

**April 13, 2011**

**ATTACHED ARE COMMENTS  
FOR A NOVEMBER 20, 2010  
MEETING WITH IAEA**

**Comments on IAEA Draft Safety Guide “External Expert Support on Safety Issues” (DS429)**

COMMENTS BY REVIEWER				RESOLUTION			
Country/Organization: United States of America		Date: October 2010					
Comment No. / Reviewer	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1	General	<p>Realizing the importance of independent views and advice of the providers; the document obscures the relevance of effective independence from Ref [1]. In this context, “Independence [1]” is an issue between the regulatory body and the applicant or the licensee. The obligation is on the regulatory body to ascertain whether the advice or service can be used or taken without undue influence or conflict of interest. It seems unrealistic to impose <i>ex post facto</i> independence obligations on the external expert organizations. However, it is incumbent on the regulatory authority to ensure that there is no actual or perceived conflict-of-interest for the provider.</p> <p>This issue should require selective revisions of the text in paragraphs 2.6 and 3.1 - 3.11.</p>	<p>Clarification of the mix up between independence of the regulators and independence of the external support provider.</p> <p>We suggest keeping independence of the provider, at best, as a secondary consideration throughout the document. In other words, providers cannot be held to the same measure or pedigree of independence that is required by the regulatory body, unless the country delegates some or all of the functions of its regulatory body to an external organization.</p>				
2	General Definition P3,	The Definition “Providers of External Support,” presented in the footnote contemplates that the	Providers of external expert support may not always be identified				

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	Footnote	provider needs to be recognized or defined within the regulatory structure. In addition, it appears to exclude commercial entities, academic institutions, and other reliable providers of expert support. In many cases, the external support organization or persons cannot be identified within the structure of the organization as support can be provided through Ad-hoc working groups or contractors especially designated to address safety issue outside of the regulatory structure. Therefore, we suggest the footnote be modified to read: <i>“A provider of external expert support is a person or organization that is not resident within a regulatory body, but is recognized of its expertise and competency in safety and which can provide support to the mission of the regulatory.”</i>	within the structure of the organization but can be designated to provide technical support on <i>ad-hoc</i> basis as needed by the regulatory body or the concerned organization.				
3	General Scope,	Under the scope of the SG, it was stated: “This guide covers all forms of support for safety issues that may be required by a regulatory body, whether technical, legal, analytical or other, <b>but does not deal with support that may be</b>	Clarification and Completeness: The guide needs to acknowledge synergies and interface of safety and security and emphasize the need for				

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		<p><b>requested for security issues.</b> Safety and security are complementary and there could be advantages if the processes and procedures applied to both safety and security are similar.”</p> <p>We note that the IAEA has recognized the synergies between safety and security and established a “<i>Joint AdSec CSS Task Force</i>” to address interface and integration of safety and security. In other words, providers of supports pertaining to safety need to be cognizant of security issues and <i>vice-versa</i>, so that advice and decisions can be made early based on informed assessment of both safety and security issues. The current guidance appears to contemplate that safety issues need to be dealt with independent of security issues.</p>	the expert support providers to be cognizant of such synergies and interface.				
4	Para. 2.2	Add a sentence to the end of the paragraph to read as: “It is incumbent on the regulatory body to clearly attribute those recommendations adopted and rejected from the expert organization for the purpose of clarity and transparency.	In cases where only some recommendations from external expert organizations are included in decision-making, or in cases where recommendations are rejected, the regulatory				

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			body must be clear and precise that in any such departure, there is justification and transparency, to avoid allocating inaccurate attribution to such external expert organizations.				
5	2.3	“However, in using a provider of external expert support processes and procedures should be put in place so that the advice is provided in a <b>properly-structured predetermined</b> manner.”	Without further reference or explanation, it is not clear what is the meaning of “properly structured.” The process and procedures should be predetermined by the regulator.				
6	Para. 2.3	Modify to read as: “...a properly structured manner. <b>Within the context of the available resources and existing infrastructure</b> , this <del>structure</del> should include: <ul style="list-style-type: none"> <li>• how the need for external advice is determined, .....</li> </ul> <p>In addition, some perspective of a graded approach to address the bulleted items in this paragraph needs to be articulated.</p>	Clarity and Completeness: There should be some acknowledgement that if a country or governmental organization requires “outside advice”, to expect a detailed documented strategy outlining the origins, problems, tactics and strategic means for upgrading or even				

