

# REGULATORY ANALYSIS

## DRAFT REGULATORY GUIDE DG-1305

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

(Proposed New Regulatory Guide)

#### 1. Statement of the Problem

The NRC has not published a regulatory 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. This new regulatory guide describes dedication methods, including technical evaluation and acceptance, to provide reasonable assurance that commercial computer programs for design and analysis meet regulatory requirements and approves 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.”

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, which, 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 U.S. Nuclear Regulatory Commission (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 for nuclear power plants. This regulatory guide 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.

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

### **Conclusion**

Benefits of issuing this new guidance include clarifying expectations for acceptance of commercial-grade computer programs, more effect oversight in NRC inspections and industry audits, and enhanced SSC quality. Detractors include the costs of considering and potentially implementing the methodology, which is already developed and available free of cost.

---

<sup>1</sup> 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 charts, 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).

As a result, the NRC staff concludes that issuing specific guidance for the acceptance of design and analysis computer programs is warranted. The action will enhance use of existing NRC approved methods and industry standards currently accepted by the NRC and will provide detailed guidance for licensees and applicants.