From:	Paul Leonard
To:	RulemakingComments Resource
Subject:	Comments on Proposed 10 CFR 50.46c Rulemaking Docket ID NRC-2008-0332
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Attachments:	50 46c GSI-191 Language Comments Final 8-21-14.docx Cover Letter for FRN Comments 8-21-14.docx

Attached please find a cover letter and enclosure containing comments on the proposed rulemaking. The cover letter describes the extent of the FRN upon which comments were made and the associated comments.

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The Nuclear Regulatory Commission has published a proposed rule to amend the current requirements governing emergency core cooling systems, per Reference **Error! Reference source not found.**. Other minor revisions to Appendices A and K to Part 50, and to Part 52, are also required to reflect the proposed §50.46c. The proposed rule also includes change and error reporting requirements for the risk-informed approach, and an implementation plan. Finally, the proposed rule includes an alternate risk-informed approach for addressing the effects of debris on long-term cooling, which is an appropriate option for resolving GSI-191 and sump suction issues.

The purpose of this letter, which was prepared by the non-pilot plants pursuing risk-informed resolution of GSI-191, is to provide collective comments on the proposed §50.46c rule package. The objective of the comments is to obtain final rule language and regulatory guide(s) that will better serve both the industry and the NRC in the resolution of GSI-191.

The non-pilot plants have significant concerns with the current NRC wording in the draft rule, and changes are needed to avoid initial and long-term compliance issues that are both technical and an economic burden to the industry.

1. The definition of Debris evaluation model needs to be substantially modified to provide the necessary linking between the calculational framework and the plant PRA which ultimately determines that associated risk associated with debris.
2. The reporting requirements for the Debris evaluation model, and analysis changes and errors should be deleted from the rule. Existing reporting processes including Part 21, §50.72, and §50.73 are sufficient. The non-pilot plants endorse development of an NEI document on error/change reporting to be endorsed by NRC that would lead to standardization in the industry, similar to the §50.59 industry initiative that produced NEI-96-07.
3. There is ambiguity within the proposed rule language that makes it difficult to clearly understand which aspects of the proposed rule directly apply to the alternate risk-informed approach.

Consistency in the final rule language and the statement of considerations is essential to avoid future misinterpretations by both the regulator and the industry, and uncertainty in what constitutes compliance.

In addition to comments on the FRN, provided in Enclosure 1 of this document, it is also requested that NRC consider revision of RIS 2005-20 and associated inspection guidance to allow use of a licensed risk-informed approach for evaluation of non-conforming and degraded conditions, for those plants that are granted a license amendment for this approach.

Enclosure 1 contains those portions of the FRN that either directly apply to alternate risk-informed approach or could be interpreted as to having application to the risk-informed approach, and comments, where determined to be applicable.

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Part II

Nuclear Regulatory Commission

10 CFR Parts 50 and 52

Performance-Based Emergency Core Cooling Systems Cladding Acceptance Criteria; Proposed Rule

ITEM	FEDERAL REGISTER LANGUAGE	COMMENTS
	SUMMARY (16106)	
1	Further, the proposed rule contains a provision that would allow licensees to use an alternative risk-informed approach to evaluate the effects of debris for long- term cooling.	1) The language of the proposed rule should also allow BWRs to adopt an alternative risk-informed approach for resolution of debris issues.
2	**DATES:** Submit comments on the rule and draft guidance by June 9, 2014. To facilitate NRC review, please distinguish between comments submitted on the proposed rule and comments submitted on the draft guidance. Submit comments on the information collection aspects of this rule by April 23, 2014. Comments received after these dates will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after these dates.	No comments
	EXECUTIVE SUMMARY – *Purpose of the Regulatory Action* (16107)	
3	Finally, the proposed rule would allow individual nuclear power plant licensees to resolve GSI–191, ''Assessment of Debris Accumulation on PWR [Pressurized Water Reactor] Sump Performance,'' by using a risk-informed approach for evaluating the effects of debris on long-term cooling.	1) Since the BWRs are not currently required to resolve GSI-191, this paragraph should be revised to identify their specific circumstance and the effort being undertaken to address debris issues.
	EXECUTIVE SUMMARY – *Summary of the Significant Changes in the Proposed Rule* (16107	
4	The proposed rule contains a provision that would allow licensees to use an alternative risk-informed approach to evaluate the effects of debris for long-term cooling. The proposed rule contains acceptance criteria that would apply to the risk-informed approach and its required content. Additionally, the proposed rule would add reporting requirements that pertain to the risk-informed approach.	1) There are no comments on this specific language, but there are comments on the specific language in the rule.

EXECUTIVE SUMMARY – *Costs and Benefits* (16107)		
5	The benefits of the proposed rule are several. The proposed rule would result in savings by obviating the need for exemption requests to use additional claddings and exemption requests stemming from the risk-informed alternative. As a more general matter, adopting a performance-based approach to demonstrating ECCS adequacy may afford applicants and licensees greater flexibility in complying with the NRC's ECCS requirements. This may result in reduced applicant and licensee costs with no adverse effect on public health and safety.	1) The use of the word "may" in this paragraph suggests that the necessary rigor was not applied in performing a cost benefit analysis. 2) The proposed rule will afford greater flexibility for compliance.
II. BACKGROUND – *B. Generic Safety Issue (GSI)- 191 and Long-Term Cooling* (16108)		
6	As a result of evolving staff concerns related to the adequacy of PWR recirculation sump designs, the NRC opened Unresolved Safety Issue (USI) A–43, ''Containment Emergency Sump Performance.'' The resolution of USI A– 43 was subsequently documented in Generic Letter (GL) 1985–022, ''Potential for Loss of Post-LOCA Recirculation Capability Due to Insulation Debris Blockage,'' dated December 3, 1985 (ADAMS Accession No. ML031150731). The NRC staff found in GL 1985–022 that the 50 percent blockage assumption, identified in Regulatory Guide (RG) 1.82, ''Sumps for Emergency Core Cooling and Containment Spray Systems,'' Revision 0 (ADAMS Accession No. ML111680318), should be replaced with a more comprehensive requirement to assess debris effects on a plant-specific basis. Following the resolution of USI A–43, industry events at Barsebeck and Limerick Generating Station challenged the conclusion that no new requirements were necessary to prevent the clogging of ECCS strainers at operating boiling water reactors (BWR). As described in NRC Bulletin 95–02, ''Unexpected Clogging of a Residual Heat Removal (RHR) Pump Strainer While Operating in Suppression Pool Cooling Mode,'' dated October 7, 1995 (ADAMS Accession No. ML082490807), a safety relief valve at the Limerick Generating Station inadvertently opened and could not be closed, the plant was manually scrammed, and the RHR system was started in the suppression pool cooling mode to remove the heat added by the open relief valve. The A train of the RHR exhibited signs of pump cavitation and was secured. The B train of the RHR was started to remove the heat from the relief valve discharge. After the plant was stabilized, a diver inspected the pump suction strainers and found a mat of fibers and sludge covering them. The	1) The language of the proposed rule should also allow BWRs to adopt an alternative risk-informed approach for resolution of debris issues. 2) If this level of detail is necessary to describe the background for the PWRs, then additional information should also be provided to reflect the current status of the BWRs.

	licensee determined that the discharge from the relief valve did not contribute debris to the suppression pool. As described in NRC Bulletin 96–03, ‘‘Potential Plugging of Emergency Core Cooling Suction Strainers by Debris in Boiling-Water Reactors,’’ dated May 6, 1996 (ADAMS Accession No. ML082401219), a Swedish BWR, Barseback Unit 2, experienced plugging of two containment vessel spray system (CVSS) suction strainers. The strainers were partially plugged with mineral wool (a fibrous insulation) that was dislodged by a steam jet from an open pilot operated relief valve. The operators noticed an indication of high- differential pressure across the strainers and were able to back flush them to keep the CVSS operating. Also described in NRC Bulletin 96–03 are two ECCS suction strainer plugging events that occurred at the Perry Nuclear Power Plant, a BWR located in the United States. The first event resulted from general maintenance material and dirt in the suppression pool collecting on the RHR suction strainers. The differential pressure caused by the debris resulted in deformation of the suction strainers. After the suppression pool was cleaned and the suction strainers replaced, a second event occurred when several safety relief valves lifted. The RHR system was used to cool the suppression pool after the steam discharge. The suction strainers were inspected and found to be covered with fibrous debris and corrosion products. A test of the system found that the B train pump suction pressure dropped to zero. The fibrous debris originated from temporary drywell cooling filter media that was accidentally dropped into the suppression pool and not retrieved. The fibers created a filtering bed on which particles collected, resulting in a high- resistance debris bed. In response to these events, the NRC issued generic communications requesting that BWR licensees take appropriate actions to minimize the potential for the clogging of ECCS suction strainers by debris accumulation following a LOCA. The NRC staff concluded that all BWR licensees have sufficiently addressed these bulletins in a memorandum, ‘‘Completion of Staff Reviews of NRC Bulletin 96–03, ‘Potential Plugging of Emergency Core Cooling Suction Strainers by Debris in Boiling-Water Reactors,’ and NRC Bulletin 95–02, ‘Unexpected Clogging of a Residual Heat Removal (RHR) Pump Strainer While Operating in Suppression Pool Cooling Mode’,’’ dated October 18, 2001 (ADAMS Accession No. ML012970229).	

