

Member States Comments on

DS429

“EXTERNAL EXPERT SUPPORT FOR THE REGULATORY BODY”

TABLE OF RESOLUTION
CONTENTS

Member States	Nb of Comments	Accepted	Rejected	Nature of Comments	
				Editorial/Clarity	Technical accuracy/ Completeness
Belgium	5	4	1	65%	35%
France	50	49	1		
Germany	56	52	4		
Indonesia	54	51	3		
Italy	40	37	3		
Japan	40	40	0		
Morocco	04	4	0		
Russia	05	3	2		
Sweden	00	/	/		
Swiss	00	/	/		
UK	47	43	4		
Ukraine	15	9	6		
USA	26	26	0		
Total:	342	318 (93%)	24 (7%)		

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COMMENTS BY REVIEWER

Co un- trie s	No.	Pa- ra/Li ne No.	Proposed new text	Reason	Ac- cept- ed	Accepted, but modi- fied as follows	Re- ject ed	Reason for modi- fication/rejection
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Japan	1	General	Regulatory evaluation of the work performed by external experts may not the same level of severity because roles and responsibilities of external experts vary according to the requests from their contracted regulatory bodies. We made comments in this regard on paras. 4.1, 4.7, 4.8, 4.11 and 4.12.		Yes			
Russia - Rosatom	1	Con- tents & General com- ments	Really, this document provides a reasonable overview of the feasible method for attraction of the external expert support could be required by RB or other organizations which were involved into national nuclear programmes with civil purposes. Primary comments by several national RBs and international organizations including EC comments as well as GRS, ASN, JNES, STUK, BelV etc., dated October-November 2010. However, it could be reasonable to add the brief Glossary to this guide. Such Para could be useful for States which are seeking to develop new facilities or activities posing radiation risks, within development of national guidelines in respect of mobilization of external expert support. Footnotes 1 to 5 could be provided in this Glossary. Also it could be reasonable to replace the term "individuals" (individual experts) by the term "detached experts" and clarify this term in Glossary. Just "detached expert" may have the verified and approved computer codes based on the experience of laboratories and dedicated nuclear area organizations. The ROSATOM supports the draft DS429 ver. 08.12.2010 in general, although it might be worth noting that any Paras could be supplemented with some details, in particularly: the Para 1, 2 and 4				No	General comment. The limited number of new definitions do not necessitate to add a glossary

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UK	1	General	<p>This is a generally well-written document, which provides sensible information and guidance on the use of external experts for support on safety issues. Occasional sections of text would benefit with some editing for clarity, and although the document structure is good there is some repetition across the document, which would again benefit with some editing. Some elements of the guidance do not sit well in the sections to which they are currently allocated and could benefit from being moved.</p> <p>The draft guide is a little long-winded in achieving its objectives, but the guidance appears to be sound and reflects a good common sense approach.</p> <p>The UK supports the progression of this version of the safety guide, taking account of the comments below.</p>		Yes	Editing errors were corrected and paragraphs were rearranged to avoid repetitions.		
UK	2	General	<p>The guidance focuses on the use of external support to regulators, but does from time to time recognise that many of the principles set out in it could apply to all organisations addressing safety issues. It would help if the context of the safety guide (which is written for regulators but can apply to a range of organisations with responsibility for safety) were made clear from the start. Alternatively it could be edited to make the entire document apply to all organisations addressing safety – much of what is set out will be useful guidance for organisations with the Intelligent Client (Customer) role, which contract specialist advice on safety issues.</p>		Yes	The guide is now mainly turned to the RB seeking external expert support.		
UK	3	General	<p>It should be recognised that competence often may reside with individuals, not provider organisations. The guidance should include consideration of this matter. Contracts with providers should not enforce the continuance of a relationship should the competent individuals no longer be available.</p>		Yes	The section “competence” was enlarged. Individual experts are considered in new par 3.16		

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UK	4	General	The guidance is unnecessarily prescriptive with respect to conflicts of interest. The onus on the regulator should be to identify and manage any potential conflicts, rather than to seek providers with absolutely no conflicts. In practice, the range of potential providers is often limited and this should not be narrowed unnecessarily.		Yes	The guide should be now more accurate in this regard.		
UK	5	General	Some of the references to higher-level documents are very general; the specific parts of the document referred to needs to be indicated. This is done in some cases but not in others.		Yes	The guide should be now more accurate in this regard.		
Belgium	1	General	We suggest that, when available, the outcome of the IAEA TSO Conference (Tokyo, 25-29/10/2010) be considered to further improve thw draft	Use the latest information	Yes	Comments made by MS take into account the outcome of TSO conference		
USA	1	List of Section Title and Subtitles under “CONTENTS”	<ol style="list-style-type: none"> <u>Section 3</u>: Insert subtitle “INDEPENDENCE” and its page no. between GENERAL and TECHNICAL COMPETENCE. <u>Section 3</u>: “CONFIDENTIALITY” <u>Section 4</u>: Using capital letters for all subtitles 	<ol style="list-style-type: none"> The subtitle “INDEPENDENCE” was not listed under Section 3 subtitles. The subtitle “confidentiality” is not consistent with the rest. The lowercase subtitles are not consistent with other sections. 	Yes			
UK	6	Title	Consider modifying to read: External Expert Support for Regulatory Bodies on Safety Issues	Clarification. The document is primarily focused on expert support to regulators but this is not reflected in the title. A more appropriate title is preferable.	Yes	The proposed title is: External Expert Support for the Regulatory Body		

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France	1	Title	Technical support to competent Regulatory Bodies in the fields of nuclear safety and radiation protection.	It is necessary to indicate who is the beneficiary of the technical support : Regulatory Bodies,	Yes	The proposed title is: External Expert Support for the Regulatory Body		
France	2	1.1	(A first conference entitled “Challenges Faced by Technical and Scientific Support Organizations in Enhancing Nuclear Safety” held in Aix-en-Provence in April 2007 followed by a second one entitled “Challenges faced by Technical and Scientific Support rganizations (TSO) in Enhancing Nuclear Safety and Security“ held in Tokyo in October 2010 (Ref. [1]) highlighted the roles, functions and value of TSOs in enhancing nuclear and radiation safety while drawing attention to the subject of providing external expert support to States developing and maintaining nuclear power programmes).	More accurate reflection of the outcomes of the Conference, as it is reported in the conclusions.	Yes			
Belgium	2	1.1	The conference of Aix-en-Provence in 2007 is mentioned. It seems useful to also mention the Tokyo conference of 2010		Yes			
France	3	1.1	Delete “In many cases, regulatory bodies, particularly those which are forming, are not able to recruit sufficient staff with the necessary expertise and skills to meet all of their needs. Thus many”	Superfluous	Yes			
Japan	9	1.1/1	All organizations involved with <u>nuclear</u> safety in relation to radiation risks...	completeness	Yes	Nuclear was not added. In the glossary: “Safety means nuclear safety unless otherwise stated...”		
Japan	20	1.1/1-2	... radiation risks where their internal resources are not able to meet their needs, may need to obtain expert advice from organizations or individuals external to their own organization.	Editorial; Delete the redundant text.	Yes			

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Germany	1	1.1 1 st sen- tence	“All organizations involved with safety in relation to <u>nuclear and radiation risks ...</u> ”	Clarification. In the 2 nd sentence of this Para “nuclear and radiation related activities” are mentioned.			No	A footnote is added to precise “radiation risk”
Indonesia	1	1.1/5	In many cases, regulatory bodies, particularly those which are forming....	Not clearly mentioned safety guide is intended. Should be clearly mentioned that this is for the Regulatory body. clarify	Yes	Sentence is deleted		
France	4	1.1/7	Replace “identified the need for” by “generally identified the need, more or less developed, for”	To soften the sentence by adding flexibility	Yes			
Italy	1	1.2 Last line	... suitable additional expert support provide <u>safety assessment information</u> which can be used in making regulatory decision...		Yes	“Input” instead of “information”		
Ukraine	1 (Ale-kseeva)	Docu- ment on the whole	It is desirable to add that a provider of external expert support can make direct contact with licensees where the facility status may lead to increased risk of safety violation and to enhance safety	This is not mentioned in the document	Yes	Licensees could seek a provider of external support at any time (new para 1.5)		
France	5	Foot- note 1	Delete “is not resident within a regulatory body” and “of the regulatory body”	Why limiting to the regulatory body? See §1.6	Yes	“is not a part of the RB”		

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Morocco	1	Para 1.2 Back- ground	Depending on the type of regulatory body, the State legal system and traditions, and the nuclear program , different structures and arrangements may exist	The nuclear program has an effect on the structures and arrangements that may exist.	Yes	“and the national nuclear programme”		
Indonesia	2	1.2/4 task. Depending on the type of regulatory body, the state legal system and culture , different		Yes			
Indonesia	3	1.2/9	‘...suitable external expert support to provide informations’	To provide more simple sentence, word ‘external’ already has ‘additional’ meaning.	Yes	Sentence was removed		
Indonesia	4	Foot note 1/2 Guide with the same meaning, is an individu or organization that is not resident of a regulatory body state but is ...	Consistency in using term and editorial	Yes			
Japan	22	1.2/5-10	The <u>A</u> regulatory body may who has have insufficient resources, in terms of number of staff, range of expertise and relevant experience to carry out its functions and responsibilities to the extent necessary and within the required schedule. Therefore, the regulatory body should have a process and procedures in place...	Editorial	Yes	One sentence added according French comment 7		
France	6	1.2	1.2. While some regulatory bodies have sufficient staff and expertise to carry out their responsibilities within their own organization, ...	Performing regulatory functions is not only a matter of staff but also of expertise.	Yes			

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France	7	1.2	Depending on the type of regulatory body, the State legal system and traditions, different structures and arrangements may exist. <u>As a result, the regulatory body may not have the resources</u> , in terms of number of staff, range of expertise and relevant experience, to carry out its functions and responsibilities to the extent necessary and within the required schedule. <u>It may also choose to call on external support for other reasons, e.g. to benefit from the best expertise available.</u> Therefore, the regulatory body should have a process and procedures in place to obtain suitable external expert support to provide input which can be used in making regulatory decisions (Ref. [2]).	Calling on external expertise may be a policy or management decision rather than an obligation, see points above. Expert support is not only or necessarily “additional”, see above. Support is broader than the mere provision of information.	Yes			
Italy	2	1.3 First line	The objective of this Safety Guide is to provide guidance and recommendations on meeting the ...		Yes			
Indonesia	5	1.3/6	‘... for the work. It also considers how the support ...’	The main sentence is too complex and need to be separated.	Yes			
Japan	23	1.3/L2	The objective of this Safety Guide is to provide recommendations on meeting the requirements of Ref.[3] on obtaining expert advice or services <u>for the regulatory body mainly</u> .	The organization which this Safety Guide intends for in this paragraph is the regulatory body mainly. (add the words “for the regulatory body mainly”)	Yes			
Japan	24	1.3/7-9	It is fundamental that while using the information provided by the external expert support in its decision-making process, the regulatory body retains responsibility for and makes the final decision.	Delete this repeating content with the 1 st sentence of para. 2.2. Moreover, this content is not OBJECTIVE of this guide.	Yes			

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France	8	1.3	1.3. The objective of this Safety Guide is to provide recom-mendations to regulatory bodies on meeting the requirements of Ref. [3] on obtaining expert advice or services. This Safety Guide aims to provide guidance on both how the regulatory body should obtain advice and how to use that advice. It considers the process in the regulatory body to determine the need for and interest of external expert advice,	The guide is meant for reg-ulatory bodies. In addition, Ref.[3] deals with the gov-ernmental, legal and regu-latory framework for safety. Calling on external support may be based on interest as well as on need, see above.	Yes			
UK	7	Para 1.3, last sen-tence	Modify to read: “.....the regulatory body retains the responsibility for making any decisions on regulatory and nuclear safety issues. ”	Improve clarity.	Yes			
France	9	1.4/5	Replace “is not always” by “may not be”	Alternative wording	Yes			
Germany	2	1.4 Add to para-graph	...regulatory body. <u>This may also cover the case, that a regulatory body issues or revises regulations and needs input from specialists.</u>	Broaden the scope of the experts' task. Needed in particular when regulatory bodies want to update regulations or ordi-nances and need input from experts.	Yes			
Japan	10	1.4/L1	The guidance will be useful both for States which are seeking to <u>introduce and</u> develop new facilities or activities ...	add the words “introduce”	Yes			

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Japan	11	1.4/4-7	Expert advice in specialized areas is not always available within a State and so arrangements with organizations in other States may be required, which can raise specific issues that should be considered by the requesting regulatory body.	This sentence is not OBJECTIVE of this guide but SOURCES OF EXPERT SUPPORT relevant. It is better to move to para.2.6, just after the 1 st sentence.	Yes			
Germany	3	1.5 2 nd sen- tence	“Because all States ... facilities or activities posing to <u>nuclear</u> <u>and</u> radiation risks ...”	Clarification. In the 2 nd sentence of Para 1.1 “nuclear and radiation related activities” are mentioned.			No	A footnote is added to precise “radiation risk”
Indonesia	6	1.5/3	‘...risks, have regulatory bodies with...’	Too complex, need a comma.	Yes			
Indonesia	7	1.5/4	..., this safety Guide is <u>primarily</u> written as guidance for regulatory bodies	Need to explain to whom the safety guide is intended	Yes			
Italy	3	1.6	<u>eliminate all paragraph</u>	It introduces confusion, the SG should deal only with support to RB			No	But para was adapted in order to not introduce confusion.

