



DRAFT REGULATORY GUIDE

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DRAFT REGULATORY GUIDE DG-1292 (Proposed New Regulatory Guide)

DEDICATION OF COMMERCIAL-GRADE ITEMS FOR USE IN NUCLEAR POWER PLANTS

A. INTRODUCTION

Purpose

This regulatory guide (RG) describes methods that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable in meeting regulatory requirements for dedication of commercial-grade items used in nuclear power plants.

Applicability

All individuals, partnerships, corporations, or other entities as defined in Title 10 of the *Code of Federal Regulations*, Part 21, “Reporting of Defects and Noncompliance” (10 CFR Part 21) (Ref. 1), Section 21.2, “Scope,” with considerations for the exceptions specifically provided and annotated in Section 21.2.

Applicable Rules and Regulations

- 10 CFR Part 21, “Reporting of Defects and Noncompliance,” establishes the framework for an acceptance process under the definition for “dedication” and this process is undertaken to provide reasonable assurance that a commercial-grade item to be used as a basic component will perform its intended safety function. Specifically, the definition for “dedication” requires that the dedication process be conducted in accordance with the applicable provisions of Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” to 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities” (Ref. 2).
- 10 CFR Part 50, Appendix B, Criterion III, “Design Control,” includes the provisions for quality assurance (QA) and quality control which are applicable to the acceptance and dedication process for commercial-grade design and analysis computer programs. 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 dedication programs. Criterion III design control measures require, in part, for the selection and the review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems, and

This regulatory guide is being issued in draft form to involve the public in the development of a regulatory guidance in this area. It has not received final staff review or approval and does not represent an NRC final staff positions. Public comments are being solicited on this draft guide and its associated regulatory analysis. Comments should be accompanied by appropriate supporting data. Comments may be submitted through the Federal-rulemaking Web site, <http://www.regulations.gov>, by searching for Docket ID:NRC-2016-0133. Alternatively, comments may be submitted to the Rules, Announcements, and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Comments must be submitted by the date indicated in the *Federal Register* notice.

Electronic copies of this draft regulatory guide are available through the NRC’s interactive rulemaking Web page (see above); the NRC’s public Web site under Draft Regulatory Guides in the Regulatory Guides document collection of the NRC Library at <http://www.nrc.gov/reading-rm/doc-collections/>; and the NRC’s Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>, under Accession No. ML15313A425. The regulatory analysis may be found in ADAMS under Accession No. ML15313A423.

components (SSCs), and are applicable to a commercial-grade design and analysis computer program associated with basic components.

- 10 CFR 50.34(a)(7) and 10 CFR 50.34(b)(6)(ii) refer to 10 CFR Part 50, Appendix B for establishing and implementing a QA program for the design and construction of nuclear power plants and fuel reprocessing plants licensed or approved under 10 CFR Part 50 or 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants” (Ref. 3).
- 10 CFR 52.17(a)(1)(xi) refers to 10 CFR Part 50, Appendix B for establishing and implementing a QA program for site-related activities for the future design and construction of nuclear power facility early site permits under 10 CFR 52.
- 10 CFR 52.47(a)(19) refers to 10 CFR Part 50, Appendix B for establishing and implementing a QA program for the design of nuclear power facility standard design certifications under 10 CFR Part 52.
- 10 CFR 52.79(a)(25) refers to 10 CFR Part 50, Appendix B for establishing and implementing a QA program for the design and construction of nuclear power facilities with combined licenses under 10 CFR Part 52.

Related Guidance

- Regulatory Guide 1.28, “Quality Assurance Program Criteria (Design and Construction)” (Ref. 4), describes an acceptable method for establishing and implementing a QA program for the design and construction of nuclear power plants and fuel reprocessing plants that meets the requirements of Appendix B to 10 CFR Part 50.
- Regulatory Guide 1.33, “Quality Assurance Program Requirements (Operation)” (Ref. 5), describes an acceptable method for complying with the Commission’s regulations regarding overall quality assurance program requirements for the operation phase of nuclear power plants that meet the requirements of Appendix B to 10 CFR Part 50.

Purpose of Regulatory Guides

The NRC issues RGs 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. Regulatory guides are not substitutes for regulations and compliance with them is not required. Methods and solutions that differ from those set forth in RGs will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission.

