RULEMAKING ISSUE
(AFFIRMATION)

March 16, 2016 SECY-16-0033

FOR: The Commissioners

FROM: Victor M. McCree
Executive Director for Operations

SUBJECT: DRAFT FINAL RULE – PERFORMANCE-BASED EMERGENCY CORE COOLING SYSTEM REQUIREMENTS AND RELATED FUEL CLADDING ACCEPTANCE CRITERIA (RIN 3150-AH42)

PURPOSE:

To obtain Commission approval to publish a final rule (final rule) that amends the U.S. Nuclear Regulatory Commission's (NRC) current requirements governing emergency core cooling systems (ECCS), which are set forth in § 50.46 of Title 10 of the *Code of Federal Regulations* (10 CFR). This paper does not address any new commitments or resource implications.

SUMMARY:

The NRC staff has prepared a final rule (enclosure 1) that replaces (in a structured manner) the current requirements for ECCS, found in 10 CFR 50.46, by establishing performance-based requirements. The final rule incorporates recent research findings that identified previously unknown cladding embrittlement mechanisms and expanded the NRC's knowledge of previously identified mechanisms. The final rule also expands applicability of ECCS acceptance criteria to all light water reactors, regardless of fuel design or cladding materials (this requirement addresses petition for rulemaking (PRM) PRM-50-71). Additionally, the final rule requires licensees to evaluate the thermal effects of crud and oxide layers that may have developed on the fuel cladding during normal operation (this requirement addresses PRM-50-84).

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Finally, the final rule allows licensees to use a risk-informed alternative to address the effects of debris in the long-term (this addresses Commission direction in the January 7, 2013, Staff Requirements Memorandum (SRM)-SECY-12-0034, "Proposed Rulemaking – 10 CFR 50.46c: Emergency Core Cooling System Performance during Loss-of-Coolant Accidents (RIN 3150-AH42), (Accession No. ML13007A478 in the NRC's Agencywide Document Access and Management System (ADAMS)).

The NRC research program identified that zirconium-based fuel cladding materials may be subject to embrittlement at a lower combination of temperature and level of oxygen absorption than allowed under the current regulations due to absorption of hydrogen during normal operation. Therefore, under the current regulations, post-quench ductility (which is necessary to ensure coolable core geometry)[1] is not assured following a postulated loss-of-coolant accident (LOCA). The portion of the final rule addressing post-quench ductility is necessary to ensure adequate protection of the public health and safety. The final rule effectively maintains reasonable assurance of adequate protection that the NRC thought was achieved (throughout the entire term of licensed operation) by the current regulations, but new research shows is not necessarily the case. The other portions of the final rule - establishing technology-neutral, performance-based and risk-informed requirements for ECCS and the fuel system - replace the current deterministic requirements. The current deterministic requirements are considered to be necessary for adequate protection.[2] Therefore, the new 10 CFR 50.46c requirements, which replace the older deterministic requirements and establish the risk-informed alternative are intended to be regarded as adequate protection, in as much as they are intended to provide the same level of protection to public health and safety albeit in a different manner (technology-neutral/performance based, and risk-informed, respectively). Finally, the portion of the final rule that sets forth a voluntary alternative for risk-informed consideration of debris during long-term cooling addresses a matter of adequate protection. For these reasons, the final rule is described as addressing adequate protection to the health and safety of the public; accordingly, a backfit analysis need not be prepared under the adequate protection exception in 10 CFR Part 50.109(a)(4)(ii). In addition, the applicability and implementation approach as applied to 10 CFR Part 52 licenses and regulatory approvals is such that there is no violation or inconsistency with any issue finality provision in 10 CFR Part 52. This is consistent with past Commission direction on this rulemaking in SRM-SECY-12-0034.

BACKGROUND:

In SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR Part 50 – 'Domestic Licensing of Production and Utilization Facilities,'" dated December 23, 1998 (ADAMS Accession No.

[1] The Commission concluded, as part of the 1973 ECCS rulemaking, that retention of ductility in the zircaloy cladding material was determined to be the best guarantee of it remaining intact during the hypothetical LOCA, thereby maintaining a coolable core geometry. *See Acceptance Criteria for Emergency Core Cooling Systems for Light-Water-Cooled Nuclear Power Reactors,* CLI-73-39, *at page 1098* (December 28, 1973).

[2] As the NRC staff discussed in Attachment 3 to SECY-13-0132, "U.S. Nuclear Regulatory Commission Staff Recommendation for the Disposition of Recommendation 1 of the Near-Term Task Force Report," dated December 11, 2013 (ADAMS Accession No. ML13277A413) many of the NRC's technical safety requirements were adopted without a clear statement as to their character as needed for adequate protection, or adopted as a safety enhancement. The ECCS requirements in 10 CFR Part 50.46, originally adopted in an on-the-record rulemaking in 1974, are an example where one can strongly infer that the regulation was regarded as an adequate protection measure, but where no express Atomic Energy Commission (predecessor to the NRC) statement to that effect can be identified in the rulemaking record.

