

REGULATORY ANALYSIS

DRAFT REGULATORY GUIDE DG-1439 GUIDANCE FOR TECHNOLOGY-INCLUSIVE RISK-INFORMED CHANGE EVALUATION (Proposed New Regulatory Guide 1.261)

1 Statement of the Problem

The NRC is reviewing applications for a new generation of non-light water reactors (non-LWRs) and preparing associated guidance related to the design, licensing, and operation of such facilities. These efforts have included the development of several key guidance documents. Some important activities are related to the Licensing Modernization Project (LMP), which was a cost-shared initiative led by nuclear utilities and supported by the U.S. Department of Energy (DOE). The LMP provides a technology-inclusive, risk-informed, and performance-based methodology to inform the licensing of non-LWRs. The LMP activities led to the publication and submittal of Nuclear Energy Institute (NEI) 18-04, Revision 1, “Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development,” and its subsequent endorsement in Regulatory Guide (RG) 1.233, “Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors.” The methodology described in NEI 18-04 is different enough from those used for the current fleet of LWRs to warrant a distinct construct of safety analysis reports for applications under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, “Domestic Licensing of Production and Utilization Facilities,” and 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.” Guidance related to those portions of safety analysis reports directly related to the LMP methodology is provided in NEI 21-07, Revision 1, “Technology Inclusive Guidance for Non-Light Water Reactors, Safety Analysis Report Content for Applicants Using the NEI 18-04 Methodology,” which the NRC staff endorsed in RG 1.253, “Guidance for a Technology-Inclusive Content-of-Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors.” Guidance for the content of applications in those portions of a safety analysis report that are not directly supported by the LMP methodology are addressed in other guidance documents. At the time of the publication of this RG, those guidance documents are described in interim staff guidance DANU-ISG-2022-01, “Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap.”

Following the issuance of the guidance for important safety analysis methodologies in RG 1.233 and contents of applications in RG 1.253, the LMP-related series of guidance documents is being extended to include the evaluation of changes after a plant enters operations. An industry led and DOE supported project was initiated and it led to the publication and submittal of NEI 22-05, Revision 0, “Technology Inclusive Risk Informed Change Evaluation (TIRICE), Guidance for the Evaluation of Changes to Facilities Utilizing NEI 18-04 and NEI 21-07.” The guidance in NEI 22-05 builds from both (1) the available guidance in NEI 96-07, Revision 1, “Guidelines for 10 CFR 50.59 Implementation,” for evaluating changes under 10 CFR 50.59, “Changes, tests, and experiments,” and (2) the methodology described in NEI 18-04 and contents of applications described in NEI 21-07. The development of the guidance in NEI 22-05 and this RG provide criteria for evaluating changes that are relevant to

the key parts of the licensing basis and content of applications associated with safety analysis reports developed using the guidance in NEI 18-04 and NEI 21-07.

This RG endorses, subject to the clarifications in Section C of the RG, NEI 22-05 as one acceptable alternative to using the criteria in 10 CFR 50.59 for evaluating changes under the special circumstances introduced when a plant is licensed using the guidance in NEI 18-04 and NEI 21-07. The licensee would be responsible for preparing any necessary requests for an exemption from specific requirements in 10 CFR 50.59 and related proposed license condition to support this alternative.

2 Objective

The objective of this regulatory action is to provide guidance on using a technology-inclusive, risk-informed, and performance-based methodology to evaluate changes to a plant after it begins operation, as an alternative approach to the criteria in 10 CFR 50.59 due to the special circumstances introduced when a plant is licensed using the guidance in RG 1.233 and RG 1.253.

3 Alternative Approaches

The NRC staff considered the following two alternative approaches:

- (1) Do not develop RG 1.261
- (2) Develop RG 1.261

Alternative 1: Do Not Develop Regulatory Guide 1.261

Under this alternative, the NRC would not develop the RG, retaining the current guidance developed for large LWR designs. If the NRC does not take action, there will not be any changes in costs or benefits for the public, licensees, or the NRC. The NRC considers this the “no-action” alternative and provides it as a baseline condition from which to assess any other alternatives. However, the “no-action” alternative does not address how a non-LWR design licensed using the guidance in RG 1.233 and RG 1.253 impacts the current large LWR-focused criteria in 10 CFR 50.59. Each applicant for a non-LWR design or non-LWR licensee would need to address the criteria in 10 CFR 50.59 individually, including any alternative approaches. The NRC would continue to review each application on a case-by-case basis, extending the time to prepare and review each submitted approach, potentially resulting in excessive costs and delays.

Alternative 2: Develop Regulatory Guide 1.261

Under this alternative, the NRC would develop the RG. This initial issuance would provide designers, applicants, and licensees of advanced reactors with risk-informed, technology-inclusive, and performance-based guidance and would include guidance on how to evaluate changes to the facility using an alternative approach to the criteria in 10 CFR 50.59. By doing so, the NRC would ensure that guidance is available in this area and accurately reflects the NRC staff’s position.

The NRC would incur costs to prepare and issue the new regulatory guidance for advanced reactor designs that is risk-informed, technology-inclusive, and performance-based. The public would have voluntary costs associated with reviewing and providing comments to the

NRC during the public comment period. The NRC staff and its applicants and licensees would benefit from enhanced efficiency and effectiveness by using a common guidance document as the technical basis for an alternative approach to the criteria in 10 CFR 50.59. The costs to applicants and licensees of implementing the optional new guidance are justified by the benefits gained with the use of a guidance document that is risk-informed, technology-inclusive, and performance-based that provides a standardized method to an alternate approach to the criteria in 10 CFR 50.59, recognizing the special circumstances of non-LWR designs licensed using the guidance in RG 1.233 and RG 1.253. Further, the NRC staff anticipates that the new guidance would streamline its review of alternative approaches to the criteria in 10 CFR 50.59, relative to a case-by-case basis review due to a lack of applicable guidance and, therefore, result in the least cost alternative for reviewing these approaches.

4 Conclusion

Based on this regulatory analysis, the NRC staff concludes that issuance of a new regulatory guide is warranted. This action will enhance the ability of advanced reactor applicants and licensees to prepare and submit alternative approaches to the criteria in 10 CFR 50.59 for facilities licensed using the guidance in RG 1.233 and RG 1.253. This could also lead to cost savings for the industry, especially with regard to the time needed for applicants/licensees to develop their own guidance and to the time needed for the NRC to review each alternative approach on a case-by-case basis.