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			establishing a regulatory infrastructure may be unrealistic				
7	2.3	After 2 <sup>nd</sup> bullet, add three new bullets to read: <ul style="list-style-type: none"> <li>• Process of determining clearance of provider from conflict-of-interest.</li> <li>• Adoption of code of ethics and confidentiality protocols.</li> </ul>	These listed elements are necessary to be incorporated in the structure of establishing processes and procedures for the external support procurement.				
8	2.4/3	“The source should be <b>an truly</b> expert <b>in the area of interest</b> and capable of providing the necessary advice. This competence can be clearly demonstrated through formal processes, such as examples of previous work <b>experience</b> , CVs of staff etc.”	Adds clarity.				
9	Para. 2.4	Either delete the last sentence or else modify it to read as: If the external source uses experts from outside its own organization as subcontractors, who in turn may use other subcontractors, the <b>primary provider of the expertise should document the independence, reliability and competence</b> of these organizations and individuals. <del>should be demonstrated during the</del>	Correctness and clarity: This paragraph is too dogmatic; because the composition of expert team would not necessarily be configured with such control by the Member State requesting the assistance.  <b>The independence of subcontractors also</b>				

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		<del>subsequent procurement processes.</del>	needs to be established and confirmed.				
10	Para. 2.6 ALL	Delete all these phrases using <b>independence</b> and properly introduce them in Chapter 3. At which point these should be defined and distinguished. The Safety Glossary does not define any of these terms.	Use of phrases such as <b>independent, fully independent</b> and <b>effectively independent</b> are not appropriately portrayed nor clearly distinguished. Whereas competency, reliability, accuracy and relevance are marginalized.				
11	2.6/entire section	General Comment: The current text regarding sources of expertise is of a top-level nature. If feasible, it is suggested that an appendix be added to the IAEA DS429 document to list organizations according to the categories of Section 2.6 which have performed significant work related to nuclear safety in the past X (to be determined) years.	In light of the requirement of competence which may be demonstrated by "previous work," it is useful to provide a reliable list of sources that a regulatory body can deliberate on for obtaining external expert support.				
12	Para. 2.6, bullet 3	Delete bullet. If the dedicated organization exists within the confines of the State's legal structure, then it is not an external expert organization.	Correctness & Clarity				
13	2.6/bullet 4 and 5	General Comment: It is stated under the fourth bullet, "advice	Certain State regulatory bodies, in particular				

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		[from State regulatory bodies] can be obtained through individual contacts or international forums.” Depending on the nature of the advice, the currently stated vehicles of communication among State regulatory bodies may not be sufficient. It is suggested that IAEA establish a way (e.g., website, contact list included in DS429, etc.) to serve as a point of contact for referring a State regulatory body in need of assistance to other State regulatory bodies which may be able to provide that assistance. A new paragraph may be needed to describe how this would be done.	those in most need of assistance, may not have established extensive contacts with other State regulatory bodies with the developed capabilities to provide them with assistance.				
14	Para. 2.6, bullet 5	Rewrite as: Vendor State... in a State from where <del>the reactor has been purchased</del> <b>structures, components and services to the applicant licensee are provided; for example reactor vessels.</b>	To have an inclusive statement. Vendors provide more services and products than just reactors. Waste packages, disposal/cleanup services, etc...				
15	2.6/bullet 7	“contracts with these organizations may be overarching so that their advice can be called on when needed or <b>the contracts can be specific</b> as each issue arises”	For clarity				
16	2.6/bullet	“while they may also work for the	The independence and				

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	9, line 3	operator, the issue of independence is <b>of lesser important</b> "	quality of testing and measurement services obtained by the regulator are necessary and often critical to support regulatory inspection and enforcement actions.				
17	Section 2.7- General	Consider developing a database of external support experts by discipline for all entities to share.					
18	2.8	Add Bullet to list of types of external support <ul style="list-style-type: none"> <li>Operations support including development and interpretation of nuclear plant technical specifications</li> </ul>	Seems like a specific area not previously included in the list.				
19	2.8/bullet 6	Drafting of <del>regulations and guides</del> regulatory documents; or	External expert support may be asked for drafting additional regulatory documents.				
20	Section 2.8	After last bullet, add two new bullet: <ul style="list-style-type: none"> <li>QA/QC and audit</li> </ul>	Completeness				
21	3.2	At end of paragraph, add: <p><b>"Exception may be granted due to lack of expertise in certain technical areas (e.g., criticality, climate, and seismology)."</b></p>	Recognition of lack of expertise in certain technical areas and therefore exception may be granted with proper overview of the regulator for appropriate decision-making.				
22	3.5, 1 <sup>st</sup>	Delete sentence.	Clarity and correctness:				

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	sentence		The expert organization may be or may have been involved in providing services to an applicant or licensee in the past. This would seem to apply <i>ex post facto</i> disqualification to such external expert organizations.				
23	3.5, 3 <sup>rd</sup> sentence	Delete: "The ability of the provider of external expert support to develop its own research assists in the development of state-of-the-art knowledge and techniques, and foster independent judgement."	Correctness: The last sentence may not be necessarily true.				
24	3.6	Perhaps suggest more firmly that hiring nuclear industry consultants who work primarily for industry may not be the optimum solution.  Staff noted that other countries, like Finland, also chose independent agencies, for example, when they tested for BWR bubble characteristics.	NRC has generally chosen not to employ contractors who predominantly work for licensees, to avoid the potential appearance of a conflict. Although with <del>GI 103, NRC has contracted with Purdue Univ who has also been contracted by PWROG on GL-08-01, a related issue.</del>				
25	3.6/3	"This means that all situations	Adds clarity.				