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Russia - Rosatom	2	1.6 Objective	<p>It was pointed that this Safety Guide has been written with a focus on support to regulatory bodies, much of the advice can, with only minor adjustment, be used by other bodies seeking external expert support. "...Other organizations with legal, professional or functional responsibilities for safety may benefit from using this Safety Guide". In this case, it could be more sensibly replace the Para 1.6 to Para 1.1 and combine the both text 1.1 and 1.6. The full prevalence of this document shall be stated in the beginning of Guide.</p> <p>In addition, it could be sensibly replace the hereinafter referred term "regulatory body" by the more covering term "customer of external expert support" through the text of this Guide. Otherwise, the title of DS429 should be replaced by "External Expert Support for Regulatory Bodies". Then big quantity of details related to "conflict of interests" and "independence of external expert support" will be fully justified.</p>		Yes	<p>Paras remains but with modifications.</p> <p>The proposed title is: External Expert Support for the Regulatory Body</p>		
Indonesia	8	1.6/1	'...this Safety Guide is intended for regulatory bodies...'	To provide simple sentence.	Yes			
Japan	25	1.6/1	Although this Safety Guide can also be used, has been written with a focus on support to regulatory bodies, much of the advice can, with only minor adjustment, be used by other bodies organizations seeking expert support from outside of their own organizations.	Editorial Rephrase the redundant text.	Yes			
Indonesia	9	1.6/3	'...obtain expert support. It's also useful for States ...'	The main sentence is too complex and need to be separated.	Yes	The initial location was para 1.4		

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Indonesia	10	1.6/7	‘...this Safety Guide. They may include operators...’	Too complex, need to be separated.	Yes			
Ukraine	1 (Sholomitsky)	General after Para 1.6	It is proposed to add to the “Introduction” of the Safety Guide (e.g., after para 1.6 in “Objective”) new para. explaining that the guidance establishing the requirements and/or good practices for TSO, recommendations for their infrastructure and technical needs, and more generally, for their operation for providing support to regulatory authorities will be provided in some other guide (to be developed by the Agency).	The document as is addresses mostly the needs of regulatory authorities related to selection of a TSO and to establishing appropriate formal relations with them etc. Another guide could provide requirements / recommendations for everyday practices of the TSOs.			No	It is not the purpose of this guide to announce the creation of another one. This comment will be take into account in the TSO Forum
USA	2	4/1.6/last sentence	...and consignors and carriers .	Misspelled word corrected and removed operational group unlikely to rely on external expertise for safety.	Yes			
Germany	4	1.7 1 st sentence	“This Safety Guide covers ... that may be requested for security <u>and safeguard</u> issues.”	Amendment.	Yes			
Italy	4	1.7 Second line	by a regulatory body, whether technical, <u>scientific</u> , legal, analytical or other, but does not deal with		Yes			

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USA	3	5/1.7/line 7	Thus in this Safety Guide consideration is only given to issues related to the security....	Consistent with the changes that you made in many places in this revision, replacing “guide” by “Safety Guide.”	Yes			
Indonesia	11	1.7/9	‘...third parties. This guide also considers the need...’	Too complex, need to be separated.	Yes			
UK	8	Para 1.7	Clarification needed. Is it clear that the guidance applies to radiological environmental safety regulation, as well as safety?				No	It should be clear according the Glossary’s definition: “Safety’ as used here and in the IAEA safety standards includes the safety of nuclear installations, radiation safety, the safety of radioactive waste management and safety in the transport of radioactive material;
Italy	5	1.8	The Safety Guide also considers the ways and forms that external support can be provided: dedicated support organizations (e.g. statutorily mandated technical support organizations); other commercial technical support organizations either through overarching contracts or specific contracts; other institutions regulatory bodies ; advisory committees; research organizations; academic bodies; individual experts or others.				No	Here it refers to commercial organizations

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UK	9	Paras 1.7 and 1.8	Consider changing the order of the information in these two paragraphs, so that the first paragraph says what the scope of the document is (which is given in the first two lines of Para 1.7 and Para 1.8) and the second paragraph specifies what the scope does not include (Para 1.7 from “....but does not deal with....” to the end).	For clarity.	Yes			
Japan	26	1.8/2	Replace ‘dedicated support organization’ with ‘dedicated organization’.	Consistency of the terminology defined in para. 2.7.	Yes			
Japan	27	1.8/4	Replace ‘advisory committees’ with ‘advisory bodies’.	Consistency of the terminology defined in para. 2.7.	Yes			
France	10	1.8	The Safety Guide also considers the ways and forms that external support can be provided: dedicated support organizations (<u>e.g. statutorily mandated Technical Support Organizations</u>); commercial organizations either through overarching contracts or specific contracts; other regulatory bodies; advisory committees; research organizations; academic bodies; individual experts or others.	TSO are generally non-commercial organizations.	Yes			

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Belgium	3	Paras 1.8, 2.1, and 2.7	<p>In Belgium, there exists an advisory committee, the “Scientific Council”. Its role in the licensing process is defined by a royal decree.</p> <p>So, the Belgian regulatory Body (RB) is not really “governing” its action: this committee doesn’t directly work under the direction of the RB. Also the RB must follow a negative advice of this committee, and cannot just take it in its final evaluation as an “advice”.</p> <p>We thought that, at least in Belgium, the role of the advisory committee is very different of the role of other external expert supports – and that the recommendations of this guide are not straightforward applicable to the “advisory committees”. This should be excluded from the scope.</p>					No This comment may alight to the fact that the prime responsibility for safety doesn’t remains entirely with the Belgians RB. RB in Belgium may derive from the Scientific Council. In this case the Scientific Council should not be considered as an advisory committee but as the highest part of the regulatory organisation.
Indonesia	12	1.9/2	‘... external expert support is and what it can provide...’	To be easier to understand.	Yes			
Morocco	2	Para 2.1	The IAEA’s Fundamental Safety Principles (Ref. [4]) state that “an independent Regulatory Body, should be established and sustained” with “adequate ... human and financial resources to fulfil its responsibilities” (Principle 3). "Principle 3" should be replace by "Principle 2"		Yes			
Germany	5	2.1 1 st sentence	... “an independent Rregulatory Bbody, must-should be established and sustained” with “adequate ... human and financial resources to fulfil its responsibilities” (Principle 2-3).	Correct citation; text refers to Principle 2 of Ref. [4].	Yes			

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Germany	6	2.1 2 nd sen- tence	... “regulatory body shall employ a sufficient number of ... qualified and competent staff ... to perform its functions and to discharge its responsibilities” (Requirement 18).	Full citation. The number of staff is important, but the number on its own says nothing about quality. Requirement 18 of Ref. [3] emphasizes qualification and competency of staff as crucial criteria.	Yes			
France	11	2.1/6	However, Ref. [3] recognizes that a regulatory body may “obtain technical or other expert advice ... in support of its regulatory functions”	Calling on external support is not necessarily based on need, see above.	Yes			
Germany	7	2.1 3 rd sen- tence	... “obtain technical or other expert professional advice ... in support of its regulatory functions” (Requirement 20) emphasizing that such advice “shall not relieve the regulatory body of its ... responsibilities” (Requirement 20).	Correct citation; cite Requirement 20 once only to improve readability of the sentence.	Yes			
France	12	2.2	In some cases, there may be value in allowing the provider of external support to take part in the decision-making process. In any case the expert advice should be properly justified, explained, documented and clearly understood.	It is always recommendable that advice be justified, explained, documented and clearly understood.	Yes			
Ukraine	1 (Kocha)	2.2	It is proposed to describe in detail (or to provide reference to other document / chapter of this document) how an external support provider can participate in decision-making.	It is necessary to understand rights and duties of both the regulator and a technical support organisation.			No	Sentence was deleted. The provider participates in the decision making process by the input he provides.
France	13	2.2/6	Delete “In some cases, there may be value in allowing the provider of external support to take part in the decision-making process. In this case”	Superfluous. Depends on regulatory processes If not deleted, could become a footnote at the end of 2.2	Yes			

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France	14	2.2/8	Delete “It should be used, communicated, and documented,”	Duplicates the idea of the previous sentence.	Yes			
Indonesia	13	2.2/10-11	‘...attribute those recommendations from the expert organizations adopted or rejected for...’	To avoid mis-interpretation	Yes			
Italy	6	2.2 Central sentences	In obtaining external expert advice, arrangements should be put in place to ensure that the regulatory body retains the responsibility for making the decision and is not unduly influenced by the support provider. This means that the regulatory body should have an adequate core competence on the subject as a minimum to retain the ability to both frame the request for advice and understand the advice when it is received. In some cases, there may be value in allowing the provider of external support to take part in the decision-making process. In this case The expert advice should be properly justified, explained, documented and clearly understood. It should be used, communicated, and documented, and there should be no ambiguity or dilution in the responsibility of the regulatory body which will make the final decision. <u>In some cases, there may be value in allowing the provider of external support to take part in the decision-making process. This participation shall be solely in support to the Regulatory Body</u>		Yes	This sentence was deleted as suggested by others comments. It should be a part of regulatory processes		
Italy	7	2.2 Last sentence	It is incumbent on the regulatory body to clearly attribute those recommendations adopted and rejected from the expert organization for the purpose of clarity and transparency.	Not clear	Yes			

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Co un- trie s	No.	Pa- ra/Li ne No.	Proposed new text	Reason	Ac- cept- ed	Accepted, but modi- fied as follows	Re- ject ed	Reason for modi- fication/rejection
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Japan	21	2.2 3.2 2 nd bullet 3.4 5.7	Change “expert organization” to “external expert support provid- er”.	The “expert organization” is not explained in footnote 1. Simplify the terminology.	Yes			
Italy	8	2.3	The regulatory body’s staff should have sufficient technical knowledge to enable them to identify problems, to determine whether it would be appropriate to seek assistance from an ex- ternal expertise, to manage the external support during its elabo- ration and at the end to evaluate the external expert’s advice.	For clarity	Yes			
Ukraine	1 (Dybach)	2.3	The regulatory body’s personnel should have sufficient technical knowledge to enable them to identify problems, to determine whether it would be appropriate to seek assistance from an ex- ternal expert and at the end to evaluate and use the external expert’s advice.	The RB should be capable of making correct regulato- ry decisions based on ex- perts’ advice (not only of evaluating their advice)	Yes			
USA	1	6/2.3/3	Add “relevant” after “the external expert’s”	Clarify only applicable ad- vices would be considered.	Yes			
USA	2	7/2.4/1 st para- graph, last sen- tence	...processes and procedures should be put in place so that the advice is provided in a predetermined manner accordance with an established system or infrastructure.	“...the advice is provided in a predetermined manner” is misleading. It could be wrongfully interpreted as the advice was predeter- mined by the regulatory body and the external ex- pert support provider.	Yes			
USA	3	7/2.4/1 st sub- bullet of 2 nd bul- let	Delete “it only lets.” Add “are placed” after “significant,” and delete “to” after word “significant.”	Improve clarification of an overall message.	Yes			

