other, but does not deal with support that may be requested for security issues. Safety and security are	Clarification and Completeness: The guide needs to acknowledge synergies and interface of safety and security and emphasize the need for the expert support providers to be cognizant	X	Added in the para		

COMMENTS BY REVIEWER				RESOLUTION			
Country/Organization: United States of America		Date: October 2010					
Comment No. / Reviewer	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		<p>complementary and there could be advantages if the processes and procedures applied to both safety and security are similar.”</p> <p>We note that the IAEA has recognized the synergies between safety and security and established a “<i>Joint AdSec CSS Task Force</i>” to address interface and integration of safety and security. In other words, providers of supports pertaining to safety need to be cognizant of security issues and <i>vice-versa</i>, so that advice and decisions can be made early based on informed assessment of both safety and security issues. The current guidance appears to contemplate that safety issues need to be dealt with independent of security issues.</p>	of such synergies and interface.				
4	Para. 2.2	Add a sentence to the end of the paragraph to read as: “It is incumbent on the regulatory body to clearly attribute those recommendations adopted and	In cases where only some recommendations from external expert organizations are included in decision-making, or in	X			

COMMENTS BY REVIEWER				RESOLUTION			
Country/Organization: United States of America		Date: October 2010					
Comment No. / Reviewer	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		rejected from the expert organization for the purpose of clarity and transparency.	cases where recommendations are rejected, the regulatory body must be clear and precise that in any such departure, there is justification and transparency, to avoid allocating inaccurate attribution to such external expert organizations.				
5	2.3	“However, in using a provider of external expert support processes and procedures should be put in place so that the advice is provided in a properly structured predetermined manner.”	Without further reference or explanation, it is not clear what is the meaning of “properly structured.” The process and procedures should be predetermined by the regulator.	X			
6	Para. 2.3	Modify to read as: “...a properly structured manner. Within the context of the available resources and existing infrastructure , this structure should include: • how the need for external advice	Clarity and Completeness: There should be some acknowledgement that if a country or governmental organization requires	X			

COMMENTS BY REVIEWER				RESOLUTION			
Country/Organization: United States of America		Date: October 2010					
Comment No. / Reviewer	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		is determined, In addition, some perspective of a graded approach to address the bulleted items in this paragraph needs to be articulated.	“outside advice”, to expect a detailed documented strategy outlining the origins, problems, tactics and strategic means for upgrading or even establishing a regulatory infrastructure may be unrealistic				
7	2.3	After 2 nd bullet, add three new bullets to read: <ul style="list-style-type: none"> •Process of determining clearance of provider from conflict-of-interest. •Adoption of code of ethics and confidentiality protocols. 	These listed elements are necessary to be incorporated in the structure of establishing processes and procedures for the external support procurement.	X			
8	2.4/3	“The source should be an truly expert in the area of interest and capable of providing the necessary advice. This competence can be clearly demonstrated through formal processes, such as examples of previous work experience , CVs of staff etc.”	Adds clarity.	X			

COMMENTS BY REVIEWER				RESOLUTION			
Country/Organization: United States of America		Date: October 2010					
Comment No. / Reviewer	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
9	Para. 2.4	Either delete the last sentence or else modify it to read as: If the external source uses experts from outside its own organization as subcontractors, who in turn may use other subcontractors, the primary provider of the expertise should document the independence, reliability and competence of these organizations and individuals. —should—be demonstrated—during—the subsequent—procurement processes.	Correctness and clarity: This paragraph is too dogmatic; because the composition of expert team would not necessarily be configured with such control by the Member State requesting the assistance. The independence of subcontractors also needs to be established and confirmed.	X			
10	Para. 2.6 ALL	Delete all these phrases using independence and properly introduce them in Chapter 3. At which point these should be defined and distinguished. The Safety Glossary does not define any of these terms.	Use of phrases such as independent, fully independent and effectively independent are not appropriately portrayed nor clearly distinguished. Whereas competency, reliability, accuracy and relevance are marginalized.	X			
11	2.6/entire	General Comment: The current text	In light of the requirement		Not added in		

