

# REGULATORY ANALYSIS

## DRAFT REGULATORY GUIDE DG-1305

### ACCEPTANCE OF COMMERCIAL-GRADE DESIGN AND ANALYSIS COMPUTER PROGRAMS USED IN SAFETY-RELATED APPLICATIONS FOR NUCLEAR POWER PLANTS

(Proposed Revision 0 of Regulatory Guide 1.231)

#### 1. Statement of the Problem

The Nuclear Regulatory Commission (NRC) is considering issuing a new guide to provide licensees and applicants with agency-approved guidance for complying with the requirements of Title 10 of the *Code of Federal Regulations*, Part 21, “Reporting of Defects and Noncompliance” (10 CFR Part 21), and Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” to 10 CFR Part 50, “Licensing of Production and Utilization Facilities,” Criterion III, “Design Control,” for acceptance methods (“dedication”) for commercial-grade products associated with basic components.

Title 10 CFR Part 21 defines *Dedication* as an acceptance process undertaken to provide reasonable assurance that a commercial grade-item to be used as a basic component will perform its intended safety function. The 10 CFR Part 21 definition of *Basic Component* states, “In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware...” Design and analysis computer programs are associated with component hardware and could have failure mechanisms such that the safety function of safety-related structures, systems, and components (SSCs) is adversely affected. Appendix B to 10 CFR Part 50, in part, requires the establishment of a quality assurance program with design control measures, which include the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the SSCs.

Use of commercial-grade design and analysis computer programs is common in the nuclear power plant industry, but acceptance processes for these programs vary. Current industry dedication guidance was developed in the late 1980’s, 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.

#### 2. Objective

The objective of this regulatory action is to issue NRC guidance to provide licensees and applicants with acceptance methods that the staff of the NRC considers acceptable in meeting regulatory requirements in 10 CFR Part 21 and Appendix B to 10 CFR Part 50 for the acceptance of commercial-grade design and analysis computer programs used in safety-related applications for nuclear power plants. This RG also describes one acceptable method to demonstrate compliance with the selection and the review for suitability requirement of Criterion III, “Design Control,” of Appendix B to 10 CFR Part 50 for commercial-grade design and analysis computer programs associated with basic components. This proposed new RG describes dedication methods, including technical evaluation and acceptance, to provide reasonable assurance that commercial computer programs for design and analysis meet regulatory requirements and endorses the use of 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.”

The proposed acceptance methodology specifically provides guidance for non-process (that is, not installed in plant SSCs) computer programs used in the design and analysis of plant safety-related structures, systems, and components (SSCs). As such, the proposed acceptance methodology would not be acceptable for process (installed or embedded) computer programs or software tools<sup>1</sup> associated with process computer programs.

### **3. Alternative Approaches**

The NRC staff considered the following alternative approaches:

1. Do not issue a new regulatory guide
2. Issue a new regulatory guide

#### Alternative 1: Do Not Issue a New Regulatory Guide

Under this alternative, the NRC would not issue specific guidance for acceptance of commercial-grade design and analysis computer programs associated with basic components. If NRC does not take action, there would not be any changes in costs or benefit to the public, licensees or NRC. However, the “no-action” alternative would not address significant changes in the use of computer programs in the nuclear industry. Most computer programs for design and analysis are commercially developed and their complexity has made verification of calculations by alternative methods challenging.

#### Alternative 2: Issue a New Regulatory Guide

Under this alternative, the NRC would issue specific guidance for acceptance of commercial-grade design and analysis computer programs associated with basic components. This alternative would provide one acceptable method to accept commercial-grade design and analysis computer programs associated with SSCs. The acceptance methodology provides additional assurance that the design and analysis computer programs do not exhibit failure mechanisms that adversely affect the safety function of associated SSCs.

The impact to the NRC would be the costs associated with preparing and issuing the regulatory guide revision. The impact to the public would be the voluntary costs associated with reviewing and providing comments to NRC during the public comment period. The value to NRC staff and its applicants would be the benefits associated with enhanced efficiency and effectiveness in using a common guidance document as the technical basis for license applications and other interactions between the NRC and its regulated entities.

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<sup>1</sup> Software tools are used in the design, development, testing, review, analysis, or maintenance of process 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 process computer programs include programmable logic devices, such as Complex Programmable Logic Devices (CPLDs) and Field Programmable Gate Arrays (FPGAs).

## **Conclusion**

Based on this regulatory analysis, the NRC staff concludes that issuance of a new regulatory guide is warranted. The action will enhance use of existing NRC approved methods and industry standards currently accepted by the NRC, will provide detailed guidance for licensees and applicants, and could provide a cost savings realized during the review of licensee submittals where the licensee has adopted the guidance.