ML992870048), the NRC began to explore approaches to risk-informing its regulations for nuclear power reactors. The industry identified two regulations that would benefit from risk-informed changes: 10 CFR 50.44 (on control of combustible gases) and 10 CFR 50.46 (on emergency core cooling). In the SRM to SECY-02-0057, "Update to SECY-01-0133, 'Fourth Status Report on Study of Risk-Informed Changes to the Technical Requirements of 10 CFR Part 50 (Option 3) and Recommendations on Risk-Informed Changes to 10 CFR 50.46 (ECCS Acceptance Criteria),'" dated March 23, 2003 (ADAMS Accession No. ML030910476), the Commission directed the NRC staff to move forward to risk-inform its regulations in a number of specific areas. Included in this SRM was the direction to the staff to modify the ECCS acceptance criteria to provide for a performance-based approach to meeting the ECCS requirements in 10 CFR 50.46.

Additionally, on March 14, 2000, as amended on April 12, 2000, the Nuclear Energy Institute (NEI) submitted a PRM (ADAMS Accession No. ML010880245), docketed as PRM-50-71 (65 FR 34599, dated May 31, 2000), requesting that the NRC amend its regulations in 10 CFR 50.44 and 50.46 to expand the applicability of these regulations beyond the two zirconium-based fuel claddings identified in the regulations (zircaloy and ZIRLO™). The petition noted that these two regulations apply only to zircaloy and ZIRLO™, but that reactor fuel vendors had developed new cladding materials other than the two acknowledged by the regulations, and that in order for licensees to use these new materials under the existing regulations, licensees had to request NRC approval of exemptions from 10 CFR 50.44[3] and 50.46.

Separately from the Commission's efforts to modify its regulations to provide a more risk-informed, performance-based regulatory approach, the NRC had also undertaken a fuel cladding research program intended to investigate the behavior of high exposure fuel cladding under accident conditions. The effects of both alloy composition and fuel burnup (the extent to which fuel is used in a reactor) on cladding embrittlement (i.e., loss of ductility) under accident conditions were studied in this research program. The research identified new cladding embrittlement mechanisms and expanded the NRC's knowledge of previously identified mechanisms. One of the major findings of the research program was that hydrogen, which is absorbed in the cladding during normal operation, has a significant influence on the embrittlement during a postulated LOCA. The research findings have been summarized in Research Information Letter (RIL) 0801, "Technical Basis for Revision of Embrittlement Criteria in 10 CFR 50.46" (ADAMS Accession No. ML081350225).

On March 15, 2007, Mr. Mark Leyse submitted a PRM to the NRC (PRM-50-84, ADAMS Accession No. ML070871368). The petitioner requested rulemaking in three specific areas, including the consideration of the thermal effects of crud and oxide layers and the inclusion of a maximum allowable percentage of hydrogen content in [fuel rod] cladding. A notice of receipt for the petition was published in the *Federal Register* on May 12, 2007 (72 FR 28902), and public comments were requested. After evaluating the public comments, the NRC resolved the petition by deciding that each of the petitioner's issues should be considered in the rulemaking process. This decision was published in the *Federal Register* on November 25, 2008 (73 FR 71564).

[3] On September 18, 2003, (68 FR 54123) the NRC amended 10 CFR 50.44 to remove the terms "zircaloy" and "ZIRLO™" in response the concern raised in PRM-50-71.

The technical basis for this rulemaking was published for public comment in the *Federal Register* on July 31, 2008 (73 FR 44778). Comments received can be found at http://www.regulations.gov by searching on Docket ID NRC-2008-0332. On August 13, 2009, the NRC published an Advance Notice of Proposed Rulemaking (ANPR). The NRC received a total of 19 comment submissions during the ANPR's public comment period. As a result of these comments, the NRC made a number of changes to the daft final rule and provided the proposed rule to the Commission for vote in SECY-12-0034. The Commission approved publication of the proposed rule and provided additional direction on January 7, 2013.

Of note, the staff was directed to include in the proposed rule a provision that allows NRC licensees, on a case-by-case basis, to use risk-informed alternatives to assess the impact of debris on long-term core cooling. This would allow some licensees to use risk-informed approaches to address Generic Safety Issue (GSI)-191, "Assessment of Debris Accumulation on Pressurized-Water Reactor Sump Performance" (ADAMS Accession No. ML022410135) without the need for exemptions from 10 CFR 50.46 or the general design criteria (GDC) that pertain to ECCS and containment spray performance (i.e., GDCs 35, 38, and 41).

On March 24, 2014, the NRC published the proposed rule and three associated draft regulatory guides for comment (79 FR 16106). These draft regulatory guides (DG) were as follows: 1) "Conducting Periodic Testing for Breakaway Oxidation Behavior" (ADAMS Accession No. ML110840089); 2) "Testing for Post-Quench Ductility" (ADAMS Accession No. ML110840283); and 3) "Establishing Analytical Limits for Zirconium-Based Alloy Cladding" (ADAMS Accession No. ML110871607). The draft guidance for implementing a risk-informed alternative, "Alternate Risk-Informed Approach for Addressing the Effects of Debris on Post-Accident Long-Term Cooling" (ADAMS Accession No. ML15023A022) was published for comment on April 20, 2015, (75 FR 21658) concurrent with the final rule (per Commission's approval). The staff developed this guidance in parallel with its review of the South Texas Project pilot which was approved in SRM-SECY-12-0093, "Closure Options for Generic Safety Issue - 191, Assessment of Debris Accumulation on Pressurized-Water Reactor Sump Performance."