	The findings regarding BWR strainers prompted the NRC to open GSI–191, ''Assessment of Debris Accumulation on PWR Sump Performance,'' to ensure that post-accident debris effects would not impede long-term core cooling at PWRs. After completing its technical assessment of GSI–191, the NRC issued Bulletin 2003–01, ''Potential Impact of Debris Blockage on Emergency Sump Recirculation at Pressurized-Water Reactors,'' dated June 9, 2003 (ADAMS Accession No. ML031600259). This bulletin did not require licensees to immediately perform deterministic evaluations for debris effects, but requested that plants take compensatory measures to reduce risk or otherwise enhance the capability of the ECCS and containment spray system (CSS) recirculation functions. The bulletin also informed licensees that the staff was preparing a generic letter that would request that plants demonstrate through deterministic methods that long-term core cooling would not be compromised by debris effects. Generic Letter 2004–02, ''Potential Impact of Debris Blockage on Emergency Recirculation During Design Basis Accidents at Pressurized-Water Reactors,'' dated September 13, 2004 (ADAMS Accession No. ML042360586), was issued to all operating PWRs requesting that they perform a mechanistic evaluation of the effects of debris on the ECCS and CSS recirculation functions. The affected plants are currently working to address the issues identified by the generic letter. All operating PWRs have installed larger strainers and taken other actions toward the final resolution of the issue. Final closure of the generic letter has been delayed to allow industry and the NRC staff to develop appropriate methodologies for evaluation of debris related issues that were identified after the issuance of the generic letter. The staff generated two SECY papers on this issue to provide options and solicit feedback from the NRC Commissioners. On December 14, 2012, the Commission issued an SRM (ADAMS Accession No. ML12349A378) for SECY–12–0093, ''Closure Options for Generic Safety Issue—191, Assessment of Debris Accumulation on Pressurized-Water Reactor Sump Performance'' (ADAMS Accession No. ML121320270). In this SRM, the Commission directed the following: *The forthcoming § 50.46c proposed rulemaking should contain a provision allowing NRC licensees on a case-by-case basis, to use risk-informed alternatives. The license amendment process would be used to reconstitute the long-term core cooling licensing basis. Stakeholder*	

	comments should be solicited on the proposed provision. Consistent with this SRM, the proposed rule includes a provision that would allow licensees to use an alternative risk-informed approach to evaluate the effects of debris for long- term cooling.	
III. OPERATING PLANT SAFETY – *B. GSI-191 and Long-Term Core Cooling* (16111)		
7	Section II. B., "GSI–191 and Long-Term Cooling," of this document provides background information on GSI–191 and long-term cooling. That section includes information on action taken by the NRC and licensees to address the potential effects of debris on long-term cooling. These actions have contributed significantly to the safety of operating plants. The NRC staff provided information to the Commission in two SECY papers: SECY–10–0113, "Closure Options for Generic Safety Issue—191, Assessment of Debris Accumulation on Pressurized Water Reactor Sump Performance," dated August 26, 2010 (ADAMS Accession No. ML101820296); and SECY–12–0093, "Closure Options for Generic Safety Issue—191, Assessment of Debris Accumulation on Pressurized Water Reactor Sump Performance," dated July 9, 2012 (ADAMS Accession No. ML12130270). The Commission issued guidance for the closure of the issue in two SRMs associated with each SECY paper. The SRM to SECY–10–0113 ("Staff Requirements—SECY–10–0113— Closure Options for Generic Safety Issue—191, Assessment of Debris Accumulation on Pressurized Water Reactor Sump Performance" (ADAMS Accession No. ML103570354)) was issued on December 23, 2010. With respect to operating plant safety the SRM stated: *The staff should take the time needed to consider all options to a risk-informed, safety conscious resolution to GSI–191. While they have not fully resolved this issue, the measures taken thus far in response to the sump-clogging issue have contributed greatly to the safety of U.S. nuclear power plants. Given the vastly enlarged advanced strainers installed, compensatory measures already taken, and the low probability of challenging pipe breaks, adequate defense-in-depth is currently being maintained.* On December 14, 2012, the Commission issued the SRM to SECY–12–0093 (ADAMS Accession No. ML12349A378). With respect to operating plant safety, the SRM reiterated the direction in SRM–SECY–10–0113.	No comments

	As directed by the Commission, the NRC staff is currently working with licensees to assure adequate safety by closing the issue and updating their licensing bases to reflect full compliance on a schedule consistent with Commission direction.	
V. PROPOSED REQUIREMENTS FOR ECCS PERFORMANCE DURING LOCAs ***B. Performance-Based Aspects of the Proposed Rule*** (16118)		
8	*5. Long-Term Cooling* The current regulation in § 50.46(b)(5) requires that for long-term cooling the calculated core temperature be maintained at an acceptably low value following any calculated successful initial operation of the ECCS. It also requires that decay heat be removed for the extended period of time required by the long-lived radioactivity remaining in the core. The proposed rule would define a performance-based requirement to ensure acceptable fuel performance during long-term cooling. Specifically, the proposed rule would require that a specified and NRC-approved analytical limit on peak cladding temperature be established that corresponds to the measured ductile-to-brittle transition for the zirconium-based alloy cladding material based upon an NRC-approved experimental technique. It would also require that the calculated maximum fuel element temperature should not exceed the established analytical limit.	1) There needs to be additional clarity and definition as to which aspects of the proposed rule apply to licensees intending to implement the risk-informed approach for debris considerations. 2) Refer also to the comments on Item 69.
9	*6. Use of Risk-Informed Approaches to Address Debris for Long-Term Cooling* The proposed rule would allow all entities to use an alternative risk-informed approach to evaluate the effects of debris for long-term cooling. The adverse effects of debris on ECCS performance have been documented in the NRC's actions to resolve GSI–191, ''Assessment of Debris Accumulation on PWR Sump Performance.'' Debris may cause increased head loss across the ECCS and CSS pump suction strainer and restrict the flow of water to the ECCS and CSS pumps. Debris may also pass through the strainer and cause blockage of components or the core, or damage to components downstream of the strainer. For these reasons, the effects of debris on long-term ECCS cooling performance must be evaluated. However, the NRC believes that risk- informed methodologies have progressed to the point where the NRC may allow their use in considering the effects of debris on the adequacy of long-term ECCS	1) The 4th bullet, "Incorporate monitoring and performance measurement strategies" is not discussed in the proposed rule language. If this is to be a requirement (law), then there should be some discussion in the rule or to be published regulatory guide. We recommend that the discussion be contained in the proposed regulatory guide. 2) The statement, "The applicant would need to address the intent of the general design criteria (or similar licensing basis design criteria), national standards, and engineering principles (e.g., single failure criterion) in evaluating the impact of the alternative approach on defense-in-depth.", is not consistent with the language in the proposed rule. In fact, there is not similar language in the rule. The proposed changes to the Appendix A design criteria suggests that potential impacts on the design criteria and defense-in-depth from debris in the coolant are addressed by the results of the risk-informed

	cooling performance. The entity's application and the NRC's review and approval of the application will close that entity's required actions under GSI–191. For the purpose of § 50.46c provisions on the risk-informed alternative to long- term cooling, debris is material within containment that may be transported to the suction strainer(s) for the ECCS and CSS. Debris includes (but is not limited to) loose materials that may transport and materials that may be damaged by a LOCA jet to the extent that they become transportable. Debris sources of interest typically include insulation, coatings, dust, dirt, concrete, fire barrier material, signs and tags, and materials left in containment; however, debris may originate from other sources. Debris may also result from chemical interactions that cause precipitation of materials. Debris may cause increased head loss across the strainer and restrict the flow of water to the ECCS and CSS pumps. Debris may also pass through the strainer and cause blockage of components or the core, or damage to components downstream of the strainer. The proposed § 50.46c provisions allowing a risk-informed approach for evaluating the effects of debris on long- term cooling performance would require that the defense-in-depth philosophy and safety margins be maintained and, as a result, defense-in-depth and safety margins must be explicitly considered. This consideration of defense-in-depth and safety margins is consistent with the NRC's general guidance regarding risk-informed decisionmaking contained in RG 1.174, ''An Approach for Using Probabilistic Risk Assessment in Risk Informed Decisions on Plant Specific Changes in the Licensing Basis,'' Revision 2, dated May 2011 (ADAMS Accession No. ML100910006). The RG provides guidance on an acceptable approach to risk-informed decision-making, consistent with the Commission's Policy Statement on the Use of Probabilistic Risk Assessment (PRA) dated August 16, 1995 (60 FR 42622). The RG sets forth a set of five key principles, four of which are relevant to the proposed rule: • Maintain the defense in depth philosophy; • Maintain sufficient safety margins; • Any changes allowed must result in no more than a small increase in core damage frequency or risk, consistent with the intent of the	evaluation. Further clarification of this aspect is needed. 3) Much of the language in this paragraph is not in the proposed rule. Granted, much of it comes from RG 1.174, but it may be beneficial to better define the relationship of RG 1.174 to the rule. Caution must be exercised however to not codify the RG. 4) For the following statement, "In addition, § 50.46c contains requirements for corrective action and reporting, to the NRC, conditions where the established risk- informed approach results exceed the risk acceptance criteria. Together, these requirements would maintain the validity of the risk-informed approach such that the risk-informed decisionmaking principles would continue to be satisfied over the life of the facility.", The language of the proposed rule appears to be much more demanding than discussed in this paragraph. 5) By definition any margin greater than 0 is acceptable. 10 CFR 50 are minimum requirements to ensure safety and has safety margin built into its requirements. If a margin greater than zero is required, then that margin will need to be defined, quantified and the basis provided. 6) It is recommended that a statement on the intent of the Commission's Safety Goal Policy be provided in the rule. 7) Much of the discussion is open to interpretation – what over reliance is, is in the eye of the beholder. Reasonable balance is different to different people. 8) This rule appears to incorporate by reference RG 1.174 Rev 2, whereas the external events criteria which distinguishes Rev 2 over Rev 1 is not necessary for determination of the debris effects from a LOCA which is an internal event. 9) 10CFR50.55a is currently being revised. What version of the Codes referenced therein apply? Note that licensees only update to these new requirements on a periodic basis. Could plants update to later editions and credit reduced probability of failures? 10) Define "reasonable confidence" versus "reasonable assurance".

