
**Backfitting and Issue Finality Assessment Supporting
the Mitigation of Beyond-Design-Basis Events Final
Rule**

**U.S. Nuclear Regulatory Commission
Office of Nuclear Reactor Regulation**

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Mitigation of Beyond-Design-Basis Events Final Rule: Backfitting and Issue Finality

This document provides the U.S. Nuclear Regulatory Commission's (NRC's) evaluation of backfitting and issue finality for the final mitigation of beyond-design-basis events (MBDBE) rule. Section 1.0 contains the changes to the backfit analysis in the proposed MBDBE rule stemming from the consideration of public comments on the proposed rule. Section 2.0 describes the MBDBE requirements that make Order EA-12-049, "Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events," (the Mitigation Strategies Order) and Order EA-12-051, "Order Modifying Licenses with Regard to Reliable Spent Fuel Pool Instrumentation," (the Spent Fuel Pool Instrumentation (SFPI) Order) generically applicable. These provisions do not constitute backfits and are consistent with issue finality. Section 3.0 provides the NRC's assessment of backfitting and issue finality for any remaining requirements that are not a result of making the Mitigation Strategies Order and the SFPI Order generically applicable.

1.0 Changes to the MBDBE Rule Backfitting Assessment

As a result of the consideration of public comments provided on the proposed MBDBE rule, the NRC made several changes to improve and clarify it. These changes led to changes for the backfitting justification supporting the MBDBE rule. This section presents an overview of those changes.

Multiple Source Term Dose Assessment

The NRC received public comment concerning the backfitting justification conducted under Title 10 of the *Code of Federal Regulations* (10 CFR) 50.109, "Backfitting," for the multiple source term dose assessment requirements that were included in the proposed MBDBE rule. The comment claimed that, while the NRC had correctly identified these requirements as backfits, it had failed to justify their imposition as necessary for adequate protection of public health and safety. Consequently, the NRC had not satisfied 10 CFR 50.109(a)(4)(ii) and was required to prepare a backfit analysis to justify the backfits. The commenter stated that the NRC's analysis failed to overcome the presumption that compliance with current regulations and orders ensures adequate protection. The commenter quoted from the statement of considerations for the 1988 Backfit Rule: "[T]hat presumption can be overcome only by significant new information or some showing that the regulations do not address some significant safety issue." The commenter also noted that, beyond the extensive, required actions that licensees are already taking, the industry is voluntarily implementing multiple source term dose assessment capabilities to assist in the mitigation of remote, yet potentially serious, beyond-design-basis external events. The comment stated that the NRC needs to provide a systematic and documented analysis that imposition of the new requirements would result in a cost-justified substantial increase in safety.

The NRC agrees that the backfit justification supporting the proposed multiple source term dose assessment requirements was insufficient and has subsequently concluded that the requirements should be removed from the final rule for the reasons stated in Section IV.E of the MBDBE final rule notice.

Relocation and Revision to Staffing and Communications Requirements

The NRC received public comment that the proposed wording for 10 CFR Part 50, Appendix E, Section VII, requirements could be interpreted by future readers that the proposed staffing and communications requirements must be described in the licensee's emergency plan, notwithstanding the proposed rule language to the contrary. The commenter said that the clarity of these proposed provisions could be improved if they were moved into 10 CFR 50.155. The commenter proposed that these requirements be incorporated into 10 CFR 50.155 as a separate subparagraph. The NRC agrees that relocating the staffing and communications requirements to 10 CFR 50.155 improves clarity. These requirements in the final MBDBE rule may constitute backfits and are addressed below in Section 3.0.

Consideration of Reevaluated Hazards within the Mitigation Strategies

The NRC received comments stating that the need for a licensee's strategies and guidelines to be capable of execution in the context of the reevaluated flooding and seismic hazards should be addressed in 10 CFR 50.155(b), rather than in 10 CFR 50.155(c)(2). The commenters noted that this change would provide greater flexibility regarding how a licensee can address the hazard effects through changes to mitigation strategies and guidelines, to include changes to equipment protection. Additionally, commenters indicated that the regulation should allow for alternative approaches that would not necessarily address the damage state assumed for 10 CFR 50.155(b)(1), nor necessarily assume the same success criteria, and that should also allow for the use of risk-informed approaches. The NRC agrees with this comment and concludes that it would also result in a regulation that is better aligned with the supporting implementation guidance in Regulatory Guide (RG) 1.226, "Flexible Mitigation Strategies for Beyond-Design-Basis Events," which provides the flexibility the commenters suggested should be in the rule. The NRC concludes that this revision to the final rule is not a backfit, as discussed below in Section 2.0.

