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

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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/evaluation of backfitting and issue finality for any the remaining change to 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.

### Removal of Multiple Source Term Dose Assessment Requirements

The NRC received public comment concerning the backfitting justification conducted under Title 10 of the *Code of Federal Regulations* (10 CFR) 50.109, "Backfitting," (the Backfit Rule) 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 Removal of 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 including~~ the staffing and communications requirements ~~to~~ in 10 CFR Part 50.155 improves, ~~Appendix E detracted from the clarity. These of the proposed rule.~~ Moreover, the NRC has reexamined the requirements in the ~~final MBDBE rule may constitute backfits~~ NRC Order EA-12-049, "Order Modifying Licenses With Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events" (Mitigation Strategies Order), for which ~~staffing and are~~ communications were addressed below in Section 3.0 at the regulatory guidance level without requirements for staffing and communications, and determined that imposition of requirements in this area would constitute backfitting.

~~Consideration~~ The Mitigation Strategies Order did not include a requirement for staffing. Instead, the order included a performance-based requirement for licensees to develop, implement and maintain guidance and strategies to maintain or restore core cooling, containment and spent fuel pool (SFP) cooling capabilities following a beyond-design-basis external event. The order further required that the strategies be capable of mitigating a simultaneous loss of all alternating current (ac) power and a loss of normal access to the ultimate heat sink and have adequate capacity to address challenges to core cooling, containment, and SFP cooling capabilities at all units on a site subject to the order. In order to address these requirements, the nuclear industry proposed regulatory guidance in Nuclear Energy Institute (NEI) document 12-06, Revision 0, which the NRC staff found to provide an acceptable means of achieving compliance with the Mitigation Strategies Order in Japan Lessons-Learned Project Directorate (JLD) Interim Staff Guidance (ISG) document JLD-ISG-2012-01, Revision 0. NEI 12-06 provides criteria for the development and implementation of the mitigation strategies under the Mitigation Strategies Order that includes staffing considerations in section 11.7. In later versions of NEI 12-06, validation guidance has been added to Appendix E of the document, which includes performance of an integrated review to show that resources, which includes personnel, are adequate and not credited more than once for any given time. These versions included Revision 2 and Revision 4, which the NRC staff found to provide acceptable methods of achieving compliance with the Mitigation Strategies Order in JLD-ISG-2012-01, Revisions 1 and 2 respectively. NEI 12-06, Revision 4 is further found to provide an acceptable method of achieving compliance with the MBDBE rule in Regulatory Guide (RG) 1.226, "Flexible Mitigation Strategies for Beyond-Design-Basis Events."

In parallel with the activities under the Mitigation Strategies Order, power reactor licensees performed and submitted an assessment of the staffing that would be needed to accomplish the strategies in response to a request for information under 10 CFR 50.54(f) that the NRC issued on March 12, 2012. The NRC staff reviewed and evaluated the staffing assessments provided by all power reactor licensees and has reviewed and provided a safety evaluation for licensees' integrated plans for achieving compliance with the Mitigation Strategies Order as they complete their implementation of those plans. Following a licensee's achieving compliance and the issuance of the NRC staff's safety evaluation for the mitigation strategies, the NRC staff completes an inspection of that implementation using Temporary Instruction (TI) 2515/191, "Inspection of the Licensee's Responses to Mitigation Strategies Order EA-12-049, Spent Fuel

Pool Instrumentation Order EA-12-051 and Emergency Preparedness Information Requested in NRC March 12, 2012,” which includes the implementation of the staffing plans provided in response to the March 12, 2012 request for information under 10 CFR 50.54(f).

The licensees similarly relied upon the regulatory guidance in NEI 12-06 (see, e.g., section 3.2.2.8) and the commitments made in conjunction with communications assessments developed in response to the March 12, 2012 request for information under 10 CFR 50.54(f) to provide the necessary communications between locations on a site during response to a postulated beyond-design-basis external event and between the site and offsite response organizations. The NRC staff similarly reviewed, evaluated and inspected these communications under the Mitigation Strategies Order and TI 2515/191.

