REGULATORY ANALYSIS

DRAFT REGULATORY GUIDE DG-2007
GUIDANCE FOR IMPLEMENTATION OF 10 CFR 50.59, "CHANGES, TESTS AND EXPERIMENTS," AT NONPOWER PRODUCTION OR UTILIZATION FACILITIES

(Proposed New Regulatory Guide)

1. Statement of the Problem

The U.S. Nuclear Regulatory Commission (NRC) is considering issuing a new regulatory guide (RG) to provide nonpower production and utilization facilities (NPUF) licensees, as defined in the RG, with guidance on complying with the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) 50.59, "Changes, tests and experiments," when performing changes to their facilities and procedures as described in the final safety analysis report (FSAR) (as updated) and conducting tests or experiments not described in the FSAR (as updated) without obtaining a license amendment pursuant to 10 CFR 50.90, "Application for amendment of license, construction permit, or early site permit." The proposed Regulatory Guide (RG) would endorse an industry guide that provides guidance to NPUF licensees performing 10 CFR 50.59 evaluations.

As a result of lessons learned from operating experience and other initiatives related to control of conformance of facilities with their FSAR descriptions, the NRC determined that additional action was necessary to provide clarity and consistency in implementation of the rule. In November 2000, the NRC issued RG 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, And Experiments" (with later revisions in May 2019, June 2020, and June 2021) (Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML003759710, ML17195A655, ML20125A730 and ML21109A002), endorsing Nuclear Energy Institute (NEI) 96-07, "Guidelines for 10 CFR 50.59 Implementation." NEI 96-07 provides guidance to nuclear power plants performing changes to their facilities and procedures. Because of the limited applicability of NEI 96-07 to NPUFs, 10 CFR 50.59 reviews present challenges to the NPUF licensees and create additional regulatory burden during inspections. NEI and the National Organization of Test, Research, and Training Reactors (TRTR) submitted its 10 CFR 50.59 guidance document to the NRC for review and endorsement in August 2021 (ADAMS Accession No. ML21236A089). The NRC staff development of this regulatory guide serves to endorse the NEI guidance to address licensing and oversight issues identified by the licensee associated with implementing 10 CFR 50.59 associated with implementing 10 CFR 50.59.

2. Objective

The objective of this regulatory analysis is to evaluate alternatives and assess the need to address the problems identified above and provide NPUF applicants and licensees with a new method to demonstrate compliance with the 10 CFR 50.59 requirements for changes, tests, and experiments.

3. Alternative Approaches

The NRC staff considered the following alternative approaches:

(1) Do not develop a RG to endorse TRTR guidance on complying with the requirements of 10 CFR 50.59.

(2) Develop a RG to endorse TRTR guidance on complying with the requirements of 10 CFR 50.59.

Alternative 1: Do Not Develop a Regulatory Guide

Under this alternative, the NRC would not develop an RG to endorse industry guidance. If the NRC does not take action, there would not be any changes in costs or benefit to the public, licensees, or the 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 because of the absence of more comprehensive NRC guidance for NPUFs to comply with requirements of 10 CFR 50.59. NPUF licensees would continue to use RG 1.187, which endorses NEI 96-07. NEI 96-07 provides guidelines for 10 CFR 50.59 evaluations performed at nuclear power plants but does not directly address NPUFs or provide relevant examples for NPUF licensees. It is left to the licensee to justify to the NRC its rationale related to the use of NEI 96-07. This may result in increased NRC staff time and the need for NRC staff to request information from licensees during inspections. Licensees would then have to expend resources responding to the requests for information.

Alternative 2: Develop a Regulatory Guide

Under this alternative, the NRC would develop an RG to endorse guidance for NPUF licensees to comply with the requirements of 10 CFR 50.59. This RG would incorporate the latest information from industry guidelines, supporting guidance, and review practices. By doing so, the NRC would ensure that the 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 a new RG. 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 licensees would be the benefits associated with enhanced efficiency and effectiveness in using a common guidance document as the technical basis for NPUF licensee changes, tests, and experiments made pursuant to 10 CFR 50.59 and other interactions between the NRC and its regulated entities. Further, the new guidance would give applicants and licensees the updated NRC staff’s positions on these matters, thereby minimizing RAIs and resubmittals and providing guidance that ensures that safety analyses are adequate to ensure that regulatory requirements are met.

Conclusion

Operating experience demonstrates that NPUF licensees have difficulty complying with the regulations in 10 CFR 50.59, as documented in multiple licensee notices of violations. NRC endorsement of the TRTR guidance that addresses the aspects unique to nonpower reactors related to 10 CFR 50.59 will improve the safety review of changes at the facilities and reduce the frequency of noncompliance with 10 CFR 50.59.

Based on this regulatory analysis, the NRC staff concludes that the issuance of a new RG (Alternative 2) is warranted. The action will enhance safety at NPUFs by endorsing guidance related to the safety review of changes, tests, and experiments at NPUFs. It could also lead to cost savings for the regulated community, especially with regard to reduction of regulatory uncertainty related to changes, tests, and experiments at the facility and increased safety from improved safety reviews of facility changes, tests, and experiments while ensuring consistency with the facility's FSAR.