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Public availability of this draft document is intended to inform stakeholders of the current status of the NRC staff's preliminary draft final rule package and associated documents for § 50.46c of Title 10 of the Code of Federal Regulations (10 CFR). These preliminary draft documents are in support of an October 22, 2015, Category 3 public meeting, and a November 3, 2015, Advisory Committee on Reactor Safeguards (ACRS) subcommittee meeting. This document is intended to be inserted in the placeholder found in Section IX. Backfitting and Issue Finality, at ADAMS Accession Number ML15281A196.

This draft document has not been subject to all levels of NRC management review. Accordingly, it is incomplete and may be in error in one or more respects. The document may be subject to further revision before the staff provides the final draft rule language package to the Commission (currently scheduled to be provided to the Commission in February 2016).

DRAFT Revised Backfitting and Issue Finality Discussion: 50.46c Final Rule

IX. Backfitting and Issue Finality.

The final rule is applicable to all existing and future nuclear power plant designs, regardless of fuel design or cladding material, but the time by which compliance must be achieved will vary as set forth in the final rule. The final rule replaces existing “technology-specific” (*i.e.*, identifying fuel systems by commercial brand name) and deterministic ECCS evaluation requirements in existing § 50.46 with technology-neutral, and more risk-informed, performance based requirements. In addition, the final rule includes new ECCS evaluation requirements to address new information and newly-identified issues with respect to burn-up related phenomena, corrosion related phenomena, fabrication-related phenomena. The rule also includes new requirements which address, in express language, phenomena/conditions which has not always been considered in ECCS evaluation or been considered in an *ad hoc* manner. These new requirements relate to debris consideration, long term cooling regulatory acceptance criteria, and consideration of crud and oxide. Lastly, the final rule provides an option (“voluntary alternative”) to address consideration of the effects of debris on long-term cooling (following a LOCA) using a risk-informed approach, and to use the same risk-informed approach for consideration of debris with respect to long-term cooling to demonstrate compliance with GDC-35, GDC-38, and GDC-41 in appendix A to 10 CFR part 50.

The final rule applies to and is imposed on (“applies to”) all current nuclear power plant

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licensees. These licensees include holders of: operating licenses issued under part 50; renewed operating licenses under parts 50 and 54; combined licenses under 10 CFR part 52; and renewals of combined licenses under parts 52 and 54. The final rule also applies to current and future applicants for combined licenses under 10 CFR part 52, including those applicants referencing one of the existing standard design certification rules in appendices A through E to 10 CFR part 52. The final rule also applies to future applicants for and holders of manufacturing licenses for nuclear power plants under part 52, subpart E (there are no current applicants for or existing holders of manufacturing licenses).

The final rule also applies to NRC regulatory approvals for nuclear power reactors under part 52, which are standard design approvals and standard design certification rules. The final rule does not apply to existing standard design approvals, but it applies to all future standard design approvals issued after the effective date of the final rule. This includes standard design approvals whose application were docketed prior to the effective date of the final rule. The final rule applies to the existing standard design certification rules in 10 CFR part 52, appendices A through E, although the final rule does not require the existing five design certifications in appendices A through E to 10 CFR part 52 to comply with the final rule until their renewal (this recognizes that the existing design certifications may be amended, in response to a “voluntary” amendment application, to comply with § 50.46c in advance of their renewal). As applied to the ABWR, for which two applications for renewal have been filed and are currently under NRC consideration, the final rule effectively requires that the ABWR comply with the final rule’s requirements upon issuance of the requested renewals. The final rule applies to current and future applicants for LWR standard design certification rules under 10 CFR part 52.

The backfitting and issue finality discussion is divided into two sections. The first section, **A. Final § 50.46c Rule**, addresses the § 50.46c regulation itself. The second, **B. Regulatory Guides**, addresses the four regulatory guides associated with this rulemaking.