COMMENTS BY REVIEWER				RESOLUTION			
Country/Organization: United States of America		Date: October 2010					
Comment No. / Reviewer	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
	section	regarding sources of expertise is of a top-level nature. If feasible, it is suggested that an appendix be added to the IAEA DS429 document to list organizations according to the categories of Section 2.6 which have performed significant work related to nuclear safety in the past X (to be determined) years.	of competence which may be demonstrated by "previous work," it is useful to provide a reliable list of sources that a regulatory body can deliberate on for obtaining external expert support.		the text. But good idea that could be a part of the scope of the future TSO forum		
12	Para. 2.6, bullet 3	Delete bullet. If the dedicated organization exists within the confines of the State's legal structure, then it is not an external expert organization.	Correctness & Clarity			X	A dedicated organization could exist but not be part of the regulatory body (like IRSN in France)
13	2.6/bullet 4 and 5	General Comment: It is stated under the fourth bullet, "advice [from State regulatory bodies] can be obtained through individual contacts or international forums." Depending on the nature of the advice, the currently stated vehicles of communication among State regulatory bodies may not be sufficient. It is suggested that IAEA establish a way (e.g., website,	Certain State regulatory bodies, in particular those in most need of assistance, may not have established extensive contacts with other State regulatory bodies with the developed capabilities to provide them with assistance.		Not added in the text. That could be a part of the scope of the future TSO forum		

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Country/Organization: United States of America		Date: October 2010					
Comment No. / Reviewer	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		contact list included in DS429, etc.) to serve as a point of contact for referring a State regulatory body in need of assistance to other State regulatory bodies which may be able to provide that assistance. A new paragraph may be needed to describe how this would be done.					
14	Para. 2.6, bullet 5	Rewrite as: Vendor State... in a State from where the reactor has been purchased structures, components and services to the applicant licensee are provided; for example reactor vessels.	To have an inclusive statement. Vendors provide more services and products than just reactors. Waste packages, disposal/cleanup services, etc...	X			
15	2.6/bullet 7	"contracts with these organizations may be overarching so that their advice can be called on when needed or the contracts can be specific as each issue arises"	For clarity	X			
16	2.6/bullet 9, line 3	"while they may also work for the operator, the issue of independence is of lesser important "	The independence and quality of testing and measurement services obtained by the regulator are necessary and often		According to the remark 10, this part of the sentence was removed.		

COMMENTS BY REVIEWER				RESOLUTION			
Country/Organization: United States of America		Date: October 2010					
Comment No. / Reviewer	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
			critical to support regulatory inspection and enforcement actions.				
17	Section 2.7- General	Consider developing a database of external support experts by discipline for all entities to share.			That could be a part of the scope of the future TSO forum		
18	2.8	Add Bullet to list of types of external support <ul style="list-style-type: none"> • Operations support including development and interpretation of nuclear plant technical specifications 	Seems like a specific area not previously included in the list.	X			
19	2.8/bullet 6	Drafting of regulations and guides regulatory documents; or	External expert support may be asked for drafting additional regulatory documents.	X			
20	Section 2.8	After last bullet, add two new bullet: <ul style="list-style-type: none"> • QA/QC and audit 	Completeness	X			
21	3.2	At end of paragraph, add: “Exception may be granted due to lack of expertise in certain technical areas (e.g., criticality, climate, and seismology).”	Recognition of lack of expertise in certain technical areas and therefore exception may be granted with proper overview of the regulator	X			