The public comment periods for the proposed rule and three draft regulatory guides provided interested stakeholders an opportunity to comment on the draft preliminary provisions under consideration by the NRC. In addition, the NRC sought comment on 12 specific questions. The comment period was originally 75 days and was subsequently expanded to 150 days in response to multiple extension requests. The comment periods for the proposed rule and three draft regulatory guides closed on August 21, 2015. The NRC received 36 comment submissions; 17 were from private citizens, and 19 were from the nuclear industry. Enclosure 2 provides a detailed breakdown and analysis of the comments. In response to public comments, the staff held 4 additional public meetings to facilitate NRC resolution of the comments. A list of the key public meetings that the NRC staff conducted throughout this rulemaking is provided in ADAMS under Accession No. ML16011A007.

DISCUSSION:

The final rule establishes a performance-based rule governing ECCS performance for light water nuclear power reactors (LWR), regardless of fuel design or cladding material. This represents a significant change from the current ECCS regulations, which apply to "uranium oxide pellets within cylindrical zircaloy or ZIRLO™ cladding." Because ECCS requirements must be expressed independent of fuel type, and because ECCS performance ultimately must

be based upon maintaining the fuel used in a safe (analyzed) condition, the new final rule separates the ECCS requirements from the need for the applicant/licensee to establish the *fuel system design performance criteria* constituting a safe condition.

The following table provides a summary of the major changes from 10 CFR 50.46 to the final 10 CFR 50.46c; these changes are further discussed in the text below.

Category	Item	§ 50.46	§ 50.46c
Overall ECCS Methodology	Rule Structure	Prescriptive	Performance-Based
	Applicability	Zircaloy or ZIRLO Cladding	All LWR Cladding
	Burnup Related Phenomena	None	Cladding Inner Surface Oxygen Ingress
	Corrosion Related Phenomena	None	Hydrogen-Enhanced Embrittlement
	Fabrication Related Phenomena	None	Breakaway Oxidation
	Debris Consideration	Implicit	Explicit
	LTC Regulatory Criteria	General	Explicit
	Crud Treatment	None	Explicit
Risk-Informed Alternative to Address the Effects of Debris on Long-Term Cooling	Risk-informed Debris Treatment	N/A	Allowed

In the final rule, the specified performance objectives of the systems, structures, and components of the ECCS are to provide residual heat removal during and following a postulated LOCA. As with the current regulations, the proposed rule requires demonstrating adequate ECCS performance using acceptable evaluation models. Specific performance objectives and analytical limits, which account for recent research findings, have been established for fuel designs consisting of uranium oxide or mixed uranium-plutonium oxide pellets within zirconium cladding alloys. For other fuel designs, new performance objectives and analytical limits may be necessary. Such objectives and limits need to take into consideration all degradation mechanisms and any unique performance features of the particular fuel system. Additionally, the final rule provides a provision that allows an entity[4] to use a risk-informed approach to address the effects of debris on long-term cooling.

The final rule follows the general regulatory approach of the existing regulations, yet it establishes non-prescriptive, performance-based regulatory requirements for demonstrating

[4] "Entity" refers to holders of licenses, applicants for licenses, and applicants for standard design certification rules (including such applicants after NRC issuance of a final standard design certification rules), as described in paragraph (a), *Applicability*, of the draft final rule.

acceptable ECCS performance and determining the fuel performance characteristics. In addition, the regulatory approach in the current regulations for fuel with zirconium-based cladding, to define acceptance criteria for each degradation mechanism, continues to be acceptable (although the set of criteria is incomplete, as discussed below). Therefore, the final rule retains the existing acceptance criteria (located in § 50.46(b)(1) through (3)) for fuel with zirconium-based cladding, including the 2200 °F peak cladding temperature limit as well as limitations on core-wide oxidation and hydrogen generation.

Applicability and NEI PRM

The final rule is applicable to applicants for and holders of construction permits, operating licenses, combined licenses and standard design approvals and for applicants for certified designs and for manufacturing licenses. The only exception to the applicability of the final rule is for any licensee that has submitted certifications for permanent cessation of operations and permanent removal of fuel from the reactor vessel, in accordance with 10 CFR 50.82(a)(1) or 52.11(a)(1).

The final rule also expands the applicability of the rule and addresses PRM-50-71 submitted by NEI in 2000 by removing the terms “zircaloy” and “ZIRLO™” from 10 CFR 50.46. This eliminates the need for a licensee to seek an exemption to use cladding alloys other than zircaloy or ZIRLO™, thereby facilitating the introduction of advanced zirconium-based alloy claddings.

The applicability of this final rule is largely unchanged from the proposed rule stage, but has been revised to clarify that the rule applies to certain applicants, and applies to renewed 10 CFR Part 50 operating licenses, renewed 10 CFR Part 52 combined licenses, and renewed manufacturing licenses.