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Italy	9	2.4 1st bul- let	How The identification of the need for external advice is deter- mined, as well as the usage of external advice in regulatory ac- tivity		Yes			
USA	4	7/2.4/2 nd bullet	“The regulatory body should ensure that it lets contracts for work with safety significance to only contractors with suitable compe- tence, acceptable standards and adequate resources.	To emphasize the contrac- tors’ competence, accepta- ble standards and ade- quate resources, instead of safety significance.	Yes			
Italy	10	2.4 3 rd bul- let	The regulatory body should ensure that it only lets contracts for work with safety significance to contractors with suitable compe- tence, acceptable standards and adequate resources.		Yes			
USA	4	7/2.4/6 th bullet	How the external expert advice provider and its advice are man- aged and how the advice of the provider is considered in the regulatory decision making process;	The word “manage” may be better than “control.” Also, disposition of a provider’s recommendations should be based on solid technical basis and regulatory impli- cations. This is how they are considered.	Yes			
Italy	11	2.4 8 th bullet	How the external expert advice provider and its advice are man- aged and controlled and the degree to which the advice of the provider is considered in the regulatory decision making pro- cess;		Yes			
France	15	2.3/3	Before “evaluate”, add “understand and”	Clarification	Yes			

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Indonesia	14	2.4/1	... The regulatory body should choose	editorial	Yes			
France	16	2.4	When applicable or possible , the regulatory body should choose between sourcing work in-house or from external expert support providers.	In-house work or external support is not accessible or possible in all situations.	Yes			
Indonesia	15	2.4/Pag e7/Line 17	‘which the advice is considered ...’	Word ‘of the provider’ is not necessary.	Yes			
Indonesia	16	2.4, line 4 from above	Put a comma after ‘support’ and before ‘processes’.	To make the sentence clearer.	Yes			
UK	10	Para 2.4, 1 st sentence	Modify to read: “The regulatory body should choose between sourcing...”	Typo	Yes			
UK	11	Para 2.4	Consider adding another bullet point to read: “A process for checking that the provider has the requisite level of security clearance to undertake the work;”	For completeness. As the level of security clearance may vary from one project to another, it is worthwhile checking this for each project.			No	It is now in contradiction with the scope para 1.7

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Ukraine	2 (Kocha)	Para 2.4 bullet 5, para 3.7, 3.8, 4.6	An appropriate procedure should be provided for and it should be described in detail how to avoid conflict of interest with respect to present corresponding information by an external support provider. It is important to select a competent and independent support provider.	To establish a legal basis to select a competent and independent support provider.			No	More details on the text now. Conflict of interest should be managed
Morocco	3	Para 2.4 Bullet 7	<ul style="list-style-type: none"> Processes for understanding the external advice and incorporating it in the regulatory decision-making process. 	Processes for evaluating and making use of the external advice should be also considered.	Yes			
Germany	8	2.5 Add to Paragraph	... Organizations and individuals. <u>Furthermore, the employment of subcontractors should be properly communicated to the regulatory body.</u>	Regulatory body must know when somebody is doing work for him whom he did not employ/hire directly.	Yes			
Indonesia	17	2.5/2	The source should be an expert and competence in the area of interest and capable of providing the necessary advice.	should be expert and competent in their fields.	Yes			
Italy	12	2.5 2 nd line	... should have expertise be an expert in the area of interest and capable of providing the necessary advice. This....	1.	Yes			
USA	5	7/2.5/ 3 rd sentence	Delete “competence” and replace with “competency.”	Grammar usage	Yes			
Japan	28	2.5/3	This competence can be clearly demonstrated through formal processes, such as examples of previous work experience, staff experience, etc.	Clarification The wording “formal processes” is unclear. It should be explained/ clarified.	Yes	Example are given to explain what could be a “formal processes”		

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Indonesia	18	2.5/4	previous work experience, or staff liscence , etc.		Yes			
Germany	9	2.6 Replace old paragraph with new text	<p>2.6. Regulatory bodies should consider the availability of expertise and/or service and consider which source is best suited to its needs. When 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; however, it may be difficult, on security information² or commercial confidentiality³ grounds, to have a full interaction with an external expert advice provider in another State. Legal requirements regarding how contracts are let, including tendering requirements may also affect the choice of external expert advice provider.</p> <p><u>Care should be taken not to underestimate the fact that the influence of regulatory conditions in one State may not necessarily apply to another. This covers the regulatory body itself as well as the work of external expert organizations.</u></p>	<p>Delete whole paragraph. This concern may be sufficiently covered with a confidentiality agreement. We do not envisage any problems with the involvement of external expert organisations if these have implemented barriers to avoid the unauthorized communication of classified information.</p> <p>Sentence transferred from paragraph 2.7/5th bullet, as it is applicable to all interactions between two states.</p>	Yes		No	The para was rearranged. Details on confidentiality are given in paras 3.19 to 3.21
Indonesia	19	2.6/3	‘State’ with a capital S.	Correction	Yes			
USA	6	8/2.6/1 st sentence	Add “and determine” after word “consider.”	Clarification of intent of sentence.	Yes			

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Country	No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
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USA	7	8/2.6/line 3	...it should be kept in mind that although the other State may have considerable experience with....	Consistent with your format of capitalizing “state” at all places.	Yes			
USA	8	8/2.6/footnote 3	Even within a State, a company may wish to put restrictions on those outside the regulatory body, making them privy to certain aspects of the plant.	A potential typo.	Yes			
UK	12	Para 2.6, Footnote 2	Consider strengthening the guidance by modifying the first sentence to read: “.....certain security information without the agreement of the owner and taking into account any International Agreement or Regulatory requirement. ”	This footnote includes an assumption about disclosure not being allowed without agreement of the owner. This can also be affected by International Agreements signed between States, Security Regulation with the State (including export licences), and UN Resolutions.	Yes	Footnote 3 is deleted and now is the new para 3.22		
USA	5	8/2.6/footnote 2	...within the rules set out by the relevant competent authority.	Whether the authority is competent or incompetent is not an issue here.	Yes			
Belgium	4	Para 2.6, Footnote 3	The guide gives very specific and relevant information about restriction on sharing the utilities information (footnote 3 para 2.6). But there is little information/consideration on other practical issues. One of them is very important for non-English speaking country: the problem of language & translation... More guidance/suggestion on such issue (language and translation) should be welcome in this guide.		Yes	New paras 2.7 (4 th bullet) and 4.5 (last bullet) deal with that comment		

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Japan	12	2.6/2	Regulatory bodies should consider the availability of expertise and/or service and consider which source is best suited to its needs. <u>Expert advice in specialized areas is not always available within a State and so arrangements with organizations in other States may be required, which can raise specific issues that should be considered by the requesting regulatory body.</u> When 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...	See the comment No. 11; comment on para. 1.4.	Yes			
Japan	13	2.7/the 2 nd bullet	International organizations: organizations such as the IAEA, Nuclear Energy Agency (NEA), International Organization for Standardization (ISO) etc can be sources of advice on specific issues which may be provided through...	Better to move the ISO to under the bullet of standards organizations. See the comment No. 14.	Yes			
Russia - Rosatom	3	Sources of Expert Support	Some experts of WANO could be invited as provider of external expert support because of they have extensive knowledge in nuclear installation operation. Also the broad experience of some national engineer community, for instance ASME, could be helpful as supplier of professional advices. The World Health care Organization (WHO) also could be used as source of external expert support.		Yes	The list in the Guide is not exhaustive...		
Italy	13	2.7 4 th bullet	Other State regulatory bodies: advice can be obtained through individual contacts, <u>international cooperation agreement</u> or international forums, which can be particularly useful when designs utilized in one State are considered in another;		Yes			
Ukraine	4 (Yastre)	2.7 Bul-let 5	Participation of the RB and technical support organizations in selection of equipment to be purchased (e.g., to build new NPP units) and definition of delivery terms are to be discussed	To improve the process of decision making in the field of nuclear industry development.			No	Out of the scope of the present Guide.

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USA	9	9/2.7/5 th bullet	...: advice related to the regulatory structure and its application in a State from where structures, components and services to the applicant licensee are provided, for example reactor vessels, maybe obtained from that State.	Consistent with other bullets, the wordings right after the colon is changed into a sentence.	Yes			
USA	10	9/2.7/9 th bullet 9/2.7/10 ^h bullet 10/2.7/1 3 th bullet	<ul style="list-style-type: none"> ...: certain measurements required on a regular basis, such as dose monitoring or water quality, can be carried out for the regulatory body.... ...provide advice on a range of scientific, technical and engineering issues.... ...can provide advice on matters such as the financial status.... 	Potential typos.	Yes			
Italy	14	2.7 7 th bullet	Commercial / manufacturing / industrial Engineering/ service/ Commercial / manufacturing / industrial organizations: in many States commercial Engineering/ service /manufacturing / industrial organizations have been set up to sell technical, engineering, scientific etc services and these can provide a source of advice to regulatory bodies; 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; the overarching contracts may cover a range of areas or be restricted depending on the expertise that the provider of external expert support has;		Yes			
Japan	14	2.7/the 7 th bullet	Standards organizations, quality assurance organizations and professional bodies: these bodies which may be national or international such as International Organization for Standardization (ISO) can provide advice within their fields of expertise;	See the comment No. 13.	Yes			
Germany	10	2.7 1 st bullet	“... criteria for their selection (see Ref. [2], paras 3.30 - 3.32);”	Completeness of citation.	Yes			

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Indonesia	21	2.7, 2 nd bullet	the IAEA, Nuclear Energy Agency (NEA), International Organization for Standardization (ISO), etc, can...’ (with a comma before and after the word ‘etc.’)	Correction	Yes			
France	17	2.7/2 nd bullet	Delete “These organizations may be particularly useful for States embarking on nuclear energy programmes;”	Superfluous (even if true although for well established regulators....)	Yes			
Germany	11	2.7 4 th bullet	Other State regulatory bodies: advice can be obtained through individual contacts or international forums, which can be particularly useful when designs <u>or regulatory procedures</u> utilized in one state are considered in another	This applies not only for designs but also for regulatory procedures.	Yes			
Germany	12	2.7 5 th bullet	... reactor vessels. This can be extremely useful but care should be taken not to underestimate the fact that the influence of regulatory conditions in one State may not necessarily apply to another.	This argument is valid for all interactions between two States and it is therefore proposed to shift it to paragraph 2.6	Yes			
France	18	2.7/5 th bullet/4	Delete “the influence of”	Superfluous	Yes			
Indonesia	22	2.7, 7 th bullet	organizations have been set up to provide services in the fields of technical, engineering, scientific, etc. These organizations can provide advice to regulatory bodies; (no spaces before and after the punctuation mark ”/”)	Correction	Yes			

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Ukraine	1 ¹ (Yastre)	2.7, 7 th bullet	Delete the text “ 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; the overarching contracts may cover a range of areas or be restricted depending on the expertise that the provider of external expert support has. ”	This is a full list of expertise sources. But problem of contracts (and payment) for expert activities is noted only for commercial / manufacturing / industrial organizations. TSOs, universities, individual experts, etc., have problems with contracts too.	Yes			
Germany	13	2.7 10 th bullet	... research program, provide advice on a range of scientific technical and engineering issues; they can also be a useful source for training the staff of a regulatory body;	No need to emphasize academic institutions for training. Experts and other institutions can do it as well as universities.	Yes			
France	19	2.72/10 th bullet /1	After “universities”, add “(and other academic institutions such as engineering schools, technological institutes...)”	To increase the potential sources of advice.	Yes			
Germany	14	2.7 11 th bullet	“Individual acknowledged experts in specific fields of competence (<u>Consultants</u>): ... useful source of advice; <u>The technical qualifications and experience of consultants used to perform selected tasks should be at the same level as or greater than those of the staff of the regulatory body who are performing similar tasks (see Ref. [2], paras 3.28 and 3.29).</u> ”	Amendment and clarification. Ref. [2] provides further guidance.	Yes			
Japan	29	2.7/the 11 th bullet	Individual acknowledged experts in specific fields of competence: many acknowledged experts in specific fields do not belong to organizations. This does not mean that they are not appropriate sources of expert advice; recent retirees from regulatory bodies or other bodies could be a particularly useful source of advice;	Delete the content that is self-evident.	Yes			

