# Response to Public Comments on Draft Regulatory Guide (DG)-1305
# "Acceptance of Commercial-Grade Design and Analysis Computer Programs for Nuclear Power Plants"
# Proposed Revision 0 of Regulatory Guide (RG) 1.231

On July 1, 2015, the NRC published a notice in the *Federal Register* (80 FR 37666) that Draft Regulatory Guide, DG-1305 (Proposed Revision 0 of RG 1.231), was available for public comment. The Public Comment period ended on August 31, 2015. The NRC received comments from the organizations listed below. The NRC has combined the comments and NRC staff responses in the following table.

Comments were received from the following:

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| C. Earls | | General Comment on DG-1305 | Various | 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. | The staff agrees with the comment. See the specifics in the remainder of comment 1. |
| | 1 | | | <u>Proposed change</u>:<br>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." | The staff agrees with the comment and the insertion is underlined. |
| | | | | 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 | The staff agrees with this comment and the insertion is underlined. |

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| | | | | regulatory requirements for acceptance and dedication of commercial-grade design and analysis computer programs used in safety-related applications 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." | The staff agrees with this comment and the insertion is underlined. |
| | | | | 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. | The staff disagrees with the comment and made no changes to the RG. As discussed in Criterion III, the applicant identifies what is covered by the quality assurance program and provides the necessary controls over activities affecting the quality of the identified items to an extent consistent with their importance to safety. |
| | | | | 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 | The staff disagrees with the comment and made no changes to the RG. The title of the RG addresses the scope of application. Also, providing specific examples may lead to further confusion. |

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| | | | | programs that are not used in safety-related applications or that were developed under a quality assurance program in accordance with 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. | Different users may apply the same computer programs for a safety-related or non safety-related application. |
| C. Earls | 2 | Section A Introduction - Applicable Rules and Regulations (second bullet) Page 1 | Criterion III fulfills the Appendix B to 10 CFR Part 50 requirement established by the definition of "dedication" in 10 CFR Part 21 for commercial-grade design and analysis computer programs. | The second sentence is confusing and potentially inaccurate as written.<br><br><u>Proposed change</u>:<br>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." | The staff agrees with the comment and the proposed change was incorporated. |
| C. Earls | 3 | General Comment on DG-1305 | Various | 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. | The staff agrees with the comment and the changes are underlined. Additional change on p.5, C1. Staff Regulatory Guidance Position (third bullet). See also comment 34. |

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| | | | | Proposed change:<br>In the following locations, replace the word “standard” with “guidance”:<br>p.3, B. Discussion, Reason for Issuance, last sentence: “…EPRI 1025243 (Ref. 13) was the first guidance to provide…”<br>p.4, B. Discussion, Background, last paragraph, first sentence: “The EPRI 1025243 guidance was specifically developed…”<br>p.4, B. Discussion, Documents Discussed in Staff Regulatory Guidance, fourth sentence: “…an acceptable approach for meeting an NRC requirement, then the secondary reference constitutes a method acceptable…” | |
| C. Earls | 4 | Section B Discussion - Harmonization with International Standards, Page 4 | Although the Safety Guide relates primarily to computer programs used in important to safety systems and EPRI 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. | Sentence is confusing and potentially inaccurate.<br><br>Proposed change:<br>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 used in computer based systems” includes “design and analysis computer | The staff agrees with the comment and the proposed change was incorporated. |

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| | | | | 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." | |
| C. Earls | 5 | Section B Discussion - Documents Discussed in Staff Regulatory Guidance Page 4 | Regulatory guides approve the use of one or more codes or standards developed by external organizations, and other third party guidance documents. | The text could be interpreted to incorrectly suggest that regulatory guides only approve documents from external organizations.<br><br><u>Proposed change</u>:<br>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")." | The staff agrees with the comment and the proposed change was incorporated.<br>Additionally, every issued RG states its purpose: "The NRC issues RGs to describe and make available to the public methods that the NRC staff considers acceptable to use in implementing specific parts of the agency's regulations… |
| C. Earls | 6 | Section C.1 Staff Regulatory Guidance Position Page 5 | The requirements included in Revision 1 of EPRI Topical Report 1025243, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in | The sentence inaccurately represents EPRI-1025243 as establishing requirements. Requirements are only established by the regulations and are not established by guidance. | The staff agrees with the comment and the proposed change was incorporated. |