	Commission's Safety Goal Policy Statement; and • Incorporate monitoring and performance measurement strategies. The proposed rule is consistent with the defense in depth principle of RG 1.174. Defense-in-depth has traditionally been applied in reactor design and operation to provide multiple means of accomplishing safety functions and to prevent the release of radioactive material. The applicant would need to address the intent of the general design criteria (or similar licensing basis design criteria), national standards, and engineering principles (e.g., single failure criterion) in evaluating the impact of the alternative approach on defense-in-depth. Defense- in-depth is considered sufficient if the overall redundancy and diversity among the plant's systems and barriers, including the containment and its support systems, is sufficient to ensure that the risk acceptance criteria of § 50.46c(e)(1)(i) are met, and the following attributes are maintained: • Reasonable balance is preserved among prevention of core damage, prevention of containment failure or bypass, and mitigation of consequences of an offsite release. • There is not an over-reliance on programmatic activities to compensate for weaknesses in plant design. • System redundancy, independence, and diversity are preserved commensurate with the expected frequency of challenges, consequences of failure of the system, and associated uncertainties in determining these parameters. • Defenses against potential common cause failures are preserved and the potential for the introduction of new common cause failure mechanisms are assessed and addressed. • Independence of barriers is not degraded. • Defenses against human errors are preserved. • The intent of the plant's design criteria is maintained. Regarding the maintenance of sufficient safety margins, the applicant would need to address the impact of implementing the alternate approach on current safety margins. Consistent with RG 1.174, Revision 2, sufficient safety margins are considered to be maintained when: • Codes and standards or their alternatives approved for use by the NRC	

	are met. • Safety analysis acceptance criteria in the licensing basis are met or proposed revisions provide sufficient margin to account for analysis and data uncertainty. The risk-informed provisions for considering the effects of debris on long-term cooling would also require that any potential net increase in risk from implementation of the risk-informed approach be assessed and that reasonable confidence is provided that this change in risk is small. The NRC regards "small" changes for plants with total baseline core damage frequencies (CDF) of 10^{-4} per year or less to be CDF increases of up to 10^{-5} per year and plants with total baseline CDF greater than 10^{-4} per year to be CDF increases of up to 10^{-6} per year. However, if there is an indication that the CDF may be considerably higher than 10^{-4} per year, the focus of the applicant should be on finding ways to decrease rather than increase CDF and the licensee may be required to present arguments as to why steps should not be taken to reduce CDF in order for the alternate approach to be considered. For plants with total baseline large early release frequency (LERF) of 10^{-5} per year or less, small LERF increases are considered to be up to 10^{-6} per year, and for plants with total baseline LERF greater than 10^{-5} per year, small LERF increases are considered to be up to 10^{-7} per year. Similar to the CDF metric, if there is an indication that the LERF may be considerably higher than 10^{-5} per year, the focus of the licensee should be on finding ways to decrease rather than increase LERF and the licensee may be required to present arguments as to why steps should not be taken to reduce LERF in order for the alternate approach to be considered. This perspective is consistent with the guidance in Section 2.2.4 of RG 1.174, Revision 2. Finally, § 50.46c contains requirements that would ensure that the plant-specific PRA is of sufficient scope, level of detail, and technical adequacy for this approach and is updated and maintained over time and that the risk- informed approach is evaluated periodically. The technical adequacy of the plant-specific PRA would be assessed by the NRC taking into account appropriate standards and peer review results. The NRC has prepared an RG (RG 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," dated March 2009 (ADAMS Accession No. ML090410014)) on	

	determining the technical adequacy of PRA results for risk-informed activities. As one step in the assurance of technical adequacy, the PRA must have been subjected to a peer review process assessed against a standard or set of acceptance criteria that is endorsed by the NRC. Therefore, the NRC staff would rely on the NEI Peer Review Process, as modified in the NRC's approval, or the American Society of Mechanical Engineers (ASME)/American Nuclear Society (ANS) Peer Review Process, as modified in the NRC's approval; both processes are documented in RG 1.200. Changes and data, including: (1) Operational practices; (2) the facility configuration; (3) plant and industry experience; and (4) structure, system, and component (SSC) performance would be required to be fed back into the PRA and the § 50.46c risk-informed analyses and, when appropriate, adjustments would be made to maintain the validity of these processes. In addition, § 50.46c contains requirements for corrective action and reporting, to the NRC, conditions where the established risk- informed approach results exceed the risk acceptance criteria. Together, these requirements would maintain the validity of the risk-informed approach such that the risk-informed decisionmaking principles would continue to be satisfied over the life of the facility. In as much as § 50.46c contains requirements that would (1) provide reasonable confidence that any net risk increase from implementation of its requirements is small; (2) maintain defense-in-depth; (3) maintain safety margins; and (4) require the use of monitoring and performance measurement strategies, the proposed rule is consistent with the Commission's policy on the use of PRA for risk- informed decision-making and, more importantly, would maintain adequate protection of public health and safety.	

Future Development of Draft Guidance for the Risk-Informed Alternative (16119)		
10	South Texas Project Nuclear Operating Company (STPNOC) submitted a letter of intent to pilot a risk-informed approach for addressing GSI–191 (ADAMS Accession No. ML103481027) in December 2010. Subsequently, the NRC received a pilot submittal from STPNOC on January 31, 2013 (ADAMS Accession No. ML13043A013), supplemented on June 19, 2013 (ADAMS Accession No. ML131750250). In parallel with the NRC's review of the application, the NRC will develop draft guidance for the risk-informed alternative to address the effects of debris on long-term cooling. That draft guidance will be published for comment upon completion, which is currently anticipated for early- to mid- calendar year 2015. The NRC will then evaluate public comments received on the draft guidance, and develop the final guidance on a timeline that ensures all guidance (both for the risk-informed alternative and the new proposed embrittlement criteria) is available when the NRC staff provides the final § 50.46c rule to the Commission (currently scheduled for February 2016).	1) It is recommended that as elements of the guidance are developed that they be shared with the industry to enable those non-pilot plants that are pursuing the risk-informed approach the opportunity to evaluate their proposed paths and provide near term feedback to the Staff.
C. Corrective Actions and Reporting Requirements – 2. Risk-Informed Alternative To Address Debris for Long-Term Cooling (16120)		
11	Section 50.46c(e) of the proposed rule would require reasonable confidence that any calculated increase in CDF or LERF associated with debris is small. In the context of this paragraph, the calculated increases in CDF and LERF represent the difference between the as- built, as-operated plant (accounting for the effects of debris) and the "baseline" plant where the effects of debris are assumed to be negligible. This approach quantifies the portions of CDF and LERF attributable to debris and designates them as DCDF and DLERF. These metrics inform the NRC staff's decision on whether the effects of debris are acceptably small and consistent with the Commission's Safety Goal Policy Statement. Subsequent changes to the plant or the PRA model may change the baseline CDF and LERF values as well as DCDF and DLERF. Because the NRC staff's original decision was based in part on these metrics, subsequent changes to their values should be assessed to ensure that the bases for this decision are still valid. It should be noted that the cumulative effects of operating changes (including plant modifications, procedural changes, and SSC performance) must be maintained within the rule's risk acceptance criteria over the life of the plant and, therefore, the evaluation	1) See the comments on Items 86 through 89. 2) There is discussion in this paragraph describing that the NRC will provide the specific criteria for which reporting would be required during the approval (Safety Evaluation Report?). This appears to not be completely consistent with the proposed rule language. 3) There is also discussion in this paragraph that the NRC will ensure the licensee's licensing basis will be updated to reflect certain criteria associated with the approach. This is not discussed in the proposed rule language and probably doesn't belong in the rule and would be more appropriate for the proposed regulatory guide.

	of subsequent changes needs to address the cumulative effect of these changes. Therefore, the proposed rule contains a corrective action and reporting requirement that would ensure that changes and errors are evaluated, reported to the NRC (as appropriate), and corrected in a timely manner (as appropriate). Consistent with the NRC's integrated approach to decisionmaking, changes that can impact risk, defense- in-depth, or safety margins need to be evaluated and, as appropriate, reported to the NRC. These terms, while frequently used, can have different definitions to different stakeholders. Therefore, the NRC intends to ensure that licensees using the risk-informed approach to debris update their UFSAR to list applicable plant-specific capabilities of defense-in-depth and safety margins with respect to the proposed rule. In addition, the NRC's approval under § 50.46c(e)(3) would specify the circumstances under which the entity would be required to notify the NRC of changes or errors in the risk evaluation approach used to address the effects of debris on long-term cooling. This requirement would ensure that if errors in the approach are identified subsequent to the NRC approval or if the entity seeks to change specific aspects of their approach that were determined by the NRC to be important to the NRC approval, such as the scope or level of detail of the PRA, these circumstances would be clearly identified in the NRC's approval. These requirements would ensure conditions that result in exceeding the § 50.46c(e) acceptance criteria are identified, corrected, and reported in a timely manner, and thus, ensure the effects of debris on long-term core cooling continue to be appropriately addressed. The corrective action and reporting requirements for the aspects of the rule related to entities using the risk- informed alternative approach of § 50.46c(e) would be established in § 50.46c(m)(4). The proposed rule recognizes that there are different corrective and reporting requirements for different entities, as depicted in Table 1, Corrective Actions and Reporting: Risk-Informed Approach.	

