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Design and Analysis Computer Commercial-Grade Dedication Requirements

Comment On: NRC-2015-0153-0001
Acceptance of Commercial-Grade Design and Analysis Computer Programs for Nuclear Power Plants; Draft Regulatory Guide; Request for Comment

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General Comment

My name is P. Lynne Valdez. I live and work in Arizona. I have worked with Software Quality Assurance for eight years and involved in two industry groups; Nuclear Information Technology Strategic Leadership and the American Society of Mechanical Engineers. I was involved in working with EPRI to develop the first revision of the document that is being considered for endorsement. At that time, a small group working on the document had some concerns with the methodology described in the EPRI document to address commercial grade dedication of design and analysis software. The positive of having this document is outweighed by the negatives. Until a process that is more specific to software used as a tool to perform calculations and analyses is developed, this will not result in the desired meaningful guidance. It would greatly benefit the industry to have meaningful guidance, but this guidance is not ready for endorsement. See the attached comments.

Attachments

15-1305 DG comments

SUNSI Review Complete
Template = ADM - 013
E-RIDS= ADM-03
Add= *J. Lipscomb (hs62)*
S. Murton (5xb3)

Comments on Draft Regulatory Guide DG-1305
“Acceptance of Commercial-Grade Design and Analysis Computer Programs for Nuclear Power Plants”
(Docket ID NRC-2015-0153)

It is my recommendation that the Nuclear Regulatory Commission not endorse the proposed regulatory guidance as presently written until fundamental issues are resolved ensuring effective guidance on the commercial procurement and acceptance of design and analysis software.

The first fundamental issue is that this guidance proposes applying similar methodologies to design and analysis software as is used for items or software installed in the plant. Software quality assurance is similar to hardware QA, but there are substantial differences (reference NUREG/CR-4640). As a result, a hardware QA program cannot be directly applied to that of software; it must be modified to account for the differences. Methodology for accepting software used for design and analysis has its own special needs in order to be meaningful. The EPRI guidance did not go far enough into design and analysis software special needs to be meaningful. See related comments 1a through 1f.

Secondly, the guidance assumes design and analysis software is associated with Systems, Structures, and Components (SSCs). In reality, design and analysis software is associated with the calculation, engineering study, or analysis. The calculation, study, or analysis is associated with the SSC. See related comments 2a-2c.

Next, parts of the EPRI guidance document have faulty logic. For example, the document assumes SQA programs are not adequate. It also assumes design and analysis software is relied upon for making design and analysis decisions without any other controls. See related comments 3a-3g.

Editorial comments are documented in #4a-4b.

#	Document, Section, Page, Paragraph	Comment	Proposed Resolution
Issue 1: Treating Design and Analysis software similar to that of items and process software			
1a	DG-1305, Section A, Page 2, Related guidance, second bullet	Generic Letter 91-5 does not include methodologies specific to design and analysis software	Remove as it is not relevant to Design and Analysis software.
1b	DG-1305, Section A, Page 2, Related Guidance, 5 th bullet	Regulatory Guide 1.152 is specific to software installed in the plant. This does not apply to design and analysis software	Remove as it is not relevant to Design and Analysis software.
1c	DG-1305, Section A, Page 2, Related Guidance, bullet 6	Safety Evaluation Report, “Review of EPRI Topical Report TR-106439, ‘Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications ’” does not apply to design and analysis software. It is specific to digital equipment installed in the plant.	Remove as it is not relevant to Design and Analysis software.
1d	DG-1305, Section B, Page 3, Background, last paragraph on the page	This paragraph discusses digital upgrades and guidance on the acceptance of commercial-grade computer programs that supported digital upgrades. This is not relevant to the guidance for commercial grade dedication of design and analysis software.	Remove the phrase between “In the 1990s” and “on improving high-level quality assurance programmatic guidance relating to control of computer programs.”

#	Document, Section, Page, Paragraph	Comment	Proposed Resolution
1e	EPRI document, page x, Section titled Use of Commercial-Grade Dedication to Accept Computer Programs	This paragraph lists EPRI documents as requirements. These documents (EPRI NP-5652, EPRI TR-102260 and EPRI TR-106439) are applicable to items and not specific to design and analysis software.	This section of the document should not be endorsed as they do not specifically apply to design and analysis software.
1f	EPRI document, page 1-12, Section 1.6.1 Consistency with Previously Published/ Endorsed EPRI Reports	The entire list is specific to items (hardware) or digital equipment. These references are not relevant to design and analysis software.	NRC should not endorse this section of the EPRI document.
Issue 2: The guidance assumes design and analysis software is associated with specific SSCs			
2a	EPRI document, Page ix, Background, last paragraph	First sentence discusses specific functions of the computer program as they may relate to the safety-related functions of associated SSCs...	The design and analysis software would be associated with the design activity; i.e., calculation or analysis activities.
2b	EPRI document, Page 5-3, Section 5.4 Functional Safety Classification, Paragraph that begins "The safety classification..."	The first sentence states, "The safety classification of computer programs is performed to determine if any function(s) performed by the computer program could prevent associated SSCs from performing their safety-related functions." Comment: Design and analysis software is rarely acquired in association with a specific SSC. The software may perform design activities – such as design of pipe supports or hangars and then be used on various SSCs.	This issue should be addressed before endorsement.
2c	EPRI document, Page 7-4, Section 7.1.3 Implementation of the Acceptance Process	Last paragraph of the section starts with, "Note that, in this example..." This paragraph concludes that if the software were to be used in a different safety-related application, then an additional dedication would be necessary. Association of the design and analysis software with SSCs will not be economically feasible. Instead of associating the software with SSCs, the software could be qualified for a range of uses and the acceptance criteria written for the limiting use.	The fifth paragraph of Section 5.4.1.6 opens the door for associating the software with an intended use – as opposed to associating the software with an SSC. But, the document needs to be re-written to take the emphasis off the association of the software with the SSCs. The NRC should not endorse until this is corrected.
Issue 3: Issues with EPRI guidance reasoning			