The requirements imposed by the Mitigation Strategies Order were sufficient to provide reasonable assurance of adequate protection of public health and safety and no new information was developed with regard to staffing and communications that would modify this conclusion. The imposition of requirements for staffing and communications would not result in a substantial increase in the overall protection of public health and safety or the common defense and security. This follows the Commission’s direction in SRM-SECY-11-0124 that “[i]n order to be effective, approaches should be flexible and able to accommodate a diverse range of circumstances and conditions. In consideration of events beyond the design basis, a regulatory approach founded on performance-based requirements will foster development of the most effective and efficient, site-specific mitigation strategies, similar to how the agency approached the approval of licensee response strategies for the ‘loss of large area’ event under its B.5.b program.” As a result, the imposition of requirements for staffing and communications would not meet the provisions of the Backfit Rule and the issue finality provisions of 10 CFR Part 52 and, therefore, the requirements were removed from the final MBDBE Rule.

Under 10CFR 50.109(a)(3), when the exceptions of paragraph (a)(4) of that section (in this case, the exception for regulatory actions necessary to assure adequate protection of public health and safety) do not apply, the NRC may require backfitting of a facility when it determines, based upon an analysis as described in paragraph (c) of that section, that there is a substantial increase in the overall protection of public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of the increased protection.

#### Removal of Reevaluated Hazards ~~within~~from the ~~Mitigation Strategies~~MBDBE Rule

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~~The NRC agrees that inclusion of requirements for reevaluated

hazard treatment in 10 CFR 50.155(c)(2) would limit licensee flexibility in addressing the reevaluated hazards.

The NRC further reevaluated the inclusion of the proposed requirements for treatment of the reevaluated flooding and seismic hazards in the MBDBE Rule and concluded that doing so would be inappropriate under the Backfit Rule and inconsistent with the issue finality provisions of 10 CFR Part 52. The mitigation strategies under § 50.155(b)(1) originated in the Mitigation Strategies Order and were justified as necessary to provide adequate protection of public health and safety in light of the uncertainties associated with beyond-design-basis external events and the possibility that extreme natural phenomena could challenge the prevention, mitigation, and emergency preparedness defense-in-depth layers. In COMSECY-14-0037, "Integration of Mitigating Strategies for Beyond Design-Basis External Events and The Reevaluation of Flooding Hazards," dated November 21, 2014, the NRC staff recognized the interaction between the development and implementation of mitigation strategies for beyond-design-basis external events under the Mitigation Strategies Order and the reevaluation of flooding hazard levels using present-day regulatory guidance and methodologies from flooding evaluations used for early site permits and combined license reviews under NTTF Recommendation 2.1. ~~To resolve this interaction, in COMSECY 14-0037, the staff "ask[ed] the Commission to support the planned approach by affirming that the MBDBE rulemaking needs to require mitigating strategies that are able to address the reevaluated flooding hazards developed in response to the § 50.54(f) letters in order to ensure reasonable assurance of adequate protection of the public health and safety."~~In its SRM dated March 30, 2015, "Staff Requirements - Integration of Mitigating Strategies for Beyond Design-Basis External Events and the Reevaluation of Flooding Hazards," the Commission addressed this interaction by, in part, ~~did not make the affirmation as requested by the staff. Indeed, if the Commission had made such an affirmation, it would have been obliged to address whether there was an imminent threat to public health and safety. The lack of such an analysis either in COMSECY-14-0037 or SRM COMSECY-14-0037 or elsewhere indicates that the Commission did not conclude that adequate protection of public health and safety necessitates that the mitigation strategies for beyond design basis external events be capable of addressing the reevaluated hazard information.~~

~~Under paragraph (a)(3) of the Backfit Rule, when the exceptions of paragraph (a)(4) of that section do not apply, the NRC may require backfitting of a facility when it determines, based upon an analysis as described in paragraph (c) of that section, that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of the increased protection. To support that analysis, the Commission directed the staff to evaluate potential changes to the guidance for the integrated assessment of the effects of the flooding hazards on operating reactors and to introduce more realism for the purpose of identifying potential safety enhancements for operating reactors.~~