Removal of the Severe Accident Management Guidelines Discussion

The Commission considered a proposed severe accident management guidelines (SAMG) backfit analysis, provided as part of SECY-15-0065, "Proposed Rulemaking: Mitigation of Beyond-Design-Basis Events." The Commission concluded that the imposition of SAMG requirements was not warranted. Consequently, SAMGs are not requirements in the MBDBE rule and instead continue to be implemented and maintained through a voluntary industry initiative. For more information on that proposal, refer to the proposed rule published in the *Federal Register* on November 13, 2015 (80 FR 70609).

2.0 MBDBE Rule Provisions that Do Not Constitute Backfits

The requirements in the MBDBE rule that make the Mitigating Strategies Order and the SFPI Order generically applicable do not qualify as "backfitting," as that term is defined in 10 CFR 50.109. Appendix B to the regulatory analysis evaluates the costs of these provisions (i.e., the historical cost analysis). This section discusses why these regulatory requirements do not constitute backfits. Because of differences in the application of 10 CFR 50.109 (the Backfit Rule) and the pertinent issue finality provisions in 10 CFR Part 52 to licensees; entities with existing reactor design certifications (DCs); and future applicants for combined licenses (COLs), DCs, manufacturing licenses (MLs), and standard design approvals (SDAs), the NRC addresses each class separately.

Generic Applicability of the Mitigation Strategies Order and the SFPI Order to Holders of Operating Licenses, Construction Permits, and Combined Licenses

The NRC determined that the requirements in the final MBDBE rule that make generically applicable the requirements in the Mitigation Strategies Order and the SFPI Order—as applied to current power reactor licensees and construction permit holders to whom the Mitigation Strategies Order and the SFPI Order were directed—do not constitute backfitting under 10 CFR 50.109. These requirements have already been imposed by the orders, so the rule requirements cannot meet the definition of “backfitting” in 10 CFR 50.109(a)(1).

With regard to the current COL holders, at the time of the issuance of the Mitigation Strategies Order and the SFPI Order on March 12, 2012, only Southern Nuclear Operating Company (for Vogtle Electric Generating Plant, Units 3 and 4 (Vogtle)) was a COL holder. The NRC’s Mitigation Strategies Order constituted a change to the Vogtle COLs that was necessary for adequate protection under 10 CFR 52.98(a) and 50.109(a)(4)(ii). When issuing the SFPI Order for Vogtle, the Commission exempted itself from the backfitting and issue finality requirements. All other new reactor licensees under 10 CFR Part 52—Detroit Edison Company (for Enrico Fermi Nuclear Plant, Unit 3), South Carolina Electric & Gas Company (for Virgil C. Summer Nuclear Station, Units 2 and 3) (Summer), Nuclear Innovation North America LLC, et al. (for South Texas Project, Units 3 and 4), and Duke Energy Florida, LLC (for Levy Nuclear Plant, Units 1 and 2)—were still under review and had not received their COLs when the orders were issued. These COL holders were issued license conditions that are equivalent to the order requirements, with the exception of Summer, which received Order EA-12-063 for SFPI. The MBDBE rule is making these previously imposed license conditions and order requirements generically applicable, and is removing the license conditions and rescinding the order requirements. For these requirements, the final MBDBE rule is not imposing new requirements inconsistent with issue finality for these COL holders.

MBDBE Rule: Reevaluated Hazards

The MBDBE rule contains requirements for licensees who received the March 12, 2012, NRC request for information issued under 10 CFR 50.54(f) to consider the effects of the reevaluated hazards information developed in response to that request, if the magnitude of those hazards exceeds the external events design basis of the facility. The MBDBE rule requires licensees to address the effects of the reevaluated hazard information using one or both of the following two approaches:

- (1) the mitigation strategies and guidelines required by 10 CFR 50.155(b)(1), as implemented or as modified; or
- (2) event-specific approaches.

As discussed above, these provisions were moved from 10 CFR 50.155(c)(2) in the proposed rule to 10 CFR 50.155(b)(2) in the final rule, in response to public comment, to enable better alignment with supporting guidance and provide greater flexibility for addressing the reevaluated hazard information.

