

REGULATORY ANALYSIS

DRAFT REGULATORY GUIDE DG-1415 DEDICATION OF COMMERCIAL-GRADE ITEMS FOR USE IN NUCLEAR POWER PLANTS

(Proposed Revision 1 of Regulatory Guide 1.164)

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) 1.164, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants." 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 1.164 in June of 2017 to provide guidance on dedication of commercial-grade items and services used in nuclear power plants in accordance with the Title 10 of the Code of Federal Regulations (10 CFR) Part 21, "Reporting of Defects and Noncompliance" and applicable provisions of Appendix B to 10 CFR Part 50. Since the issuance of Revision 0 of RG 1.164, the NRC developed a formal definition for counterfeit, fraudulent, and suspect items (CFSI). Therefore, RG 1.164 needs to be revised to incorporate the NRC's definition of CFSI such that users of RG 1.164 would be able to apply consistent guidance when addressing CFSI during dedication activities.

3. Objective

The objective of this regulatory action is to assess the need to update NRC guidance to licensees, applicants, and individuals, partnerships, corporations, or other entities subject to the scope of 10 CFR Part 21 to provide a definition for CFSI.

4. Identification and Analysis of Alternative Approaches

The NRC staff considered the following alternative approaches:

1. Do not revise Regulatory Guide 1.164
2. Withdraw Regulatory Guide 1.164
3. Revise Regulatory Guide 1.164

Alternative 1: Do Not Revise Regulatory Guide 1.164

Under this alternative, the NRC would not revise or issue additional guidance, and the current guidance would be retained. If the NRC does not take action, there would not be any changes in costs or benefit to the public, licensees, applicants and others subject to the scope of 10 CFR Part 21, 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 in the current version of the regulatory guide.

Alternative 2: Withdraw Regulatory Guide 1.164

Under this alternative the NRC would withdraw this regulatory guide. This would eliminate the only readily available guidance for applicants, licensees, and others subject to the scope of 10 CFR Part 21, on dedication of commercial-grade items for use in 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 1.164

Under this alternative, the NRC would revise Regulatory Guide 1.164. This revision would incorporate a definition for CFSI to ensure consistency in application of guidance when addressing CFSI during the dedication process. 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 and its licensees and 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.

5. Comparison of Alternatives

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

With respect to safety, Alternative 1 does not signify unsafe results because the method for performing dedication of commercial-grade items in the current regulatory guide continue 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 to allow licensees, applicants, and the NRC staff to have a consistent understanding on this definition.

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 and therefore the need for applicants/licensees to perform additional analyses to address them. A revised RG would also minimize regulatory uncertainty during inspections of suppliers’/dedicating entities’/applicants/licensees, estimated to be lower with Alternative 3.

6. Decision Rationale

Based on this regulatory analysis, the NRC staff concludes that revision of Regulatory Guide 1.164 is warranted. The action will incorporate a definition for counterfeit, fraudulent, and suspect items (CFSI) into regulatory guide to allow 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 applicants, licensees, suppliers, and dedicating entities subject to the scope of 10 CFR Part 21 and 10 CFR 50.55(e), and thus reducing the cost and resources during inspections for these entities and NRC inspectors.