The changes to the regulatory decision-making process directed in the SRM to COMSECY-14-0137 reflected the recognition that the present-day regulatory guidance and methodologies are intended to identify a necessary level of protection from flooding that would meet the principal design criterion of an application for an operating license or combined license corresponding to Criterion 2 of 10 CFR part 50, appendix A, "General Design Criteria for Nuclear Power Plants," which states that "[s]tructures, systems and components important to safety shall be designed to withstand the effects of natural phenomena such as earthquakes, tornadoes, hurricanes, floods, tsunami, and seiches without loss of capability to perform their safety functions. The design bases for these structures, systems and components shall reflect: (1) appropriate consideration of the most severe of the natural phenomena that have been historically reported

for the site and surrounding area, with sufficient margin for the limited accuracy, quantity, and period of time in which the historical data have been accumulated, (2) appropriate combinations of the effects of normal and accident conditions with the effects of the natural phenomena and (3) the importance of the safety functions to be performed.” Historically, the margin specified in this criterion has been achieved through the incorporation of conservatisms in the analyses used to determine the flooding design bases for power reactors rather than by the use of a minimum margin above the results of the analyses. The existence of these conservatisms was addressed by the Commission in its direction in the SRM to reduce any unnecessary conservatisms and identify any areas with insufficient conservatisms. Adequate protection of public health and safety does not require the operating power reactor licensees to provide protection against natural phenomena protection levels determined under Criterion 2 of appendix A to 10 CFR part 50 in response to the § 50.54(f) letters issued March 12, 2012. The imposition of generic requirements for that level of protection would not result in a substantial increase in public health and safety and any backfitting in this area should be accomplished on an individual plant basis under the provisions of the Backfit Rule. The consideration of whether, in light of the reevaluated external hazards analyses, the operating licenses for power reactor licensees should be modified, suspended, or revoked is being accomplished under the NRC efforts associated with the request for information issued under 10 CFR 50.54(f) on March 12, 2012.

The generic imposition of requirements to address the reevaluated seismic and flooding hazards would be inappropriate under the Backfit Rule and inconsistent with the issue finality provisions of 10 CFR Part 52, so these provisions from the proposed rule have been removed from the final MBDBE rule.

#### Removal of Integration Requirements

In the Proposed MBDBE Rule, the NRC had included a potential requirement for an overarching integrated response capability comprised of the mitigation strategies for beyond-design-basis external events implemented under the Mitigation Strategies Order and the extensive damage mitigation guidelines (EDMGs) from NRC Order EA-02-026, “Interim Safeguards and Security Compensatory Measures,” dated February 25, 2002, as made generically applicable in the former § 50.54(hh)(2). In addition, the proposed requirements included the integration of this capability with the emergency operating procedures (EOPs). The NRC did not include a documented evaluation under paragraph (a)(4) of the Backfit Rule or a backfit analysis under paragraph (c) of the Backfit Rule to support this proposed requirement.

In formulating the final MBDBE Rule, the NRC recognized that neither § 50.54(hh)(2) nor the Mitigation Strategies Order included a requirement for integration of the strategies with each other or with the EOPs. Instead, the need for integration was addressed at the regulatory guidance level, more particularly for the Mitigation Strategies Order because it was issued after the EDMGs were already in existence. This guidance can be found in, for example, NEI 12-06, Revision 0, section 11.4. Since the publication of the Proposed MBDBE Rule, all operating power reactor licensees have come into compliance with the Mitigation Strategies Order and most have been inspected under TI 2515/191. In performing these inspections, NRC inspectors have observed the implementation of the integration of the Mitigation Strategies Order’s strategies following this regulatory guidance. This integration is further demonstrated in the validation that was conducted for the mitigation strategies using the regulatory guidance in, for example, NEI 12-06, Revision 2, Appendix E, in order to conform to the regulatory guidance in NEI 12-06, sections 3.2.1.7.6 and 11.4. The requirements imposed by the Mitigation Strategies and the Interim Safeguards and Security Compensatory Measures Orders were sufficient to

provide reasonable assurance of adequate protection and no new information was developed with regard to integration that would modify this conclusion. In addition, requirements for integration would not result in a substantial increase in the overall protection of public health and safety. Therefore, imposing requirements for an integrated response capability and integration with the existing emergency operating procedures would not meet the provisions of the Backfit Rule. The final rule has been revised to remove the proposed requirements for an integrated response capability and integration with the existing emergency operating procedures