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The first section, on § 50.46c itself, is further divided into several parts. The first part contains a general discussion on the risk-informed voluntary alternative in paragraph (e) of § 50.46c, which may be used by all of the entities subject to this rule. The remaining parts address backfitting and issue finality (as applicable) for each type (class) of entities subject to this rule.

A. Final § 50.46c Rule.

General backfitting and issue finality discussion for the risk-informed voluntary alternative provision in paragraph (e) of § 50.46c

The final rule includes the option of allowing any of the entities to whom this rule is applicable (as identified in paragraph (a) of § 50.46c) to address the effects of debris on long-term cooling with respect to ECCS performance requirements in § 50.46c and GDC-35 using a risk-informed approach. Inasmuch as paragraph (e) provides a voluntary alternative to requirements on ECCS, its inclusion in the final rule does not represent an imposition of a new or changed requirement constituting backfitting under the definition of backfitting in 10 CFR 50.109(a)(1). Moreover, the inclusion of this provision is not inconsistent with any applicable issue finality provision in 10 CFR part 52.

Operating Licenses for nuclear power reactors under part 50, and renewed operating licenses under parts 50 and 54.

A portion of the final § 50.46c rule, that replaces the existing deterministic ECCS requirements in 10 CFR 50.46 with technology neutral, and more risk-informed, performance-based regulatory requirements, constitutes backfitting. This aspect of the rulemaking addresses, in part, a petition for rulemaking (PRM-50-71) filed by the Nuclear Energy Institute (NEI), and in comments and public meetings the industry stakeholders have generally supported this aspect of the rulemaking. Inasmuch as the final rule's replacement of the deterministic ECCS requirements with technology neutral, and more risk-informed, performance-based regulatory requirements was requested by the affected entities, the NRC believes that it is reasonable to

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conclude that the portion of the final rule accomplishing the requested action are not being “imposed” on the affected Part 50 entities. Alternatively, the NRC believes that no current Part 50 licensee will be required to perform any additional analysis or make any change to its design or operating procedures which are attributable to the final rule’s replacement of the deterministic ECCS requirements in 10 CFR 50.46 with technology neutral, and more risk-informed, performance-based requirements in the final rule. The NRC has expressly stated that the final rule’s technology neutral, more risk-informed and performance-based provisions – representing the equivalent of the existing 50.46 deterministic requirements – will not require the development, preparation or implementation of any new analyses, tests or demonstrations, or changes to design of the ECCS and fuel systems for existing licensees. Therefore, the NRC believes it is reasonable to conclude that this portion of the final rule, in reality, does not result in changes to the systems, structures or components (SSCs), design, procedures or organization needed to operate a nuclear power plant as compared with the existing deterministic requirements in § 50.46. Instead, this portion of the § 50.46 provision represents a different way of expressing NRC’s underlying regulatory expectations but with no consequent changes in plants’ SSCs, design, procedures or organization needed to operate a nuclear power plant. For these reasons, the NRC concludes that this portion of the final rule does not constitute backfitting as defined in 10 CFR 50.109(a)(1).

The final rule includes new ECCS evaluation requirements addressing burn-up related phenomena, corrosion related phenomena, fabrication related phenomena, debris consideration, long term cooling regulatory acceptance criteria, and consideration of crud and oxide. All existing holders of part 50 operating licensees must comply with these new requirements. Therefore, the NRC has determined that imposition of these new requirements on existing part 50 licensees constitutes backfitting as defined in 10 CFR 50.109(a)(1). The NRC believes that these new requirements must be imposed upon holders of existing nuclear

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power plant licenses in order to provide reasonable assurance of adequate protection to the public health and safety. The safety basis for this determination is discussed earlier in the SUPPLEMENTARY INFORMATION portion of this document, under the headings, I.

Background, II. Operating Plant Safety, and III.C. Fuel-Specific Performance and Analytical Requirements. The NRC has determined that these new requirements involve adequate protection to the health and safety of the public, and that a backfit analysis as described in § 50.109(a)(3) and (b) need not be prepared under the exceptions in § 50.109(a)(4)(ii) and/or (iii).