Paperwork Reduction Act

This RG contains and references information collections covered by 10 CFR Part 21, 10 CFR Part 50, and 10 CFR Part 52 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collections were approved by the Office of Management and Budget (OMB), control numbers 3150-0035, 3150-0011, and 3150-0151.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

B. DISCUSSION

Reason for Issuance

This new RG approves for use, in part, Revision 1 to the Electric Power Research Institute (EPRI) NP-5652 and TR-102260, “Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items In Nuclear Safety-Related Applications” (Ref. 6), with respect to acceptance of commercial-grade dedication of items used as basic components for nuclear power plants.

Background

Use of commercial-grade dedication for items used in nuclear power plants is common in the nuclear industry, but the acceptance processes vary for these programs. Industry guidance for acceptance of commercial-grade products was developed in the late 1980s. In the early 1990s, the NRC performed a series of procurement inspections at licensees’ facilities that identified weaknesses in licensees’ procurement and dedication programs. In the mid-1990s, the industry issued supplemental guidance in the initial version [Revision 0] of EPRI NP-5652 (Ref. 7), to do the following: 1) provide clarifications in certain areas, 2) share lessons learned, and 3) address industry and regulatory developments after the issuance of the original industry guidance.

The use of commercial-grade dedication continued to increase and a revision was made to 10 CFR Part 21 that enhanced the definitions of key terms such as dedication, commercial-grade item, and critical characteristics. The NRC and industry both recognized the challenges associated with commercial dedication and provided various types of supplemental guidance to address these challenges.

Generic Letter 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products” (Ref. 8), was issued in March 1989. This generic letter described the staffs’ perspective on good practices in procurement and dedication and provided the NRC's conditional endorsement of an industry standard (EPRI NP-5652, Revision 0) on methods of commercial-grade procurement and dedication.

Generic letter 91-05, “Licensee Commercial-Grade Procurement and Dedication Programs” (Ref. 9), was issued in April 1991. This generic letter presented the staffs’ positions regarding implementation of existing regulatory requirements, as contained in Appendix B to 10 CFR Part 50. A backfit analysis was performed and the staff concluded, that the requirements contained within GL 91-05 were a compliance backfit and prepared the generic letter in accordance with 10 CFR 50.109 (a)(4)(i).

Commission paper SECY-11-0135, “Staff Plans to Develop the Regulatory Basis for Clarifying the Requirements in Title 10 of the *Code of Federal Regulations* Part 21, Reporting of Defects and Noncompliance” (Ref. 10), was issued in September 2011. In September 2014, EPRI issued Revision 1 to EPRI NP-5652 and TR-102260. The NRC determined that this latest EPRI dedication guidance is consistent with the existing 10 CFR Part 21.

Revision 1 to EPRI NP-5652 and TR-102260 in Appendix I, “Qualification versus Dedication,” describes the difference between the process for qualification of a component and the commercial-grade dedication process. Appendix I states that attempting to use one process to accomplish the objectives of both qualification and commercial-grade dedication is inappropriate because it could result in inadequately qualified equipment or specification of unnecessary acceptance requirements. As noted by EPRI, equipment qualification is a part of the design process covered under 10 CFR Part 50, Appendix B, Criterion III, which demonstrates that an item exhibits design characteristics that allow it to function or

survive a set of environmental conditions and/or seismic spectra. The purpose of commercial-grade dedication acceptance is to provide reasonable assurance that the component supplied can perform the same safety function as the design that was qualified. Therefore, equipment qualification requirements become an important input to the commercial-grade acceptance process when the selection of critical characteristics is performed. In addition, the EPRI report in Step 5.2.2, “Is the Item Required to Comply with Codes and/or Standards?” indicates that dedication is a process used to accept an item by establishing reasonable assurance that it will perform its safety function, and is not intended for use as a basis for providing certification to a Code or standard. The EPRI report specifies that if absolute assurance of compliance with all applicable requirements of a Code or standard is required, the item should be procured as a basic component.

Revision 1 to EPRI NP-5652 and TR-102260 in Section 5.14, “Screen for Eligibility Process: Steps 5.2.1-5.2.6,” states that one option to obtain information that will help determine if an item can be dedicated is “reverse engineering” of the component. Operating experience has revealed challenges associated with the use of reverse engineering in determining significant design and performance attributes for replacement components in nuclear power plants. Revision 1 to EPRI NP-5652 and TR-102260 does not address the application of reverse engineering for replacement components as part of the commercial-grade dedication process. EPRI is preparing a separate guidance document for the use of reverse engineering to provide reasonable assurance of the capability of replacement components to perform their intended functions consistent with the design and performance of the original component.