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| | | | Nuclear Safety-Related Applications," addresses the acceptance of commercial-grade nuclear power plant design and analysis computer programs. | Proposed change:<br>Revise the term "requirements" in the first sentence to "guidelines." | |
| C. Earls | 7 | Section C.1<br>Staff Regulatory Guidance Position<br>Page 5 | Revision 1 of EPRI 1025243 is acceptable to the NRC staff in providing an adequate basis for dedication as defined in 10 CFR Part 21, and fulfills the QA requirement in Appendix B to 10 CFR Part 50, subject to the following conditions: | 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 programs.<br><br>Proposed change:<br>Revise the sentence to state: "The NRC staff considers the methods in EPRI Topical Report 1025243, Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications, 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 analysis computer programs as basic components for use in safety-related applications:" | The staff agrees with the proposed change was incorporated prior to "subject to the following conditions:". |

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| C. Earls | 8 | Section C.1 Staff Regulatory Guidance Position (first bullet) Page 5 | As such, the NRC staff does not accept the use of Revision 1 of EPRI 1025243 dedication methodology for integral (installed or embedded) computer programs or software tools associated with integral computer programs. | 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.<br><br>Proposed change:<br>Clarify the meaning of these terms consistent with their definitions in Revision 1 of EPRI 1025243. | The staff agrees with the comment and have revised the paragraph to align with wording provided in EPRI 1025243: "Revision 1 of EPRI 1025243 states that its scope and basic intent is to provide acceptance guidance for non-process (*that is, not installed in plant SSCs*) computer programs used in the design and analysis of plant SSCs. As such, the NRC staff does not accept the use of Revision 1 of EPRI 1025243 dedication for integral (installed or embedded) computer programs or software tools[2] associated with integral computer programs." |
| C. Earls | 9 | Section C.1 Staff Regulatory Guidance Position (second bullet) Page 5 | Although the NRC's limited acceptance is not meant to preclude a user from using a tailored version of the guidance for other applications, this regulatory guide expresses no position on the capability or acceptability of the EPRI guidance in such applications. | The use of the term "a tailored version of" is confusing and unnecessary.<br><br>Proposed change:<br>Revise the sentence to delete the term as follows: "Although the NRC's limited acceptance is not meant to preclude a user from using the guidance for other applications, this regulatory guide expresses no position on the capability or acceptability of the EPRI guidance in such applications." | The staff agrees with the comment and the proposed change was incorporated. |

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| C. Earls | 10 | Section C.1<br>Staff Regulatory Guidance Position<br>(third bullet)<br>Page 5 | Because of their importance to safety, the guidelines (indicated by the verb "should") contained in Revision 1 of EPRI 1025243 shall be treated the same as the requirements (indicated by the verb "shall") of the standard, with the following exceptions: | 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.<br><br>Proposed change:<br>Revise the sentence to state: "Because of their importance to safety, users must meet all of the guidelines (indicated by the verbs "should" and "shall") contained in Revision 1 of EPRI 1025243 in order to meet the NRC's endorsement within this regulatory guide with the following exceptions:" | The staff agrees with this comment in part. The staff revised Section B to add a statement that the regulatory position in Section C is met when all the guidance in EPRI 1025243 is met. Any deviation from the guidance is permissible; however, as stated in part, in the "Purpose of Regulatory Guides," methods and solutions that differ from those set forth in the regulatory position, Section C, will be deemed acceptable if they provide a basis for the difference. |
| C. Earls | 11 | References<br>Pages 8 and 9 | Reference 11 - EPRI TR-106439.<br>Reference 12 - EPRI 1025243, Revision 1.<br>Reference 13 - EPRI 1025243. | The footnote for References 11, 12, and 13 is incorrect. These references currently reference footnote 4 on page 8 that discusses "voluntary" and "voluntarily". Footnote 6 on page 8 discusses how to get copies of EPRI documents.<br><br>Proposed change:<br>Change footnote from "4" to "6" for References 11, 12, and 13. | The staff agrees with the comment and has removed the editorial error. |