The basis for requiring these provisions within the MBDBE rule is provided in COMSECY-14-0037, “Integration of Mitigating Strategies for Beyond-Design-Basis External Events and the Reevaluation of Flooding Hazards,” and its associated staff requirements memorandum (SRM). As discussed in COMSECY-14-0037, the requirements of the Mitigation

Strategies Order were imposed in parallel with the agency's March 12, 2012, request for information on the reevaluation of external hazards. The Mitigation Strategies Order included a requirement for licensees to provide reasonable protection from external events for equipment associated with the required mitigation strategies without specific reference to the necessary level of protection. The appropriate level of protection from external hazards, particularly flooding, was the subject of discussion in the course of NRC-held public meetings leading up to the issuance of the NRC Japan Lessons-Learned Project Directorate Interim Staff Guidance (JLD-ISG)-2012-01, "Compliance with Order EA-12-049, 'Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events,'" and its endorsement of the industry guidance for the Mitigation Strategies Order, Nuclear Energy Institute (NEI) 12-06, Revision 0, "Diverse and Flexible Coping Strategies (FLEX) Implementation Guide."

Section 6.2.3.1 of NEI 12-06, Revision 0, specifies that the level of protection for flooding should be "the flood elevation from the most recent site flood analysis. The evaluation to determine the elevation for storage should be informed by flood analysis applicable to the site from early site permits, combined license applications, and/or contiguous licensed sites." The choice of this hazard level was driven by the recognition that, while the flooding hazard reevaluations by holders of operating licenses and construction permits may not be complete in advance of the development and implementation of the mitigation strategies, information available from flood analyses for nearby sites could be taken into account in choosing the appropriate level to avoid the need for rework or modification of the strategies. Many licensees took the former approach, using their best estimates of potential hazard levels and providing additional margin to the current licensing basis.

In COMSECY-14-0037, the NRC staff requested that the Commission affirm that (1) licensees for operating nuclear power plants need to address the reevaluated flooding hazards within their mitigation strategies for beyond-design-basis external events, (2) licensees for operating nuclear power plants may need to address some specific flooding scenarios that could significantly damage the power plant site by developing targeted or scenario-specific mitigation strategies, possibly including unconventional measures, to prevent fuel damage in reactor cores or spent fuel pools, and (3) the NRC staff should revise the flooding assessments and integrate the decisionmaking into the development and implementation of mitigation strategies, in accordance with the Mitigation Strategies Order and this rulemaking. These principles reflect the NEI 12-06 reference to the "most recent flood analysis" previously discussed and the documentation by licensees in their overall integrated plans for the mitigation strategies that, at the time of their submittals, "flood and seismic reevaluations pursuant to the 10 CFR 50.54(f) letter of March 12, 2012, are not completed and therefore not assumed in this submittal. As the reevaluations are completed, appropriate issues would be entered into the corrective action system and addressed on a schedule commensurate with other licensing bases changes." In SRM-COMSECY-14-0037, the Commission approved the first two items (which pertain to the MBDBE rule) recommended by the NRC staff, regarding the need for operating nuclear power plant licensees to address the reevaluated flood hazards within the mitigation strategies and the potential for using targeted or scenario-specific mitigation strategies. The Commission did not approve the third recommendation, but that recommendation is outside the scope of this rulemaking effort. The MBDBE rule reflects this direction.

Accordingly, the NRC concludes that the requirements for licensees to address the effects of the reevaluated hazards information are an essential part of the Mitigation Strategies Order requirements to develop, implement, and maintain guidance and strategies to maintain or restore core cooling, containment and spent fuel pool cooling capabilities following a beyond-

design-basis external event. Therefore, the incorporation of these requirements within the MBDBE rule does not constitute a new instance of backfitting.

Administrative Amendments to Emergency Response Data System Requirements

In 10 CFR Part 50, Appendix E, Section VI, the MBDBE rule removes references to the use of modems in order to make the Emergency Response Data System (ERDS) requirements technology neutral. The NRC considers this revision a minor administrative change to make the NRC's regulatory requirements consistent with a technological initiative that has already been implemented by industry. The subject requirement, for the NRC to supply replacement equipment in the event of failure, remains unchanged. Because this amendment is an administrative change to a requirement applicable to the NRC in the ERDS regulations, it is not subject to the Backfit Rule.

Existing Design Certifications

The MBDBE rule does not contain new reactor design requirements and, as such, is not applicable to DC applicants.

Current and Future Applicants

Applicants and potential applicants (for licenses, permits, and regulatory approvals, such as DCs) are not, with certain exceptions, protected by either the Backfit Rule or any issue finality provisions under 10 CFR Part 52. Neither the Backfit Rule nor the issue finality provisions under 10 CFR Part 52—with certain exclusions not applicable here—were intended to apply to every NRC action that substantially changes the expectations of current and future applicants.