ECCS Performance Criteria

The current ECCS rule is specific to uranium oxide pellets within cylindrical zircaloy or ZIRLO™ cladding and therefore, the current rule does not provide specific performance objectives for the ECCS. In the final rule, the specified performance objectives of the systems, structures, and components of the ECCS are to provide residual heat removal during and following a postulated LOCA. This aspect of the final rule is unchanged from the proposed rule stage.

Zirconium-clad Uranium Fuel Assemblies

The existing ECCS performance rule applies specifically to uranium oxide pellets within cylindrical zircaloy or ZIRLO™ cladding. The existing rule also requires, among other things, that (1) the peak cladding temperature remain below 2200 °F, and (2) the calculated total oxidation of the cladding nowhere exceed 17 percent of the total cladding thickness before oxidation. The latter requirement was established to prevent cladding embrittlement. Although the findings from the fuel cladding research program confirmed that the peak cladding temperatures should remain below 2200 °F, the findings also showed that more highly exposed fuel can embrittle at total calculated oxidation levels less than 17 percent. In the final rule, the objectives and methodology for evaluating ECCS performance for uranium oxide or mixed uranium-plutonium oxide pellets within cylindrical zirconium-alloy cladding remain largely the same as the existing ECCS performance regulations. However, the criteria in the existing

ECCS performance regulations are technically appropriate only to zirconium-based cladding. The final rule provides a technology-neutral, performance-based approach for developing design-specific criteria which account for the effects of exposure.

Implementation Guidance

The staff will publish four regulatory guides (RGs) concurrent with the publication of the final rule. The three RGs associated with fuel performance are RG 1.222, "Measuring Breakaway Oxidation Behavior," (ADAMS Accession No. ML15238B044), RG 1.223, "Determining Post Quench Ductility," (ADAMS Accession No. ML15238B079) and RG 1.224, "Establishing Analytical Limits for Zirconium-Alloy Cladding Material" (ADAMS Accession No. ML15238B155). The comment responses for these three RGs, which are associated with new fuel-related requirements, are included in the comment response document for the final rule (enclosure 2). The comment responses for the fourth RG on the risk-informed alternative, RG 1.229, "Risk Informed Approach for Addressing the Effects of Debris on Post-Accident Long-Term Core Cooling," (ADAMS Accession No. ML15252A125), will be provided in a separate document that will be published by June 2016.

Post-Quench Ductility Performance Requirement

For uranium oxide or mixed uranium-plutonium oxide pellets within cylindrical zirconium-alloy cladding, the final rule requires analytical limits for peak cladding temperature and integral time-at-temperature to be developed that account for the effects of exposure. The RG 1.223, "Determining Post Quench Ductility," was developed to provide a test method to measure embrittlement behavior for zirconium alloys. The RG 1.224, "Establishing Analytical Limits for Zirconium-Alloy Cladding Material," was developed to provide a method for using test data to develop and support analytical limits for peak cladding temperature and integral time-at-temperature that account for the effects of exposure. This requirement is substantively unchanged from the proposed rule. There were few comments on this part of the proposed rule, and no changes were made to the rule or associated RGs as a result of these comments.

Breakaway Oxidation Performance Requirement

The findings of the NRC's fuel cladding research program also developed significant understanding of a phenomenon termed "breakaway oxidation" which is not addressed with the existing ECCS performance regulations. The final rule requires an analytical limit to prevent breakaway oxidation under postulated LOCA conditions. This requirement, along with a periodic test requirement, would confirm that slight composition changes or manufacturing changes have not inadvertently altered the cladding's susceptibility to oxidation. The RG 1.222, "Measuring Breakaway Oxidation Behavior," was developed to provide a test method for measuring breakaway oxidation behavior. The requirement to establish a breakaway oxidation analytical limit has not changed from the proposed rule; however, the testing and reporting requirements have changed. In the proposed rule, there was a requirement to report the results of periodic testing to the NRC on an annual basis. In the *Federal Register* notice (FRN) for the proposed rule, the NRC requested comment on the type of data that should be reported and the required frequency of testing for breakaway oxidation. The NRC received many comments on this part of the proposed rule. The commenters generally expressed views that the sample frequency should be reduced and be more flexible. The NRC agreed that the objective of the rule can be achieved with rule language that requires a fuel vendor to submit breakaway

oxidation testing program for NRC review and approval and that the requirement for licensees to report breakaway oxidation results could be removed. The NRC changed the rule and the RG as a result of these comments.

Applicability of Ductility-Based Analytical Limits in the Rupture Region

During a postulated LOCA, fuel rods may be predicted to balloon and rupture as a result of elevated cladding temperature and differential pressure (i.e., difference between rod internal pressure and system pressure, which is decreasing due to a break in the reactor coolant pressure boundary). Although it is typical for undistorted fuel rods to undergo oxygen diffusion embrittlement under LOCA conditions, a ballooned or ruptured section of a fuel rod may experience additional degradation mechanisms. These mechanisms include significant amounts of hydrogen uptake from steam entering the fuel rod through the rupture. The RG 1.223 developed to support implementation of this performance-based rule, provides a test method to measure embrittlement behavior for zirconium alloys that uses uniform, unflawed cladding segments, and these measurements may not fully represent the region of the fuel rod surrounding the cladding rupture. Furthermore, the overall goal of preserving cladding ductility may not apply to ballooned or ruptured fuel, which may contain non-uniform distributions of flaws, cladding thickness, hydrogen distribution, and oxidation levels.

