



DRAFT REGULATORY GUIDE

Technical Lead
G. Lipscomb

DRAFT REGULATORY GUIDE DG-1305

(Proposed New Regulatory Guide)

ACCEPTANCE OF COMMERCIAL-GRADE DESIGN AND ANALYSIS COMPUTER PROGRAMS FOR NUCLEAR POWER PLANTS

A. INTRODUCTION

Purpose

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

Applicable Rules and Regulations

- Title 10 of the Code of Federal Regulations, Part 21, "Reporting of Defects and Noncompliance," (10 CFR Part 21) (Ref. 1) 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 design and analysis computer 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,

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received final staff review or approval and does not represent an official NRC final staff position. 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 **NRC-2015-0153**. 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. ML14119A286. The regulatory analysis may be found in ADAMS under Accession No. ML14119A282.

and 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 Appendix B to 10 CFR Part 50 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 Appendix B to 10 CFR Part 50 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 Part 52.
- 10 CFR 52.47(a)(19) refers to Appendix B to 10 CFR Part 50 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 Appendix B to 10 CFR Part 50 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

- Generic Letter 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products,” (Ref. 4) provides guidance on the commercial-grade dedication process and conditionally approves Electric Power Research Institute (EPRI) NP-5652 “Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07).” (Ref. 5)
- 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.
- Regulatory Guide 1.28, “Quality Assurance Program Criteria (Design and Construction),” (Ref. 7) 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. 8) describes an acceptable method for complying with the Commissions’ 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.
- 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.
- Safety Evaluation Report, “Review of EPRI Topical Report TR-106439, ‘Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety 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.

Purpose of Regulatory Guides

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. Regulatory guides are not substitutes for regulations and compliance with them is not required. Methods and solutions that differ from those set forth in regulatory guides 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 regulatory guide contains information collection requirements covered by 10 CFR Part 21, 10 CFR Part 50, and 10 CFR Part 52 that the Office of Management and Budget (OMB) approved under OMB control number 3150-0035, 3150-0011, and 3150-0151, respectively. The NRC may neither conduct nor sponsor, and a person is not required to respond to, an information collection request or requirement unless the requesting document displays a currently valid OMB control number.

B. DISCUSSION

Reason for Issuance

This new regulatory guide is being issued to approve Revision 1 of EPRI Technical Report 1025243, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications," (Ref. 12) with respect to acceptance of commercial-grade design and analysis computer programs associated with basic components for nuclear power plants. The initial version of EPRI 1025243 (Ref. 13) was the first standard to provide a detailed acceptance methodology specific to commercial-grade design and analysis computer programs for nuclear power plants.

Background

Use of commercial-grade design and analysis computer programs is common in the nuclear industry, but acceptance processes for these programs vary. Current industry guidance for acceptance of commercial-grade products was developed in the late 1980s, before the common use of complex computer programs, and focused on components. Although still applicable to computer programs from a process perspective, the guidance did not specifically consider the unique failure modes and characteristics of computer programs, nor the evaluation and testing challenges of off-the-shelf commercial computer programs.

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 programmatic or developed for other specific applications.

The EPRI 1025243 standard was specifically developed to guide the technical evaluation and acceptance of commercial-grade *design and analysis* computer programs¹. It incorporates knowledge of other existing industry standards and operational experience in the formulation of QA guidance supporting both operating nuclear plant operations and upgrades, and new nuclear plant design and construction.

Harmonization with International Standards

The International Atomic Energy Agency (IAEA) has established a series of safety guides 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 regulatory guide, the IAEA Safety Standards, and its Safety Guide No. NS-G-1.1, “Software for Computer Based Systems Important to Safety in Nuclear Power Plants,” (Ref. 14), provide computer program guidance for systems that are important to safety in nuclear power plants. 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. This regulatory guide incorporates similar quality assurance guidance and is consistent with the basic safety principles provided in the IAEA Safety Standard.

Documents Discussed in Staff Regulatory Guidance

Regulatory guides approve the use 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 regulatory guide 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 regulatory guide. If the secondary reference has neither been incorporated by reference into NRC regulations nor approved for use in a regulatory guide, 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.

¹ This RG does not apply to acceptance of commercial-grade computer programs at nuclear power plants which are not design and analysis (e.g. programs which perform instrumentation and control functions).

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 commercial grade design and analysis computer programs for nuclear power plants. The below guidance accepts with clarification 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.