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| R. Martin | 12 | Section A<br>Introduction - Purpose of Regulatory Guides<br>Page 3 | The NRC issues regulatory guides to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific problems or postulated accidents, and to provide guidance to applicants. | Chapter 15 of the NRC's "Standard Review Plan (SRP) for the Review of Safety Analysis Reports for Nuclear Power Plants" (NUREG-0800) and the "Standard Format and Content of Safety, Analysis Reports for Nuclear Power Plants" (Regulatory Guide 1.70) describe a subset of the transient and accident events that must be considered in the safety analyses required by 10 CFR 50.34. In support of that activity, Regulatory Guide 1.203, "Transient and Accident Analysis Methods" describes a multi-step process for developing and assessing evaluation models, and provides guidance on related subjects, including software quality assurance, documentation, and a graded approach to process.<br><br>Related safety analysis software invokes simplifications, assumptions, models and correlations subject to uncertainty, and inherent compensating errors. RG 1.203 recognizes the unique challenge placed on such software and introduces the concept of the Evaluation Model for assuring the appropriate selection, classification, quality assurance, | The staff disagrees with the comment and no changes were made to the RG. The purpose of this RG is to provide an acceptance method for commercial-grade design and analysis computer programs for safety-related applications. It does not provide guidance on the use of the computer program.<br><br>Additionally, the referenced paragraph is a generic explanation to stakeholders on why the NRC issues RGs. It is not intended to describe the scope of what is addressed in a specific RG. |

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| | | | | and use of these computer codes in this setting. Further, while SRP Section 15.0 makes specific reference to the applicability of RG 1.203, the NRC has noted on at least one other occasion (i.e., USEPR DCA RAI No. 1, ADAMS Accession #ML081490343) that it is applicable in other areas.<br><br>By explicitly mentioning accident analysis, DG-1305 (via EPRI 1025243) is confusing in that it appears to introduce an alternative acceptance pathway for related activities applicable to RG 1.203. Consequently, coincident use of these two guidance documents is error prone. It is recommended that the proposed regulatory guide clearly distinguish the scope and any interfaces between these two guidance documents. As RG 1.203 is clear about user expectation, it is preferable for DG-1305 to include a statement such as "the applicability of the EPRI 1025243 excludes the selection, classification and quality assurance of software for accident and transient analysis addressed in RG 1.203." | |
| R. Martin | 13 | Section C | General | 10 CFR 50 Appendix B Section V states, "activities affecting quality shall be prescribed by documented instructions, | The staff disagrees with the comment and no changes were made to the RG. As stated in |

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| | | Staff Regulatory Guidance<br>Page 5 | | procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished." In addition, ASME NQA-1 Subpart 2.7, Quality Assurance Requirements for Computer Software for Nuclear Facility Applications, endorsed in Section 17.5 of NUREG-0800, identifies among the attributes of the software dedication process "instructions for use (for example, the user manual) within the limits of the dedicated capabilities". Such statements imply that software is not complete until the parametric definition subject to user discretion has been appropriately vetted (i.e., verified and validated).<br><br>EPRI 1025243 provides limited treatment on this aspect of the dedication process. For example, in Table 5-1, a conceptual error is a failure mechanism "resulting when the computer program is applied outside its intended use." | Section A of the DG, the dedication process is conducted in accordance with the applicable provisions of Appendix B.<br><br>Further, the staff does not dictate the level of detail required for an applicant's instructions or procedures. This is wholly dependent on the complexity of the activity being described, the applicant's determination of user needs, user qualifications, etc. |

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| | | | | In Table 6-5, critical input parameters and valid ranges are identified as an "interface", appearing to be something outside the scope of dedication. In Section 6.5, there appears to be an expectation that user guides would be provided to customers for their review. In these examples, EPRI 1025243 fails to provide definitive expectation or instruction to this software dedication attribute, one explicitly identified in 10 CFR 50 Appendix B and NQA- 1. Notably, a software user should expect that during the dedication process such documentation may need to be prepared to prevent incomplete or improper software input.<br><br>It is recommended that DG-1305 1) acknowledge the applicability of the 10 CFR 50 Appendix B Section V to software dedication and 2) clarify that for computer codes allowing application outside of hardcoded limits, user instructions explicitly describing limits of use are expected. Such limits of use should, in part, be based on the scope of testing prepared in the development and/or dedication process. It would also be useful if DG-1305 provided explicit definition of the | |