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Japan	30	2.7/Order of the bullets	<p>Proposal of the category and the order of the resources.</p> <p>a) Inter State resources: <input type="checkbox"/> Advisory bodies: ... <input type="checkbox"/> Dedicated organizations: ... <input type="checkbox"/> Government laboratories or research centres; ... <input type="checkbox"/> Legal organizations: <input type="checkbox"/> Other government organizations that may have mandated input on regulatory decisions but without specific decision-making responsibilities.</p> <p>b) Outer State resources: <input type="checkbox"/> International organizations: ... <input type="checkbox"/> Other State regulatory bodies... <input type="checkbox"/> Vendor State regulatory bodies: ...</p> <p>c) Inter/Outer State resources: <input type="checkbox"/> Standards organizations, quality assurance organizations and professional bodies: ... <input type="checkbox"/> Commercial / manufacturing / industrial organizations: ... <input type="checkbox"/> Certified testing and analytical services: ... <input type="checkbox"/> Academic institutions: <input type="checkbox"/> Individual acknowledged experts in specific fields of competence: <input type="checkbox"/> Financial and economic organizations:</p>	<p>For better understanding to readers.</p> <p>The order of the bullets can be changed as proposed in order to see clearly the resource groups.</p>	Yes			
Indonesia	20	2.7/4 -..	bullet in the section will be better prepared in the form of tables. In addition, the contents of this bullet looks like definition, so it needs glossary	need to change the form of sentences	Yes	Bullets are categorized in 3 sub paras according Japan's comment 30		
Indonesia	23	2.7, line 6 from above (13 th bullet)	Examples of international organizations should also include 'World Bank' and "International Monetary Fund (IMF)"	Some developing countries rely on these two organizations as their advisor for financial situations.			No We should assume that the list is not exhaustive or limited...	

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Ukraine	2 (Yastre)	2.7 End	Add the sentence: “Contracts with different types of organiza-tions, institutions, bodies, individual experts, etc., may be over-arching so that their advice can be called on when needed or when specific contracts are concluded as each issue arises; the overarching contracts may over a range of areas or be restricted depending on the expertise that the provider of external expert support has.”	This is a full list of expertise sources. But problem of contracts (and payment) for expert activities is noted only for commercial / manu-facturing / industrial organi-zations. TSOs, universities, individual experts, etc., have problems with con-tracts too.	Yes			
Ukraine	3 (Kocha)	2.7 Foot-note 3	“No restrictions can be placed on information required by the regulatory body, but this does not necessarily give it the authori-ty to provide that information to third parties”. It is advisable that recommendations be added how a legal basis should be established to define and range kinds of information to be obligatory provided to the regulator, define which scope of information is not obligatory to be submitted by the TSO to the regulator to protect its intellectual property.	To establish a legal frame-work for use of information and its circulation.			No	Information needed should be deter-mined on case by case basis
Germany	15	2.8	... should consider <u>have relevant information on</u> the specific	The focus should be pos-sessing the suitable infor-mation in order to allow for quick decisions	Yes			
Indonesia	24	2.8, line 2 from below	Put a comma after ‘notice and before ‘having.	To make the sentence clearer.	Yes			

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Japan	31	2.8	<p>It is suggested that a regulatory body should consider the specific organizations which exist in their State or to which they have access. For example there may be only a few universities in a State that can give expert advice on a specific nuclear topic, such as mechanical systems, even though in principle all universities may cover mechanical engineering. If there is a need for advice at short notice having <u>have</u> sources readily available for the case that there is a need for advice at short notice. could be extremely useful.</p>	<p>Clarification</p> <p>Current text is very much redundant. The message of para. 2.8 should be; a regulatory body should have sources readily available...</p>	Yes			
Italy	15	2.8.	<p>It is suggested that a regulatory body should consider the specific organizations which exist in their State or to which they have access with indication of their field of competence and capability for technical support to RB (for example there may be only a few universities in a State that can give expert advice on a specific nuclear topic, such as mechanical systems, even though in principle all universities may cover mechanical engineering). If there is a need for advice at short notice having sources readily available could be extremely useful.</p>		Yes			
Italy	16	2.9 bullets	<ul style="list-style-type: none"> • Research activity <input type="checkbox"/> Scientific and engineering analysis; • Review of safety analysis • Independent verification <input type="checkbox"/> Legal advice; <input type="checkbox"/> Operations support including development and interpretation of nuclear plant technical specifications; <input type="checkbox"/> Financial advice; <input type="checkbox"/> Testing, measurement and analysis services • Training; <input type="checkbox"/> Drafting of regulatory documents; <input type="checkbox"/> Project management and administrative support; <input type="checkbox"/> QA/QC; <input type="checkbox"/> Audit, review, assessment; <input type="checkbox"/> Inspection. 	For completeness	Yes			

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Japan	32	2.9	<p>As mentioned in the previous section, any field of expertise related to safety could be provided through external support. More generally, external experts are used by a regulatory body to assist in performing tasks that necessitate an additional level or area of expertise, which may arise occasionally, or to provide an alternative or confirming view on important issues. These may include:</p> <p>According to the scope mentioned in Para. 1.7 areas for external expert support may be categorized as following 10 items:</p>	Replace the current redundant text with intended short sentence proposed here.	Yes			
Japan	33	2.9/5 th bullet	<ul style="list-style-type: none"> Testing, measurement and analysis services; training; <u>Staff training</u>; 	Editorial	Yes			
Russia - Rosatom	4	Areas for External Expert Support	In-depth training at the foreign nuclear facilities as well as research laboratories, regulatory body offices and its TSOs under the leading of external experts could be used as sources of external expert support.				No	Comment not understood... need more development.
Germany	16	2.9 3 rd bullet	Operations support including <u>development and</u> interpretation <u>and execution</u> of nuclear plant technical specifications;	Development of technical specifications does not belong to the tasks of the regulatory body. Instead they may need help with the execution i.e. the practice of the specifications and how to deal with them in the plants	Yes	But bullet was deleted in accordance with previous comments		
Germany	17	2.9 5 th bullet	“Testing, measurement and analysis services; <u>training</u> ;”	Different areas for external expert support should be cited in separate bullet points.	Yes			

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Morocco	4	Para 2.9 Bullet 5	<ul style="list-style-type: none"> Testing, measurement, monitoring and analysis services; training; 	Monitoring is a task that may be performed by external experts.	Yes			
Germany	18	2.9 6 th bullet	<ul style="list-style-type: none"> Testing, measurement and analysis services; <u>training</u>; 	Avoid coupling of unrelated subjects	Yes			
Germany	19	2.9 new bullet	<ul style="list-style-type: none"> <u>Training</u> 	Clarification	Yes			
Indonesia	25	2.9, 5 th bullet	the word ‘training’ should be put in a different bullet.	To get better interpretation.	Yes			
France	20	2.9	<input type="checkbox"/> Testing, measurement and analysis services; <input checked="" type="checkbox"/> <u>training</u> ;	Training is different from the services listed before, should be kept a separate item as in the previous version.	Yes			
France	21	2.9/3 rd bullet	Delete “including development and interpretation of nuclear plant technical specifications;”	Too specific. And already covered by 1 st bullet	Yes			
Indonesia	26	2.9, last line	Delete ‘training’ in the line with ‘Testing, measurements and analysis services’, and add a new line of ‘Education and training’.	Training should be put in a highlight, together with the education.	Yes			

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Germany	20	2.9 8 th bullet	“ <u>Management system-QA/QC</u> ”;	See IAEA Safety Standards Series No. GS-R-3, Para 1.4: The term ‘management system’ reflects and includes the initial concept of ‘quality control’ and its evolution through ‘quality assurance’ and ‘quality management’.	Yes			
USA	6	11/2.9/8 ^t h bullet	• <u>Management systems, including</u> QA/QC;	The IAEA Safety Glossary has instituted use of the term “management systems” to include QA/QC.	Yes			
Japan	19	2.9/8 th bullet	• <u>QMS/QA/QC</u>	Completeness	Yes			
Italy	17	Section 3 Title	REQUIREMENTS CHARACTERISTICS OF EXTERNAL EXPERT SUPPORT				No	The word “requirement” should be avoided in a Guide. Moreover, it is “characteristics”.
Germany	21	3.1 1 st sen- tence	... from interested parties” (Ref. [4], <u>para</u> 3.10).	Completeness of citation.	Yes			
Germany	22	3.1 2 nd sen- tence	... of its assignend responsibilities” (<u>Ref. [3]</u> , Requirement 20).	Cite Ref. [3] once only to improve readability of the sentence.	Yes			

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Co-untries	No.	Para/Li-ne No.	Proposed new text	Reason	Ac-cept-ed	Accepted, but modi-fied as follows	Re-ject-ed	Reason for modi-fication/rejection
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France	22	3.1	Further, the IAEA Safety Requirements on Governmental, Legal and Regulatory Framework for Safety (Ref. [3]) establish the following requirement ...		Yes			
France	23	3.2/3	Delete “Exception may be granted due to lack of expertise in certain technical areas (e.g., criticality, climate, and seismology).”	It is unclear : exception to what ?	Yes			
Germany	23	3.2	...external expert support. Exception may be granted due to lack of expertise in certain technical areas (e.g. criticality, climate and seismology). Furthermore <u>In particular</u> , when selecting...	There shall be no exception from the requirements of independency and regulatory responsibilities as stated in paragraph 3.1	Yes			
Italy	18	3.2	It follows that when seeking external expert support, the regulatory body should ensure that these requirements are reflected in the conditions that dictate the relationship between the regulatory body and the provider of external expert support. Exception may be granted due to lack of independent expertise in certain technical areas (e.g., criticality, climate, and seismology) . Furthermore, when selecting a provider of external expert support, the regulatory body should ensure it will not compromise its <u>effective</u> independence.		Yes			
UK	13	Para 3.2, 2 nd sentence	Delete the 2 nd sentence.	Improve clarity. It is not clear what the “exception” clause refers to when linking back to Para 3.1. There should be no exceptions to the characteristics given in Para 3.1, ie that the regulatory body is independent of the licensee and it fulfils its regulatory duties. Para 3.8 gives a better description.	Yes			

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Germany	24	3.4 last line	with advice and services- (Ref. [3], paras 4.18 and 4.20).	Correct citation; text refers solely to Para 4.20 of Ref. [3].	Yes			
France	24	3.4/3		It should be clarified “conflict of interest” with whom? The last sentence of 3.4 might be deleted as the idea is better expressed in 3.5			No	REF [3] para 4.6: “...a regulatory body that is effectively independent in its decision making and that has functional separation from entities having responsibilities or interests that could unduly influence its decision making...” It is important to maintain this para to establish the liaison between independence and conflict of interest.
Indonesia	27	3.5, first sentence	Modify the first sentence to be ‘Independence of advice means that the provider of external expert support should be able to form and express its technical integrity judgment free from commercial, finance and other pressures from interested parties’	The additional words of ‘integrity’, ‘commercial’ and ‘finance’ put emphasize on those issues.	Yes			
USA	7	13/3.5/2 nd sentence	Add “and security awareness” after word “culture.”	Awareness of potential safety and security activities to overall advice impact.	Yes			

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Indonesia	28	3.5/3	... parties. Technical competency and sustainable improvement safety culture in the provider of ...	More impressive and deep term	Yes			
UK	14	3.5 ?	The reference to a well-developed safety culture as a defence against undue influence on a provider is misleading. For many types of provider, the strict safety culture may be limited to safe operations in an office environment. There seems to be some confusion between the need for a provider to understand the safety culture necessary for a nuclear operator and the provider actually adopting such a culture itself. It might be more appropriate to refer to something like a strong ethos of professionalism in this context.		Yes	Para was rewording		
Germany	25	3.5/ and footnote 4 (delete foot- note)	Technical competence ⁴ (see 3.10 – 3.13) and a well ... ⁴The technical competency represents the ability of the provider to develop its own research and therefore develop a state-of-the-art knowledge and techniques, which foster independent judgment.	The term “technical competence” is defined in paragraphs 3.10 to 3.13, therefore there is no need for the footnote (which, in addition, provides a different, not suitable focus)	Yes			
UK	15	Para 3.5, 2 nd sen- ten- ce	Delete Footnote 4	The technical competency of an external body is overstated; it is not correct to say that the technical competency contributes to independence. Para 3.12 states it better.	Yes			