TABLE 1—CORRECTIVE ACTIONS AND REPORTING: RISK-INFORMED APPROACH (16121)

Entity (and applicable proposed requirement)	Requirement to re-evaluate?	Requirement to report?	Requirement to make necessary changes?
Design certification applicant before issuance of final design certification rule (covered by § 50.46c(m)(4)(i)).	No (But known errors and discoveries must be corrected).	Yes (Submit amended application).	Yes (Changes in amended application).
Design certification applicant during the period of validity under § 52.55(a) and (b)—not currently referenced in any combined operating license (COL) application or COL (covered by § 50.46c(m)(4)(ii)).	No	Yes (Only if referenced in a COL; then within 30 days).	No.
Design certification applicant during the period of validity under § 52.55(a) and (b)—once referenced in a COL application or COL (covered by § 50.46c(m)(4)(iii)).	Yes	Yes	No.
Design certification renewal applicant (covered by § 50.46c(m)(4)(iv)).	Yes	Yes (as part of renewal application).	Yes.
Combined license applicant (covered by § 50.46c(m)(4)(v)).	No (But known errors and discoveries must be corrected).	Yes (Submit amended application).	Yes (Changes in amended application).
Combined license holder before finding under § 52.103(g) (covered by § 50.46c(m)(4)(vi)).	No	Yes	Yes.
Operating license holder or combined license holder after finding under § 52.103(g) (covered by § 50.46c(m)(4)(vii)).	Yes	Yes	Yes.

12	For design certification applicants (i.e., prior to issuance of the final design certification rule), the proposed rule would require that, if any errors are discovered, the applicant must submit a report to the NRC within an amended application. That amended application would describe any changes to the certified design and/or changes in the analyses, evaluations, and modeling (including the debris evaluation model and the PRA and its supporting analyses); and would demonstrate that the acceptance criteria in § 50.46c(e)(1) are met.	No comments for operating license plants.
13	For design certification applicants during the period of validity under § 52.55(a) and (b) that are not currently referenced in any COL application or COL, there would be no evaluation, reporting, or change requirement. However, once the design certification is referenced by a COL applicant, any information regarding compliance with § 50.46c(e)(1) must be reported in accordance with the requirements in 10 CFR part 21.	No comments for operating license plants.

14	For design certification applicants during the period of validity under § 52.55(a) and (b) that *are* referenced in a COL application or COL, the proposed rule would require the design certification applicant to evaluate and report any information concerning compliance with the acceptance criterion of § 50.46c(e)(1). However, there would be no requirement to make changes to the analyses, evaluations, and modeling until the time of renewal.	No comments for operating license plants.
15	For design certification renewal applicants, the proposed rule would require the applicant to re-evaluate the analyses, evaluation, and modeling; report any changes or errors; and include in its application any necessary changes to the certified design, debris evaluation model, PRA, or supporting analyses to demonstrate that the renewed certified design meets the acceptance criteria in § 50.46c(e)(1).	No comments for operating license plants.
16	For combined license applicants, the proposed rule would require the applicant to report any errors that are discovered within 30 days of the completion of that determination. The combined license applicants would be required to report the errors and make any necessary changes to the analyses, evaluation, or modeling within the amended application.	No comments for operating license plants.
17	For combined licenses before the finding under § 52.103(g), the proposed rule would require that any errors that are discovered be updated in the analyses, evaluations, and modeling no later than the scheduled date for initial fuel loading under § 52.103(a). The licensee must also confirm that the acceptance criteria of § 50.46c(e)(1) continue to be met. Once this update is submitted, and until the Commission has made the finding under § 52.103(g), the licensee shall re-perform the review to ensure the acceptance criteria of § 50.46c(e)(1) continue to be met in a timely manner; this ensures that updating occurs if there are extended delays in the scheduled date for initial fuel loading. If the licensee determines that any acceptance criterion of § 50.46c(e)(1) are not met, then the licensee would be required to submit an application for amendment of its combined license and departure from a referenced design certification rule, if applicable.	No comments for operating license plants.

18	For operating licenses and combined licenses after the finding under § 52.103(g), the proposed rule would require that the licensee re-evaluate the analysis, evaluation, and modeling by no later than 48 months after the last review to confirm that the acceptance criteria of § 50.46c(e)(1) continue to be met. The licensee would also be required to take action in a timely manner to bring the licensee into compliance and report any failure to meet the acceptance criteria of § 50.46c(e)(1). Further, the amended application for the combined license would be required to include a request for exemption from a referenced design certification rule but would not need to address the criteria for obtaining an exemption. (16122)	1) See comments on Items 86 through 89.
E. Implementation – 2. Compliance With Long-Term Cooling Requirements Using Risk-Informed Approach To Address Debris Effects (16124)		
19	Implementation of the alternative approach to addressing the impact of debris on long-term cooling is independent from implementation of the requirements related to the embrittlement research findings. The NRC would allow partial early implementation of the proposed requirements of § 50.46c, limited to this alternative approach. In other words, an applicant may elect to submit its risk- informed alternative under § 50.46c(e) prior to demonstrating compliance with the other requirements of § 50.46c. In this case, the licensee would have to receive NRC approval on both its risk-informed submittal and the analytical limit for long-term cooling required under § 50.46c(g)(1)(v) prior to using the risk-informed approach. The NRC is proposing to allow early implementation because the NRC encourages licensees to complete resolution of GSI–191 and this risk-informed alternative is one way of resolving the issue. The NRC has determined that a licensee's decision to use a risk- informed methodology to evaluate the effects of debris on ECCS and CSS with respect to long-term cooling following a LOCA should be reviewed and approved by the NRC prior to implementation. The ECCS and CSS are significant safety systems that provide necessary defense-in-depth. The design bases for the ECCS are of high regulatory significance to the NRC, as reflected in the detailed requirements applicable to the ECCS (and the associated fuel system) in § 50.46 and appendix K to 10 CFR part 50. In addition, the design bases for the ECCS and the CSS affect the design bases for many other SSCs throughout the nuclear power plant. Therefore, changes to the design assumptions for the ECCS and CSS may have significant effects on the design bases for other SSCs	1) One of the stated intents of this paragraph is to allow licensees to submit their application for use of the risk-informed alternative in advance of the application for the other rule requirements. Due to the timing of this rule, its guidance, and the expected SE for the STP pilot effort, and based on the timeline provided in the rule, there is a possibility that many of the early plants (24 months), of which many are non-pilot risk-informed plants, the expected submittal dates may be after the timeline in the rule. This needs to be further evaluated including the need to stagger submittals to prevent an unnecessary resource challenge for the Staff. 2) Refer also to the comments on Item 91.

	throughout the plant. These potential effects include changes in the consequences of postulated accidents, margins of safety, and defense-in-depth. The NRC also determined that § 50.59, properly implemented, would not allow a change to the design bases of a plant to use a risk-informed methodology for evaluating the effects of debris on long- term cooling. A risk-informed methodology for addressing the effects of debris on long-term cooling is a departure from the method of evaluation described in the current UFSAR, as updated and used in establishing the design bases in the safety analysis as defined in § 50.59(a)(2). Hence, under § 50.59(c)(2)(viii), a licensee's departure from the existing methodology for evaluating long-term cooling must be reviewed and approved by the NRC as a license amendment. In sum, given the importance of the ECCS and CSS, the ''cascading'' effects of changes in ECCS and CSS design on the design bases of other SSCs of a nuclear power plant, the NRC believes that a licensee's decision to use a risk- informed methodology to evaluate the effects of debris on ECCS with respect to long-term cooling should be reviewed and approved by the NRC. Under the proposed rule, the NRC's review and approval is accomplished through the license amendment process in accordance with §§ 50.90 through 50.92.	
VI. SECTION-BY-SECTION ANALYSIS (16124)		
20	The organization and 10 CFR designations of the NRC's requirements governing emergency core cooling (currently in § 50.46) and reactor cooling venting systems (currently in § 50.46a) are expected to change. These changes would result from: (1) The current schedule for Commission serial adoption of two rulemakings: (i) The finalization of the proposed rule on risk-informed changes to ECCS systems, currently referred to as the § 50.46a rulemaking, followed by; (ii) the finalization of this proposed rule on performance-based changes to ECCS requirements and cladding acceptance criteria, currently referred to as the § 50.46c rulemaking; (2) The proposed schedule for implementation of these rules; and (3) The need to maintain current requirements in place for those reactors that have not transitioned to the new requirements under the	1) The effort to obtain approval for 50.46a in parallel with 50.46c may result in delay in obtaining approval of 50.46c. This has the potential to delay submittal of licensing actions for those plants intending to utilize a risk-informed approach. The basis for this comment is that with limited NRC resources, it may be impractical to provide the necessary support to both rules. 2) Also since some NRC staff are supporting both the 50,46 rulemaking and review of current Risk-Informed applications, how is NRC managing the resource? Concern also is that many of the NRC who developed and worked with the deterministic approach have either transferred or left the NRC. What methods are in place to assure that resolved issues are not re-reviewed with different results?

implementation schedule to be specified in the final rule.