The current rule explicitly prescribes how to calculate the equivalent cladding reacted in ballooned and ruptured regions of fuel rods. In the proposed rule, this prescription was removed from the final rule language. The NRC developed RG 1.224 to describe an acceptable approach for evaluating post-quench ductility for the ballooned region. The NRC did not receive any comments on this part of the proposed rule. Therefore, this approach is reflected in the final rule and final RG.

Long-Term Cooling Performance Requirement

The final rule requires entities to demonstrate that the long-term ECCS recirculation coolant delivery to the core exceeds the minimum flow necessary to remove decay heat loads such that core temperature tends to decline, or for cases where debris loading interferes with coolant delivery and prompts a post-quench reheat transient, the entity must demonstrate that no further fuel cladding failure occurs. If an entity predicts a debris-induced, post-quench reheat transient that could reasonably result in further cladding failure, the entity would need to conduct research on post-quench fuel specimens. The purpose of the additional research would be to: (1) identify all degradation mechanisms, all cladding failure modes, and any unique features of fuel rod performance during the predicted long-term temperature history and, (2) establish analytical limits and analytical requirements that demonstrate no further fuel cladding failure occurs.

The final rule requirement regarding long-term cooling (LTC) has evolved relative to the proposed rule. The proposed rule introduced a new requirement in 10 CFR 50.46c (g)(1)(v) be established, based upon an approved NRC test program which will preserve cladding ductility. In the proposed rule package, the NRC requested input regarding this new performance requirement to determine (1) if cladding ductility was the most suitable performance-based metric, (2) if peak cladding temperature was the most suitable analytical limit, and (3) if a technical bases existed for long-term cladding performance. No commenter supported the proposed new requirement. Several commenters questioned whether cladding ductility was the most appropriate performance-based metric. These commenters noted that different cladding

degradation mechanisms may exist at different post-quench temperature regimes. Several commenters questioned the use of a single analytical limit on peak cladding temperature noting that time-at-temperature may be more appropriate to capture the degradation mechanisms. No commenter identified an existing technical basis for long-term, post-quench fuel performance. Several commenters requested that the existing 10 CFR 50.46 rule language be maintained. In the absence of a debris-induced post-quench reheat transient, the staff has determined that (1) currently approved analytical models and methods continue to be acceptable and (2) no further fuel testing and analysis is required to satisfy the more explicit performance requirement discussed in enclosure 1.

Crud and Oxide Layer Analytical Requirement

The final rule addresses PRM-50-84 submitted by Mr. Mark Leyse by requiring, in explicit terms, licensees to evaluate the thermal effects of crud and oxide layers that accumulate on the fuel cladding during plant operation. This requirement remains unchanged from the proposed rule.

Reporting and Corrective Action Requirements

The final rule clarifies the existing reporting and corrective action requirements in order to resolve recurring issues involving the interpretation of the current regulatory requirements. The final rule distinguishes three possible combinations of reporting criteria based upon predicted response, level of significance (i.e., significant or not significant, as defined by the proposed rule), and whether the error, change or operation would result in any exceeded acceptance criteria. For each scenario, the proposed rule provides the required actions, reports, and a time frame for providing the necessary reports. Additionally, some of the requirements apply to all entities subject to 10 CFR 50.46c; others apply to those entities demonstrating acceptable long-term cooling using the alternative risk-informed approach. Section III, “Discussion: Requirements for ECCS Performance during LOCAs,” of enclosure 1 describes the three scenarios, and requirements for each, in detail.

Presently, the reporting requirements in 10 CFR 50.46(a)(3) require that licensees report changes to or errors in an ECCS evaluation model, or in the application of the evaluation model, and the estimated effect of the changes or errors on predicted peak cladding temperature. The final rule expands the definition of a significant change or error to include integral time-at-temperature. The NRC made this change to improve the content and communications of reports submitted to the NRC. The NRC also made this change to inform the staff’s response to future changes to or errors discovered in ECCS evaluation models, or in the applications thereof.

Many comments were received on the paragraph (m) of § 50.46(c) (Reporting, corrective actions, and updates). Based on these comments, the final rule was modified to improve clarity and allow 60 days for reporting significant errors or changes that do not cause acceptance criteria to be exceeded.

Risk-Informed Alternative to Address the Effects of Debris on Long-Term Cooling

The final rule contains a provision that allows licensees to use an alternative, risk-informed approach to evaluate the effects of debris on long-term cooling. Use of the alternative approach must be requested by a licensee and approved by the NRC. The final rule contains acceptance

criteria that apply to the risk-informed approach. The final rule also specifies the content required for applications requesting to implement the alternative approach. NRC approval of a risk-informed approach would allow the entity to exclude the effects of debris in its analysis of long-term cooling as required in paragraph (d)(1)(ii) of § 50.46c. However, it is not the NRC's intent that this approach be used to justify the introduction of debris sources during plant modifications or in new reactor designs. Therefore, in these cases the final rule requires that an entity demonstrate a significant safety or security issue that cannot be practicably addressed without the use of debris sources.

