REGULATORY ANALYSIS

DRAFT REGULATORY GUIDE DG-1416
EVALUATING DEVIATIONS AND REPORTING DEFECTS AND NONCOMPLIANCE UNDER 10 CFR PART 21

(Proposed Revision 1 of Regulatory Guide 1.234)

1. Introduction

This document presents an analysis of the U.S. Nuclear Regulatory Commission's (NRC's) determination of whether NRC should expend resources to revise Regulatory Guide (RG) 1.234, "Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21." It considers the potential benefits and costs to NRC staff and stakeholders. It does not consider the cost of implementation by existing licensees because that is covered by the Regulatory Analysis done for the rule(s) upon which the guide is based. The analysis provides the public with an insight in how the NRC arrives at a decision.

2. Statement of the Problem

The NRC published Revision 0 of RG 1.234 in April of 2018 to provide guidance on evaluating and reporting defects under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Evaluation and Reporting of Defects," and 10 CFR 50.55(e). This RG endorses Nuclear Energy Institute (NEI) 14-09, "Guidelines for Implementations of 10 CFR Part 21 Reporting of Defects and Noncompliance," Revision 1, with clarifications. Since the issuance of Revision 0 of RG 1.234, the NRC has adopted a formal definition of counterfeit, fraudulent, and suspect items (CFSI). In addition, while NEI 14-09, specifies that counterfeit and fraudulent items are considered as a deviation, the NRC staff determined that this statement should be included directly and incorporated into the RG for clarity.

3. Objective

The objective of this regulatory action is to assess the need to update NRC guidance to applicants, licensees, dedicating entities, and their suppliers associated with constructing, owning, operating, or supplying of nuclear power plants subject to 10 CFR Part 21 and 10 CFR 50.55(e) to provide a definition for CFSI and specify that counterfeit and fraudulent items are considered as a deviation.

4. Identification and Analysis of Alternative Approaches

The NRC staff considered the following alternative approaches:

1. Do not revise Regulatory Guide 1.234
2. Withdraw Regulatory Guide 1.234
3. Revise Regulatory Guide 1.234

<u>Alternative 1: Do Not Revise Regulatory Guide 1.234</u>

Under this alternative, the NRC would not revise or issue additional guidance, and the current guidance would be retained. If NRC does not take action, there would not be any changes in costs or benefit to the public, licensees, applicants and others subject to 10 CFR Part 21 and 10 CFR 50.55(e), or NRC. This alternative is considered the “no-action” alternative and provides a baseline condition from which any other alternatives will be assessed. However, the “no-action” alternative would not address identified concerns with a lack of a clear definition for CFSI or specifically identify that counterfeit and fraudulent items are considered as a deviation in the current version of the regulatory guide.

Alternative 2: Withdraw Regulatory Guide 1.234

Under this alternative the NRC would withdraw this regulatory guide. This would eliminate the only readily available guidance for evaluating and reporting of defects under 10 CFR Part 21 or 10 CFR 50.55(e) that can be used by applicants, licensees, dedicating entities, and their suppliers associated with constructing, owning, operating, or supplying of nuclear power plants subject to 10 CFR Part 21, and regulated pursuant to 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” and on 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants”. Although this alternative would be less costly than revising the guide to address identified issues, it would leave stakeholders without guidance to address given regulatory requirements.

Alternative 3: Revise Regulatory Guide 1.234

Under this alternative, the NRC would revise Regulatory Guide 1.234. This revision would incorporate a definition for CFSI to ensure consistency in application of guidance when evaluating deviations to determine whether the deviation could lead to a defect. By doing so, the NRC would ensure that the RG guidance available in this area is current, and accurately reflects the staff’s position.

The impact to the NRC would be the costs associated with preparing and issuing the regulatory guide revision. The impact to the stakeholders would be the voluntary costs associated with reviewing and providing comments to NRC during the public comment period. The value to NRC staff, applicants, licensees, and others subject to 10 CFR Part 21 and 10 CFR 50.55(e), 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.

5. Comparison of Alternatives

The alternatives were compared against each other with respect to safety, as well as NRC’s and applicant’s/licensee’s resources.

With respect to safety, Alternative 1 does not signify unsafe results because the method for evaluating and reporting defects in the current regulatory guide continues to be acceptable. Alternative 3 would be superior to Alternative 1 in that it would issue a revised RG to include a clear definition of CFSI and thereby allow licensees, applicants, and the NRC staff to have a consistent understanding on this definition. Alternative 3 also clearly specifies that counterfeit and fraudulent items should be considered deviations, thereby providing a clear NRC staff position on whether these items need to be evaluated to determine whether they constitute a defect.

With respect to NRC resources, Alternative 3 represents the greatest initial cost to the NRC, which is attributable to the costs associated with preparing and issuing the RG. However, over the lifetime of the RG the overall NRC cost of Alternative 3 is estimated to be less than the overall cost of Alternative 1 by reducing the cost related to additional staff resources and schedule impacts associated with the application review and request for additional information (RAI) procedures.

With respect to suppliers'/dedicating entities'/applicants'/licensees' resources, Alternative 3 results in the least costs when compared to Alternative 1. Having a revised RG should reduce the need for RAIs to licensees and applicants and therefore the need for applicants and licensees to perform additional analyses to address RAIs. A revised RG would also minimize regulatory uncertainty during inspections of suppliers/dedicating entities/applicants/licensees. Accordingly, costs to suppliers/dedicating entities/applicants/licensees associated with these additional activities are estimated to be lower with Alternative 3.

6. Decision Rationale

Based on this regulatory analysis, the NRC staff concludes that revision of Regulatory Guide 1.234 is warranted. The action will incorporate a definition for CFSI into the regulatory guide and clearly specify that counterfeit and fraudulent items are considered deviations, thereby allowing consistent application of CFSI guidance. It could also lead to cost savings for the industry, especially with regard to an applicant's ability to prepare submittals to the NRC. An updated guide would potentially reduce staff review time and the need for RAIs thus reducing costs to licensees, applicants, and the NRC. The costs to the NRC in revising the RG and to licensees and applicants in adapting to a revised RG are deemed to be less than the benefits accrued by reducing the need for RAIs. This RG update would also provide more regulatory certainty during inspections of suppliers/dedicating entities/applicants/licensees and thus reducing the cost and resources during inspections for both the suppliers'/dedicating entities'/applicants/licensees' and NRC inspectors.