

February 27, 2013

Mr. Russell J. Bell, Director  
New Plant Licensing  
Nuclear Generation Division  
Nuclear Energy Institute  
1776 I Street, NW, Suite 400  
Washington, DC 20006-3708

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION REGARDING THE REVIEW OF ELECTRIC POWER RESEARCH INSTITUTE 1025243, "PLANT ENGINEERING: GUIDELINE FOR THE ACCEPTANCE OF COMMERCIAL-GRADE DESIGN AND ANALYSIS COMPUTER PROGRAMS USED IN NUCLEAR SAFETY-RELATED APPLICATIONS," JUNE 2012

Dear Mr. Bell:

By letter dated July 18, 2012, the Nuclear Energy Institute (NEI) submitted Electric Power Research Institute (EPRI) 1025243 for staff review and approval. EPRI 1025243 describes a dedication methodology for commercial-grade design and analysis computer programs for use in meeting regulatory requirements. The letter proposes U.S. Nuclear Regulatory Commission (NRC) endorsement of the EPRI 1025243 computer program commercial-grade dedication method, similar to the method provided in EPRI NP-5652, which the NRC conditionally endorsed in Generic Letter 89-02. The NRC staff reviewed EPRI 1025243 with reference to the dedication requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21 and Appendix B to 10 CFR Part 50.

The Quality Assurance Branch has reviewed the NEI submittal and identified that additional information is needed to continue portions of the review. The staff's request for additional information is contained in the enclosure to this letter.

R. Bell

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If you have any questions or comments regarding this matter, please contact Ms. Tanya E. Hood by telephone at 301-415-1387 or by e-mail at [Tanya.Hood@nrc.gov](mailto:Tanya.Hood@nrc.gov).

Sincerely,

*/RA/*

Amy E. Cabbage, Branch Chief  
Policy Branch  
Division of Advanced Reactors and Rulemaking  
Office of New Reactors

Project No.: 689

Enclosure:  
Request for Additional Information

R. Bell

-2-

If you have any questions or comments regarding this matter, please contact Ms. Tanya E. Hood by telephone at 301-415-1387 or by e-mail at [Tanya.Hood@nrc.gov](mailto:Tanya.Hood@nrc.gov).

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## REQUEST FOR ADDITIONAL INFORMATION

1/17/2013

ELECTRIC POWER RESEARCH INSTITUTE 1025243  
DOCKET NO. PROJECT 689  
“PLANT ENGINEERING: GUIDELINE FOR THE ACCEPTANCE OF  
COMMERCIAL-GRADE DESIGN AND ANALYSIS COMPUTER PROGRAMS USED IN  
NUCLEAR SAFETY-RELATED APPLICATIONS,” JUNE 2012

1. Page i – boxed area states: “This document does NOT meet the requirements of 10 CFR Part 50 Appendix B...”

Please elaborate on the intent of this statement. It is the staff’s understanding Electric Power Research Institute (EPRI) 1025243 was developed to meet the requirements of Appendix B to 10 CFR Part 50. The NRC’s acceptance of this document would be acknowledgment that EPRI 1025243 provides an acceptable method of meeting regulatory requirements.

2. Page xi, 2<sup>nd</sup> paragraph states: “The amount and level of detail of design and *qualification* information can impact the types of dedication acceptance methods used as well as direction in which the inspection and tests are targeted.”

Please clarify the use of the word ‘qualification’ and its derivatives within the document. The term *qualification* has multiple meanings and the staff has noted industry confusion in this area. Although the document does define three variants of ‘qualification,’ another choice of words or phrase appropriate to capture the concept of ‘suitability of design’ would help alleviate potential confusion.

3. Page 1-13, section 1.6.2 states: “The suitability of design must be established prior to initiating procurement of the item.”

Please clarify the sequence of events during structure, system, or component (SSC) design and design and analysis software dedication activities associated with the SSC. While the staff agrees that dedication’s technical evaluation and acceptance activities are not substitutes for SSC design, separation of the SSC design activities from the selection of appropriate computer program associated with those design activities, and establishing the suitability of the dedicated computer program’s design as part of dedication process, would clarify the distinction.

4. Page 4-6, first boxed area states: “When necessary, determining the *suitability of a proposed replacement computer program* that is not identical to the original”. Also related to page 5-13, bulleted list.

Enclosure

Please clarify the scenarios for use of this element and the 'industry guidance' mentioned in the implementation section. The staff noted the implementation section discusses version / edition updates for computer programs, but it is unclear if the section is intended for other applications (e.g. legacy computer program replacements). Control of computer program updates and patches and tested computer program environment changes should be clearly defined. The staff has noted that dedicating entities often overlook computer program updates and environment changes after acceptance of the initial commercial computer program.

5. Please clarify the intent of the sections below. It is unclear to the staff how it is relevant to safety-related design and analysis computer programs. Historically, endorsing documents with extended scopes of use is problematic due to varying regulatory requirements.

- a. Computer programs classified less than safety-related

Page 5-9, section 5.4.1.9 states: "Computer programs used to assess the ability of SSCs to perform their safety-related functions, but that do not directly impact SSCs capability to perform safety functions should be classified as non-safety-related, augmented quality." Also related to page 5-11, Figure 5-3 'Medium' and 'Low Impact' sections.

Please clarify if this is intended as guidance beyond the basic scope of EPRI 1025243.

- b. Computer programs outside the scope of design and analysis

Page C-4, first paragraph, states: "Detailed guidance regarding the quality and calibration of measurement and test equipment..."

The staff noted that Appendix C provides examples of many types of computer programs; however, it is unclear how a measuring and test equipment (M&TE) example is relevant to design and analysis computer programs. Please clarify if this is intended as guidance beyond the basic scope of EPRI 1025243.

- c. Computer program security

Page 6-23, first paragraph states: "Others qualify as security problems and might, for example, enable a malicious user to bypass access controls in order to obtain unauthorized privileges."

The staff has identified cyber security requirements applicable to specific computer program applications (such as instrumentation & control), and that some of these requirements may be applicable to design and analysis computer programs. In an effort to avoid implying the document meets all cyber security requirements, the staff recommends clarifying the security discussion sections as applicable to general computer program access security.

6. Page A-4, bulleted list, states: "The range of supplier documentation typically includes, as applicable, the following..."

The staff understands this is a 'typical' list of documents; however, it primarily includes programmatic Quality Assurance documents and misses key technical documents related to the specific dedicated software (e.g. User's Manual which might include range of use, installation limitations, and test requirements). Please consider expansion of key technical documentation for this list.

NEI New Reactors Mailing List

(Revised 02/27/2013)

cc:

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