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| | | | | expectations for and characteristics of user instructions in the software dedication process.<br><br>As reference, RG 1.203, "Transient and Accident Analysis Methods," notes in several locations (in particular, see Section 3.4) that user instructions and guidelines are essential in minimizing the risk of inappropriate use safety-related software. | |

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| P. Valdez | 14 | General Comment on DG-1305 | General | 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.<br><br>It is my recommendation that the Nuclear Regulatory Commission not endorse the proposed regulatory guidance as presently written until fundamental issues | The staff disagrees with the comment and made no changes to the RG. The EPRI guidance document was developed with input from multiple stakeholders, including the NRC. Use of the dedication process for software was determined to be valid. The EPRI document was found to be acceptable for use. However, the NRC staff encourages stakeholders to work with EPRI to improve future versions of the document if deemed appropriate. |

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| | | | | are resolved ensuring effective guidance on the commercial procurement and acceptance of design and analysis software. | |
| P. Valdez | 15 | General Comment on DG-1305 | General | Fundamental issue: 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 | The staff disagrees with the comment and made no changes to the RG. EPRI 1025243 was specifically developed for the acceptance of commercial-grade design and analysis computer programs for safety-related applications. The EPRI document was develop by a broad range of stakeholders, including the NRC staff. Therefore, the staff concluded |

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| | | | | 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 comments 18-23) | that the guidance is relevant to current industry practices.<br><br>NUREG/CR-4640 (ADAMS Accession Number ML012760046) was issued in 1987. It was a research project to recommend good engineering practices for software for the design and operation of nuclear power plants, and does not address the same topic as this RG. |
| P. Valdez | 16 | General Comment on DG-1305 | General | Fundamental issue: 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.<br>(see comments 24-26) | The staff disagrees with the comment and no changes were made to the RG. The DG assumes the software becomes associated with the design or analysis of the SSC under the definition of *Basic Component*. |
| P. Valdez | 17 | General Comment on DG-1305 | General | Fundamental issue: 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.<br>(see comments 27-33) | The staff disagrees with the comment and no changes were made. The EPRI guidance describes a process for acceptance of a commercial computer program to be used for safety-related applications. The guidance covers both those computer programs designed and produced in accordance with an Appendix B QA program or accepted via dedication. An existing SQA program may need |

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| | | | | | additional controls in place to support the dedication process. |
| P. Valdez | 18 | Section A Introduction – Related Guidance (second bullet) Page 2 | Generic Letter 91-5, "Licensee Commercial-Grade Procurement and Dedication Programs," (Ref. 6) describes industry dedication process implementation inadequacies and provides amplifying guidance for commercial-grade dedication. | Generic Letter 91-5 does not include methodologies specific to design and analysis software.<br><br>Proposed resolution:<br>Remove as it is not relevant to Design and Analysis software. | The staff disagrees with the comment and no changes were made to the RG. Although it is not specific to design and analysis software, it does apply to the implementation of the dedication process. |
| P. Valdez | 19 | Section A Introduction – Related Guidance (fifth bullet) Page 2 | Regulatory Guide 1.152, "Criteria for Use of Computers in Safety Systems of Nuclear Power Plants," (Ref. 9) describes an acceptable method for implementing the requirements of Criterion III of Appendix B to 10 CFR Part 50 with regard to commercial-grade dedication of computers for use in safety systems of nuclear power plants. | Regulatory Guide 1.152 is specific to software installed in the plant. This does not apply to design and analysis software.<br><br>Proposed resolution:<br>Remove as it is not relevant to Design and Analysis software. | The staff agrees with the comment and the staff agrees that RG 1.152 does not apply to design and analysis software. The reference to RG 1.152 was removed. |
| P. Valdez | 20 | Section A Introduction – Related Guidance (sixth bullet) Page 2 | Safety Evaluation Report, "Review of EPRI Topical Report TR-106439, 'Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety | 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 | The staff agrees with the comment and bullet 6 in Section A under 'Related Guidance,' was removed. |