### Modification of Training Requirements

In the Proposed MBDBE Rule, the NRC had included training requirements that relocates the training requirement from 10 CFR Part 50, Appendix E, Section IV.F.2.j. for the EDMGs and from the Mitigation Strategies Order for the mitigation strategies for beyond-design-basis external events. These requirements included proposed requirements for the qualification of personnel and the use of the systems approach to training (SAT) as defined in 10 CFR 55.4. Similar to the proposed integration requirements, the proposed qualification and SAT requirements were not accompanied by a backfit analysis or documented evaluation developed under the Backfit Rule, but had been addressed in the regulatory guidance for the EDMGs and the Mitigation Strategies Order.

The NRC inspected the training programs in 2008 for the EDMGs under TI 2515/171, “Verification of Site Specific Implementation of B.5.b Phase 2 & 3 Mitigating Strategies,” and has been inspecting these training programs on a routine basis under Inspection Procedures 71111.05T, “Fire Protection (Triennial)” and 71111.05XT, “Fire Protection – NFPA 805 (Triennial)” since January 1, 2010. The NRC reviewed and evaluated the licensees’ overall integrated plans, including their training program plans, for the Mitigation Strategies Order, for which all operating power reactor licensees have come into compliance. The NRC has also inspected training plans under the Mitigation Strategies Order for the majority of operating power reactor licensees under TI 2515/191.

The requirements imposed by the Orders were sufficient to provide reasonable assurance of adequate protection of public health and safety and no new information was developed with regard to qualification or the systems approach to training that would modify this conclusion. The NRC also considered whether there would be a substantial increase in the overall protection of the public health and safety or the common defense and security that would result from including requirements in the final rule for qualification or the systems approach to training rather than continuing the practice of addressing them in the regulatory guidance as had been done for the orders. While there would be some benefit in the form of clarity as to what had been found acceptable for compliance with the orders being made generically applicable in this rulemaking, the recharacterization of those items from regulatory guidance to requirements would not constitute a substantial increase in the overall protection of the public health and safety or the common defense and security.

A separate requirement for qualification and the systems approach to training is not needed; such a requirement could constrain an existing licensee or an applicant for a new licensee from developing innovative mitigation strategies that do not rely on them. This follows the Commission’s direction in SRM-SECY-11-0124 that “[i]n order to be effective, approaches should be flexible and able to accommodate a diverse range of circumstances and conditions. In consideration of events beyond the design basis, a regulatory approach founded on performance-based requirements will foster development of the most effective and efficient,

site-specific mitigation strategies, similar to how the agency approached the approval of licensee response strategies for the 'loss of large area' event under its B.5.b program." The final rule has been revised to remove requirements for qualification and the use of the systems approach to training.

#### Removal of Requirements for Drills or Exercises

In the Proposed MBDBE Rule, the NRC included a requirement for the performance of an initial drill or exercise and recurring drills or exercises of the mitigation strategies for beyond-design-basis external events and EDMGs. These requirements represented a movement of the existing requirement for EDMG exercises included in 10 CFR Part 50, Appendix E, Section IV.F.2.j. and the substitution of drills or exercises for the exercise requirement. In addition, similar to the proposed integration, qualification and SAT requirements, this would recharacterize the treatment of drills or exercises from inclusion in the regulatory guidance for the Mitigation Strategies Order to being a requirement. The proposed requirement was not accompanied by a backfit analysis or documented evaluation developed under the Backfit Rule.