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France	26	Foot- note 4	Replace “The technical competency represents the ability of the provider of external expert support to develop its own research and therefore develop a state-of-the-art knowledge and techniques, which foster independent judgment” by “The technical competency represents the ability of the provider of external expert support to implement state-of-the-art knowledge and techniques. One way is for example to develop its own research which foster independent judgment”	Performing independent research is one way of gaining independence, but not the only way.	Yes	Footnote was deleted. The proposed sentence is added in para 3.9		
Germany	26	Add new paragraph (perhaps after 3.5)	<u>The external expert should not be bound to directives from the regulatory authority regarding the results of its work.</u>	This sentence summarizes in one sentence the idea of independence of external experts.	Yes	The proposed sentence is added in para 3.5		
France	25	3.6/3	Replace “may not be the optimum solution” by “may be questionable”.	Alternate wording	Yes	Replaced by Germany’s comment 27		
UK	16	Para 3.6	The comments about nuclear industry consultants are too judgmental. There is no definition of what constitutes such a consultant, and it may be that virtually all relevant providers could be described in this manner. The onus should be on positive management rather than pre-judgment.		Yes	Replaced by Germany’s comment 27		
Germany	27	3.6 For example, hiring nuclear industry consultants who work primarily simultaneously for industry may not be the optimum solution <u>should be avoided.</u>	Independence and impartiality are doubtful if the consultant works for industry and regulator.	Yes			

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Indonesia	29	3.6/3 & 4	... interest. For example, hiring nuclear industry consultants who work primarily for industry may not be the optimum solution ...	Delete, because experience in another industry is an advantage aspect	Yes	Replaced by Germany's comment 27		
USA	8	13/3.6/4 ^t h sentence	Actual conflicts of interests should be eliminated immediately, or if unavoidable, mitigated to the extent possible.	Revised phrase reflects guidance on mitigative measures provided in subsequent sections.	Yes			
Japan	34	3.6/3-4	For example, hiring nuclear industry consultants who work primarily for <u>nuclear</u> industry may not be the optimum solution.	Editorial	Yes			
Japan	35	3.7/5-7	Any changes of personnel that might affect independence should be discussed with the regulatory body before <u>the changes work continues</u> are made.	Editorial	Yes			
Germany	28	3.7 2 nd bul- let	When the licensee has to pay for a technical study in order to bring due elements to the regulatory body;	This does not apply for third party services provided by independent experts that are accredited as such with the competent authority of the respective state.			No	All providers are not accredited. It depends on the countries.
Italy	19	3.7 2 nd bul- let	<input type="checkbox"/> When the licensee has to pay for an “independent” technical study in order to bring due elements to the regulatory body;		Yes			

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UK	17	Para 3.7, 3 rd bullet	Consider modifying to specify that the external experts should not be part of or closely linked to the anti-nuclear lobby.	Omission.	Yes			
Indonesia	30	3.7/15 Additional point :	When the external experts are part of an organization or country which has competition in the political and national defence with the host regulatory body country	This point is necessary to exclude the possibility of intruder	Yes			
Indonesia	31	3.7 Foot-note/1 & 2	The technical competency represents the ability of the provider of external support on state of the art knowledge and techniques, which foster independent develop on state.	The expert is needed for a consultative aspect more than to foster the research	Yes	Footnote 4 was deleted. Sentence is about in para 3.9		
Indonesia	32	Para 3.8, 2 nd bullet	‘Or when the complexity of the task to be accomplished is such that only a few large providers of external expert support are capable of coping with it and they may already have established connections with licensees.’	To be more effective and easier to understand.	Yes			
France	27	3.8/2	Delete “This would occur in very rare cases.”	Superfluous	Yes			

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UK	18	Para 3.8, 2 nd sentence	Consider deleting: “This would occur in very rare cases.”	It is naïve to assume that potential conflicts are rare, given the commonly small pool of providers. The guidance should start from the assumption that potential conflicts are common and therefore active management is required to ensure independence in practice. The guidance for cases where there is a potential conflict therefore should be applied in all cases.	Yes			
Indonesia	33	3.8/20 (additional line)	Alternative opinion from the other experts is required to avoid the conflict of interest when both of the above verification is not enough.	Alternative opinion is a best way to assure in avoiding the conflict of interest	Yes			
Germany	29	3.8 4 th bullet	Verifying whether the organization of the provider of external expert support structure allows a functional and personal separation and effective independence between units carrying out work for the regulatory body from units carrying out similar work for a licensee or other organization. The link between the units should be carefully monitored.	This should also be extended to the contributions of individuals to the respective activities of organizations. It must be monitored, that there is no extensive exchange (e.g. staff, knowledge, documents (!)) between the units. This would contradict the independence of the external expert.	Yes			

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Germany	30	3.8 4 th bullet	“... work for a licensee or other organization.”	Editorial (add punctuation mark).	Yes			
Italy	20	3.8 4 th bullet	Verifying whether the organization of the provider of external expert support structure and its internal procedures allows a functional separation and effective independence between units carrying out work for the regulatory body from units carrying out similar work for a licensee or other organization;		Yes			
Germany	31	3.8, 3.9	Combine both Paras.	Text in Para 3.9 is direct continuation of text in Para 3.8 and can't be understood in an isolated manner.	Yes			
France	28	3.9/1	Requirements <u>for</u> verifying	Typo	Yes			
UK	19	Para 3.10	The meaning of this paragraph is unclear.		Yes	Para is now different and about technical competency.		

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UK	20	Para 3.10	More generally on competence, clarity is needed on whether the expectations are placed on a providing organisation or the particular individuals providing the advice to the regulators. In practice, particular providers often would be selected because they are able to supply the services of specific individuals. Consequently, it should be recognised that competence may reside with such individuals, rather than the organisations that employ them. In such circumstances, the guidance must indicate that contracts should enable termination should the availability of specific individuals be compromised. There should not be a presumption that the provider could offer a valid alternative individual.		Yes	Para is now different and about technical competency.		
Ukraine	2 (Dybach)	3.10	New item to technical competency: Individual experts and expert organizations should know the national legislative and regulatory safety requirements put in force in the country whose regulatory body is supported.	Knowledge of the national legislative and regulatory safety requirements should be within experts' competence	Yes			
Germany	32	New paragraph (perhaps between 3.10 and 3.11)	<u>The technical competency represents profound knowledge of the respective state of science and best available technology that is necessary for a broad and comprehensive assessment of nuclear installations.</u>	Better version of footnote 4 that should be shifted to this point. Definition of technical competency, without demand of research (that is not essential for characterizing independent expert organisations)	Yes	Sentence was add in para 3.12		
Indonesia	34	3.11/additional point	- member of regional and/or international safety networks - implementation of sustainable improved nuclear knowledge management	These additional points are very advantageous to improve the competency	Yes			

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UK	21	Para 3.11	It should be clearly stated that building and/or maintaining competence is the responsibility of the regulator/government and not the provider. In practice, this cannot be a responsibility placed on a provider – the offering of services in a particular discipline would be governed by commercial concerns. Similarly, the continuance of an existing market offering, and any resulting need to maintain competence, by a provider would also be a commercial decision.		Yes			
UK	22	Para 3.12	Clarification needed. Consider reviewing this paragraph, because if the support is required on a permanent basis (as stated in the 1 st sentence of this paragraph “...whether on a temporary or a permanent basis...”.) should the regulator be looking to recruit into the regulatory body? To use a permanent external support would appear to be contrary to the rest of the document. Also, the situation of permanent external support, places reliance on such external support, which could be withdrawn for a number of reasons.		Yes			
USA	9	15/3.12/1 st bullet	<ul style="list-style-type: none"> ...For such an individual or academic expert, certification may be a factor to demonstrate continued competency <u>in their specialty area.</u> 	Need to clarify that the certification is relevant to the specialty area of technical competence in which expert support is provided.	Yes			
Japan	36	3.12/1 st bullet/1	For an individual expert, technical competency should be ensured by verifying that he/ <u>she</u> has already provided similar external support in a satisfactory way (reference list).	Editorial	Yes			
Germany	33	3.12 1 st bullet	...satisfactory way (<u>e.g.</u> reference list). For ...	Reference list is one way of several to prove technical competency.	Yes			

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Ukraine	6 (Yastre)	3.12 2 nd Bullet	Describe relationship between regulatory body and an external support provider should include bilateral cooperation, on part of the regulatory body, for example - experience exchange, sharing of skills, organization of activities related to familiarization with operator and plant operating procedures and documentation, international activities aimed at research analyses, participation in international activities related to safety, purchasing of software products and other cooperation areas.	To expand description of relationship between regulatory body and an external support provider.	Yes	Added as a new bullet		
Germany	34	3.12 2 nd bullet	For an expert organization established in a long term provider of external expert support relationship with the regulatory body, the above mentioned (Ref. [3], para. 2.35) need to build and maintain competence through technical training, development and research work This can be demonstrated by the existence of one or more of the following actions:	Research capabilities are not essential for characterizing independent expert organizations. As these elements are already mentioned in the previous paragraph and in the following bullets, there is no need to repeat them once more. In addition, within the range from very small local to global organizations the means stated in paragraph 3.11 and again in this paragraph will be complied with two different degrees. Therefore, the notion that each and every one of these means has to be complied with should be avoided.	Yes			
France	29	3.12/2 nd bullet/2	Replace “the above mentioned” by “this organization”	Clarification	Yes			

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UK	23	Para 3.12, 2 nd bullet	Modify to read: “.....build and maintain competence through technical training, development or research work can be demonstrated...”	The technical competency of an external body is over-stated.	Yes			
Germany	35	3.12 2.2 bul-let	<ul style="list-style-type: none"> Strong Research activities in its field of competence. 	“Strong” research capabili-ties are not essential for characterizing independent expert organizations.	Yes			
Germany	36	3.12 Addi-tional bullet in second bullet list	<ul style="list-style-type: none"> <u>Demonstrated experience of performing safety related tasks</u> 	The application of compe-tence in actual work is the ultimate and necessary way to demonstrate knowledge; see also paragraph 3.11 and paragraph 3.13, as well as requirement in para-graph 4.7 2 nd bullet	Yes			
Indonesia	35	3.12	For an individual expert, technical competency should be en-sured by verifying that he has already provided similar external support in a satisfactory way <u>or by a recommendation from an-other experienced well-known expert</u> (reference list). ...	This additional line is to accommodate the first time expert who has no experi-ence beforehand, but his expertise is recognized by other experts.	Yes			

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Italy	21	3.12 2 nd bul- let	<p><input type="checkbox"/><input type="checkbox"/> For an expert organization established in a long term provider of external expert support relationship to the regulatory body, the above mentioned (Ref. [3], para. 2.35) need to build and maintain competence through technical training, development and research work can be demonstrated by the existence of:</p> <ul style="list-style-type: none"> <input type="checkbox"/><input type="checkbox"/> A strategy for training its own staff and taking part in training activities in the technical safety field; <input type="checkbox"/><input type="checkbox"/> Involvement in Strong significant research activities in its field of competence; <input type="checkbox"/><input type="checkbox"/> A continuous, up to date, technology development programme. <input type="checkbox"/><input type="checkbox"/> effective international cooperation 		Yes			
Italy	22	3.13.	Competency, as addressed above, often relies on the experience of having done similar, appropriate work before. Confidence in the competency of external expert support can be gained by contracting with a provider of external expert supports (organizations or individuals) having performed safety related task, knowing the regulatory function and view of the RB and consistently demonstrating a global vision with a multidisciplinary capability broad scope.		Yes			
Germany	37	3.13	... related tasks and consistently demonstrating a global vision with a broad scope.	“a global vision with a broad view” is not an attribute, which can be realistically expected from every individual expert or certain local/regional organizations	Yes	Sentence was modified		
Ukraine	3 (Yastre)	3.14	Add: “...the requirements for measuring, assessing and improving the management system, the requirement on knowledge base. ”	Knowledge base is an important part of the management system.	Yes			