The following table shows how the organization and 10 CFR designation of these rules will evolve, if the NRC sequentially adopts the two final rules and licensees complete implementation of the alternate cladding requirements. The NRC notes that, in an SRM, ''SRM– SECY–10–0161—'Final Rule: Risk- Informed Changes to Loss-of-Coolant Accident Technical Requirements (10 CFR 50.46a)','' dated April 26, 2012 (ADAMS Accession No. ML12117A121), the Commission approved the NRC staff's request to withdraw SECY–10– 0161, ''Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements (10 CFR 50.46a),'' from Commission consideration (ADAMS Accession No. ML121500380). The NRC does not plan to publish a notice in the Federal Register withdrawing the § 50.46a proposed rule. The NRC staff plans to resubmit the draft final rule for Commission consideration in conjunction with the Near-Term Task Force (NTTF) Recommendation 1 activities. (For information on NTFF Recommendation 1, see ''Recommendations for Enhancing Reactor Safety in the 21st Century,'' dated July 12, 2011, ADAMS Accession No. ML 112510271.) Therefore, the § 50.46a rulemaking still may be finalized before the § 50.46c rulemaking, as assumed in the following table.

Existing NRC requirements and proposed new regulations (bolded rules are currently in effect)	Rulemaking and implementation activities		
	Adoption of final risk-informed ECCS requirements (§ 50.46a)	Initial codification of final performance-based fuel cladding requirements	End of phased implementation period for performance-based cladding requirements
§ 50.46 ECCS Acceptance Criteria	§ 50.46 ECCS Acceptance Criteria (*unchanged*).	§ 50.46 ECCS Acceptance Criteria (*unchanged*).	§ 50.46 ECCS Acceptance Criteria (*see discussion for § 50.46c under this column*).
Risk-Informed ECCS Requirements *(currently designated in final rulemaking package as § 50.46a)*.	§ 50.46a Risk-Informed ECCS Requirements.	§ 50.46a Risk-Informed ECCS Requirements.	§ 50.46a Risk-Informed ECCS Requirements.
§ 50.46a Reactor Coolant Venting Systems.	Redesignated as § 50.46b.	NA (*Redesignation as § 50.46b completed*).	NA (*Redesignation as § 50.46b completed*).
Performance-based ECCS and Cladding Requirements *(currently designated in draft proposed rulemaking package as § 50.46c)*.	NA	§ 50.46c Alternate Fuel Cladding Requirements.	NA *(Administrative rulemaking would: (i) remove superseded fuel cladding requirements in § 50.46, and (ii) redesignate § 50.46c as § 50.46.)*.

	A. Section 50.46c – Heading (16125)	
21	A new section, § 50.46c, would be created in 10 CFR part 50 by this rulemaking. The heading of § 50.46c would be ‘‘Emergency core cooling system performance during loss-of- coolant accidents.’’	No comments
	B. Section 50.46c(a) – Applicability (16125)	
22	Paragraph (a) would define the applicability of the proposed rule, which remains limited to LWRs, but would be expanded beyond fuel designs consisting of uranium oxide pellets within cylindrical zircaloy or ZIRLOTM cladding. The proposed rule would also be applicable to applicants for and holders of construction permits, operating licenses, combined licenses, and standard design approvals, and also to applicants for standard design certifications and for manufacturing licenses.	No comments
	C. Section 50.46c(b) – Definitions (16125)	
23	Paragraph (b) would provide definitions for terms used in this section. The definitions of *Loss-of- coolant accident* and *Evaluation model* would remain unchanged from those currently located in § 50.46(c)(1) and (c)(2), respectively. The definition of *Breakaway oxidation* and *Debris evaluation model* would be added.	1) There should be clarity in the definition for Evaluation model as it pertains to the risk-informed approach. Maintaining the traditional definition will lead to substantial ambiguity on the part of both the applicants and the reviewers since an evaluation model for a risk-informed analysis is substantially different than that used for traditional core cooling considerations.
	D. Section 50.46c(c) – Relationship to Other NRC Regulations (16125)	
24	Paragraph (c) would describe the relationship of § 50.46c to other NRC regulations. The description in proposed paragraph (c) would remain largely unchanged from that of the current regulation found in § 50.46(d). However, the description would be revised to make clear that an approach approved by the NRC under § 50.46c(e) may also be used when evaluating the effects of debris to demonstrate compliance with other requirements of this part, including GDC–35, GDC–38, and GDC–41 (as allowed by § 50.46c and requested in the application).	1) This is an area that may need additional clarification. Since, by definition, ECCS does not include containment spray (GDC-38) and containment heat removal (GDC-41), are there other rules that may require change to justify use of a debris based risk-informed approach for meeting the applicable rule requirements, for example 50.67?

	E. Section 50.46c(d) – Emergency Core Cooling System Design (16125)	
25	Paragraph (d)(1) would define performance-based requirements for the ECCS. Paragraph (d)(2) would require that ECCS performance be demonstrated using an NRC-approved ECCS evaluation model meeting specific requirements for a range of postulated LOCAs of different sizes, locations, and other properties, sufficient to provide assurance that the most severe postulated LOCA has been identified. The provisions for a realistic ECCS model or appendix K to 10 CFR part 50 model would remain unchanged from the current regulation found in § 50.46(a)(1)(i) and (ii), respectively. Similarly, the model requirement that calculated changes in core geometry must be addressed would remain unchanged from the current regulation found in § 50.46(b)(4). Paragraph (d)(2)(iii) would explicitly require that the ECCS evaluation model address calculated changes in core geometry, and consider factors that may alter localized coolant flow or inhibit delivery of coolant to the core. Demonstration of ECCS performance in the post-accident recovery period, or long-term cooling, is expected to consider inhibition of core flow that can result from such factors as, but not limited to, pump damage, piping damage, boron precipitation, and deposition of debris and/or chemicals associated with the long-term cooling mode of recirculation coolant collection from the reactor building sump. Consideration of debris and/or chemical deposition is already required by the current rule, and the proposed rule does not alter the current efforts to address such factors under programs such as GSI–191. Demonstration of consideration of such factors may also be achieved through analytical models that adequately represent the empirical data obtained regarding debris deposition. The proposed rule would alternatively allow the use of risk- informed approaches to evaluate the effects of debris on localized coolant flow and delivery of coolant to the core during the long-term cooling (post- accident recovery) period. In addition, paragraph (d)(2)(iv) of the proposed rule would specifically require that ECCS performance be demonstrated for both the accident and the post-accident recovery and recirculation period. Paragraph (d)(2)(v) would require that the ECCS model address the fuel system modeling requirements in paragraph (g)(2) if the reactor uses uranium oxide or mixed uranium-plutonium oxide pellets within zirconium	1) As discussed in the definitions section, a risk-informed approach does not use a traditional evaluation model for the risk-informed aspects of debris in the coolant. The traditional evaluation model will continue to be used to demonstrate core cooling capability. This aspect could be a potential deal breaker for those plants looking to exercise a risk-informed approach. The evaluation models currently in use would have to undergo significant changes to account for debris in the coolant and boric acid precipitation concerns. 2) It is not clear what is meant by “Consideration of debris and/or chemical deposition is already required by the current rule, and the proposed rule does not alter the current efforts to address such factors under programs such as GSI-191.” Localized effects on the cladding are considered, but the attribute of partial or full blockage of the core are not considered in the current rule, to our understanding. 3) Clarification on post-accident recovery and recirculation period are needed. Currently, 30 days is used as the duration that must be evaluated. However, a different time period may be justified. Further, for complete clarity, only DBA events should be considered.

	cladding (e.g., currently operating reactors). Paragraph (d)(3) would provide the ECCS evaluation model documentation requirements currently provided in appendix K, Section II, ‘‘Required Documentation.’’	
F. Section 50.46c(e) - Alternate Risk-Informed Approach for Addressing the Effects of Debris on Long-Term Core Cooling (16125)		
26	Paragraphs (d)(2)(iii) and (e) would allow entities to use a risk-informed approach for addressing the effects of debris on long-term core cooling. Paragraphs (e)(1)(i) through (e)(1)(iv) would provide the acceptance criteria for an acceptable alternative risk- informed approach for addressing the effects of debris on long-term core cooling and would establish minimum requirements for the plant PRA and how it is to be used in the alternate risk- informed approach. These proposed requirements are intended to ensure that the implementation of the alternate risk- informed approach to address debris effects on long-term core cooling would provide reasonable confidence that any resulting increase in CDF and LERF will be small, and that sufficient defense-in-depth and safety margins are maintained. These proposed requirements are consistent with the key principles of risk-informed decisionmaking described in RG 1.174, Revision 2.	No comments
27	Paragraph (e)(1)(i) of the proposed rule would require that there be reasonable confidence that any potential risk increase be small. Paragraph (e)(1)(ii) would require that sufficient defense-in-depth and safety margins be maintained as part of the implementation of the alternate risk- informed approach. Further, paragraphs (e)(1)(iii) and (iv) would contain the minimum requirements for the plant PRA and how it is to be used in the alternate risk-informed approach.	1) Clarify the difference between reasonable confidence and reasonable assurance.
28	Paragraph (e)(2) would require those applicants seeking to use the alternative risk-informed approach under paragraph (e)(1) to submit an application that contains the information provided in paragraphs (e)(2)(i) through (e)(2)(v).	1) (e)(2)(v) requires an analytical limit that is defined in another part of the rule that appears to be related to an ECCS evaluation model independent of debris. 2) Refer also to the comments on Item 83.