The NRC expects entities to minimize the introduction of additional debris sources during the design process. The NRC expects that this alternate risk-informed approach would be used to address GSI-191 Experimental Studies of Loss-of-Coolant-Accident-Generated Debris Accumulation and Head Loss with Emphasis on the Effects of Calcium Silicate Insulation (NUREG/CR-6874, LA-UR-04-1227) or other pre-existing debris issues. The final rule also requires the entity to justify there are no other means practicable to avoid the need for the use of materials which could become debris sources. Consideration of "other means" includes, but is not limited to, deterministic testing and analysis, minimizing or removing debris source material in the design phase, and encapsulation of potential debris sources.

Based on public comments, the staff revised the description of the risk-informed approach by reorganizing it for greater clarity, including an explicit requirement for a monitoring program, and adding a requirement for a quality assurance program.

On December 3, 2015, the NRC staff met with the Advisory Committee on Reactor Safeguards (ACRS). Subsequent to this meeting, the ACRS requested an additional subcommittee and full committee meeting to discuss Regulatory Guide 1.229, "Risk-Informed Approach for Addressing the Effects of Debris on Post-Accident Long-Term Core Cooling." These meetings have been scheduled for March 22, 2016, and April 7, 2016, respectively. Assuming that these meetings do not lead to significant changes to the regulatory guide, the staff expects to send RG 1.229 to the Commission by June 7, 2016, in accordance with the standard regulatory guide development process.

Non-concurrence Regarding the Risk-Informed Alternative

An NRC staff member expressed concerns regarding the scope and applicability of the risk-informed alternative in the final rule and submitted a non-concurrence (NCP-2015-010). The individual was concerned that the rule would allow the introduction of problematic insulation and other debris sources to new reactors or as a result of a modification to currently operating reactors. NRC management evaluated the concerns raised in the non-concurrence, agreed with the position in the non-concurrence, and directed that the final rule be changed to allow plant modifications and new reactors designs that introduce new debris sources *only* when they are needed to address a significant safety or security issue that cannot be practicably addressed by other means. Additional detailed discussion of the intent of this rule language was added to the statement of considerations in the *Federal Register* notice promulgating the rule. The non-concurrence package is provided for the Commission's information in enclosure 3. It includes a discussion of the resolution of the non-concurrence along with a description of the associated changes that were made to the final rule package.

Implementation Approach

The proposed 10 CFR 50.46c rule included a 3-track implementation plan with codified plant assignments. The goal of this proposed approach was to manage the workload with consideration of available ECCS performance margin and the anticipated work scope on both the agency and the industry, given the limited vendor resources. Comments received from the industry emphasized a desire for greater flexibility and identified an alternative plan, which eliminated the track assignments from the final rule. The staff held multiple public meetings on implementation to discuss the industry's plan and identify a strategy to manage the workload related to implementation on a defined schedule. As a result of these comments and public meetings, the staff revised this aspect of the rule language by requiring licensees to submit an implementation plan within 180 days of the effective date of the final rule. Schedule requirements have been established within the final rule for: (1) submitting a license amendment request documenting compliance and (2) complying with the final rule. Licensees must submit a license amendment request in accordance with their plant-specific implementation plan and no later than 60 months after the effective date of the final rule. Licensees must be in compliance with 10 CFR 50.46c no later than 84 months after the effective date of the final rule. This prolonged implementation period is justifiable based on the ECCS performance safety assessment that is being maintained by the staff, and which shows positive margin to the proposed regulations for each plant in the fleet. Additionally, the SOC clarifies resolution of debris issues (e.g., GSI-191), whether by deterministic or risk-informed approach, is being addressed outside of the 10 CFR 50.46c implementation schedule. The implementation provisions in paragraph (p) of the final rule have also been re-written and expanded to clarify the compliance path for each type of applicants, licensee and regulatory approval.

The organization and CFR designations of the NRC's requirements governing ECCS (currently in 10 CFR 50.46) and reactor cooling venting systems (currently in 10 CFR 50.46a) are subject to change as a result of: (1) multiple ongoing rulemaking activities; (2) the implementation schedule for those activities; and (3) the need to maintain the current requirements in place for those licensees that have not transitioned to the new requirements (following the implementation schedule provided in the final rule). A detailed description of the transition of CFR designations is provided in Section VI, "Section by Section Analysis," of the FRN for the draft final rule (enclosure 1).

Operating Plant Safety

In response to the research findings in RIL-0801 the NRC performed a preliminary safety assessment of currently operating reactors (ADAMS Accession Nos. ML081620302 (Proprietary), ML090340073 (Non-Proprietary)). This assessment found that, due to cladding performance measured during the NRC's LOCA research program, realistic fuel rod power history, and current analytical conservatisms, sufficient safety margin to the proposed new requirements exists for operating reactors. Therefore, the staff determined that immediate regulatory action was not required, and that changes to the ECCS acceptance criteria to account for these new findings can reasonably be addressed through the rulemaking process.