1. Staff Regulatory Guidance Position

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 Nuclear Safety-Related Applications,” addresses the acceptance of commercial-grade nuclear power plant design and analysis computer programs. 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:

- Revision 1 of EPRI 1025243 states that its scope and basic intent is to provide acceptance guidance for non-process 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 methodology for integral (installed or embedded) computer programs or software tools² associated with integral computer programs.
- Revision 1 of EPRI 1025243 states that portions of the guidance can be used for any commercially procured computer program. Additionally, the EPRI document provides guidance for a range of safety classifications and for computer programs used for purposes other than design and analysis. The NRC staff’s approval of the EPRI document is limited to design and analysis applications. 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.
- 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:
 - Acknowledgements and Appendices
 - Section 2
 - Activities associated with computer programs used for applications classified as augmented quality or non-safety-related

² Software tools are used in the design, development, testing, review, analysis, or maintenance of integral computer programs installed in SSCs. Examples of software tools include compilers, assemblers, linkers, comparators, cross-reference generators, decompilers, editors, flow charters, monitors, test case generators, integrated development environments, and timing analyzers. Examples of integral computer programs include programmable logic devices, such as Complex Programmable Logic Devices (CPLDs) and Field Programmable Gate Arrays (FPGAs).

D. IMPLEMENTATION

The purpose of this section is to provide information on how nuclear licensees and applicants³ 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 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 voluntarily⁴ 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 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 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 are 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.

³ 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.

⁴ 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 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 either 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 the guidance in NUREG-1409, "Backfitting Guidelines" (Ref. 15) and NRC Management Directive 8.4, "Management of Facility-specific Backfitting and Information Collection" (Ref. 16).

REFERENCES⁵

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. *U.S. Code of Federal Regulations*, 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities.”
3. *U.S. Code of Federal Regulations*, 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.”
4. Generic Letter 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products,” U.S. Nuclear Regulatory Commission, Washington, DC. Agencywide Documents Access and Management System (ADAMS) Accession No. ML031140060.
5. Electric Power Research Institute (EPRI) NP-5652, “Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07),” issued June 1988.⁶
6. Generic Letter 91-5, “Licensee Commercial-Grade Procurement and Dedication Programs,” U.S. Nuclear Regulatory Commission, Washington, DC. ADAMS Accession No. ML031140508.
7. Regulatory Guide 1.28, “Quality Assurance Program Criteria (Design and Construction),” U.S. Nuclear Regulatory Commission, Washington, DC.
8. Regulatory Guide 1.33, “Quality Assurance Program Requirements (Operation),” U.S. Nuclear Regulatory Commission, Washington, DC.
9. Regulatory Guide 1.152, “Criteria for Use of Computers in Safety Systems of Nuclear Power Plants,” U.S. Nuclear Regulatory Commission, Washington, DC.
10. Safety Evaluation Report, “Review of EPRI Topical Report TR-106439, ‘Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications’ (TAC No. M94127),” dated July 17, 1997, U.S. Nuclear Regulatory Commission, Washington, DC. ADAMS Accession No. ML092190664.
11. EPRI TR-106439, “Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications,” issued October 1996.⁴

⁵ 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

⁶ Copies of EPRI documents may be obtained from EPRI, 3420 Hillview Avenue, Palo Alto, CA 94304-1338; telephone 800-313-3774. Documents may be free of charge. Additional information is available on the EPRI Web site at <http://www.epri.com/>.

12. EPRI 1025243, “Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications,” Revision 1, issued December 2013.⁴
13. EPRI 1025243, “Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications,” issued June 2012.⁴
14. International Atomic Energy Agency Safety Standards Series, Safety Guide No. NS-G-1.1, “Software for Computer Based Systems Important to Safety in Nuclear Power Plants,” issued September 2000.⁷
15. NUREG 1409, “Backfitting Guidelines,” U.S. Nuclear Regulatory Commission, Washington, DC.
16. Management Directive 8.4, “Management of Facility-Specific Backfitting and information Collection,” U.S. Nuclear Regulatory Commission, Washington, DC.

⁷ Copies of International Atomic Energy Agency (IAEA) standards may be obtained from IAEA, Wagramerstrasse 5, P.O. Box 100, A-1400 Vienna, Austria; Telephone: +43 1 2600 22529 (or 22530). Documents may be free of charge. Additional information is available on the IAEA Web site at <http://www.iaea.org/Publications/index.html>.