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August 21, 2015

Ms. Cindy K. Bladey  
Office of Administration  
Mail Stop: O12-H08  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

7/1/2015  
80 FR 37666

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2015 AUG 24 PM 3:59

RULES AND DIRECTIVES  
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**Subject:** Industry Comments on Draft Regulatory Guide (DG), DG-1305, *Acceptance of Commercial Grade Design and Analysis Computer Programs for Nuclear Power Plants* [Docket ID NRC-2015-0153]

**Project Number: 689**

Dear Ms. Bladey:

On behalf of the nuclear energy industry, the Nuclear Energy Institute (NEI)<sup>1</sup> is providing comments on draft Regulatory Guide (DG), DG-1305, *Acceptance of Commercial Grade Design and Analysis Computer Programs for Nuclear Power Plants* [Docket ID NRC-2015-0153].

We appreciate this effort by the NRC to establish new guidance that describes methods that the NRC staff considers acceptable in meeting regulatory requirements for acceptance and dedication of commercial-grade design and analysis computer programs for nuclear power plants. DG-1305, *Acceptance of Commercial Grade Design and Analysis Computer Programs for Nuclear Power Plants*, approves Revision 1 of EPRI Technical Report 3002002289, *Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications, Revision 1 of 1025243*. We first submitted EPRI guidance for NRC review and endorsement through a Regulatory Guide in July 2012. In response to the NRC's February 2013 request for additional information, we submitted a revision to the EPRI guidance in January 2014.

<sup>1</sup> NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

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In our attached comments, we identify a few areas where the guidance can be further enhanced to clarify the scope of the guidance, and the NRC-accepted methods for dedicating commercial-grade design and analysis computer programs as basic components for use in safety-related applications at nuclear power plants.

If you have any questions or require additional information, please contact Marc Nichol (202-739-8131; mrn@nei.org) or me.

Sincerely,



Christopher E. Earls

Attachment

c: Mr. Brian E. Thomas, RES/DE, NRC  
Mr. Michael C. Cheok, NRO/DCIP, NRC  
Mr. Thomas H. Boyce, RES/DE/RGGIB, NRC  
Mr. Richard A. Rasmussen, NRO/DCIP/EVIB, NRC  
Mr. Stephen C. Burton III, RES/DE/RGGIB, NRC  
Mr. George A. Lipscomb, NRO/DCIP/EVIB, NRC  
NRC Document Control Desk

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**[Docket ID NRC-2015-0153]**

Comment #	Location	Comment	Proposed Change
1	General	<p>The scope and intended application of the Regulatory Guide (RG) is not stated clearly, and there is not a clear description of how this RG fits within the broader regulatory context. Potential users may be confused as to whether this guidance is applicable in their specific situation. As a result users may mistakenly apply the guidance to computer programs for which it was not intended to be used, or, conversely, incorrectly believe the guidance is not applicable, when in fact it is.</p>	<p>Revise the title of the Regulatory Guide to state: "Acceptance of Commercial-Grade Design and Analysis Computer Programs <u>Used in Safety-Related Applications</u> for Nuclear Power Plants." Revise the first sentence in the Purpose section, and similar statements throughout the guidance to state: "This regulatory guide (RG) describes acceptance methods that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable in meeting regulatory requirements for acceptance and dedication of commercial-grade design and analysis computer programs <u>used in safety-related applications</u> for nuclear power plants." Include a sentence that states, "The scope of this guidance does not include the use of the computer program after it has been dedicated as a basic component, which must be controlled under a QA program, in compliance with Criterion III Design Control of 10 CFR Part 50 Appendix B."</p> <p>Include a description of the broader regulatory context and references to other NRC guidance that describes how to determine whether a design and analysis computer program is safety-related and considered a basic component. Add to the Purpose section a discussion of what types of computer programs are not included (e.g., in-process computer programs, design and analysis computer programs that are not used in safety-related applications or that were developed under a quality assurance program in accordance with</p>