Recognizing that finalization and implementation of the new ECCS requirements would take several years, the staff decided that a more detailed safety assessment was necessary. As a voluntary industry effort and alternative to responding to an NRC request for information under 10 CFR 50.54(f), the Pressurized Water Reactor (PWR) Owners Group (OG) (ADAMS Accession No. ML11139A309) and Boiling Water Reactor Owners Group (BWROG) (ADAMS

Accession No. ML111950139), under the auspices of NEI, submitted ECCS margin assessment reports. After grouping plants based on similar design features, cladding alloys, or evaluation models and defining cladding alloy-specific analytical limits, the OG reports identified, where necessary, analytical credits or performed new LOCA analyses to demonstrate that the limiting plant within each grouping had positive margin relative to the proposed new requirements. The NRC conducted an audit of the OG reports and supporting General Electric – Hitachi, AREVA, and Westinghouse engineering calculations. Based on the OG reports and supplemental information collected during the audits, the staff was able to confirm and document, for every operating reactor, current safe operation. In other words, in the unlikely event that an actual LOCA had occurred at any operating reactor, there is a level of assurance that the ECCS would have performed in an acceptable manner (relative to the new requirements) and a coolable core geometry would have been maintained. This conclusion is partly based on analyses that may not contain the level of conservatism or precision inherent in currently approved models and methods.

As documented in the audit report and safety assessment ("ECCS Performance Safety Assessment and Audit Report," dated February 10, 2012 (ADAMS Accession No. ML12041A078)), the NRC intends to verify, on an annual basis, continued safe operation until each licensee has implemented the new ECCS requirements. Recent updates to the ECCS safety assessment are available in ADAMS under Accession Nos. ML14022A161 and ML14358A493.

While the updated safety assessment provides a level of assurance that no imminent safety hazard exists for operating reactors with respect to burn-up, corrosion and fabrication-related phenomena, applicants and licensees should be required by regulation to demonstrate acceptable ECCS performance with respect to those phenomena. Inclusion of the requirements in the regulation would: (i) be consistent with the NRC's longstanding regulatory approach of placing the burden on the applicants/licensees (and their vendors) to demonstrate that their licensed activities provide adequate protection, (ii) allow the NRC to discontinue updating the safety assessment with respect to the lack of imminent safety hazard, and (iii) provide regulatory transparency and stability, inasmuch as the regulation would expressly identify the three phenomena as safety matters which must be addressed.

Cumulative Effects of Regulation

The staff has fully engaged external stakeholders throughout this rulemaking, including the publication of an Advance Notice of Proposed Rulemaking (ANPR) on August 12, 2009 (74 FR 40767). The ANPR provided interested stakeholders an opportunity to comment on the options under consideration by the NRC during a formal, 75-day public comment period.

In developing the proposed § 50.46c rule, the NRC met with stakeholders related to possible implementation approaches for this rule. A 2-day public workshop was conducted on April 28-29, 2010, during which the draft proposed rule language staff responses to major comments on the ANPR were discussed. In addition, possible bases for an NRC confirmation of current plant safety pending a final rule were discussed. The summary of this public workshop can be found in ADAMS under Accession No. ML101300490.
The FRN for the proposed rule included a request for specific comment on the cost estimates provided in the Regulatory Analysis, implementation schedule, and potential unintended consequences of the proposed rule. The staff published three draft regulatory guides for public

comment together with the proposed rule. A fourth draft regulatory guide was later published for public comment, with a 75 day public comment period (80 FR 21658; April 20, 2015). The availability of these four draft regulatory guides for public comment meets the intent of SRM SECY-11-0032, "Consideration of the Cumulative Effects of Regulation in the Rulemaking Process," dated October 11, 2011 (ADAMS Accession No. ML112840466). The staff intends to publish the four regulatory guides in final form concurrent with the final rule.

After the close of the formal period for submission of public comments on the proposed rule, the NRC conducted six public meetings to continue dialogue with stakeholders on key issues, and facilitate development of the final rule. On March 17-19, 2015, the NRC conducted a public meeting to seek clarification regarding comments previously received on implementation and the regulatory analysis associated with the proposed rule. As a result of this public meeting, the NRC held a series of three follow-on public meetings to further discuss a draft preliminary implementation plan that would represent an alternative to that in the proposed rule. These follow-on meetings were held on April 23, 2015, May 7, 2015, and June 4, 2015. Additionally, on April 29-30, 2015, the NRC conducted a public meeting at Oak Ridge National Laboratory to discuss specific comments received on the DGs referenced above. On June 9, 2015, the NRC conducted a public meeting to discuss the long-term cooling provision in the proposed rule.

In addition to publishing the new regulatory guides, the staff has also identified existing guidance that may need to be updated to "conform" the guidance to the draft final requirements (e.g., to add references to specific paragraphs of the final rule, add new discussion which explain how the current rule's provisions and existing guidance relate to the new requirements in the final rule). The conforming changes, while they would be desirable to ensure that all guidance documents represent a complete, integrated set of guidance on ECCS requirements in 10 CFR §§ 50.46, 50.46a and 50.46c, are not needed to provide guidance to licensees on how to comply with the final rule. Because of the resources and scope of effort required to revise this guidance which is not needed to implement the final § 50.46c, the staff has determined that it would not be prudent to revise these supporting guides until the Commission has completed its review of the final rule and primary implementing guidance in the four regulatory guides.