Section C of this RG approves the use, in part, of EPRI NP-5652 and TR-102260. By approving the use, in part, of EPRI NP-5652 and TR-102260, this guidance affords stakeholders the ability to allow the use of these revised references with the exceptions and clarifications noted.

Harmonization with International Standards

The International Atomic Energy Agency (IAEA) has established a series of safety guidelines and standards constituting a high level of safety for protecting people and the environment. IAEA safety guides present international good practices and increasingly reflect best practices to help users striving to achieve high levels of safety. Pertinent to this RG, the IAEA Safety Standards, and its Safety Guide No. GS-G-3.1, “Application of the Management System for Facilities and Activities” (Ref. 11), provides guidance for activities in the procurement process for nuclear power plants. Also, IAEA Technical Document (TECDOC)-919, “Management of Procurement Activities on a Nuclear Installation” (Ref. 12), provides the fundamental concepts and methodologies to organize and manage procurement activities in support of a nuclear installation. This RG incorporates similar quality assurance guidance and is generally consistent with the basic safety principles provided in the IAEA Safety Standard and the TECDOC.

The Nuclear Energy Agency’s (NEA) Committee on Nuclear Regulatory Activities, issued Report NEA/CRNA/R (2012)7, “Regulatory Oversight of Non-Conforming, Counterfeit, Fraudulent, and Suspect Items (NCFSI)” (Ref. 13), dated February 13, 2013. Pertinent to this RG, the NEA report discusses different approaches to managing NCFSI and notes that existing controls may need to be put in place throughout the supply chain. This RG incorporates quality assurance guidance and is generally consistent with the basic safety principles provided by the NEA.

Documents Discussed in Staff Regulatory Guidance

This RG approves the use, in part, of one or more codes or standards developed by external organizations, and other third party guidance documents. These codes, standards, and third party guidance documents may contain references to other codes, standards, or third party guidance documents (“secondary references”). If a secondary reference has itself been incorporated by reference into NRC

regulations as a requirement, then licensees and applicants must comply with that standard as set forth in the regulation. If the secondary reference has been approved for use in a RG as an acceptable approach for meeting an NRC requirement, then the standard constitutes a method acceptable to the NRC staff for meeting that regulatory requirement as described in the specific RG. If the secondary reference has neither been incorporated by reference into NRC regulations nor approved for use in a RG, then the secondary reference is neither a legally-binding requirement nor a “generic” NRC approval as an acceptable approach for meeting an NRC requirement. However, licensees and applicants may consider and use the information in the secondary reference, if appropriately justified and consistent with current regulatory practice, consistent with applicable NRC requirements.

C. STAFF REGULATORY GUIDANCE

Title 10 of the Code of Federal Regulations, Part 21, “Reporting of Defects and Noncompliance,” states in part that, “In all cases, the dedication process must be conducted in accordance with 10 CFR Part 50, Appendix B.” In support of this requirement, Appendix B to 10 CFR Part 50 provides evaluation and acceptance requirements that are applicable to dedication of commercial-grade items for use in nuclear power plants. The below guidance accepts for use with exception or clarification Revision 1 to EPRI NP-5652 and TR-102260, “Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications.”

Staff Regulatory Guidance Position

Revision 1 to EPRI NP-5652 and TR-102260, “Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications,” addresses the acceptance of commercial-grade dedication of parts for use in nuclear power plants. Revision 1 of EPRI NP-5652 and TR-102260 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 exceptions or clarifications:

1. Revision 1 of EPRI NP-5652 and TR-102260, in Section I.3 refers to two EPRI guidance documents, NP-7874 “Seismic Technical Evaluation of Replacement Items for Nuclear Power Plants (STERI)” (Ref. 14), and TR 105849, “Plant Support Engineering: Generic Seismic Technical Evaluations of Replacement Items for Nuclear Power Plants,” Revision 1 (Ref. 15). The NRC does not find these two EPRI documents to be acceptable for use, and in general does not find the use of generic testing data bases acceptable as a means for maintaining or providing seismic qualification of seismically sensitive replacement components. The results of previously performed and properly documented and controlled seismic testing may be applied where an equivalency evaluation has been performed to ensure that no changes have been made to the component in question since the original testing was completed. Refer to Section 6.6, Appendix B, and Appendix I for guidance on documenting an adequate technical justification.
2. Revision 1 of EPRI NP-5652 and TR-102260, Section 14.1 on digital equipment and computer programs integral to plant SSCs, lists six EPRI guidance documents for accepting digital devices. Only TR-106439 “Guideline on Evaluation and Acceptance of Commercial-Grade Digital Equipment for Nuclear Safety Applications” and TR-107330 “Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants,” have been reviewed and endorsed by the NRC in letters dated July 17, 1997 (Ref. 16) and July 30, 1998 (Ref. 17), respectively, as an acceptable approach for meeting an NRC requirement. The remaining four guidance documents, EPRI 1025283, “Commercial-Grade Digital Equipment for High-Integrity Applications: Oversight and Review of Evaluation and Acceptance Activities” (Ref. 18); EPRI TR-107339, “Evaluating Commercial Digital Equipment for High-Integrity Applications: A Supplement to EPRI Report TR-106439” (Ref. 19); EPRI 1011710, “Handbook for Evaluating Critical Digital Equipment and Systems” (Ref. 20); and EPRI TR-103291 “Handbook for Verification and Validation of Digital Systems” (Ref. 21), have not been approved by the NRC as an acceptable approach for meeting an NRC requirement

D. IMPLEMENTATION

The purpose of this section is to provide information on how nuclear licensees and applicants¹ may use this guide and information regarding the NRC's plans for using this regulatory guide. In addition, it describes how the NRC staff complies with 10 CFR Part 50.109, "Backfitting," and any applicable finality provisions in 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

Use by Nuclear Licensees and Applicants

Nuclear licensees and applicants may voluntarily² use the guidance in this document to demonstrate compliance with the underlying NRC regulations. Methods or solutions that differ from those described in this regulatory guide may be deemed acceptable if they provide sufficient basis and information for the NRC staff to verify that the proposed alternative demonstrates compliance with the appropriate NRC regulations. Current licensees may continue to use guidance the NRC found acceptable for complying with the identified regulations as long as their current licensing basis remains unchanged.

Licensees may use the information in this regulatory guide for actions that do not require NRC review and approval such as changes to a facility design under 10 CFR Part 50.59, "Changes, Tests and Experiments." Licensees may use the information in this regulatory guide or applicable parts to resolve regulatory or inspection issues.

Use by NRC Staff

The NRC staff does not intend or approve any imposition or backfitting of the guidance in this regulatory guide. The NRC staff does not expect any existing licensee to use or commit to using the guidance in this regulatory guide, unless the licensee makes a change to its licensing basis. The NRC staff does not expect or plan to request licensees to voluntarily adopt this regulatory guide to resolve a generic regulatory issue. The NRC staff does not expect or plan to initiate NRC regulatory action that would require the use of this regulatory guide. Examples of such unplanned NRC regulatory actions include issuance of an order requiring the use of the regulatory guide, requests for information under 10 CFR Part 50.54(f) as to whether a licensee intends to commit to use of this regulatory guide, generic communication, or issuance of a rule requiring the use of this regulatory guide without further backfit consideration.

During regulatory discussions on plant-specific operational issues, the staff may discuss with licensees various actions consistent with staff positions in this regulatory guide, as one acceptable means of meeting the underlying NRC regulatory requirement. Such discussions would not ordinarily be considered backfitting even if prior versions of this regulatory guide were part of the licensing basis of the facility. However, unless this regulatory guide is part of the licensing basis for a facility, the staff may not represent to the licensee that the licensee's failure to comply with the positions in this regulatory guide constitutes a violation.

¹ In this section, "licensees" refers to licensees of nuclear power plants under 10 CFR Parts 50 and 52; and the term "applicants" refers to applicants for licenses and permits for (or relating to) nuclear power plants under 10 CFR Parts 50 and 52, and applicants for standard design approvals and standard design certifications under 10 CFR Part 52.

² In this section, "voluntary" and "voluntarily" mean that the nuclear licensee or applicant is seeking the action of its own accord, without the force of a legally binding requirement or an NRC representation of further licensing or enforcement action.