#	Document, Section, Page, Paragraph	Comment	Proposed Resolution
3a	EPRI document, page viii, Background, 2 nd paragraph	This is a true statement: that verification and validation are included in typical SQA programs. However, these are only two parts of the lifecycle. Gathering and understanding the software requirements is the first and key step in a typical SQA program. The SQA requirements would include the critical characteristics.	The EPRI document is written so that it leads the reader to believe that verification and validation are the only practice relied upon to control software (also reference the EPRI document, page ix, first sentence). The NRC should not endorse this document until this faulty perspective of SQA programs is straightened out.
3b	EPRI document, page xi, Acceptance versus Design, last paragraph	SQA programs also include a requirements phase. This is an important phase not credited in the EPRI document.	This is a faulty assumption and should not be endorsed.
3c	EPRI document, page 1-5, Section 1.2.3, third paragraph	The second sentence states, "In Scenario C, the computer program is relied upon as the sole basis for making design and/or analysis decisions." Comment: Design and analysis software is used within the design or analysis quality related activity and all the controls of 10CFR50, appendix B, criteria III apply.	The EPRI document contains a faulty assumption – specifically, that the computer program is relied upon as the sole basis for making design and/or analysis decisions. Therefore, it should not be endorsed.
3d	EPRI document, page 1-17, Section 1.6.7 Adoption of ASME NQA-1a-2009	A piece of software written in the 1980's and controlled under an SQA program should not have to "be brought up to standard". Legacy software is not "Otherwise Acquired" and should not automatically require backfitting.	The NRC should not endorse section 1.6.7 as it imposes backfitting requirements.
3e	EPRI document, page 6-5, Section 6.4 Identify Critical Characteristics for Acceptance	The paragraph that begins, "When detailed design information is available..." This paragraph adds confusion because design can mean different things. There is plant design, design activities, and software design. The software design will rarely be delivered when the software is purchased commercial. However, the plant design is available. The critical characteristics for the software would be determined by its intended use (the plant design) and therefore would be available. Also of note, the FMEA of the computer program would only inform a part of the critical characteristics – the 'what if it doesn't work' part. It does not inform what the computer program should do.	The NRC should have EPRI clarify this section before endorsing. This section should include two things: 1) the critical characteristics specific to what the computer program needs to do and 2) the results of the FMEA to inform the acceptance criteria.

#	Document, Section, Page, Paragraph	Comment	Proposed Resolution
3f	EPRI document, page 6-27, Section 6.8 Considerations When Selecting Acceptance Methods, paragraph five	<p>Paragraph five concludes that the acceptance may rely heavily on special testing and inspection. This is true, especially for commercial-off-the-shelf software. However, this conclusion conflicts with the idea that verification and validation may not be good enough.</p> <p>This document was put together based on hardware and process software guidance. It was not modified sufficiently to result in adding value to the qualification of commercial design and analysis software as evidenced by the conclusion in paragraph 5 of section 6.8.</p>	<p>The conclusion of this paragraph of the EPRI document provides further proof that the guidance did not address the special needs of design and analysis software. The NRC should not endorse this document until there is enough depth into the special needs of design and analysis software to make it more meaningful than the current SQA programs built on IEEE or ASME NQA-1 guidance already do.</p>
3g	EPRI document, page 7-3, Section 7.1.3 Implementation of the Acceptance Process	<p>The first three bullets on the page are illustrations of critical characteristics. These characteristics are so vague as to be meaningless. The software is to be correct. What does correct mean? The software is to be complete? How would you know if it was not complete?</p>	<p>It is understandable that specific criteria cannot be used in an example. However, because these characteristics are so vague, it might lead the document user to also be vague.</p> <p>The issue is that when the critical characteristics are vague, the tests and inspections to test those characteristics will not yield meaningful results.</p> <p>The NRC should not endorse the EPRI document at this time.</p>
Issue 4: Editorial comments			
4a	DG-1305, Section B, Background, Page 4, Last paragraph of the Background section	<p>The EPRI 1025243 is a Technical Report or a Guideline document. It is not a standard</p>	<p>Revise to identify the document correctly.</p>
4b	DG-1305, Section C, Page 5, Staff Regulatory Guidance Position, 2 nd bullet	<p>Typographical error in the 2nd sentence.</p>	<p>Change "ERPI" to "EPRI"</p>