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| | | | Applications' (TAC No. M94127)," (Ref. 10) states that TR-106439 (Ref. 11) contains an acceptable method for dedicating commercial-grade digital equipment for use in nuclear power plant safety applications. | design and analysis software. It is specific to digital equipment installed in the plant.<br><br><u>Proposed resolution</u>:<br>Remove as it is not relevant to Design and Analysis software. | |
| P. Valdez | 21 | Section B Discussion - Background Page 3 | In the 1990s, the nuclear industry and the NRC supported digital upgrades to operating nuclear power plants issuing guidance on the acceptance of commercial-grade computer programs that supported digital upgrades or on improving high-level quality assurance programmatic guidance relating to control of computer programs. More recently, standards organizations such as the American Society of Mechanical Engineers (ASME) and the Institute of Electrical and Electronics Engineers (IEEE) have issued improved guidance related to control and use of computer programs and worked with the NRC to ensure regulatory compliance, but this guidance was generally either | 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.<br><br><u>Proposed resolution</u>:<br>Remove the phrase between "In the 1990s" and "on improving high-level quality assurance programmatic guidance relating to control of computer programs." | The staff disagrees with the comment and no changes were made to the RG. This is strictly a historical account of the use of the dedication process for acceptance of computer programs. |

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| | | | programmatic or developed for other specific applications. | | |
| P. Valdez | 22 | EPRI 1025243<br>Page x | The key elements involved in commercial-grade dedication are the technical evaluation and acceptance processes. These processes find basis in the requirements included in 10CFR, Part 21, EPRI NP-5652, EPRI TR-102260, and EPRI TR-106439. | 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.<br><br>Proposed resolution:<br>This section of the document should not be endorsed as they do not specifically apply to design and analysis software. | The staff disagrees with the comment and no changes were made to the RG. The context of the paragraph is simply to describe key elements of the dedication process.<br><br>Additionally, the paragraph cited is in the Executive Summary; not in an implementation section of the document. There would be no effect on the implementation of the dedication process. |
| P. Valdez | 23 | EPRI 1025243<br>Section 1.6.1<br>Page 1-12 | The guidance presented in this report is consistent with previously published / endorsed EPRI technical reports that address nuclear procurement processes, which include:<br><br>• *Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants*, TR-107330<br><br>• *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)*, NP-5652 | The entire list is specific to items (hardware) or digital equipment. These references are not relevant to design and analysis software.<br><br>Proposed resolution:<br>NRC should not endorse this section of the EPRI document. | The staff disagrees with the comment and no changes were made to the RG. EPRI 1025243 is simply stating that guidance contained is consistent with other previously issued EPRI guidance documents. |

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| | | | • *Guideline on Evaluation and Acceptance of Commercial-Grade Digital Equipment for Nuclear Safety Applications*, TR-106439 and U.S. NRC Safety Evaluation Report "Review of EPRI Topical Report TR-106439, Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications," Adams Accession number 9810150223<br><br>• *Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants*, 1008256<br><br>• *Handbook for Evaluating Critical Digital Equipment and Systems*, 1011710<br><br>• *Plant Support Engineering: Information for Use in Conducting Audits of Supplier Commercial Grade Item Dedication Programs*, 1016157<br><br>• *Supplemental Guidance for the Application of EPRI Report NP-5652 on the* | | |

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| | | | *Utilization of Commercial Grade Items*, TR-102260 | | |
| P. Valdez | 24 | EPRI 1025243<br>Background<br>Page ix (last paragraph) | Although verification and validation typically involve comprehensive testing and examination of the computer program, current verification and validation documentation may not always identify specific functions of the computer program as they may relate to the safety-related functions of associated SSCs or impact design analysis activities. | First sentence discusses specific functions of the computer program as they may relate to the safety-related functions of associated SSCs...<br><br>Proposed resolution:<br>The design and analysis software would be associated with the design activity; i.e., calculation or analysis activities. | The staff disagrees with the comment and no changes were made to the RG. The discussion is clarified by stating how the computer program relates to the safety-related functions of associated SSCs or impacts design analysis activities. |
| P. Valdez | 25 | EPRI 1025243<br>Section 5.4<br>Page 5-3 (fourth paragraph) | 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. | 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.<br><br>Proposed resolution:<br>This issue should be addressed before endorsement. | The staff disagrees with the comment and no changes were made to the RG. The sentence states that the safety classification of the computer program is based on its use having an adverse effect on any associated SSC. Safety-related pipe supports or hangers could be examples of associated SSCs if the computer program was used on these components. Regardless, the core issue is the application of the computer program and its effect on safety function. Any computer program |