COMMENTS BY REVIEWER				RESOLUTION			
Country/Organization: United States of America		Date: October 2010					
Comment No. / Reviewer	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
			for appropriate decision-making.				
22	3.5, 1 st sentence	Delete sentence.	Clarity and correctness: The expert organization may be or may have been involved in providing services to an applicant or licensee in the past. This would seem to apply <i>ex post facto</i> disqualification to such external expert organizations.	X	The sentence moved as: "Independence of advice means that the provider of external expert support should be able to form and express its technical judgment free from undue pressure from interested parties."		
23	3.5, 3 rd sentence	Delete: "The ability of the provider of external expert support to develop its own research assists in the development of state-of-the-art knowledge and techniques, and foster independent judgement."	Correctness: The last sentence may not be necessarily true.	X			

COMMENTS BY REVIEWER				RESOLUTION			
Country/Organization: United States of America		Date: October 2010					
Comment No. / Reviewer	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
24	3.6	Perhaps suggest more firmly that hiring nuclear industry consultants who work primarily for industry may not be the optimum solution. Staff noted that other countries, like Finland, also chose independent agencies, for example, when they tested for BWR bubble characteristics.	NRC has generally chosen not to employ contractors who predominantly work for licensees, to avoid the potential appearance of a conflict. Although with GI-193, NRC has contracted with Purdue Univ who has also been contracted by PWROG on GL-08-01, a related issue.	X			
25	3.6/3	“This means that all situations should be analyzed for actual, potential or perceived conflicts of interest. Actual conflicts of interests should be eliminated immediately, to the extent possible. This does not mean that external support provider cannot work on a particular issue for the regulatory body on one facility and an operator on another, but all such situations and any potential or perceived conflicts of interests need to be openly	Adds clarity. Actual conflicts of interests should be eliminated immediately. Potential and perceived conflict of interest should be openly discussed and managed.	X			

COMMENTS BY REVIEWER				RESOLUTION			
Country/Organization: United States of America		Date: October 2010					
Comment No. / Reviewer	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		discussed and managed carefully.”					
26	Section 3.6	The second sentence stated “ <i>This does not mean that external support provider cannot work on a particular issue for the regulatory body on one facility and an operator on another.</i> ” This may contemplate an appearance of a conflict of interest if the provider works simultaneously for the operator and the regulator and the two assignments are somehow interrelated. The statement should be clarified to make sure that the two assignments are not related whatsoever.’	Clarification	X			
27	Para 3.7, 2 nd bullet	Delete this bullet. Licensee could conduct its own technical studies and regulators should verify and conduct own studies if necessary to examine correctness of licensee’s analysis.	This implies that the licensee cannot rely on technical support information it pays for.	X	The sentence changed as: “When the licensee has to pay for a technical study in order to bring due elements to the regulatory body.”		

COMMENTS BY REVIEWER				RESOLUTION			
Country/Organization: United States of America		Date: October 2010					
Comment No. / Reviewer	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
28	Para. 3.8 ALL	Delete the paragraph.	This guidance is not realistic. There may not be any external expert organizations that can comply with such an exclusion and disqualification. Developing countries, which are the most needing of external expert advice, may not be in the position to make such determinations.	X			
29	3.9/2	“It may be impossible for the regulatory body to find a specific external expert free from potential conflicts of interest. This would occur in very rare cases. Such may be the case for example.”	Adds emphasis that this would not be common practice.	X			
30	3.16/bullet 1	General Comment: Without specifying the nature and type of the certification, this sentence does not have adequate context, especially when consideration of the certification is not essential.		X	The sentence is adapted: “For an individual expert, technical		

COMMENTS BY REVIEWER				RESOLUTION			
Country/Organization: United States of America		Date: October 2010					
Comment No. / Reviewer	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		Alternatively, to provide context, a statement addressing the value of certification of an individual expert, who is not an academic expert, should be added to the preceding sentence, "For an individual expert, technical competency should be ensured by verifying that he has already provided similar external support in a satisfactory way (reference list)."			competency should be ensured by verifying that he has already provided similar external support in a satisfactory way (reference list). For an academic expert, a publication list is a useful additional tool, and documented research activity should be adequate to the task assigned. For such		