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		<p>should be analyzed for actual, potential or perceived conflicts of interest. Actual conflicts of interests should be eliminated immediately, to the extent possible. This does not mean that external support provider cannot work on a particular issue for the regulatory body on one facility and an operator on another, but all such situations and any potential or perceived conflicts of interests need to be openly discussed and managed carefully.”</p>	Actual conflicts of interests should be eliminated immediately. Potential and perceived conflict of interest should be openly discussed and managed.				
26	Section 3.6	The second sentence stated “ <i>This does not mean that external support provider cannot work on a particular issue for the regulatory body on one facility and an operator on another.</i> ” This may contemplate an appearance of a conflict of interest if the provider works simultaneously for the operator and the regulator and the two assignments are somehow interrelated. The statement should be clarified to make sure that the two assignments are not related whatsoever.’	Clarification				
27	Para 3.7, 2 <sup>nd</sup> bullet	Delete this bullet. Licensee could conduct its own technical studies and regulators	This implies that the licensee cannot rely on technical support				

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		should verify and conduct own studies if necessary to examine correctness of licensee's analysis.	information it pays for.				
28	Para. 3.8 ALL	Delete the paragraph.	This guidance is not realistic. There may not be any external expert organizations that can comply with such an exclusion and disqualification. Developing countries, which are the most needing of external expert advice, may not be in the position to make such determinations.				
29	3.9/2	"It may be impossible for the regulatory body to find a specific external expert free from potential conflicts of interest. <b>This would occur in very rare cases.</b> Such may be the case for example:"	Adds emphasis that this would not be common practice.				
30	3.16/bullet 1	General Comment: Without specifying the nature and type of the certification, this sentence does not have adequate context, especially when consideration of the certification is not essential.  Alternatively, to provide context, a					

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		statement addressing the value of certification of an individual expert, who is not an academic expert, should be added to the preceding sentence, "For an individual expert, technical competency should be ensured by verifying that he has already provided similar external support in a satisfactory way (reference list)."					
31	3.16/bullet 2	<p>2<sup>nd</sup> bullet</p> <ul style="list-style-type: none"> <li>For an expert organization, the existence of a <b>certified</b>-quality management system is a useful characteristic: <ul style="list-style-type: none"> <li>through the traceability of processes and documentation, it helps demonstrate the technical competency of the organization;</li> <li>in case of the establishment of a long term support (e.g. dedicated support organization), the existence of a <b>certified</b> quality management system, provides confidence that technical competency will be maintained on the long term.</li> </ul> </li> </ul> <p>(See para 3.19 for guidance on an adequate management system).</p>	Without further reference or explanation, it is not clear what is the meaning of "certified quality management system." Certified to what standards or certified by what organization? In most other IAEA Safety Standards, the term "management system" is used in place of quality assurance or quality management program.				
32	Para. 3.22-23	Realistically, once information is provided to a regulatory body, any	Implementation aspects and correctness:				

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		guarantees -- not originating from the regulatory body – to vouchsafe the confidentiality may be moot. It may be advisable for this safety guide to recommend redaction of portions of such data or information, as a means of protecting confidentiality.	If information is provided by a foreign source requesting confidentiality or security of a portion of the advice information, what option does the external expert organization have to resist the national government's demand that the information be provided to the government? Not all countries have judicial systems with authority to sanction governmental agencies violating legal confidentiality.				
33	3.23/6	“The regulatory body should inform the owner of the IPR its intension to pass information to a third party....” IPR should be spelled out.	IPR is not defined.				
34	4.4 to 4.9/NA	Sections 4.4 to 4.7 are missing; Section 4.8 is placed after Section 4.9	A potential typographical error.				
35	4.11/bullet 3	Does the provider of external expert support have a potential, actual, or perceived conflict of interest?	Consider deleting. Section 3.16 explained what should be done in the cases of actual, potential and perceived conflict of interest.				