29	Paragraph (e)(2)(i) would require applicants to follow established regulatory guidance that the NRC expects to finalize concurrent with the final rule. If an applicant wishes to use a different approach, the submittal must provide a sufficient description of how the alternative risk-informed approach would be conducted and why it is acceptable.	1) As written, (e)(2)(i) does not require applicants to follow established regulatory guidance or discussion of the information required if a different approach is chosen. 2) Since there is no current guidance, and the intent of and the actual guidance can change, there is not a method to evaluate this item which leads to regulatory uncertainty.
30	Paragraph (e)(2)(ii) would require that initiating events from sources both internal and external to the plant and for all modes of operation, including low power and shutdown modes, be considered when evaluating the effects of debris on long-term core cooling using the alternate approach. This aspect of the rule recognizes that the minimum PRA that would be required by paragraph (e)(1)(iv) may not address all sources of initiating events and modes of operations, and as such, other approaches may be used. Therefore, the application would need to describe the measures taken to assure the scope, level of detail, and technical adequacy of all the analyses performed to address severe accidents are sufficient for this application and address the full spectrum of initiating events and modes of operation.	1) Why would shutdown modes be included since events during this condition do not generate debris, and for most if not all licensees, Technical Specifications do not require operability of the containment recirculation function during Modes 5 and 6. 2) The description in this paragraph appears to be much less restrictive than the wording provided in the associated paragraph in the rule. 3) Severe accidents are not in the scope of DBA and should not be referred to in this rule. 4) Consideration of external events should be limited to those that directly cause a DBA or directly affect mitigation of a DBA. 5) Refer also to the comments on Items 51 and 80.
31	Paragraph (e)(2)(iii) would specifically address the need to provide the results of the PRA review process. This aspect includes such items as any peer reviews performed, any actions taken to address peer review findings that are important to the application, and any efforts to compare the plant- specific PRA to the ASME/ANS PRA standard, as endorsed by the NRC in RG 1.200.	No comments.
32	In paragraph (e)(2)(iv), the applicant would be required to include information about the evaluations they conduct to provide reasonable confidence that any potential increase in risk would be small. The applicant would be required to provide sufficient information to the NRC, describing the evaluations and the basis for their acceptability as appropriately representing the potential increase in risk from implementation of the requirements in this rule.	No comments.
33	In paragraph (e)(2)(v), the applicant would be required to provide a description of the analytical limit on long-term peak cladding temperature established in accordance with paragraph (g)(1)(v).	1) Refer to the comments on Items 28 and 83.

34	Paragraph (e)(3) would provide that the NRC may approve an application to implement the alternative risk-informed approach if it determines that the proposed approach satisfies the requirements of paragraph (e)(1) and establishes an acceptable long-term peak cladding temperature limit. The NRC staff would review the description of the alternative risk-informed approach set forth in the application, and the associated evaluations, to confirm that it contains the elements required by the rule. The NRC staff would also review the information provided about the plant-specific PRA and other systematic evaluations used to evaluate severe accidents in support of the application to assure that the scope, level of detail, and technical adequacy of the analyses are commensurate with the reliance on the risk information. This aspect of the review would involve the NRC assessment of the information provided about: 1) the peer review process to which the plant-specific PRA was subjected, 2) the reliance on other systematic evaluations to address areas not covered by the plant-specific PRA, and 3) the approach for maintaining sufficient defense-in-depth and safety margins. The NRC staff intends to use review guidance for this purpose. The NRC's approval of the use of the risk- informed approach to address long-term cooling would specify the circumstances under which the entity would be required to notify the NRC of changes or errors in the risk evaluation approach used to address the effects of debris on long-term cooling. Depending upon the nature of the underlying application (e.g., license, design certification rule, or design approval), the approval and notification requirement will be implemented through a license condition, a provision in the design certification rule, or a condition of the design approval, as applicable.	1) As stated in this paragraph, the NRC intends to use review guidance. When will this guidance be available to licensees to better inform their applications? 2) It is highly recommended that the magnitude of changes or errors that would require reporting be specifically described and not so restrictive as to not enable changes that result in minimal changes from being implemented at a plant without having to enter the reporting or application process. 3) This paragraph also identifies that a license condition will be the implementation methodology. Is this really necessary or should approval of the change in the licensing basis be the methodology?
G. Section 50.46c(g)—Fuel System Designs: Uranium Oxide or Mixed Uranium-Plutonium Oxide Pellets Within Cylindrical Zirconium-Alloy Cladding (16126)		
35	Paragraph (g)(1)(v) would be added to establish a performance-based requirement to ensure acceptable fuel performance during long-term cooling. This performance requirement is consistent with the current requirement to ''maintain the calculated core temperature at an acceptably low value'' located in § 50.46(b)(5). (Note: This paragraph is referred to in Item 32 wording)	1) Under what methodology would the acceptable long-term peak cladding temperature be established that ensures the ductile-to-brittle transition for the zirconium-alloy cladding material using and NRC-approved experimental technique? This is beyond the current scope of the risk-informed approach and is more appropriate for the non-risk-informed aspects of this rule. 2) Refer also to the comments on Item 84.

	J. Section 50.46c(m)—Corrective Actions and Reporting (16127)	
36	Paragraph (m) would provide reporting requirements applicable to the ECCS evaluation model and reporting requirements applicable to entities that elect to use the risk-informed alternative to address the effects of debris on long- term cooling. Paragraphs (m)(1) through (m)(3) would apply to all entities subject to § 50.46c; paragraphs (m)(4) would apply to those entities demonstrating acceptable long-term core cooling under the provisions of paragraph (e).	1) See comments on Items 86 through 89.
37	Paragraph (m)(1) would establish required action and reporting requirements if an entity identifies any change to, or error in, an ECCS evaluation model or the application of such a model, or any operation inconsistent with the evaluation model. For clarity, this paragraph was divided into three categories of changes or errors, each with its own proposed actions and reporting. These requirements are unchanged from the current § 50.46(a)(3), with the exception of conforming to analytical limits established in the proposed rule.	1) See comments on Item 86.
38	Paragraph (m)(1)(i) would establish required action and reporting requirements if an entity identifies any change to, or error in, an ECCS evaluation model or the application of such a model, or any operation inconsistent with the evaluation model, that does not result in any predicted response that exceeds any acceptance criteria and is itself not significant.	1) See comments on Item 86.
39	Paragraph (m)(1)(ii) would establish required action and reporting requirements if a licensee identifies any change to, or error in, an ECCS evaluation model or the application of such a model, or any operation inconsistent with the evaluation model, that does not result in any predicted response that exceeds any acceptance criteria but is significant (as defined in paragraph (m)(2)).	1) See comments on Item 87.
40	Paragraph (m)(1)(iii) would establish required action and reporting requirements for an entity who identifies any change to, or error in, an ECCS evaluation model.	1) See comments on Item 88.

41	Paragraph (m)(2) would be added to provide the definition of a significant change or error. The definition would be expanded, relative to the 50 □F change in calculated peak cladding temperature in § 50.46(a)(3)(i), to include a 0.4 percent ECR change in calculated cladding oxidation.	1) See comments on Item 89.
42	Paragraph (m)(4) would establish required action and reporting requirements for entities choosing to implement the alternative risk-informed approach for addressing the effects of debris on long-term core cooling. Paragraph (m)(4) would specify the evaluation, reporting, and change requirements for the various categories of entities that may elect to use the risk- informed approach.	1) See comments on Item 90.
K. Section 50.46(o)—Implementation (16127)		
43	This section would establish the implementation requirements and schedule for the existing fleet and for new reactors.	1) See comments on Item 91.
44	Paragraph (o)(4) would require operating licenses under 10 CFR part 50 (as of the effective date of the rule) to comply with the requirements of § 50.46c by no later than the applicable date set forth in the implementation table for operating reactors.	1) See comments on Item 91.
45	Entities that elect to use the voluntary alternative to the long-term cooling requirements of the proposed rule using a risk-informed approach can do so in advance of the date for compliance with the rule. In this case, the entity would have to receive NRC approval on both its risk-informed submittal and the analytical limit for long-term cooling required under § 50.46c(g)(1)(v) prior to using the risk-informed approach.	1) See comments on Item 91.
N. Changes Throughout 10 CFR Parts 50 and 52 (16128)		

46	Section 50.8 would be amended to add the proposed rule to the list of approved information collections. Where §§ 50.34(a)(4), 50.34(b)(4), 52.47(a)(4), 52.79(a)(5), 52.137(a)(4), and 52.157(f)(1) refer to § 50.46, the proposed rule would add "and § 50.46c, as applicable.'' Where §§ 50.34(a)(4), 52.47(a)(4), 52.79(a)(5), 52.137(a)(4), and 52.157(f)(1) refer to § 50.46a, the proposed rule would instead refer to § 50.46b.	No comments.
47	Changes are also made to GDC–35, GDC–38, and GDC–41 in appendix A to 10 CFR part 50 to promulgate the acceptability of using a risk-informed alternative for long-term cooling when demonstrating compliance with these regulations, as allowed by § 50.46c and requested in the application.	1) See comments on Items 92, 93, and 94.