COMMENTS BY REVIEWER				RESOLUTION			
Country/Organization: United States of America		Date: October 2010					
Comment No. / Reviewer	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
					individual or academic expert, certification may be a factor to demonstrating continued competency.”		
31	3.16/bullet 2	<p>2nd bullet</p> <ul style="list-style-type: none"> For an expert organization, the existence of a certified—quality management system is a useful characteristic: <ul style="list-style-type: none"> through the traceability of processes and documentation, it helps demonstrate the technical competency of the organization; in case of the establishment of a long term support (e.g. dedicated support organization), the existence of a certified quality management system, provides confidence that technical competency will be maintained on the long term. 	<p>Without further reference or explanation, it is not clear what is the meaning of “certified quality management system.”</p> <p>Certiifed to what standards or certified by what organization? In most other IAEA Safety Standards, the term “management system” is used in place of quality assurance or quality management program.</p>	X	This bullet is placed after bullet 3.19		

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Country/Organization: United States of America		Date: October 2010					
Comment No. / Reviewer	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
		(See para 3.19 for guidance on an adequate management system).					
32	Para. 3.22-23	Realistically, once information is provided to a regulatory body, any guarantees -- not originating from the regulatory body -- to vouchsafe the confidentiality may be moot. It may be advisable for this safety guide to recommend redaction of portions of such data or information, as a means of protecting confidentiality.	Implementation aspects and correctness: If information is provided by a foreign source requesting confidentiality or security of a portion of the advice information, what option does the external expert organization have to resist the national government's demand that the information be provided to the government? Not all countries have judicial systems with authority to sanction governmental agencies violating legal confidentiality.	X	Also a difficult issue that should be delt case by case. That could be discussed, in the future TSO forum		
33	3.23/6	"The regulatory body should inform the owner of the IPR its intension to pass information to a third party...." IPR should be spelled out.	IPR is not defined.	X	intellectual property rights		

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Country/Organization: United States of America		Date: October 2010					
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34	4.4 to 4.9/NA	Sections 4.4 to 4.7 are missing; Section 4.8 is placed after Section 4.9	A potential typographical error.	X			
35	4.11/bullet 3	Does the provider of external expert support have a potential, actual, or perceived conflict of interest?	Consider deleting. Section 3.16 explained what should be done in the cases of actual, potential and perceived conflict of interest.	X	The sentence has changed: "The provider of external expert support should not have an actual conflict of interest. In case of a potential or perceived conflict of interest, the situation should be explicitly discussed and managed"		
36	4.11	Consider Adding: "Is the expert knowledgeable, by direct	Prior Experience: The ASME PRA Standard	X			

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		experience, of the specific methodology, code, tool, or approach for which he is employed. Understanding and competence in the assigned area shall be demonstrated by the range of the individual's experience in the number of different, independent activities performed in the assigned area, as well as the different levels of complexity of these activities.”	has a section on this which can also be reviewed for further insights. This suggested wording paraphrases some draft language floated around 2001 that firms up the requirements for selecting an expert.				
37	4.14/5	“...and any related recommendations that may assist are requested by the regulatory body.”	Unwanted recommendations or opinions tend to be subjective and may not assist the regulatory body’s decision-making process.	X	The sentence has changed: “The written report provided by the external expert, should support the regulatory body’s evaluation.”		
38	5.2/line 6	“For this reason, all such interfaces should be led by an appropriate regulatory representative. with an “intelligent customer” capability. ”	The term “intelligent customer” is introduced in paragraph 2.2 with reference to a UK			X	The notion of “intelligent customer” is removed from para 2.2 and appears here