The final rule applies to future applicants for, and holders of operating licenses under part 50 issued after the effective date of this rule, as well as to future applicants for renewed operating licenses under parts 50 and 54. Future applicants are not protected by the Backfit Rule. The Backfit Rule was not intended to apply to every NRC action which substantially changes the expectations of current and future applicants. Therefore, the NRC concludes that the final rule, as applied to those future applicants and license holders, does not constitute backfitting as defined in § 50.109(a)(1).

Combined License Holders as of the Date of the Final § 50.46c Rule.

Currently, there are three holders of combined licenses. Two of the combined license holders are for the *Vogtle* and *Summer* facilities, each referencing the AP1000 standard design certification rule. A third combined license holder is for the *Fermi* facility, referencing an Economic Simplified Boiling Water Reactor (ESBWR) standard design certification rule (10 CFR part 52, appendix E). In addition, there may be other combined licenses issued referencing one or more of the standard design certification rules approved in the appendices to 10 CFR part 52, by the time that a final § 50.46c rule is issued by the NRC. The NRC has determined that the portion of the final rule requiring existing holders of combined licenses to comply with the technology neutral, more risk-informed and performance-based requirements of the final rule

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does not represent a violation of the general issue finality provision applicable to combined licenses in §§ 52.83 and 52.98 (and, by extension, the issue finality provision applicable to standard design certifications in § 52.63 as well as the specific issue finality provision included in each design certification rule at Paragraph VI, *Issue Resolution*). As discussed earlier with respect to Part 50 operating licenses, this portion of the rulemaking addresses a petition for rulemaking (PRM-50-71) filed by the Nuclear Energy Institute (NEI), and in comments and public meetings the industry stakeholders have generally supported this aspect of the rulemaking. For the reasons stated earlier, the NRC believes that it is reasonable to conclude that the portion of the final rule accomplishing the requested action are not being “imposed” on the affected combined license holders. Alternatively, as described earlier, the NRC believes it is reasonable to conclude that the portion of the final rule (replacing the deterministic ECCS requirements in § 50.46 with technology neutral, and more risk-informed, performance-based requirements), in reality, does not result in changes to the systems, structures or components (SSCs), design, procedures or organization needed to operate a nuclear power plant as approved in the combined licenses for these three facilities – including the referenced design certifications. For these reasons, the NRC concludes that this portion of the final rule does not constitute a violation of the issue finality provisions applicable to combined licenses in §§ 52.83 and 52.98.

The final rule includes new ECCS evaluation requirements addressing burn-up related phenomena, corrosion related phenomena, fabrication related phenomena, debris consideration, long term cooling regulatory acceptance criteria, and consideration of crud and oxide. The three existing holders of part 52 combined licensees must comply with these new requirements. Therefore, the NRC has determined that imposition of these new requirements on existing part 52 combined licensees are inconsistent with the issue finality provisions applicable to combined licenses in §§ 52.83 and 52.98 (and, by extension, the general issue

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finality provision applicable to standard design certifications in § 52.63 as well as the issue finality provision in Paragraph VI, *Issue Resolution*, in the referenced AP1000 and ESBWR standard design certifications). The NRC has determined that these new requirements must be imposed upon holders of existing nuclear power plant licenses in order to provide reasonable assurance of adequate protection to the public health and safety. The safety basis for this determination is discussed earlier in the SUPPLEMENTARY INFORMATION portion of this document, under the headings, I. *Background*, II. *Operating Plant Safety*, and III.C. *Fuel-Specific Performance and Analytical Requirements*. Therefore, the NRC believes that the NRC has met the relevant criteria for not applying issue finality to the new ECCS requirements in the final § 50.46c rule.

Current and Future Combined License Applicants referencing an existing standard design certification.