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| | | | | | dedication would need to be conducted for the range of computer program application that affects safety function. |
| P. Valdez | 26 | EPRI 1025243<br>Section 7.1.3<br>Page 7-4 (last paragraph) | Note that, in this example, the commercially procured computer program was successfully dedicated for one particular application. This same commercial computer program would not require dedication if it was designated only for use in non-safety-related applications. If the commercial computer program is subsequently required for use in a different safety-related application with different design input parameters and values (for example, analyzing pipe stress in the main steam system), an additional dedication applying the same rigor would be necessary to accept the program for use in the new application. | 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.<br><br><u>Proposed resolution</u>:<br>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. | The staff disagrees with the comment and no changes were made to the RG. This was an example simply illustrating one option available for dedicating the computer program for one particular application. There was no intent to limit a user to evaluating and justifying a particular computer program for multiple applications. It is up to the user to determine the scope of use of a computer program when developing the technical evaluation. |
| | 27 | EPRI 1025243<br>Background | Processes known as *verification* and *validation* are included in typical SQA programs. These processes have been widely applied in the acceptance of | 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 | The staff disagrees with the comment and no changes were made to the RG. The focus of EPRI 1025243 is on acceptance of commercial computer programs. |

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| | | Page viii (second paragraph) | commercially produced computer programs in the commercial nuclear power industry and other industries. | software requirements is the first and key step in a typical SQA program. The SQA requirements would include the critical characteristics.<br><br><u>Proposed resolution</u>:<br>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. | The acceptance is in conjunction with an applicant's existing SQA program, not in lieu of it. |
| P. Valdez | 28 | EPRI 1025243<br>Acceptance verses Design<br>Page xi (last paragraph) | In addition to acceptance of computer programs, SQA programs often include provisions for examination and evaluation of the entire software life cycle. The software life cycle includes the processes used by the manufacturer / developer to design, develop, qualify, and accept the software as well as the processes in place to address reported error and control changes to the software. Some of the activities associated with the software life cycle are associated with the design | SQA programs also include a requirements phase. This is an important phase not credited in the EPRI document.<br><br><u>Proposed resolution</u>:<br>This is a faulty assumption and should not be endorsed. | The staff disagrees with the comment and no changes were made to the RG. The paragraph states that 'some of the activities associated with the software life cycle are associated with the design and establishing suitability of the design.' This infers reference to the requirements phase of the life cycle. |

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| | | | and establishing suitability of the design of the software. In this respect, software verification and validation can extend beyond the acceptance process. The fact that the computer program is being dedicated for use should not be used as a basis to forgo activities related to selecting the product and establishing that it is suitable for use in the intended applications (for example, design reviews) required by SQA programs. | | |
| P. Valdez | 29 | EPRI 1025243<br>Section 1.2.3<br>Page 1-5 (third paragraph) | In Scenario C, the computer program is relied upon as the sole basis for making design and/or analysis decisions. | 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.<br><br>Proposed resolution:<br>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. | The staff disagrees with the comment and made no changes to the RG. The scenario provides a specific example where it is the sole basis for making design and/or analysis decisions. In this case, as stated in the diagram, pre-verification that the computer program provides the correct results for each type of calculation was conducted. |
| P. Valdez | 30 | EPRI 1025243<br>Section 1.6.7<br>Page 1-17 | Once an organization institutes procedures to comply with ASME NQA-1a-2009 Part II, Subpart 2.7, paragraph 302, non-complying computer | 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 | The staff disagrees with the comment and no changes were made to the RG. As stated, the organization has determined to comply with an updated standard for future use. Therefore, |

