

# REGULATORY ANALYSIS

## DRAFT REGULATORY GUIDE DG-1292 DEDICATION OF COMMERCIAL GRADE ITEMS (Proposed New Regulatory Guide)

### 1. Statement of the Problem

The U.S. Nuclear Regulatory Commission (NRC) has not published a regulatory guide to provide licensees and applicants with agency-approved guidance for complying with the requirements for acceptance methods (“dedication”) for commercial-grade products. The increased need for commercial grade dedication coupled with regulatory uncertainty associated with the lack of clear NRC guidance, results in a lack of assurance that commercial grade dedication of parts and services used in nuclear power plants do not adversely affect the safety function of associated structure, systems, and components (SSCs).

In Title 10 of the Code of Federal Regulations, Part 21 “Reporting of Defects and Noncompliance” (10 CFR Part 21), the NRC 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.” 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” 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.

The industry use of the commercial grade dedication process has significantly increased over time as the number of suppliers with nuclear quality assurance programs has decreased. However, current industry dedication guidance was developed in the late 1980s and the NRC has only previously endorsed Electric Power Research Institute (EPRI) dedication guidance in Generic Letter 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products,” and Generic Letter 91-05, “Licensee Commercial-Grade Procurement and Dedication Programs.” Hence, there is a need for the NRC to review and endorse the latest EPRI guidance for commercial grade dedication. That EPRI guidance is contained in Revision 1 of EPRI NP-5652 and TR-102260, “Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications.”

### 2. Objective

The objective of this regulatory action is to issue NRC guidance to provide licensees and applicants with methods that the staff considers acceptable in meeting regulatory requirements in 10 CFR Part 21, 10 CFR 50.55(e), “Conditions of Construction Permits, Early Site Permits, Combined Licenses, and Manufacturing Licenses”, and Appendix B to 10 CFR Part 50 for commercial-grade dedication products associated with basic components. 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 basic components used in nuclear power plants. This new regulatory guide describes

dedication methods, including technical evaluation and acceptance, to provide reasonable assurance that commercial commercial-grade items used in safety related applications meet regulatory requirements.

### **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 dedication of basic components to be used in nuclear power plants. This is considered the “no-action” alternative. If NRC did not take action, there would not be any changes in costs or benefit to the public, licensees or the NRC.

However, the “NRC and industry would not have the regulatory certainty associated with clear NRC guidance, which in this case means endorsement of the latest EPRI guidance for commercial grade dedication contained in Revision 1 of EPRI NP-5652 and TR-102260, “Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications.”

Therefore, the increase in the use of commercial grade dedication would continue to be a challenge for NRC staff, licensees and applicants without using the newer industry guidance.

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

Under this alternative, the NRC would issue specific guidance for dedication methods, including technical evaluation and acceptance, as well as provide reasonable assurance that commercial-grade items used in safety-related applications meet regulatory requirements. This alternative would provide additional assurance that commercial grade dedication of parts and services used in nuclear power plants would not 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. The impact to the public would be the voluntary costs associated with reviewing and providing comments to the 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.

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

## **Conclusion**

The NRC staff concludes that issuing enhanced guidance for commercial grade dedication 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.