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36	4.11	Consider Adding: "Is the expert knowledgeable, by direct experience, of the specific methodology, code, tool, or approach for which he is employed. Understanding and competence in the assigned area shall be demonstrated by the range of the individual's experience in the number of different, independent activities performed in the assigned area, as well as the different levels of complexity of these activities."	Prior Experience: The ASME PRA Standard has a section on this which can also be reviewed for further insights. This suggested wording paraphrases some draft language floated around 2001 that firms up the requirements for selecting an expert.				
37	4.14/5	"...and any related recommendations that <del>may assist</del> <b>are requested by</b> the regulatory body."	Unwanted recommendations or opinions tend to be subjective and may not assist the regulatory body's decision-making process.				
38	5.2/line 6	"For this reason, all such interfaces should be led by an appropriate regulatory representative. <del>with an "intelligent customer" capability.</del> "	The term "intelligent customer" is introduced in paragraph 2.2 with reference to a UK document reference #9. Use of this term, undefined in the IAEA Safety Glossary should be deleted. Further use of this term in para 5.2 is not needed				

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39	5.3 to 5.6	Sections 5.4 and 5.5 are missing.	A potential typographical error.				
40	5.6/5	“However, a provider of external expert supports may provide advice in their fields of expertise to different organizations, including other regulatory bodies, <del>and may recruit their staff from the same range of organizations.</del> ”	Although a regulatory body may place restrictions on the external expert providers’ use of certain individuals on a specific contracted work, I don’t think this document intends to interfere the external expert providers’ recruiting policy.				
41	5.21/8		Consider including additional guidance on keeping traceable documents and an auditable process.				
42	5.6 to 5.21	Sections 5.7 to 5.20 are missing	A potential typographical error.				
43	5.21/line 6	“Unless there are confidentiality issues, all external advice should be published to enhance transparency as part of the <b>regulatory body’s</b> interested party engagement process.”	For clarity.				
44	5.24/last	“instructions and authorizations needed for the work to be quoted or used <b>and provide guidance on handling proprietary information.</b> ”	Consider including additional detailed instructions with regards to the external experts handling proprietary				

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			information.				
45	5.25	All communications regarding the work performed by the provider of external expert support at the request of the regulatory body should be under <b>it's the regulator's</b> control and direction.	Clarification is needed to be specific in identifying who controls and directs the communications.				
46	General	The unwritten rule of numbering references in the text according to their first appearing sequence is not strictly followed. The following is the reference number with the page number of its first appearance in the parenthesis: 1(page 4), 2(page 3), 3(page 4), 4(page 5), 5(page 14), 6(page 18), 7(page 23), 8(page 22), 9(page 6), and 10(page 16). It's better to rearrange the references.	The unwritten rule of numbering references in the text according to the first appearing sequence is not strictly followed.				
47	General	Consider including additional detailed instructions with regards to the external experts handling proprietary information.					
48	General	Consider including a section discussing management of contracts/budgets associated with external experts, as appropriate.					
49	General	Consider adding guidance for the regulator to provide feedback to their contractors as part of the contract management process.					

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<b>Clarification &amp; Technical Editing Comments Below</b>							
50	2.2	"In this case the advice should be properly documented and clearly understood. It should be used, communicated, and documented <b>correctly</b> , and there should be no ambiguity or dilution in the responsibility of the regulatory body which will <b>takemake</b> the final decision.	Without further reference or explanation, it is not clear what is the meaning of "documented correctly." Also suggest that the word "take" be revised to "make."				
51	2.4/5	"...previous work, CVs of staff etc." CV should be spelled out.	CV is not defined.				
52	2.6/bullet 5	"This can be extremely useful but care should be taken not to underestimate <del>that</del> <b>the</b> fact that the influence of conditions in one State may not necessarily apply to another."	A potential typographical error.				
53	2.6/second to last bullet	financial and economic organizations: these organizations, private or governmental, can provide advice on such matters <b>such</b> as the financial status of a potential licensee, the appropriateness of investments of decommissioning funds, potential financial conflicts of interest, etc.;	Adds clarity				

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54	2.9	“The support may be continuous, in the form <b>of</b> a fixed arrangement, or”	potential typographical error.				
55	3.5/4	“The ability of the provider of external expert support to develop its own research assists in the development of state-of-the-art knowledge and techniques, and fosters independent judgement.”	A potential typographical error.				Need to consider deleting this comment if 15-FSME is retained.
56	3.12, 3.13, 3.17 and 3.18/NA	Sections 3.12, 3.13, 3.17 and 3.18 are missing					
57	4.14/ bullets 1 and 4	<p>The regulatory body should evaluate the advice of external experts and <del>to</del> determine whether and how it is adopted. The regulatory body should maintain an ‘intelligent customer’ capability for all work carried out on its behalf by external experts that may impact upon nuclear safety.</p> <p>The regulatory body should choose between sourcing work in-house or from contractors. That process should be informed by a clear policy that takes the nuclear safety implications of those choices into account.</p>	typographical errors.				