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			Appendix B to 10 CFR Part 50). It would be helpful to provide examples of computer programs that are within the scope of this regulatory guide.
2	p. 1, A. Introduction, Applicable Rules and Regulations, second bullet	The second sentence is confusing and potentially inaccurate as written.	Replace the sentence with: "For design and analysis computer programs, acceptance of commercial-grade software in accordance with the requirements in Criterion III of Appendix B to 10 CFR Part 50 fulfills the requirements of dedication in 10 CFR Part 21."
3	Multiple	In several instances, DG-1305 refers to EPRI-1025243, Revision 1 as a "standard". EPRI-1025243, Revision 1 is intended to be guidance, as stated within that document.	In the following locations, replace the word "standard" with "guidance":  p.3, B. Discussion, Reason for Issuance, last sentence: "...EPRI 1025243 (Ref. 13) was the first <del>standard</del> <u>guidance</u> to provide..."  p.4, B. Discussion, Background, last paragraph, first sentence: "The EPRI 1025243 <del>standard</del> <u>guidance</u> was specifically developed..."  p.4, B. Discussion, Documents Discussed in Staff Regulatory Guidance, fourth sentence: "...an acceptable approach for meeting an NRC requirement, then the <u>secondary reference standard</u> constitutes a method acceptable..."
4	p. 4, B. Discussion, Harmonization with International Standards, third sentence	The following sentence is confusing and potentially inaccurate: "Although the Safety Guide relates primarily to computer programs used in important to safety systems and EPRI	Replace the sentence with: "The Safety Guide relates to software used in computer based systems important to safety, and includes an annex on the use of pre-existing or commercial off-the-shelf software. Although IAEA terms are different than NRC terms, the meanings are similar (e.g., "software

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		1025243 is specific to commercial-grade design and analysis computer programs (not used in important to safety systems), both documents provide guidance on activities associated with assuring quality in commercial-grade computer programs."	used in computer based systems" includes "design and analysis computer programs", "commercial off-the-shelf" is equivalent to "commercial grade", and "important to safety" is similar to "safety-related"). Thus, both the IAEA Safety Guide and EPRI 1025243 provide guidance on activities associated with assuring quality in commercial-grade design and analysis computer programs that are to be used as basic components."
5	p. 4, B. Discussion, Documents Discussed in Staff Regulatory Guidance, first sentence	The text could be interpreted to incorrectly suggest that regulatory guides only approve documents from external organizations.	Combine and replace the first two sentences with: "This regulatory guide approves the use of guidance developed by an external organization, which contains references to other codes, standards, or third party guidance documents ("secondary references")."
6	p.5, C. Staff Regulatory Guidance, 1. Staff Regulatory Guidance Position, first paragraph	The first sentence inaccurately represents EPRI-1025243 as establishing requirements. Requirements are only established by the regulations and are not established by guidance.	Revise the term "requirements" in the first sentence to "guidelines."
7	p.5, C. Staff Regulatory Guidance, 1. Staff Regulatory Guidance Position, first paragraph	The text does not clearly state the staff's regulatory position on the acceptability of the methods in EPRI-1025243, Revision 1 to comply with NRC regulatory requirements related to the dedication of commercial-grade design and analysis computer	Revise the last sentence to state: "The NRC staff considers the methods in EPRI Topical Report 1025243, <i>Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications</i> , Revision 1 to be acceptable for complying with the requirements of 10 CFR Part 21 and Appendix B to 10 CFR Part 50 for the dedication of design and

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		programs.	analysis computer programs as basic components for use in safety-related applications:"
8	p.5, C. Staff Regulatory Guidance, 1. Staff Regulatory Guidance Position, 1 <sup>st</sup> bullet	This bullet may lead to some confusion, as it uses two terms "non-process" and "integral (installed or embedded)" computer programs, which may not be generally understood by the user.	Clarify the meaning of these terms consistent with their definitions in Revision 1 of EPRI 1025243.
9	p.5, C. Staff Regulatory Guidance, 1. Staff Regulatory Guidance Position, 2 <sup>nd</sup> bullet	The use of the term "a tailored version of" is confusing and unnecessary.	Revise the last sentence to delete the term as follows: "Although the NRC's limited acceptance is not meant to preclude a user from using a <del>tailored version of</del> the guidance for other applications, this regulatory guide expresses no position on the capability or acceptability of the EPRI guidance in such applications."
10	p.5, C. Staff Regulatory Guidance, 1. Staff Regulatory Guidance Position, 3 <sup>rd</sup> bullet	Regulatory guides, and the industry guidance that may be endorsed by a regulatory guide, are guidance and do not establish requirements. Requirements are only established by NRC regulations. The first sentence inaccurately represents EPRI-1025243 as establishing requirements.	Revise the first sentence to state: "Because of their importance to safety, <u>users must meet all of the guidelines</u> (indicated by the verbs "should" and "shall") contained in Revision 1 of EPRI 1025243 <u>in order to meet the NRC's endorsement within this regulatory guide</u> <del>shall be treated the same as the requirements indicated by the verb "shall) of the standard with the following exceptions:"</del>
11	p. 8 and 9, References	The footnote for References 11, 12, and 13 is incorrect. These references currently reference footnote 4 on page 8 that discusses	Change footnote from "4" to "6" for References 11, 12, and 13.

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		"voluntary" and "voluntarily". Footnote 6 on page 8 discusses how to get copies of EPRI documents.	