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			document reference #9. Use of this term, undefined in the IAEA Safety Glossary should be deleted. Further use of this term in para 5.2 is not needed				for the first time in the text. The use of this term will be discussed in a further version.
39	5.3 to 5.6	Sections 5.4 and 5.5 are missing.	A potential typographical error.	X			
40	5.6/5	“However, a provider of external expert supports may provide advice in their fields of expertise to different organizations, including other regulatory bodies, and may recruit their staff from the same range of organizations. ”	Although a regulatory body may place restrictions on the external expert providers' use of certain individuals on a specific contracted work, I don't think this document intends to interfere the external expert providers' recruiting policy.	X	This para was deleted. A part is sent to chapter 3 (independence).		
41	5.21/8		Consider including additional guidance on keeping traceable documents and an auditable process.	X	That could be a part of the scope of the future TSO forum		
42	5.6 to 5.21	Sections 5.7 to 5.20 are missing	A potential typographical	X			

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			error.				
43	5.21/line 6	“Unless there are confidentiality issues, all external advice should be published to enhance transparency as part of the regulatory body’s interested party engagement process.”	For clarity.		Para was deleted		
44	5.24/last	“instructions and authorizations needed for the work to be quoted or used and provide guidance on handling proprietary information. ”	Consider including additional detailed instructions with regards to the external experts handling proprietary information.	X			
45	5.25	All communications regarding the work performed by the provider of external expert support at the request of the regulatory body should be under it’s—the regulator’s -control and direction.	Clarification is needed to be specific in identifying who controls and directs the communications.	X			
46	General	The unwritten rule of numbering references in the text according to their first appearing sequence is not strictly followed. The following is the reference number with the page number of its first appearance in the parenthesis: 1(page 4), 2(page 3),	The unwritten rule of numbering references in the text according to the first appearing sequence is not strictly followed.	X			

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		3(page 4), 4(page 5), 5(page 14), 6(page 18), 7(page 23), 8(page 22), 9(page 6), and 10(page 16). It's better to rearrange the references.					
47	General	Consider including additional detailed instructions with regards to the external experts handling proprietary information.			Will be considered in a further version		
48	General	Consider including a section discussing management of contracts/budgets associated with external experts, as appropriate.			Will be considered in a further version		
49	General	Consider adding guidance for the regulator to provide feedback to their contractors as part of the contract management process.			Will be considered in a further version		
Clarification & Technical Editing Comments Below							
50	2.2	"In this case the advice should be properly documented and clearly understood. It should be used, communicated, and documented correctly , and there should be no ambiguity or dilution in the responsibility of the regulatory body	Without further reference or explanation, it is not clear what is the meaning of "documented correctly." Also suggest that the word "take" be revised to "make."	X			

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		which will takemake the final decision.					
51	2.4/5	"...previous work, CVs of staff etc." CV should be spelled out.	CV is not defined.	X	Curriculum Vitae ("Resume" in US language). The sentence moved as: "...previous work, staff experience etc."		
52	2.6/bullet 5	"This can be extremely useful but care should be taken not to underestimate that the fact that the influence of conditions in one State may not necessarily apply to another."	A potential typographical error.	X			
53	2.6/second to last bullet	financial and economic organizations: these organizations, private or governmental, can provide advice on such matters such as the financial status of a	Adds clarity	X			

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		potential licensee, the appropriateness of investments of decommissioning funds, potential financial conflicts of interest, etc.;					
54	2.9	“The support may be continuous, in the form of a fixed arrangement, or”	potential typographical error.	X			
55	3.5/4	“The ability of the provider of external expert support to develop its own research assists in the development of state-of-the-art knowledge and techniques, and fosters independent judgement.”	A potential typographical error.	X			Need to consider deleting this comment if 15-FSME is retained.
56	3.12, 3.13, 3.17 and 3.18/NA	Sections 3.12, 3.13, 3.17 and 3.18 are missing		X			
57	4.14/ bullets 1 and 4	The regulatory body should evaluate the advice of external experts and to determine whether and how it is adopted. The regulatory body should maintain an ‘intelligent customer’ capability for all work carried out on its behalf by external experts that may impact upon nuclear safety. The regulatory body should choose	typographical errors.	X			

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		between sourcing work in-house or from contractors. That process should be informed by a clear policy that takes the nuclear safety implications of those choices into account.					