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| | | | programs (that is, legacy programs for which guidance in this document applies per Figure 1-5) must be brought up to the standard before they can be used. | not automatically require backfitting.<br><br>Proposed resolution:<br>The NRC should not endorse section 1.6.7 as it imposes backfitting requirements. | application of a later standard going forward in time would not constitute a back-fit. Additionally, the NRC does not approve vendor QA programs. It is the applicant that ultimately determines what standards are necessary for the vendor to meet and this is contractually imposed through procurement documents. |
| P. Valdez | 31 | EPRI 1025243<br>Section 6.4<br>Page 6-5 | When detailed design information is available, critical characteristics for the computer program can be derived from the design information, specified in the procurement documents, and subsequently verified during acceptance activities. If design information is not available, an FMEA based on the function of the computer program can be performed to derive critical characteristics. | 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.<br><br>Proposed resolution:<br>The NRC should have EPRI clarify this section before endorsing. This section should include two things: 1) the critical | The staff disagrees with the comment and no changes were made to the RG. As stated in the comment, the intent is that the critical characteristics for the computer program would be determined by its intended use. The guidance does not imply the critical characteristics of the computer program are already known. |

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| | | | | characteristics specific to what the computer program needs to do and 2) the results of the FMEA to inform the acceptance criteria. | |
| P. Valdez | 32 | EPRI 1025243<br>Section 6.8<br>Page 6-27 (fifth paragraph) | The selection of acceptance methods is dependent upon the degree to which the dedicating entity is able to participate in implementation of the computer program life cycle and the level of access that the application developer is willing to provide to the dedicating entity. In the case of commercial-grade computer programs, it may or may not be possible to implement controls over the entire software life cycle. Although Method 2 (commercial-grade survey) or Method 3 (source verification) could be used to provide assurance that effective controls are in place throughout the software life cycle, the ability to implement these methods is dependent upon when the licensee begins planned coordination with the manufacturer, as well as the manufacturer's willingness to provide access to these life-cycle activities. Therefore, acceptance of | 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. 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.<br><br>Proposed resolution:<br>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 | The staff disagrees with the comment and no changes were made to the RG. As specifically stated in the cited paragraph, EPRI 1025243 sufficiently considers verification and validation. The last sentence in the paragraph states, "Therefore, acceptance of commercially procured computer programs using the dedication process may rely heavily on special testing and inspection (including verification and validation) of the completed computer program. Verification and validation is considered part of Method 1. |

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| | | | commercially procured computer programs using the dedication process may rely heavily on special testing and inspection (including verification and validation) of the completed computer program. | programs built on IEEE or ASME NQA-1 guidance already do. | |
| P. Valdez | 33 | EPRI 1025243 Section 7.1.3 Page 7-3 | Characteristics identified include:<br>• Required functionality<br>- Completeness and correctness<br>- Specific safety functions and algorithms | 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?<br><br><u>Proposed resolution</u>:<br>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. The issue is that when the critical characteristics are vague, the tests and inspections to test those characteristics will not yield meaningful results. The NRC should not endorse the EPRI document at this time. | The staff disagrees with the comment and no changes were made to the RG. As stated in the comment, the critical characteristics were for illustrative purposes only and not an attempt to be specific. Table 6-5 of EPRI 1025243 provides more specific examples of critical characteristics. |
| P. Valdez | 34 | Section B Discussion - Background | The EPRI 1025243 standard was specifically developed to guide the technical evaluation and acceptance of | The EPRI 1025243 is a Technical Report or a Guideline document. It is not a standard. | The staff agrees with the comment. See resolution of comment 3. |

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| | | Page 4 (last paragraph) | commercial-grade *design and analysis* computer programs. | Proposed resolution:<br>Revise to identify the document correctly. | |
| P. Valdez | 35 | Section C<br>Staff Regulatory Guidance<br>Page 5 (second bullet) | Additionally, the ERPI document provides guidance for a range of safety classifications and for computer programs used for purposes other than design and analysis. | Typographical error in the 2nd sentence.<br><br>Proposed resolution:<br>Change "ERPI to "EPRI" | The staff agrees with the comment. This was an editorial error. |