The requirements of the final rule apply to current applicants for combined licenses under subpart C of 10 CFR part 52, all of whom have referenced an NRC-approved standard design certification (*i.e.*, a standard design certification rule in 10 CFR part 52, appendices A through E).¹ Imposing the final rule on current applicants for combined licenses under subpart C of 10 CFR part 52 who reference an *existing* standard design certification rule during the period that it may be referenced (*i.e.*, in the time period provided for in 10 CFR 52.55 and paragraph VII, *Duration of this Appendix*, in the existing design certification rules (appendices A through E of part 52), would represent an inconsistency with the issue finality provisions in 10 CFR 52.63 and 10 CFR 52.83. This is because none of the existing design certifications meet all of the requirements of the final § 50.46c rule, thereby requiring the combined license applicants to demonstrate compliance with final § 50.46c rule.

¹There are no current combined license applicants who are not referencing a standard design certification. Accordingly, the NRC need not address backfitting and issue finality with respect to this situation.

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As discussed earlier with respect to Part 50 operating licenses, the portion of the § 50.46c rule replacing the deterministic ECCS requirements in § 50.46c with technology neutral, and more risk-informed, performance-based regulatory requirements, addresses in part a petition for rulemaking (PRM-50-71) filed by the Nuclear Energy Institute (NEI), and in comments and public meetings the industry stakeholders have generally supported this aspect of the rulemaking. For the reasons stated earlier with respect to this portion of the final rule, the NRC believes that it is reasonable to conclude that the portion of the final rule accomplishing the requested action are not being “imposed” on the affected combined license applicants.

Alternatively, as discussed earlier with respect to this portion of the final rule, the NRC believes it is reasonable to conclude that the portion of the final rule (replacing the deterministic ECCS requirements in § 50.46 with technology neutral, and more risk-informed, performance-based requirements) as a practical matter does not represent a “changed” or “new” requirement as compared with the existing deterministic requirements in § 50.46. For these reasons, the NRC concludes that this portion of the final rule does not constitute an inconsistency with the issue finality provisions applicable to combined licenses in §§ 52.83 and 52.98.

With respect to the additional requirements in the final rule for consideration of crud, oxide layers, and post-quench cladding embrittlement, the NRC regards these portions of the final rule as new requirements which represent an inconsistency with the general issue finality provision applicable to standard design certifications in § 52.63, the issue finality provision included in each design certification rule at Section VI, “Issue Resolution,” of this document, and the issue finality provisions applicable to combined licenses in §§ 52.83 and 52.98. Accordingly, the NRC must explain why one or more of the criteria in these provisions which allow for an inconsistency violation of issue finality are met. As discussed earlier with respect to Part 50 operating licenses, the NRC believes that these portions of the final rule may be imposed as a change needed to provide reasonable assurance of adequate protection. Therefore, the NRC

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believes that the NRC has met the requirements in the applicable issue finality provisions for not according issue finality to the subject of ECCS performance under § 50.46c and GDC 35.

Future Combined License Applicants not referencing an existing standard design certification.

Imposing the final rule on future applicants for combined licenses under subpart C of 10 CFR part 52 who do *not* reference an existing standard design certification rule, would not constitute backfitting. Neither the Backfit Rule nor the finality provisions for combined licenses in §§ 52.83 or 52.98 protect either a current or prospective applicant for a combined license from changes in the NRC rules and regulations. The NRC has long adopted the position that the Backfit Rule does not protect current or prospective applicants from changes in NRC requirements or guidance because the policies underlying the Backfit Rule are largely inapplicable in the context of a current or future application. This position also applies to the issue finality provisions in part 52, *viz.*, §§ 52.83 and 52.98.

Existing Standard Design Certifications during their initial period of referencing².

The requirements of the final § 50.46c rule apply to the five existing standard design certification rules in appendices A through E to 10 CFR part 52, but only upon their renewal. The final rule does not require any action or change to the design certification during the initial period during which the design certification rule may be referenced. Hence, with respect to the period that the design certification may be referenced, the final rule does not directly result in any inconsistency with issue finality provisions applicable to design certifications in 10 CFR 52.69 as well as Paragraph VI. *Issue Resolution*, in each of this individual design certification rules in part 52, appendices A through E. However, the final § 50.46c rule requires any combined license applicant and holder referencing a design certification to comply with the § 50.46c rule. This raises issue finality concerns, which are addressed in the following

² The backfitting and issue finality discussion for existing standard design certifications at the time of renewal is addressed under the next heading, *Existing Standard Design Certifications at renewal*).