VII. SPECIFIC REQUEST FOR COMMENTS ON THE PROPOSED RULE ***In addition to the request for general comments on the proposed rule, the NRC also requests specific comments on the following topics:*** A. **Fuel Performance Criteria** (16128)		
48	NRC Question 3. *Analytical Long- Term Peak Cladding Temperature Limit.* Section 50.46c(g)(1)(v) of the proposed rule would require that a specified and NRC-approved limit on long-term peak cladding temperature be established which preserves a measure of cladding ductility throughout the period of long- term demonstration (e.g., 30 days). The current regulation at § 50.46(b)(5) stipulates that long-term temperature be maintained ''at an acceptably low value.'' The proposed rule would define the performance-based metric to judge an acceptably low temperature. The overall goal of preserving ductility would provide reasonable assurance that the fuel rods will maintain their coolable bundle array. The NRC is requesting input regarding this performance objective to determine if this is the most suitable performance- based metric to demonstrate long-term cladding performance. Alternatively, the proposed rule could establish an analytical limit of long-term fuel rod cladding temperature related to observed corrosion behavior. For example, the Pressurized Water Reactor Owners Group (PWROG) has applied as a long-term core cooling acceptance criterion that the cladding temperature be maintained below 800 ^{o}F (see Topical Report (TR) Westinghouse Commercial Atomic Power (WCAP)-16793–NP, Revision 2, ''Evaluation of Long-Term Cooling Considering Particulate, Fibrous and Chemical Debris in the Recirculating Fluid,'' Appendix A (ADAMS Accession No. ML11292A021)). Doing so will ensure that additional corrosion and hydrogen pickup over a 30-day period will not significantly affect cladding properties. The NRC seeks comment on the acceptance criterion for long-term cooling and whether there is justification for a different temperature limit (other than the 800 ^{o}F provided in the WCAP).	1) See comments on Items 28, 34, 35, and 84. 2) The proposed wording of the rule at 50.46c(g)(1)(v) does not provide an option of utilizing anything other than an experimentally determined and NRC-approved value for long-term peak cladding temperature. If other options for defining the specific temperature limit are or will be acceptable, then this option needs to be identified within the rule.

	B. Risk-Informed Alternative To Address the Effects of Debris (16129)	
49	NRC Question 4. *Acceptance Criteria for Risk-Informed Alternative.* Section 50.46c(e) of the proposed rule contains the high-level acceptance criteria for an alternative that would allow entities to use, on a case-by-case basis, a risk- informed approach to address the effects of debris on long-term core cooling. In addition, the NRC will develop draft regulatory guidance for this provision concurrent with the staff's review of the STPNOC's pilot application for a risk- informed approach to address the closely related topic of GSI–191. The NRC seeks comment on whether the detailed acceptance criteria should be set forth in § 50.46c, or in the associated regulatory guidance.	1) Until such time there is better definition as to what the acceptance criteria may in fact be, it is difficult to determine what, if anything, should be in the rule or remain in the guidance. The current acceptance criteria is generally acceptable as worded except for (i) which should point to RG 1.174 for definition of small change.
50	NRC Question 5. *Regulatory Approach for Risk-Informed Regulation.* The NRC seeks comment on whether the risk-informed alternative offered by this regulation should require meeting numeric-risk acceptance criteria as a matter of compliance (similar to § 50.48c) or whether other risk-informed approaches that use risk-importance insights to establish measurable criteria or performance objectives, such as those in use by §§ 50.62, 50.63, and 50.65, or approaches using both risk importance and numeric-risk acceptance criteria, such as those in use by § 50.69, would be preferable.	1) The approach should not be a single selection approach. Some plants may choose to utilize numeric-risk acceptance criteria (e.g., STP approach) whereas others may use risk-importance insights (e.g., break size risk-importance along with deterministic criteria), or a combination of both. As long as the appropriate risk threshold can be identified, and in some cases, quantified, then all approaches should be acceptable. 2) Performance objectives could provide some flexibility over that of a numeric-risk acceptance criteria. The referenced Maintenance Rule 50.65 provides an example of how this could be implemented. 3) Whatever the approach, training for both the NRC and industry should be developed and implemented as the implementation and acceptance review of the rule will be open to interpretation. Supporting this effort would be written review guidance, which may be in the initial form of the proposed RG that will help ensure consistency throughout the application process.

51	NRC Question 6. *Operational Modes Considered in Risk-Informed Alternative.* Deterministic evaluations of GSI–191 are currently required only for those modes of operation where both recirculation from the sump is relied upon and the plant accident can cause high pressure jets that can result in generation and transport of debris to the sump. By contrast, probabilistic evaluations generally consider all modes of operation. The NRC seeks comment on whether the risk-informed approach provided in § 50.46(e) could generically exclude any plant operational modes (e.g., low power or shutdown) from consideration. If so, what are the bases for excluding these operational modes from consideration?	1) The risk-informed approach should not have to consider any modes of operation for which the recirculation function is not currently required by Technical Specifications. During the non-required modes of operation, there are multiple factors that negate the need to consider the debris impacts in the coolant. First, the quantity of debris that could be generated is significantly reduced since there is not the potential for a significant break jet to form. Second, in the lower operation modes, the safety injection signal is blocked from actuation which results in significantly less flow and significantly reduced debris transport. Third, the core decay heat load is significantly reduced which if recirculation was required would result in significantly less transport of debris to the core resulting in a condition where the core cooling geometry is maintained. 2) Additionally, non-DBA events should not have to be considered as part of this rule and associated implementation guidance.

52	NRC Question 7. *Reporting Criteria for the Risk-Informed Alternative.* The NRC is proposing in § 50.46c(m) corrective actions and reporting criteria specific to the risk-informed approach for addressing the effects of debris on long-term cooling. These criteria are performance-based and similar in concept to the reporting criteria in § 50.69. Per proposed § 50.46c(m), the NRC's approval of the entity's risk- informed application would specify the circumstances under which the licensee or design certification applicant shall notify the NRC of changes or errors in the risk evaluation approach. In addition, the proposed rule would require entities to review the analyses, evaluations, and modeling for changes and errors and incorporate changes to the design, plant, operational practices, and operation experience. The entity would then be required to update the debris evaluation model and the PRA and its supporting analyses, and re-perform the evaluations of risk, defense- in-depth, and safety margins to confirm the acceptance criteria for the risk- informed approach continue to be met. The NRC seeks specific comment on the reporting criteria for the risk-informed approach. Alternatively, the NRC seeks comment on whether the reporting criteria for the risk-informed approach should be more prescriptive and establish requirements similar to those for the ECCS model (i.e., § 50.46c(m)(1) through (m)(3)). For instance, should the rule establish values for changes in D CDF, D LERF, defense-in-depth, and safety margins that would trigger specific reporting actions? If so, what values should reporting criteria establish as reporting triggers and what are the bases for selecting those values?	1) The current language in the proposed rule appears to require reporting for the effects of debris on long-term cooling the same as for a traditional ECCS evaluation model. There should be discrete criteria developed for each applicant based on their risk values. For example, if a licensee's application identifies that their risk places them in the mid-range of Region II of RG 1.174, then the most significant change or error would be one that results in the risk meeting or exceeding the Region I criteria. The next lower threshold would be one that results in an increase in risk that is greater than or equal to 50% of the margin available between their initial risk and the Region II / Region I threshold. The lowest threshold (requiring an annual report) would be one that results in an increase in risk that is greater than or equal to 25% of the margin between their initial risk and the Region II / Region I threshold. Additionally, there should also be a requirement that monitoring of cumulative changes should also be undertaken (as a matter of performance for each change or error) and if the cumulative impact meets the criteria specified above, the respective reporting and actions shall be taken. 2) For licensed defense-in-depth and safety margins, if not currently part of the licensed risk analysis, and not falling under Technical Specification requirements, then any reduction in these margins should be reported in annual report if evaluated and determined to not remove a necessary function (e.g., alternate core cooling capability) that was credited in the approval. If determined to result in a complete loss of a credited function, then the highest level of reporting should be required. 3) Since these criteria will be site specific, the establishment of the reporting criteria should be generally identified in the rule, with further supporting criteria and guidance in the RG, and distinct criteria identified in the approval for the licensee's application through discussion with the licensee. 4) In addition, it is recommended that NUREG-1022 be revised to include the newly defined reporting requirements, and RIS 2005-20 (and associated inspection guidance) be revised to allow for use of risk-informed methodologies for evaluation on nonconformances and degraded conditions. 5) The use of FLEX equipment and strategies should also be identified as acceptable defense-in-depth strategies.