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UK	24	Para 3.14	Much of this paragraph seems to have been extracted from documentation dealing with the requirements for nuclear site operators (such as Reference [5]). Many of the listed ‘general requirements’ are not relevant to a third-party provider, which commonly would not be a site operator. The focus should be on the provision of the bulleted items in this paragraph.		Yes			
UK	25	Para 3.14	In some cases, potential providers may not have a management system at all, for example many universities and individual experts. Perhaps it would be helpful to define what is meant by “basic management system principles” in the context of such potential providers. The guidance should recognise that the primary aim is to meet the stated requirements, not to have a formal management system. Although such a system is perhaps the most obvious way to meet the needs, it is not the only way.		Yes			
UK	26	Para 3.14, 2 nd bullet	Modify to read: “...the existence of a quality management system may provide confidence....”	The original statement makes an assumption on quality management systems, which is not always realised in many organisations.	Yes			
UK	27	Para 3.16, 1 st sentence	Modify to read: “.....and needs verification of the trustworthiness of the organisation and individuals working for it. ”	Although individuals are mentioned later in the paragraph, this seems to refer to information transmitted across borders. It should be made clear somewhere in the paragraph that this requirement also applies to any organisation or individual sub-contracted to the provider.	Yes			

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France	30	Title before 3.16	Replace “Security information” by “Security information as well as securing protected information”	To have the title reflect the following guidance...	Yes			
Germany	38	3.16	be transmitted <u>to any other organization outside the regulatory body or even</u> across borders to...	It does not matter whether security information is transferred across borders. It only matters that the organization which gets the security information can handle the information correctly.	Yes			
Germany	39	3.16	... individuals that <u>whose</u> trustworthiness...	Editorial	Yes			
Indonesia	36	3.16/8	‘...have a <u>“need-to-know”</u> ,...’.	Correction	Yes			
Japan	37	3.16/10	In these cases, the provider of external expert support should be able to demonstrate that the access to such information is effectively restricted to individuals that trustworthiness have been checked and have a “need to know”, that the information is kept under secure conditions, and that secure procedures to communicate the information exist (secure fax, encryption capabilities, etc.), specific to the <u>security</u> level of sensitivity of the information.	Editorial It should be specific to ‘the security level’ of the information, not to ‘the level of sensitivity’ of the information.	Yes			

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Indonesia	37	3.16, last sen- tence	Give specific number of the IAEA Nuclear Security Series.	Not all documents in the Series are relevant.			No	It is a general sentence. Information needed could be disseminated in part of several IAEA Nuclear Safety Series.
Germany	40	3.17 2 nd sen- tence	... rules and procedures <u>and organizational conditions</u> to protect this...	Organizational conditions (like locked doors and drawers) in reality do protect the information. One should think of the idea, that e.g. doors must be locked where proprietary information is kept and used when nobody is in the office.	Yes			
France	31	3.17/7	Replace “give it sufficient time to agree to the arrangements or to raise objections” by “establish commonly agreed arrangements”	Agreement should be sought	Yes			
Germany	41	3.17 last sen- tence	or to raise objections <u>concerns</u>	If the regulatory body decides to give this information to a certain third party (trusted by the regulatory body) then the first party should be able to raise concerns but not to stop the work of the regulatory body (otherwise, they could block unwanted third party experts)	Yes			

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Indonesia	39	3.18/4	Individual and collective commitment and attitude to safety on the part of the leadership, the ...	More elaborative sentence (INSAG 4)	Yes			
Indonesia	40	3.18/additional point	Training and safety culture promotion.	More elaborative sentence (INSAG 4)	Yes			
UK	28	Para 3.18	Amend this paragraph to clarify that it applies to both the regulatory body and the provider of external expert support.	It is not clear that the management system referred to is that of the provider.	Yes			
UK	29	Para 3.19	The current wording obscures the important point that it is necessary that a provider understands the nuclear safety culture required of operators. This is a key part of the necessary competence for the provision of advice, although the authors may wish to consider whether it is essential for all advice functions. Is an understanding of nuclear safety culture a fundamental competence that should be highlighted and discussed separately from all other aspects of competence?		Yes	The para mentions now that the provider should have a stated commitment regarding to the safety culture consistent with the RB's policy.		
Indonesia	38	3.19/4	... expert support should have a stated commitment regarding to the safety culture that is consistent with the ...	In safety culture area, commitment is more important than policy	Yes			

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Italy	23	3.19	In using a provider of external expert support, whether it is an organization or an individual, the regulatory body should ensure that its safety culture requirements are reflected in or similar to those of the provider of external expert support. The provider of external expert support should have a stated policy regarding safety culture that is consistent with the regulatory body’s policy. The external expert should be able to perform and provide the technical support with a regulatory view and raise safety concerns regarding the work they have conducted to the regulatory body. The regulatory body should address any safety concerns raised by the external expert, but the regulatory body is ultimately responsible for making the final safety decision. It is natural for the provider of external expert support to defend its technical positions but these positions should be technically based, justified according to applicable requirements and supported by documentation, for decision making reflecting a high priority for safety (Ref. [6], Para. 2.36).		Yes			
France	32	3.19	Is this statement “The provider of external expert support should have a stated policy regarding safety culture” appropriate for an individual, as explicitly encompassed by the first sentence of 3.19?		Yes	The para mentions now that the provider should have a stated commitment regarding to the safety culture consistent with the RB’s policy.		
France	33	3.19/8	Delete “It is natural for the provider of external expert support to defend its technical positions but these positions should be supported by documentation, for decision making reflecting a high priority for safety (Ref. [6], Para. 2.36).”	Superfluous as already mentioned in §2.2	Yes	See new para 3.19		
USA	10	18/3.19/ ast sen- tence	It is natural for the provider of external expert support to defend its technical positions but these positions should be supported by documentation. The documentation will be used by the regulatory body to support its for decision making reflecting a high priority for safety (Ref. [6], Para. 2.36).	Appears a phrase may be missing at the end of the sentence. The suggested revision attempts to clarify the apparent intent of the sentence.	Yes	See new para 3.19		

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Germany	42	3	Add new section on IMPARTIALITY Possible text, see right	The experts should not only be INDEPENDENT but also IMPARTIAL . Independence should be a basic attitude of the expert but moreover, the experts’ judgement should be based solely on technical knowledge and should in no case be bi-ased due to political opinion.	Yes	Added in para 3.3		
UK	30	Section 4	This section is rather repetitive of issues also covered in Sections 1 and 2. Some editing might be beneficial.		Yes			
Germany	43	4.1 3 rd sen-tence	“... work performed for it by external experts (Ref. [3], Require-ment 18 para. 4.5).”	Correct citation; text refers to Requirement 18 of Ref. [3].	Yes			
Japan	2	4.1/4-6	The regulatory body should have enough experienced staff to be able to perform all of the necessary regulatory functions and to evaluate the quality and results of the work performed for it by external experts (Ref. [3], para. 4.5).	Delete the content that paragraph 4.5 of Ref. [3] does not mention.	Yes	Para was deleted		
France	34	4.1/4	Replace “establishing” by “its”	It is valid even after estab-lishing the organization.	Yes			

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Indonesia	41	4.1, last sentence	Consider to paraphrase the sentence.	The sentence is somewhat similar with the sentence of para 2.3.	Yes	All para was deleted		
Indonesia	42	4.2/4	... task. Particularly, outsourcing external supports is considered for specialties ...	More elaborative sentence	Yes	All para was deleted		
UK	31	Para 4.2, last sentence	Consider deleting the last sentence.	Para 4.7 states it better.	Yes	All para was deleted		
Japan	15	4.2/8-10	Move the following sentence to Section 3 under the relevant sub-heading ; The technical qualifications and experience of 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.	This is a good guidance as for technical competency of external experts. Section 3 of this guide does not mention this point thus this should be addressed in the Section3 at TECHNICAL COMPETENCY or GENERAL.	Yes	All para was deleted		
Germany	44	4.3 1 st sentence	“There are many reasons ... considering nuclear power and/or radioactive waste management facilities for the first time, ...”	Clarification and amendment.	Yes	Part of the sentence was deleted		
France	35	4.3	The need for expertise in different specialties at different lifecycle stages, e.g. design, construction, commissioning, operation and decommissioning;	The first stage	Yes	Para was rearranged		

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France	36	4.3/2	Delete “by an established regulatory body or one considering nuclear power for the first time,”	Superfluous	Yes			
Germany	45	4.3 2 nd bul- let	“The need for expertise ..., e.g. <u>site selection</u> , construction, commissioning, operation and decommissioning/ <u>closure</u> ,”	Amendment.	Yes			
Germany	46	4.3 last bullet	“Where new sites for <u>installations</u> <u>facilities</u> are being considered, ...”	The Guide (including refer- ences) concerns to “facili- ties” and not to “installa- tions” (installations don’t involve all kind of facilities).	Yes			
Germany	47	4.3 Addi- tional bullet	<u>Lack of specific resources for tasks at hand i.e. an increase of the short-term workload</u>	The current bullets focus mainly on new de- signs/licensees/laws/sites, whereas the majority of external expert support will arise during current day-to- day business	Yes			
Indonesia	43	4.3/addi- tional point	lack of experiences related to the commissioning infrastructure includes project management	This point is very important particularly for the country which will build the first NPP	Yes			
Germany	48	4.3 last 2 lines	There may also be times when additional support is needed because of short-term workload increase.	This reason should be in- corporated as a bullet (see comment to paragraph 4.3/additional bullet), rather than just a remark	Yes			

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Italy	24	4.3	<p>There are many reasons why external expert advice may be sought, by an established regulatory body or one considering nuclear power for the first time, these may include:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Assessment of new where designs of installation are proposed that are different from those previously regulated; <input type="checkbox"/> The Need for several expertise in different specialties at different lifecycle stages, e.g. construction, commissioning, operation and decommissioning; <input type="checkbox"/> New licensees either taking over from an existing licensee or wishing to operate a new facility; <input type="checkbox"/> Legal changes that require new regulatory processes and regulations; <input type="checkbox"/> Application of new technologies for process and safety systems <input type="checkbox"/> Establishment of new safety criteria and requirements <input type="checkbox"/> Need to perform detailed independent verification <input type="checkbox"/> Need to evaluate analysis of new sites for installations having lack of experience and expertise or insufficient capability related to some siting a technical discipline (e.g. geology, etc.). <p>There may also be times when additional support is needed because of short-term workload increase.</p>	For completeness	Yes			
Italy	25	4.4	<p>For those States developing new nuclear programmes including facilities or activities there may be a need for expert support from an external organization in developing its processes and procedures, and identifying the needs and technical areas of support and for determining suitable external sources of advice. There is no one model for use of external experts. Much of when and how they can and will be used will be based on the legal system within the State. One possible way to do this, without compromising independence of the regulatory body, would be to establish a partnership with a provider of external support which could assist in organizing a system for coordinating the provision of external advice. For many newcomer nuclear programmes, this could be of assistance to know support available and the necessary questions to ask.</p>		Yes			

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Indonesia	44	4.4/8	'Many newcomers in nuclear programmes,...to know the availability of support and...'	To be more accurate and easier to understand	Yes			
UK	32	Para 4.4, last sentence	Modify to read: “...this could be of assistance to know the support available....”	Missing word	Yes			
Italy	26	4.5	There are many sources of expert support that may be available to the regulatory body as discussed in para. 2.5. When a regulatory body determines it needs additional expertise it should first: <input type="checkbox"/> Determine the objective and scope of the work required. This can be as narrow as a single task or as broad as a general arrangement for technical services. <input type="checkbox"/> Determine the expertise required to perform the work. <input type="checkbox"/> Identify the possible sources for obtaining the expertise. <input type="checkbox"/> Solicit or select the organization to provide the expertise.		Yes			
France	37	4.5	There are many sources of expert support that may be available to the regulatory body as discussed in para. 2.5. When a regulatory body determines it needs external expertise it should first: ...	See above.	Yes			
France	38	4.5/1st bullet	Add “the timescale and the different steps of the expertise” after “...the scope”	Important element with the scope	Yes			
France	39	4.5/2nd bullet	Add at the end “, and the kind of product he expects”	The report isn't the only product of an external support	Yes			

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Indonesia	45	4.5/7	Identify the possible alternative sources for ...	More meaningful sentence	Yes			
Indonesia	46	4.5/8	Solicit or select the organization or individual to provide ...	The alternative source may be contributed in individual or organization form	Yes			
UK	33	Para 4.6, 2 nd sentence	Replace “do” with “should” to read: “...specialist should not give rise to a bias in the advice given; ...”	Logically it is not possible to prove a negative (it is not possible to show that bias has not influenced advice). It would be better to indicate that the regulator should have knowledge of any potential biases, it is not appropriate to assume that there is no bias.	Yes			
UK	34	Para 4.6	Considering rewording this paragraph to clarify that it is the responsibility of the regulator to confirm the absence of bias.		Yes			
UK	35	Para 4.7	It is not clear that all of the listed items are relevant to selecting a provider. If the intention is that selection should be based on the ability of a provider to fulfil the listed requirements, this should be made clear.					