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discussion.

As discussed earlier with respect to Part 50 operating licenses, the portion of the rulemaking replacing the deterministic ECCS requirements in § 50.46c with technology neutral, and more risk-informed, performance-based regulatory requirements, addresses in part a petition for rulemaking (PRM-50-71) filed by the Nuclear Energy Institute (NEI), and in comments and public meetings the industry stakeholders have generally supported this aspect of the rulemaking. For the reasons stated earlier with respect to this portion of the final rule, these rule provisions are not being “imposed” on the affected combined license holders. Alternatively, also as described earlier, the NRC believes it is reasonable to conclude that this portion of the final rule (replacing the deterministic ECCS requirements in § 50.46 with technology neutral, and more risk-informed, performance-based requirements) as a practical matter does not represent a “changed” or “new” requirement as compared with the existing deterministic requirements in § 50.46. For these reasons, the NRC concludes that this portion of the final rule does not constitute an inconsistency with the issue finality provisions applicable to combined licenses in §§ 52.83 and 52.98.

With respect to the new ECCS evaluation requirements in the final § 50.46c rule (*i.e.*, the requirements addressing burn-up related phenomena, corrosion related phenomena, fabrication related phenomena, debris consideration, long term cooling regulatory acceptance criteria, and consideration of crud and oxide), the NRC has determined that imposition of these requirements on combined licenses referencing one of the five existing design certification rules is needed for adequate protection. The NRC’s discussion in this regard is set forth above under the heading, Combined License Applicants. Therefore, the NRC believes that the NRC has met the requirements in the applicable issue finality provisions for not according issue finality to these new ECCS evaluation requirements.

Existing Standard Design Certifications at renewal.

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The final rule requires the five existing design certifications, no later than their renewal³, to comply with § 50.46c. With respect to the new ECCS evaluation requirements in the final § 50.46c rule (*i.e.*, the requirements addressing burn-up related phenomena, corrosion related phenomena, fabrication related phenomena, debris consideration, long term cooling regulatory acceptance criteria, and consideration of crud and oxide), the NRC has determined that imposition of these requirements on those design certifications entities effectively constitutes a inconsistency with the general issue finality provision applicable to standard design certifications in § 52.63 and the issue finality provision included in each design certification rule. Accordingly, the NRC must explain why one or more of the criteria in these provisions which allow for an inconsistency violation of issue finality are met.

As discussed earlier, the NRC concludes that these new requirements involve reasonable assurance of adequate protection with respect to ECCS performance. Therefore, the NRC determines that these requirements may be imposed at renewal of the existing design certifications under the issue finality provisions in § 52.59(b)(1).

Future Standard Design Certifications.

Imposing the requirements of § 50.46c on current and future applicants for standard design certification rules would not constitute backfitting. Neither the Backfit Rule nor the finality provisions for final design certification rules in § 52.63 protect either a current or prospective applicant for a standard design certification rule from changes in the NRC rules and regulations.

Current and Future Applicants for Standard Design Certifications

Imposing the requirements of § 50.46c on current and future applicants for standard design certification rules would not constitute backfitting. Neither the Backfit Rule nor the issue finality provisions for final design certification rules in § 52.63 protect either a current or

³ The NRC expect the final 50.46c rule to be effective prior to completion of NRC action on the current applications for renewal of the ABWR standard design certification rule in 10 CFR part 52, appendix A from GE-H and Toshiba.

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prospective applicant for a standard design certification rule from changes in the NRC rules and regulations.

