

## REGULATORY ANALYSIS

### DRAFT REGULATORY GUIDE DG-1291 EVALUATING DEVIATIONS AND REPORTING DEFECTS AND NONCOMPLIANCE UNDER 10 CFR PART 21 (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 formal guidance for an acceptable method of evaluating and reporting defects under Title 10 of the *Code of Federal Regulations* Part 21, “Reporting of Defects and Noncompliance” (Part 21). The regulations in Part 21 established the need for procedures to evaluate and report in order to implement the requirements of Section 206, “Noncompliance,” of the Energy Reorganization Act of 1974, which requires that the NRC receive immediate notification that a facility, activity, or basic component (1) fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable NRC rule, regulation, order, or license of the Commission relating to substantial safety hazards or (2) contains a defect, which could create a “substantial safety hazard,” as defined by NRC regulations.

The applicability of Part 21 is broader than most NRC regulations. The requirements in Part 21 impose obligations on certain officers of NRC licensees and on certain officers of nonlicensees that construct facilities for, or supply components and services to (i.e., dedicating entities, vendors or suppliers), licensed facilities or activities. Consequently, developing programs that implement the requirements of the regulation pose different challenges for the licensees and vendors.

Since it was codified in 1977, Part 21 has presented compliance challenges to licensees and vendors. Furthermore, attempts to provide guidance for evaluating and reporting under Part 21 for power reactor licensees and vendors (e.g., presentations and questions and answers issued in conjunction with vendor workshops, generic communications) have been unable to reduce the incidence of NRC inspection findings associated with inadequate implementation of Part 21.

The Commission indicated in Staff Requirements Memorandum (SRM) SECY-16-0009, “Recommendations Resulting from the Integrated Prioritization and Re-Baselining of Agency Activities,” that the Part 21 rulemaking activity could be discontinued and concluded that there is not a basis for revising the rule itself; therefore, any necessary changes can be achieved through clarification of the regulatory guidance for the rule. Revising the RG would consolidate regulatory guidance; enhance regulatory stability and predictability for the entities to which Part 21 applies; and provide the proper regulatory framework that is needed for the commercial-grade dedication process.

#### 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 the regulatory requirements in 10 CFR Part 21.

### **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.

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

Under this alternative, the NRC would not issue specific guidance for evaluating and reporting under Part 21. This is considered the “no-action” alternative. If the NRC were to not take action, there would not be any changes in costs or benefit to the public, licensees, or the NRC. The NRC staff would rely on existing regulations and guidance documents (i.e., NUREG-0302). Taking no action would likely result in continued lack of clarity on implementing Part 21. Taking no action would also be nonresponsive to the recommendations listed in the Office of the Inspector General (OIG) audit reports OIG-10-A-20 and OIG-11-A-08. The many repetitive problems with licensees and vendors implementing Part 21 that were identified during inspections and stakeholder interactions are significant enough to warrant action. Therefore, the “no-action” alternative is not a desirable option.

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

Under this alternative, the NRC would provide specific guidance for evaluating and reporting under Part 21 by endorsing the Nuclear Energy Institute’s guidance in NEI 14-09, “Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance,” Revision 1, dated February 2, 2016. This alternative would provide clear expectations to Part 21 stakeholders in the areas of procurement documents; definitions of delivery, defect, and point of discovery; evaluating and reporting responsibilities; deferral of evaluation; use of other reporting regulations to satisfy Part 21; communications between licensees and suppliers; posting requirements; training; and others. This guidance would help NRC staff during future inspections. Also, this alternative will respond to the recommendations listed in OIG audit reports OIG-10-A-20 and OIG-11-A-08.

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, its licensees, applicants, vendors and dedicating entities would be the benefits associated with enhanced efficiency and effectiveness in using a common guidance document as the technical basis for evaluating and reporting defects under 10 CFR Part 21.

### **4. Conclusion**

The NRC staff concludes that issuing enhanced guidance for evaluating and reporting under Part 21 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.