Regulatory Analysis

The regulatory analysis for the proposed rule was substantially revised in response to public comments as well as ongoing NRC development of regulatory analyses, including reformulation of the alternatives, more detailed and quantitative consideration of costs and benefits, and more comprehensive discussion of uncertainties and sensitivities. To ensure that best available cost data is used, the NRC held several public meetings to collect industry cost estimates associated with implementing rule provisions and met separately with each fuel vendor in closed public meetings to collect commercially-sensitive cost data. The regulatory analysis for the final rule (enclosure 4) concludes that the final rule is cost beneficial from a quantitative standpoint (including considerations of uncertainties), and from a qualitative standpoint.

Fuel Fragmentation, Relocation, and Dispersal

The staff previously advised the Commission regarding fuel fragmentation, relocation, and dispersal phenomena in SECY-12-0034. In response to SRM-SECY-12-0034, the staff has recently provided the Commission with SECY-15-0148, "Evaluation of Fuel Fragmentation,

Relocation and Dispersal under LOCA Conditions Relative to the Draft Final Rule on Emergency Core Cooling System Performance during a LOCA (50.46c)," which explains the current status of NRC research on these phenomena and why this 10 CFR 50.46c rulemaking may proceed without concern that they will be revised based on the anticipated research.

Proposed Conditional Compliance Implementation Approach

In a February 25, 2016, letter to the NRC Chairman (ADAMS Accession No. ML16061A378), NEI requested that the Commission adopt a "conditional compliance schedule." Under NEI's proposal, a plant would be required to comply with 10 CFR 50.46c only if a plant change is made or error discovered requiring a "new Evaluation Model" attributable to, for example, a power uprate, a new fuel design, or changes or errors affecting peak cladding temperature. Although NEI's letter was received after the closure of the public comment period, the staff considered the proposal when finalizing the rule language. For reasons described further in Enclosure 7, the staff determined that it would not alter the implementation approach outlined in the enclosed final rule

RECOMMENDATIONS:

The NRC staff recommends that the Commission:

(1) Approve the enclosed rulemaking package and final rule (enclosure 1) for publication in the *Federal Register*.

(2) Note the following:

a. The final versions of the three fuel-related RGs supporting this rule have been made available to the Commission for information. A fourth RG on the risk-informed alternative and an associated public comment response document will be provided to the Commission by June 2016. The Commission is not being asked to approve the comment responses or the regulatory guides.

b. The staff will inform the appropriate congressional committees.

c. The Office of Public Affairs will issue a press release when the NRC publishes the final rule in the *Federal Register*.

COORDINATION:

The Office of the General Counsel has no legal objection to this SECY paper and rulemaking package.

Coordination with Advisory Committee on Reactor Safeguards

The NRC has met with the Advisory Committee on Reactor Safeguards (ACRS) 19 times since 2002 to discuss the progress of the LOCA research program and the subsequent rulemaking. Three of these meetings have been conducted with respect to the final rule package. A table listing the dates and ADAMS Accession Nos. of the relevant ACRS meetings and associated correspondence is located in ADAMS under Accession No. ML16011A007. The ACRS letter on the draft final rule is provided in enclosure 5. The NRC staff's response to the ACRS is provided in enclosure 6.

/RA/
Victor M. McCree
Executive Director
for Operations

Enclosures:
1. *Federal Register* notice
2. NRC Staff Responses to Public Comments on Proposed Rule and Three Associated Draft Regulatory Guides
3. Non-concurrence (NCP-2015-010)
4. Regulatory Analysis
5. ACRS letter
6. Staff response to ACRS letter
7. Staff evaluation of NEI letter

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A**DAMS Accession Nos.**: ML15238A947 (Pkg.); ML15238A933 (SECY); ML15238B016 (FRN); ML15238B193 (Public Comment Response Document on proposed rule); ML16028A388 (Non-concurrence NCP-2015-010); ML15323A122 (Reg. Analysis); ML16048A522 (ACRS letter); ML16040A213 (Staff response to ACRS letter); ML16070A197 (Staff evaluation of NEI letter) * via e-mail

OFFICE	NRR/DPR/PRBM:RS*	NRR/DPR/PRMB:PM	NRR/DSS*	NRR/DPR/PRMB:BC*	NRR/DPR
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DATE	9/4/2015	9/4/2015	9/9/2015	9/14/2015	9/24/2015
OFFICE	NRR/DSS:D	NRR/DRA: D*	NRO/DSRA:D*	RES/DSA:D	RES/DE:D
NAME	TMcGinty* ***(RTaylor for)***	JGiitter	JMonninger (***KWebber for)***	MCase*	BThomas
DATE	9/24/2015	9/24/2014	10/19/2015	9/24/2015	11/04/2015
OFFICE	OIS/IRSD: TL*	OE:D	NRO*	RES	Non-Concurrer
NAME	TDonnell ***(KBenney for)***	PHolahan ***(RFretz for)***	JUhle (***KWebber for)***	MWeber	SLaur*
DATE	01/19/2016	11/24/2015	11/24/2015	11/23/2015	2/11/2016
OFFICE	ADM/DAS/RADB*	OGC*	NRR	EDO	
NAME	CBladey	GMizuno/NLO	WDean	VMcCree	
DATE	11/24/2015	02/12/2016	02/15/2016	03/16/16	

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