Standard Design Approvals

The NRC is not imposing the requirements of the final rule on current standard design approvals. Under the original 10 CFR part 52 (54 FR 15372; April 18, 1989), a standard design approval was a prerequisite for a standard design certification rule, see 10 CFR 52.43(c)(1990). This requirement was removed from the NRC's regulations as part of the 2007 amendments to part 52. 72 FR 49352 (August 28, 2007), at 49442. At this time, there is only XX standard design approvals in effect, ~~XXXXXXXXXXXX~~ <STAFF to INSERT INFORMATION>. No standard design approval has ever been used apart from being referenced in an application for a standard design approval. It does not appear that any existing standard design approval will be used in the future. To require holders of the existing standard design approvals to update the standard design approvals to address the final rule's new requirements on post-quench cladding ductility would represent an unnecessary burden on existing holders of standard design approvals, given that these standard design approvals would unlikely to be used in the future. For these reasons, the final rule does not apply to existing standard design approvals. Accordingly, the NRC concludes that the final rule does not contain any provisions representing backfitting or a violation of the issue finality provision for existing standard design approvals in § 52.145.

Imposing the requirements of the final rule on current and future applicants for standard design approvals would not constitute backfitting or represent an inconsistency of the issue finality provisions in § 52.145. Neither the Backfit Rule nor the finality provisions for standard design approvals in § 52.145 protect either a current or prospective applicant for a standard design approval from changes in the NRC rules and regulations.

Manufacturing Licenses.

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Imposing the requirements of § 50.46c on manufacturing licenses would not constitute backfitting. The NRC has not issued any manufacturing licenses under 10 CFR part 52, and neither the Backfit Rule nor the finality provisions for manufacturing licenses in § 52.171 protect a prospective manufacturing applicant from changes in the NRC rules and regulations.

B. Regulatory Guides.

The NRC is issuing four regulatory guides supporting implementation of § 50.46c. Three of the regulatory guides provide guidance on compliance with requirements in the final rule on burn-up phenomena, corrosion-related phenomena, and fabrication-related phenomena. These three regulatory guides are RG 1.222, “Measuring Breakaway Oxidation Behavior” (ADAMS Accession No. **MLXXXXXXXXXX**); RG 1.223, “Determining Post Quench Ductility” (ADAMS Accession No. **MLXXXXXXXXXX**); and RG 1.224, “Establishing Analytical Limits for Zirconium-Alloy Cladding Material” (ADAMS Accession No. **MLXXXXXXXXXX**). The fourth regulatory guide provides guidance on the voluntary alternative for addressing the effects of debris on long-term cooling using a risk-informed approach. This regulatory guide is RG 1.229, “Risk-Informed Approach for Addressing the Effects of Debris on Post Accident Long-Term Core Cooling,” (ADAMS Accession No. **MLXXXXXXXXXX**).

The first issuance of new guidance on a new rule provision does not constitute backfitting, inasmuch as: i) the guidance on the new rule provision must be consistent with the regulatory requirements in the new rule provision; and ii) the backfitting basis for the new rule provision is applicable to the issuance of guidance on that new rule provision (absent new or changed guidance not relevant and necessary to implement the new rule provision).

All four new regulatory guides are limited to providing guidance on the new provisions of §50.46c. Therefore, the backfitting and issue finality considerations associated with the issuance of four new regulatory guides already been addressed by the backfitting discussion on the final § 50.46c rulemaking. The four regulatory guides do not include additional “changed” or

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“new” guidance which are not needed to implement the new provisions of § 50.46c.

Furthermore, with respect to the fourth regulatory guide providing guidance on the risk-informed alternative, the underlying regulatory provision (paragraph (e) of 10 CFR 50.46c) is a voluntary alternative and does not constitute backfitting or an inconsistency with any applicable issue finality provision.

For these reasons, the issuance of the four regulatory guides in final form does not constitute backfitting or an inconsistency with issue finality provisions requiring independent NRC consideration of backfitting and issue finality separate from the NRC’s backfitting and issue finality consideration for the final § 50.46c rulemaking.