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UK	36	Para 4.7	This paragraph appears to have been taken from Reference [7] and is rather specific. Some of the items cited appear rather peripheral to the provision of advice to a regulator (rather than to a site operator) and a further review is suggested. Statements such as “specific documentation should be required to support the regulatory decision” are confusing in the context of selecting a provider.		Yes			
UK	37	Para 4.7	Reference is made to verification. This is a jargon term that has specific (and different) meanings and should be avoided. Where verification, or some other quality check, is sought, it is not clear who should provide this (the provider or the regulator?).		Yes			
Italy	27	4.7 1 st bullet	The provider of external expert support should have experience in the area needed (for example any accreditation, certification...). It should be knowledgeable, by direct experience, of the specific methodology, applicable criteria and requirements , code, tool, or approach for which he is employed. Understanding and competence in the assigned area should 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;	This para shall be consistent with para 2.5	Yes			
Italy	29	4.7 2 nd bul- let	The external expert support should have available the tools (e.g., computer codes) and expertise necessary directly or through subcontractors to accomplish the task. For example: <input type="checkbox"/> Capability and experience The external expert should be experienced in using the tools; <input type="checkbox"/> Availability of The external expert should have the latest version of computer codes; <input type="checkbox"/> Availability of The external expert should have the computer codes verified and validated for use in the application being considered.		Yes			

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Germany	49	4.7 1 st bul- let, line 2	... example any accreditation, certification, work references).	There are likely situations where no accreditation or certification is applicable, in these instances work references should be employed	Yes			
Russia - Rosatom	5	4.7 2 nd Bullet	The external expert should have the latest version of verified and validated computer codes as well as permission from organization-proprietor of the codes for use at customer of external expert support. The right of use of these codes shall be stated in the contact between customer and provider of the external expert support.		Yes			
Ukraine	5 (Yastre)	4.7/2 nd bullet	It is proposed to supplement the subsection with the following: One of criteria to estimate the effectiveness of expert organization should be availability of its technical equipment to provide expert support. It means that equipment, instrumentation, computer software and hardware should be available to conduct, for example, research, experiments, engineering calculations, etc.	To provide more detail requirements to select expert organizations.	Yes			
Japan	38	4.7/2 nd bullet/	The external expert should have the tools (e.g., computer codes) and expertise necessary to accomplish the task. For example: <input type="checkbox"/> The external expert should be experienced in using the tools; <input type="checkbox"/> The external expert should have the latest version of computer codes should be used. ; <input type="checkbox"/> The external expert should have the computer codes Verified and validated computer codes for the purpose of the application should be used. use in the application being considered.	Editorial Delete the 1 st sub bullet which is a repeating message.	Yes	Modified in such way		
Japan	16	4.7/4 th bullet	Delete this bullet; The provider of external expert support should accommodate the regulatory body in the time frame needed to make the regulatory decision; Alternative text suggested is as follows; Regulatory body should take account the leading time into the time frame needed to make the regulatory decisions, when external experts advises are needed.	Control of the time frame such as road map and deadline needed to make decisions is regulatory body's responsibility.	Yes			

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Italy	30	4.7 5 th bullet	The provider of external expert support should be able to prepare and deliver specific documentation should be required as required to support the regulatory decision;		Yes			
Italy	31	4.7 6 th bullet	The quality should be checked commensurate with the safety significance or the issue. capability and quality of the provider of external expert support’s work should be verified. When the support is provided by a single external expert, the documentation which supports the advice should be sufficient, accurate and relevant to allow the regulatory body to judge the quality of the work.	It is misleading giving the message that for minor safety aspects we do not care about the quality of the provider	Yes			
Japan	17	4.7/6 th bullet/ 2- 5	When the support is provided by a single external expert, t The documentation which supports the advice should be sufficient, accurate ...	Irrespective of the number of the external experts, the documents provided by them should be sufficient, accurate.	Yes			
France	40	4.7/4 th bullet	At the end, add “It should be recognized that the extent of the external expert job is generally influenced by the time allowed for such job.	Clarification, (a one-month job can’t be performed in one day, even if the regulator ask for a one-day job...),	Yes			
France	41	4.7/5 th bullet	Replace “support the regulatory decision” by “formalize the advice and its rationale, thus being an auditable input in the regulatory decision”	To clarify the responsibility of the external advisor and the one of the regulator.	Yes			

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Japan	3	4.7/6 th bullet/1	<p>The quality of the provider of external expert support’s work should be verified. The quality should be checked commensurate with the safety significance or the issue.</p> <p>Proposed text; The quality of the provider of external expert support’s work should be verified. The quality should be checked <u>and</u> commensurate with the safety significance or the issue.</p>	<p>This may not the same request for all works of 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 does not need to evaluate all of them. Therefore this does not fully applicable to all works of external experts.</p>	Yes			
Japan	4	4.7/6 th bullet/ 2-5	<p>When the support is provided by a single external expert, the documentation which supports the advice should be sufficient, accurate and relevant to allow the regulatory body to judge the quality of the work.</p>	<p>The same reason as above comment No.1 and 3.</p>	Yes	Apart the end which remains		
Indonesia	47	4.7/11	<p>The external expert should have the tools (e.g. computer codes, data reference, standards and expertise necessary ...)</p>	<p>computer code should has a data reference as valuable input, while standard is beneficial in design works</p>	Yes			
Indonesia	48	4.7/14	<p>The external experts should have the adequate computer codes which have been verified and validated for use in the application being considered</p>	<p>More collaborative sentence</p>	Yes			
Indonesia	49	4.7/additional point	<p>The external expert should use the adequate national or international standards</p>	<p>Using standard is a must in design works</p>	Yes			

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Germany	50	4.7 2.2 bul-let	The external expert should have the latest version of computer codes.	It is essential to use codes which have been validated for the task at hand (cf. next bullet). (It is not necessarily the individual external expert who has to verify and validate each computer code, if this has already been done by other organizations.)	Yes	Sentence was modified		
Germany	51	4.7 2.3 bul-let	The external expert should have The computer codes used by the external expert should be verified and validated for use in the application being considered.	It is not necessarily the individual external expert who has to verify and validate each computer code, if this has already been done by other organizations. (It is essential to use codes which have been validated for the task at hand)	Yes	Sentence was modified		
Germany	52	4.7 3 rd bullet	should be explicitly discussed with all involved parties and managed	Clarification	Yes			
Germany	53	4.7 6 th bullet	...When the support is provided by a single external expert The documentation which supports the advice should be sufficient, accurate and relevant to allow the regulatory body to judge the quality of the work.	This is a general requirement which applies not only for single experts.	Yes			
Germany	54	4.7 New bullet (after last bullet)	When the use of advice from other states is considered it should be ensured that all parties involved communicate in a common language. All parties must agree that the use of translation services in a highly specialized technical area bears a risk of misunderstandings.	The use of translation services in a highly specialized technical area bears a risk of misinterpretation and misinformation.	Yes			

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Indonesia	50	4.8/2	... experts; at first , it should define the scope of work to be performed at the outset. The scope of work should be delivered to the external expert support as basis of their work. The external expert should be required to provide a detail written report based on the approved work planning.	More elaborative sentence	Yes			
Japan	18	4.8/2	Regulatory body it should have define defined the scope of work to be performed at the outset.	This sentence looks illogical; the work scope could be added later, if needed, after the utilization and evaluation of the external experts work. Moreover this is the same content with the 1st bullet of para 4.5; determine the scope of the work required. This could be deleted.	Yes			
Japan	5	4.8/1-2	Since the regulatory body should utilize and evaluate the work performed by external experts, it should have defined the scope of work to be performed at the outset.	The same reason as above comment No.1 and 3.	Yes			
UK	38	Para 4.8	A minor point, but what if the advice is not an evaluation?		Yes			
Italy	32	4.8	Since the regulatory body should utilize and evaluate the work performed by external experts, it should have defined the objective and scope of work to be performed at the outset. The external expert should be required to provide a detailed written report. The report should include the objective, the references , the basis for and the method of the external expert’s evaluation, the conclusions and any related recommendations that may assist the regulatory body.		Yes			

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UK	39	Para 4.9	This is the first mention of the concept of the ‘intelligent customer’, despite the fact that the whole document is guidance on the application of this concept. This concept should be introduced in the Introduction. It is confusing that the concept is defined here, when the whole of the preceding text is effectively also a definition of the concept.				No	This concept which appears in many other standards seems to be well located under the section 4
Germany	55	4.9	“The regulatory body should maintain ... by external experts that may impact upon nuclear <u>and radiation</u> safety.” (or alternatively: ... by external experts that may impact upon <u>safety issues.</u> ”)	Clarification (see comments to Para 1.1 and 1.5) and amendment.	Yes			
France	42	4.9/2	Delete “nuclear”	Why limiting to <i>nuclear</i> safety?	Yes			
Japan	39	4.9/2	The regulatory body should maintain an ‘intelligent customer’ (Ref. [8]) capability for all work carried out on its behalf by external experts that may impact upon nuclear safety.	Delete the redundant text. As far as the work of regulatory body is relevant to nuclear safety the work carried out by his support i.e. external experts is also relevant to nuclear safety.	Yes			
Italy	33	4.10 5 th bullet	<input type="checkbox"/> Specify the <u>objective, scope and</u> requirements so that the product received meets the intended needs;		Yes			

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Japan	40	4.10/bul-lets	<input type="checkbox"/> Know what is required and how the work will be used; <input type="checkbox"/> Fully understand the need for an external expert’s services; <input type="checkbox"/> Understand the expected outcome and time frame for de-livery; <input type="checkbox"/> Understand the context in which the work is being per-formed; <input type="checkbox"/> Specify the requirements so that the product received meets the intended needs; <input type="checkbox"/> Supervise the work in accordance with the regulatory body’s procedures; <input type="checkbox"/> Technically review the work before, during, and after im-plementation; <input type="checkbox"/> Ensure continual interaction with the provider of external expert support.	These bullets should be reviewed and arranged in order not to repeat similar content with different word-ings. Followings could be merged as they repeat similar content, otherwise state clearly the different intent of each bullet. 1) Bullet No. 1 and 5 2) Bullet No. 2 and 4 3) Bullet No. 6 and 7	Yes			
Germany	56	4.10 3 rd bullet	Understand the expected outcome; and time frame for delivery;	Don’t mix things that don’t belong together. Empha-sises the importance to understand the result a bit more. (Taken from original 3 rd bullet)	Yes			
Belgium	5	4.10 last bullet	“Ensure continual <u>regular</u> interaction with the provider of exter-nal expert support”	“continual” is too strong; “regular” is consistent with article 5.7, 3 rd line	Yes			
Germany	57	4.10 New bullet	<u>Set time frame for delivery of the work</u>	Don’t mix things that don’t belong together. Empha-sises the im-portance to understand the result a bit more. (Taken from original 3 rd bullet)	Yes			

