

## 1. Question:

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.

### Response:

The comment is a label used by EPRI’s quality assurance organization to indicate the product was not developed under the auspices of EPRI’s nuclear quality assurance program. The comment is not intended to imply that following the guidance included in the document would not result in a process that could meet the requirements of 10CFR50, Appendix B.

The label has been changed to read “The technical contents of this product were NOT prepared in accordance with the EPRI’s quality program manual that fulfills the requirements of 10CFR50 Appendix B. This product is NOT subject to the requirements of 10CFR Part 21.” The new label appears on pages i and ii of the revised document, EPRI 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.”

## 2. Question:

Page xi, 2nd 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.

### Response:

All instances where the word “qualification” occurred were reviewed. Where appropriate the word was replaced with “establish suitability for use” or other

appropriate clarification was added. These changes are reflected in the revised document, EPRI 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."

### 3. Question:

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.

### Response:

A new flow chart was added to the revised document (Figure 1-4 in the revised document) along with clarifying text to clarify the sequence of events.

As defined in 10CFR21, dedication is an acceptance process. Just as the design of a pump is complete and undergoes design review, testing, etc. prior to the purchase order being issued and order being shipped, suitability of the computer program's design must be established before the start of dedication. This typically occurs as part of the computer program selection process performed by subject matter experts.

This is a nuance, but an important one. Suitability of design is not established during the dedication process. The computer program selected for use and procurement is accepted during the dedication process based upon the design "requirements" that have already been determined.

### 4. Question:

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.

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.

**Response:**

This is intended to refer to a proposed replacement for a computer program that is no longer available. Control of computer program updates, patches, etc. is covered as part of the overall software QA program and is not the focus of this document. However, it is addressed in Section 1.2.1.2

The statements in Table 4-1 in the revised document clarify that an equivalency evaluation is performed when the vendor proposes an alternative product. In addition, a statement is added to clarify that an equivalency evaluation is not intended to address control of computer programs after they are accepted for use.

**5. Question:**

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.

**Response:**

In discussions and interactions with EPRI members and suppliers during development of the guidance, it became evident that some organizations were unclear about the scope of concern. The original intent of these organizations was to apply dedication methodology not only to design and analysis computer programs, but to any or all computer programs used at a nuclear facility. To address this concern, the Technical Advisory Committee Group determined that this document should include safety classification methodology. The safety classification methodology included can be applied to any computer program to determine if it is a basic component. For this reason, the report includes discussion on computer programs classified less than safety related and computer programs outside the scope of design and analysis.

a. Computer programs classified less than safety-related.

The discussion is intended to point out that some computer programs may not be safety-related based upon their function.

The information from NITSL on Medium and Low Impact programs is included to provide a link to the methodology being used to accept a computer program (as a specialized quality activity conducted under a QA program meeting the requirements of 10CFR50, Appendix B) by entities who determined that the computer program in question did not meet the definition of a basic component.

The following clarifying note was added to the beginning of Section 5 of the revised document:

“It is important to discuss safety classification in this document because computer programs that are classified as non-safety-related are not considered basic components and are not required to be either procured as basic components or procured as commercial grade items and dedicated.”

The following clarifying note was added to Section 5.4.1.9 in the revised document:

“Non-safety-related computer programs are not considered to be basic components and therefore do not require commercial grade dedication.”

The following clarifying note was added to Section 5.4.2 (after 4. Other) in the revised document:

“When following the NITSL methodology, it is important to recognize that software used to establish suitability of design of a safety-related SSC may not be categorized as medium impact software unless alternative methods are used to verify the results.”

The following clarifying notes were added to the bottom of Figure 5-3 in the revised document:

“Note 1: It is important to recognize that software used to establish suitability of design of a safety related SSC may not be categorized as medium impact software unless alternative methods are used to verify the results.

Note 2: The term augmented quality is used as defined in this report and is not limited to only the non-safety-related SSCs credited for regulated events described in Section 17.5V. of NUREG-0800, Standard Review Plan”

The following clarifying note was added to Note 3 following Table 5-2 in the revised document:

“It is important to recognize that software used to establish suitability of design of a safety-related SSC may not be categorized as medium impact software unless alternative methods are used to verify the results.”

b. Computer programs outside the scope of design and analysis

Individuals involved in the response believe the appendix containing examples is useful and would prefer that it not be deleted. However, the following clarification was added to the beginning of Appendix C:

“This appendix is included to point out that, although certain computer programs used to support a nuclear facility may contain certain elements of design and analysis, careful consideration may be necessary to determine if they actually should be considered as basic components that perform design and analysis functions.

The appendix also provides examples of the thought process used to determine if computer programs used for purposes other than design and analysis should be considered as basic components that perform a safety-related function or as nonsafety-related computer programs that may warrant additional controls or validation prior to acceptance for use.”

Discussion on a computer program used for calibration of M&TE was included to address questions that arose during preparation of the document regarding what was meant by “design and analysis.” It was mentioned that “calibration” might be considered as a form of analysis and computer programs used for calibration would therefore be considered “analysis” programs. The examples included are intended to help users categorize the computer programs used for M&TE and other purposes correctly.

The specific reference to National Instrument’s LabVIEW program was removed from the first paragraph in section C.4.

c. Computer program security

The technical advisory committee agrees that cyber security is a related but separate issue. The last sentence in section B.5 was removed in the revised document.

**6. Question:**

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.

**Response:**

A bullet was added to the list in Section A.3 of the revised document (now on page A-4) as follows:

- "Technical documents such as user manuals, installation instructions, and so forth."