3.0 Assessment of MBDBE Rule Provisions that May Constitute Backfits

As a result of the revisions to the MBDBE rule, including the removal of the multiple source term dose assessment requirements from the final MBDBE rule, as discussed above, the requirements in the final MBDBE rule that may constitute backfits are the staffing and communications requirements. In the proposed MBDBE rule, the NRC stated the following:

These proposed [staffing and communications] requirements are based on the NRC's information requests pursuant to 10 CFR 50.54(f). These regulatory issues are currently being addressed through Order EA-12-049 implementation guidance (i.e., NRC-endorsed guidance in NEI 12-06, Diverse and Flexible Coping Strategies (FLEX) Implementation Guide, and NEI 12-01, Guideline for Assessing Beyond Design Basis Accident Response Staffing and Communications Capabilities). Although these proposed requirements for staffing and communications stemmed from separate regulatory action, they were necessary for a proper and complete implementation of Order EA-12-049. As discussed in COMSECY-13-0010, "Schedule and Plans for Tier 2 Order on Emergency Preparedness for Japan Lessons Learned," dated March 27, 2013 (ADAMS Accession No. ML12339A262), the NRC and licensees determined that a complete implementation of a response to a site-wide, beyond-design-basis external event would require sufficient staffing and communications capabilities for both onsite and to offsite that can occur without ac power and recognizing

infrastructure damage. As such they are considered to be part of the Order EA-12-049-imposed requirements.

As discussed in the final MBDBE rule *Federal Register* notice, the NRC relocated and revised the staffing and communications requirements into 10 CFR 50.155. This revision improves clarity, and as a result, the requirements directly link to 10 CFR 50.155(b)(1). This recognizes the importance of staffing and communications to effectively implement the strategies and guidelines for beyond-design-basis external events and results in improved alignment with implementation guidance.

MBDBE Rule: Staffing and Communication Capability Requirements

The final MBDBE rule includes requirements for staffing (in 10 CFR 50.155(b)) and communications **capabilities** (in 10 CFR 50.155(c)), but as discussed above in Section 1.0 of this document, no longer contains the requirements for the performance of staffing and communications capability **analyses**. The revised and relocated communications and staffing capabilities requirements in the final MBDBE rule directly align 10 CFR 50.155 with implementation of the Mitigation Strategies Order. Specifically, successful implementation of the Mitigation Strategies Order requires sufficient staff and sufficient communications capability to successfully mitigate a beyond-design-basis external event that can affect an entire site and adversely impact surrounding telecommunications infrastructure. The NRC used the information obtained from the 10 CFR 50.54(f) responses to support reaching this determination of the regulatory importance of both staffing and communications for currently licensed reactors. Staffing must be sufficient to implement the mitigation strategies for a sitewide, beyond-design-basis external event to be able to simultaneously maintain or restore all the key functions. This staffing must be supported with communications capabilities that are functional in an event involving the loss of all ac to enable the staff implementing the strategies to effectively communicate onsite during and following such an event, and to enable communications to offsite resource centers, under conditions that may involve significant damage to surrounding telecommunications infrastructure, to request assistance and to interact with key offsite authorities. Both staffing and communications have been part of the Mitigation Strategies Order implementation guidance. As a result, in both cases, successful implementation of the Mitigation Strategies Order addresses these MBDBE requirements, such that licensees in compliance with the Mitigation Strategies Order meet the staffing and communications requirements of 10 CFR 50.155.

The NRC did not explicitly identify either the staffing or communications capability requirements of the final MBDBE rule in the Mitigation Strategies Order. Nevertheless, they are essential elements of effective mitigation strategies and guidelines (i.e., the staffing and communications capabilities are necessary for compliance with the Mitigation Strategies Order), and licensees have been demonstrating these capabilities to comply with the Mitigation Strategies Order. Therefore, the NRC maintains that the staffing and communications capabilities requirements in the final MBDBE rule are not new requirements or new or different interpretations of requirements.

Even if requiring licensees to have staffing and communications capabilities in the final MBDBE rule had been viewed to constitute backfitting on current 10 CFR Part 50 licensees or violate issue finality for current COL holders, the NRC would have imposed them following its backfitting process. These requirements are necessary for the successful implementation of the Mitigation Strategies Order, which was imposed under the adequate protection exception criterion of 10 CFR 50.109(a)(4)(ii). Therefore, the staffing and communications capabilities

requirements are necessary for adequate protection of public health and safety. These requirements would facilitate the development and implementation of the strategies and guidelines required by 10 CFR 50.155(b)(1)-(2). Without sufficient staffing or communications capabilities, a licensee would not be capable of actually executing the strategies and guidelines required by 10 CFR 50.155(b)(1)-(2). Consequently, the staffing and communications capabilities requirements satisfy the adequate protection backfit analysis exception criterion of 10 CFR 50.109(a)(4)(ii) and, as such, permit the violation of issue finality under 10 CFR 52.98(a).