In formulating the final MBDBE Rule, the NRC has reassessed the need for an drill or exercise requirement in light of the elements included in the regulatory guidance for the Mitigation Strategies Order that would satisfy the intent of the proposed requirement. In the case of the proposed requirement for an initial drill, the NRC recognized that the validation guidance, included in, for example, NEI 12-06, Revision 2, Appendix E, included the performance of scenarios in simulators, in-plant walkthroughs or demonstrations in order to show that a licensee's operating staff can perform the strategies in the time necessary to meet the conditions of the thermal-hydraulic analysis the strategies are based upon. In addition, the NRC recognized that the regulatory guidance for the Mitigation Strategies Order includes periodic drills at the same 8-year interval that had been included in the potential requirements of the Proposed MBDBE Rule. (See, NEI 12-06, Revisions 0 and 2, Section 11.6.5, and the incorporation by reference of NEI 13-06, Revision 1, into NEI 12-06, Revision 4, Section 11.6.5.)

Since the publication of the Proposed MBDBE Rule, all operating power reactor licensees have come into compliance with the Mitigation Strategies Order and the NRC has reviewed and evaluated their training programs. The NRC has completed inspections of the training programs, which includes the drill programs, of a majority of the operating power reactor licensees under TI 2515/191. The requirements imposed by the Mitigation Strategies Order were sufficient to provide reasonable assurance of adequate protection and no new information was developed with regard to drills or exercises that would modify this conclusion. Additionally, imposing a requirement for drills and exercises would not provide a substantial increase in the overall protection of public health and safety. Therefore, the imposition of a requirement for drills or exercises would not meet the provisions of the Backfit Rule. The requirement for drills and exercises has been removed from the final rule.

The removal of the EDMGs from the exercise program under 10 CFR Part 50, Appendix E, Section IV.F.2.j. had been based upon their inclusion in the proposed drill or exercise requirement under the MBDBE Rule. Because this requirement has been removed from the final MBDBE Rule, the NRC has retained the EDMGs in the exercise program of 10 CFR Part 50, Appendix E, Section IV.F.2.j, modifying that regulation to reflect the movement of the EDMG requirement to the MBDBE Rule.

#### 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 Carolinas, LLC (for ~~Levy~~ William States Lee III Nuclear Plant Station, Units 1 and 2), Virginia Electric and Power Company (for North Anna Unit 3) and Florida Power and Light Company (for Turkey Point, Units 6 and 7)—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/Evaluation 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). The NRC realized during its preparation of the final rule that one change set forth in the final rule would constitute a backfit. In its revisions to the former 10 CFR 50.54(hh)(3), the final rule revises the reference to 10 CFR 52.110(a)(1) to be 10 CFR 52.110(a) to accurately reference the regulation describing the certifications of permanent cessation of operations and permanent removal of fuel from the reactor vessel. For COL holders, a 10 CFR 52.110(a)(1) certification informs the NRC of the date when the licensee permanently ceased or will permanently cease operations, and a 10 CFR 52.110(a)(2) certification informs the NRC of the date when the licensee permanently removed fuel from the reactor vessel. This change was in the MBDBE proposed rule, and the NRC did not receive any comments on it.~~

~~Under the former 10 CFR 50.54(hh)(3), COL holders were required to maintain their 10 CFR 50.54(hh)(1) procedures only until the licensee submits the 10 CFR 52.110(a)(1) certification. Revising the sunset language to change 10 CFR 52.110(a)(1) to 10 CFR 52.110(a) requires licensees to maintain these procedures until the licensee submits its 10 CFR 52.110(a)(2) certification. Submission of the 10 CFR 52.110(a)(2) certification could occur days, weeks, or months after submitting the 10 CFR 52.110(a)(1) certification. Notwithstanding the amount of~~

time between the submissions of the two certifications, this rule change is a backfit for COL holders.

This imposition is justified as necessary for adequate protection because Order EA-02-026, from which 10 CFR 50.54(hh) derives, was justified as an adequate protection backfit. In issuing that order, the NRC determined that the 10 CFR 50.54(hh)(1) procedures were necessary for adequate protection due to the risk presented by the presence of fuel in the reactor. Because that risk exists until the fuel is removed from the reactor, a licensee's maintenance of the 10 CFR 50.54(hh)(1) procedures until the licensee submits its 10 CFR 52.110(a)(2) certification stating that fuel has been removed from the reactor, is necessary for adequate protection.