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USA	11	22/4.10	Add a new bullet: “Regulatory body should be careful to not inappropriately influence the outcome or advice from the external experts”	The document has a lot of caution for the potential conflicts of interest of experts but nothing on a caution for the regulator to not inappropriately influence the experts (such as promoting a situation that the expert tells the regulator what they want to hear). The suggested bullet provides a caution for the regulator to avoid such a situation.	Yes			
Indonesia	51	4.10/additional point	Interact the external expert with the other parties related to the task if required	More elaborative alternative way to complete the task	Yes			
France	43	4.10	Add : - Provide any information useful to the external expert; - Prevent any influence to the provider of external expertise in order that its advice is clearly reflecting its own technical opinion.		Yes			
France	44	4.10/7	Replace “before, during, and after implementation” by “whenever necessary”	To allow for flexibility	Yes			
Italy	34	4.11	The regulatory body should evaluate the work performed by external experts accordingly with the defined objective , scope of work performed at the outset. The written report provided by the external expert, should support the regulatory body’s evaluation.	Replace 4.11 with para 4.12	Yes			

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Indonesia	52	4.11/1	During implementation. After completing of the work, the regula- tory body should evaluate the advice of external experts and determine whether and how it is utilized. The evaluating on the advice should be done appropriately based on the contribution needed of external expert support.	More elaborative sentence	Yes			
Japan	6	4.11/1	The regulatory body should consider evaluate the advice of ex- ternal experts and determine whether and how it is utilized. ...	The same reason as above comment No.1 and 3.	Yes			
Japan	7	4.11/2	The evaluation of the advice could should be done according to the roles and the levels of the responsibility appropriately based on the characteristics of external expert support. ...	The same reason as above comment No.1 and 3.	Yes			
France	45	4.11/5	Delete “The documentation should summarize the review and assessment performed and should present a clear assessment of the safety significance of the decision.”	Superfluous. The way the regulator documents its decision making process may vary according to the significance of the decision.	Yes			
Japan	8	4.12/2	The evaluation of regulatory body should evaluate the work per- formed by external experts should be done accordingly with the defined scope of work performed at the outset ...	The same reason as above comment No.1 and 3.	Yes			
USA	12	23/4.12/ 2 nd sen- tence	The written report provided by the external expert, should con- tain detailed technical evaluation results supporting its conclusions, based on which support the regulatory body’s evaluation can make the appropriate regulatory decision.	“Support the regulatory body’s evaluation” maybe misinterpreted as “Support the regulatory body’s eval- uation and the regulatory decision based on the evaluation.”	Yes			

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Italy	35	4.12	The regulatory body, based on the evaluation of the external support and on their internal evaluation and consideration, should elaborate the regulatory decision. evaluate the advice of external experts and determine whether and how it is utilized. The evaluation of the advice should be done appropriately based on the characteristics of external expert support. The regulatory body should document the decisions made based on the input of the external support and internal evaluation . The basis for the decision should be recorded and documented in the appropriate form. The documentation should summarize the review and assessment performed and should give evidence of present a comprehensive and clear assessment as basis for of the safety significance of the decision.	Replace 4.12 with para 4.11	Yes			
France	46	4.12	At the end of 4.12, add “Such evaluation should help not only for the decision making process related to the case where the advice was requested but also with the purpose of assessing the suitability of this external expert for potential further work”	Preparing for future work is also a purpose of the evaluation.	Yes			
France	47	4.12	Write “The written report ... and the conditions of fulfilment should support...”	The evaluation of the report is only one way of the evaluation	Yes			
UK	40	Section 5	This section is rather confusing. The sub-section dealing with ‘Interfaces’ and subsequent sub-sections seem to be dealing with different interested parties. The former offers control where providers are required to ‘investigate’ at operators’ sites, whereas the latter deals with more general communications and interactions. These two areas could be separated into different sections.		Yes	This section should be more effective now.		
Indonesia	53	5.1/1	The external support provider does not replace the regulatory body instead of. ...	More elaborative sentence			No	Not the same meaning

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COMMENTS BY REVIEWER

Co un-tries	No.	Pa-ra/Li-ne No.	Proposed new text	Reason	Ac-cept-ed	Accepted, but modi-fied as follows	Re-ject-ed	Reason for modi-fication/rejection
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USA	11	24/5.1/line 2 24/5.1/line 4	<p>... replace the regulatory body when providing support.</p> <p>It should be made clear that the regulatory body retains the responsibility for and makes the final decision.</p>	<p>A typo.</p> <p>The previous version referenced INSAG-20; this version references INSAG-17. I suspect that the right reference is Reference 8: the NII guidance document, “Licensee use of contractors and intelligent customer.” Please verify the reference, or simply not referencing anything because the statement is a common understanding.</p>	Yes			
Indonesia	54	5.2/3	<p>... mean visiting sites, gathering data, observing performance, conducting dialogue with operating staff or management</p>	<p>More wide elaborative sentence</p>	Yes			
Italy	36	5.2	<p>There are several possible reasons why a provider of external expert support may need to interact with operators, etc who may be the subject of regulatory activities. This may mean visiting sites, gathering data, observing performance and conducting technical meetings and a dialogue with applicant-operating staff. Such interfaces should be properly controlled by the regulatory body and in no way should the external support provider be allowed to make comments or take actions that might be construed as regulatory requests or requirements. For this reason, all such interfaces should be led or framed by an appropriate regulatory representative.</p>		Yes			

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Italy	37	5.3	Where it is decided that a provider of external expert support may make direct contact with licensees, without the presence of the regulatory body, the purposes and reasons for such interfaces should be defined in the formal arrangements between the regulatory body and the provider of external expert support. In the same way, the licensees should be made aware by the regulatory body of such potential direct contacts, related scope and limits , by the external expert support provider. Timely reports on any such contacts should be made to the regulatory body. The advice provider should also inform the regulatory body of any other contacts made which are relevant to the advice being provided.		Yes			
Germany	58	5.3	Timely reports information on any such contacts should be given made to the regulatory body. The Advice support provider should also inform the regulatory body of any other contacts made, which are relevant to the advice being provided.	Clarification/Editorial	Yes			
UK	41	Para 5.3, 3 rd sentence	Clarification needed. It is assumed that “timely reports” should be made by the provider (rather than the interested party), but this is not clear.		Yes			
Ukraine	2 (Alekseeva)	Chapter 5 Interfaces	To add after para 5.3 a new item which states the following: “The situations exist where the facility status may lead to increased risk for safety violation (for instance, destroyed unit of an NPP, unsafe structures of disposal facility) and timely implementation of safety improvement measures is needed. In this instance, regular direct contact between the provider of external expert support and licensees is justified since it can reduce the time for developing appropriate measures and promote timely decision making on facility upgrading”.	To decrease the time for decision making by regulatory body			No	Such situations are under the responsibility of licensees. Providers should not be seen as an alternative to justified quickly any unsafe situation.

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UK	42	Para 5.4	Transparency to interested parties is an important concept that should apply to all aspects of the provision of advice to regulators. As noted, it is possibly slightly confusing to deal with this issue in a section that initially appears to deal with investigations on operator sites. The principle of Transparency should be mentioned earlier in the guidance.		Yes	Transparency was merged with openness		
Italy	38	5.4	The expert support provider should keep sufficient records, so that the advice can be traced and audited. This includes records of data used for all computer calculations, references to sources of data, reference to examined documentation (safety analysis report, safety justification, design documentation, etc.) and results of any tests carried out. The regulatory body may decide to provide this information to the operator. so it can understand and, if necessary dispute, this input of a regulatory decision. In this case it should be assured that no proprietary or confidential information is included.		Yes			
Ukraine	2 (Ale- kseeva)	5.4 2 nd phrase	This includes, inter alia, records of data and models used for all computer calculations, as well as their uncertainties...	For clarification	Yes			
USA	13	24/5.4/3 ^r d sen- tence	In this case it should be assured that no proprietary or confidential information is appropriately controlled included.	Arrangements are already required to be in place for proper control of proprietary information; and there may be an occasion when proprietary information is necessary to be included in the information provided.	Yes			
France	48	5.4/6	At the end, add “unless adequate provisions to protect this information have been established”	Clarification	Yes			

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UK	43	Para 5.5	The discussion on transparency does not adequately distinguish it from openness. Transparency is not simply about allowing access (this is more correctly openness), but also implies positive action to facilitate understanding. This expectation is perhaps more correctly placed on the regulator, not the provider. Guidance should be provided on the extent to which a provider should actively facilitate transparency, for example by allowing access by third parties.		Yes	Transparency was merged with openness		
UK	44	Para 5.5	Is there any need to show the SQEP status of the external support individual in documents made available to the public? <i>For information, SQEP stands for Suitably Qualified and Experienced Person. It holds some status in the UK nuclear power industry. The term is usually used to designate a professionally-qualified person (such as a Chartered Engineer or Project manager) with several years as a practitioner, who is registered in their area of expertise within the organisation, and whose judgement can be used to resolve a technical problem with some finality.</i>				No	May be further discussed. But that questioned the responsibility of the RB...
USA	12	25/5.5/li ne 3 25/5.5/li ne 10 25/5.6/li ne 2	...as well as the general public.” Publication should clearly show the identity of the external expert provider and the fact that the advice was developed for the regulatory body by this provider. Work carried out for the regulatory, as a public body, should be made available to the public in accordance with the national legal framework governing public access to documents established or possessed by public bodies.	A typo. Editorial. Editorial.	Yes			
USA	14	25/5.6/1 st sen- tence	Work carried out for the regulatory body, as a public body, should be available to the public, taking into account the national legal framework governing public access to documents established or possessed by public bodies	Word omitted in original text.	Yes	Cf. comment USA 12		

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UK	45	Para 5.6	Openness should be considered in the same manner as suggested for transparency (see comment NDA 38).		Yes	Transparency was merged with openness		
UK	46	Para 5.6	It is not clear whether this paragraph is placing any requirements on the provider. The meaning of the last sentence is not clear – consider rewording to clarify that the requirement from the provider is to obtain permission from the regulator before quoting the work.		Yes	Should be fixed now		
France	49	5.7	Move the last sentence (“In addition, there may be an agreed upon time before which an expert organization is not permitted to discuss work performed specifically for a regulatory body.”) to the end of 5.6	More appropriate location	Yes			
Germany	59	5.7	may be an agreed upon -time before	Editorial	Yes			
Italy	39	5.7	All communications regarding the work performed by the provider of external expert support at the request of the regulatory body should be under the regulator’s control and direction. There should be regular contact between the external support provider and the regulatory body. The frequency of meetings will depend on the extent of the work being performed, the knowledge and confidence the regulatory body has in the external support provider and the need for timeliness of the expected results. In addition, there may be an agreed upon time before which an expert organization is not permitted to discuss with other parties the work performed specifically for a regulatory body.		Yes			

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Italy	40	5.8	CONFIDENTIALITY In supporting the Regulatory Body, the provider of external expert support could have access to confidential proprietary information. The owner of the intellectual property should be requested by the RB to agree on this access of third party to the information. The external support provider shall have provision in its organization to ensure restrictions on the use and to protect this type of information as well.	Missing	Yes	Was para 3.17. Now it is para 3.21		
Germany	60	Ref. [7]	... IAEA Safety Standards Series No. GSR Part 4, IAEA, Vienna (2009) (2008)	The document was published in May 2009.	Yes			
Germany	61	Ref. [8]	... T/AST/049, <u>Issue 3 (2009)</u> http://www.hse.gov.uk/foi/internalops/nsd/tech_asst_guides/tast049.htm	Completeness; the website of the NII document is incorrectly cited.	Yes			
France	50	Refer- ences	[1] INTERNATIONAL ATOMIC ENERGY AGENCY, (a) Challenges Faced by Technical and Scientific Support Organizations in Enhancing Nuclear Safety, Proceedings of an International Conference held in Aix-en-Provence, 23-27 April 2007, IAEA, Vienna (2007); (b) Challenges faced by Technical and Scientific Support organizations (TSO) in Enhancing Nuclear Safety and Security “Proceedings of an International Conference held in Tokyo, 25-29 October 2010, IAEA, Vienna (2010)	To complete the reference	Yes			
UK	47	Ref [8]	Consider deleting the reference to this document	This reference should be deleted since it relates to one regulatory organisation only.	Yes			