If an existing licensee voluntarily seeks a license amendment or change and (1) the NRC staff's consideration of the request involves a regulatory issue directly relevant to this new or revised regulatory guide and (2) the specific subject matter of this regulatory guide is an essential consideration in the staff's determination of the acceptability of the licensee's request, then the staff may request that the licensee either follow the guidance in this regulatory guide or provide an equivalent alternative process that demonstrates compliance with the underlying NRC regulatory requirements. This is not considered backfitting as defined in 10 CFR Part 50.109(a)(1) or a violation of any of the issue finality provisions in 10 CFR Part 52.

If a licensee believes that the NRC is using this regulatory guide, or requesting or requiring the licensee to implement the methods or processes in this regulatory guide, in a manner inconsistent with the discussion in this Implementation section, then the licensee may file a backfit appeal with the NRC in accordance with NRC Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection" (Ref. 22) and the guidance in NUREG-1409, "Backfitting Guidelines" (Ref. 23).

REFERENCES³

1. *U.S. Code of Federal Regulations*, Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, “Reporting of Defects and Noncompliance.”
2. 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities.”
3. 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.”
4. Nuclear Regulatory Commission (NRC), Regulatory Guide (RG) 1.28, “Quality Assurance Program Criteria (Design and Construction),” Washington, DC.
5. NRC, Regulatory Guide 1.33, “Quality Assurance Program Requirements (Operation),” Washington, DC.
6. Electric Power Research Institute (EPRI), NP-5652 and TR-102260, Revision 1, “Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications,” September 2014.
7. EPRI, NP-5652, “Guideline for the Utilization of Commercial Grade Items in Nuclear Safety-Related Applications (NCIG-07),” issued June 1988. [Revision 0 or the initial version]
8. NRC, Generic Letter (GL) 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products,” Washington, DC.
9. NRC, Generic Letter 91-05, “Licensee Commercial-Grade Procurement and Dedication Programs,” Washington, DC.
10. NRC, SECY-11-0135, “Staff Plans to develop the Regulatory Basis for Clarifying the Requirements in Title 10 of the Code of Federal Regulations Part 21, reporting of Defects and Noncompliance”
11. International Atomic Energy Agency (IAEA), Safety Guide No. GS-G-3.1, “Application of the Management System for Facilities and Activities.”
12. IAEA, TECDOC-919, “Management of Procurement Activities on a Nuclear Installation.”
13. Nuclear Energy Agency, Report (2012)7, “Regulatory Oversight of Non-Conforming, Counterfeit, Fraudulent, and Suspect Items.”
14. EPRI (NP-7874), “Seismic Technical Evaluation of Replacement Items for Nuclear Power Plants.”

³ Publicly available NRC published documents are available electronically through the NRC Library on the NRC’s public Web site at: <http://www.nrc.gov/reading-rm/doc-collections/>. The documents can also be viewed on-line or printed for a fee in the NRC’s Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD; the mailing address is USNRC PDR, Washington, DC 20555; telephone 301-415-4737 or 800-397-4209; fax 301- 415-3548; and e-mail pdr.resource@nrc.gov

15. EPRI, TR 105849, "Plant Support Engineering: Generic Seismic Technical Evaluations of replacement Items for Nuclear Power Plants," Revision 1.
16. NRC, Review of EPRI Topical Report TR-106439, "Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications" (TAC No. M94127), (ADAMS Accession Number ML12205A284) dated July 17, 1997
17. NRC, Safety Evaluation by Office of Nuclear Reactor Regulation Electric Power Research Institute (EPRI) Topical Report, TR-107330, Final Report, "Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants, (ADAMS Accession Number ML12205A265) dated July 30, 1998
18. EPRI 1025283, "Commercial-Grade Digital Equipment for High-Integrity Applications: Oversight and Review of Evaluation and Acceptance Activities"
19. EPRI TR 107339, "Evaluating Commercial Digital Equipment for High-Integrity Applications: A Supplement to EPRI Report TR-106439"
20. EPRI 1011710, "Handbook for Evaluating Critical Digital Equipment and Systems"
21. EPRI TR-103291 "Handbook for Verification and Validation of Digital Systems"
22. NRC, Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection," NRC, Washington, DC.
23. NRC, NUREG 1409, "Backfitting Guidelines," U.S. Nuclear Regulatory Commission, Washington, DC.