53	NRC Question 8. *Exemptions Needed to Implement the Risk-Informed Alternative.* One objective of the proposed rule is to allow entities to submit a risk-informed alternative to address the effects of debris on long-term core cooling without the need to submit an exemption request. The NRC identified that, in order to eliminate the need for an exemption, changes may be necessary in GDCs 35, 38, and 41, as provided in the proposed rule. The NRC seeks input on whether conforming changes to other regulations would be necessary or desirable. Such conforming changes may avoid the need for entities wishing to use the risk-informed alternative to request exemptions from those regulations in order to effectively implement the risk-informed alternative. If you believe it is necessary or desirable to provide a conforming change to a regulation in order to avoid an exemption from that regulation, then please identify the specific regulation (and specific regulatory provisions, if applicable) for which a conforming change would be made, either the language of the change or a description of the conforming change's objective, and the reason(s) why an exemption would otherwise be needed if the NRC did not make a conforming change to that regulation.	1) Is GDC 19 a potential candidate for this approach? The concern is that other regulatory criteria are dependent on the success of the recirculation function to satisfy those criteria.
	C. Implementation (16129)	
54	NRC Question 9. *Staged Implementation.* The NRC is proposing, in § 50.46c(o), a staged implementation plan for the proposed rule. As part of this plan, licensees have been divided among three implementation tracks based upon existing margin to the revised requirements and anticipated level of effort to demonstrate compliance. The NRC requests specific comment on the staged implementation plan, track assignments, or alternative means to implement the requirements of the proposed rule.	1) Most of the non-pilot plants are in the current fast track (24 months) for implementation. Based on the timing of the STP SE, the availability of the supporting RG, and the desire to stagger submittals, there is a high probability that some of the plants will be outside the 24 month window. The currently proposed implementation tracks need to be modified to reflect the need to stagger those submittals which may provide for alignment for the non-pilot plants.

	D. Other Issues (16130)	
55	NRC Question 11. *Re-structuring 10 CFR Chapter I with respect to ECCS Regulations.* The NRC is considering restructuring its ECCS regulations as part of the finalization of this rulemaking due to: (1) Commission direction to include in the proposed rule a provision allowing licensees to use a risk-informed submittal to address the effects of debris during the long- term recovery period; and (2) the potential benefit and efficiency of collocating all ECCS-related requirements within the CFR. As such, the NRC seeks comment on the following potential administrative changes: • Codify the performance-based ECCS and cladding requirements (as proposed in this document) as a new section, § 50.181. • Reserve § 50.183 for the potential future risk-informed ECCS requirements rule (currently referred to as the draft final § 50.46a rule). • Codify the requirements for the risk-informed submittals (proposed as § 50.46c(e) in this proposed rule) to address the effects of debris in the long- term recovery period as a new section, § 50.185. • If this restructure is pursued, following the completion of the proposed staged implementation period, the NRC would make the following administrative changes: ○ Remove the current § 50.46, ECCS acceptance criteria, in its entirety. ○ Remove the current appendix K to 10 CFR part 50, in its entirety. (The content will exist as § 50.187.) ○ Redesignate the current § 50.46a, ‘‘Acceptance criteria for reactor coolant system venting systems,’’ as § 50.46. The tables that follow depict the described potential changes:	1) See the comments on Item 56.

	Existing NRC requirements and proposed new regulations (bolded rules are currently in effect)	Rulemaking and implementation activities	
		Initial codification of final performance-based fuel cladding requirements	End of phased implementation period for performance-based fuel cladding requirements	Finalization of risk-informed ECCS requirements (currently referred to as draft final § 50.46a)
	§ 50.46 ECCS Acceptance Criteria	§ 50.46 ECCS acceptance criteria *(no change)*.	Removed from 10 CFR Chapter I in its entirety.	Removed from 10 CFR Chapter I in its entirety.
	§ 50.46a Reactor Coolant Venting Systems ...	NO CHANGE	§ 50.46	§ 50.46.
	Draft final rule: § 50.46a Risk-Informed ECCS Requirements.	See Note 1	See Note 1	§ 50.183 Risk-informed emergency core cooling system requirements.
	Performance-based ECCS and cladding requirements *(currently designated in draft proposed rulemaking package as § 50.46c)*.	§ 50.181 Emergency core cooling system performance during loss-of-coolant accidents.	*§ 50.181*	§ 50.181.
	Requirements for risk-informed submittals to address effects of debris in the long-term post-quench cooling period *(currently designated in draft proposed rulemaking package as § 50.184)*.	§ 50.185 Requirements for risk-informed submittals to address effects of debris in the long-term post-quench cooling period.	§ 50.185 Requirements for risk-informed submittals to address effects of debris in the long-term post-quench cooling period.	§ 50.185.
	Appendix K to 10 CFR part 50: ECCS Evaluation Models.	Appendix K to 10 CFR part 50: ECCS Evaluation Models. *And* ..... § 50.187 ECCS evaluation models. See Note 2	§ 50.187 ECCS evaluation models.	§ 50.187.
	Note 1: The staff plans to submit the draft final § 50.46a rulemaking package to the Commission following completion of NTTF Recommendation 1 activities. At this time, it is uncertain whether finalization of the draft final § 50.46a rule would occur before the finalization of the proposed § 50.46c rule. **Note 2:** Until all licensees have implemented the proposed requirements (i.e., the proposed staged implementation is complete), appendix K to 10 CFR part 50, ''ECCS Evaluation Models,'' and § 50.187, ''ECCS Evaluation Models,'' would coexist.			
56	(Comments on Table above)	1) The current AORs for plants are based on the existing regulatory structure. Modifying these for a purely administrative basis will most likely result in unintended consequences especially for those personnel involved with this industry in the years to come. 2) As stated elsewhere in these comments (Item 20), this could exacerbate resource constraints for the NRC and industry, challenge knowledge transfer, and potentially re-open previously agreed upon issues.		

<table>
<tr><td></td><td colspan="2">Should this restructure be pursued, the following table depicts the structure of 10 CFR part 50 after finalization of the § 50.46a Risk-Informed ECCS Requirements and after the proposed staged implementation of the § 50.46c Performance-based ECCS and Cladding Requirements rulemaking is complete:
<table>
<tr><th>Section</th><th>Title</th></tr>
<tr><td>§ 50.46</td><td>Reactor coolant venting systems.</td></tr>
<tr><td>§ 50.181</td><td>Emergency core cooling system performance during loss-of-coolant accidents (§ 50.46c).</td></tr>
<tr><td>§ 50.183</td><td>Risk-informed emergency core cooling system requirements (§ 50.46a).</td></tr>
<tr><td>§ 50.185</td><td>Requirements for risk-informed submittals to address effects of debris in the long-term post-quench cooling period.</td></tr>
<tr><td>§ 50.187</td><td>ECCS evaluation models (appendix K to 10 CFR part 50).</td></tr>
</table></td></tr>
<tr><td>57</td><td>(Comments on Table above)</td><td>1) The proposed layout more clearly defines the requirements, but the process needed to get there may be costly.</td></tr>
<tr><td colspan="3">XIV. FINDING OF NO SIGNIFICANT ENVIRONMENTAL IMPACT: ENVIRONMENTAL ASSESSMENT
Identification of the Action (16133)</td></tr>
<tr><td>58</td><td>The proposed rule would also contain a provision that would allow licensees to use an alternative risk-informed approach to evaluate the effects of debris for long- term cooling.</td><td>No comments</td></tr>
<tr><td colspan="3">The Need for Action (16133)</td></tr>
<tr><td>59</td><td>The NRC identified the need for an approach that would allow entities to address the effects of debris on long- term cooling in a manner that would be more timely and cost-effective than the current use of deterministic methods.</td><td>1) No comments</td></tr>
</table>

	Environmental Impacts of the Proposed Action (16133)	
60	This environmental assessment focuses on those aspects of the proposed rulemaking through which the revised requirements could potentially affect the environment. The NRC has concluded that there will be no significant radiological environmental impacts associated with the implementation of the proposed rule requirements for the following reasons: 1) The proposed rule would allow entities to address the effects of debris on long-term cooling using a risk- informed approach. The effects of debris are currently addressed using deterministic methods. Any change in CDF and LERF allowed by a risk- informed approach would be small and within criteria already established in RG 1.174, Revision 2, for making risk- informed changes to plant licensing bases.	1) Rev. 2 of RG 1.174 includes requirements for external events modeling in the plant PRA MOR. Most plants do not have this level of PRA. The requirements for internal events are the same for Rev. 1 and Rev. 2 of RG 1.174. It may be a better approach to specify that plants meet the internal events criteria of RG 1.174, Revision 1 or later.
	Alternatives to the Proposed Action (16134)	
61	The proposed rule would allow entities to use a risk-informed approach to address the effects of debris for long- term cooling. An alternative to addressing debris using this risk- informed approach is to continue to address the effects of debris using deterministic methods and approved models, as described in SECY–12–0093, ‘‘Closure Options for Generic Safety Issue—191, Assessment of Debris Accumulation on Pressurized-Water Reactor Sump Performance,’’ dated July 9, 2012 (ADAMS Accession No. ML121310648). However, the NRC has added the alternative approach to provide entities the additional flexibility to address the effects of debris on long-term cooling using risk- informed methodologies, which may be implemented in a more timely and cost-efficient manner.	1) No comments
	XV. PAPERWORK REDUCTION ACT STATEMENT ***How Often the Collection is Required:*** (16134)	
62	LOCA model updates, Licensee Amendment Requests, and compliance letters will be submitted one time during implementation; significant errors will be reported on occasion (within 30 days); other errors or changes in analysis will be reported annually.	1) There needs to be improved clarity on what specifically will be required for those entities utilizing a risk-informed approach in addition to the Licensee Amendment Requests. This includes such items as errors or changes in analysis.

	Abstract (16135)	
63	The NRC is proposing to amend its regulations to revise the acceptance criteria for the emergency core cooling system for light-water nuclear power reactors as currently required by 10 CFR part 50. The rule would include a provision allowing entities to use an alternative risk-informed approach to evaluate the effects of debris for long-term cooling. If an entity voluntarily chooses to use this approach, they would need to submit an application for NRC review and approval, report all errors and changes in their plant-specific PRA, and conduct periodic updates to their PRA. The NRC is seeking public comment on the potential impact of the information collections contained in this proposed rule and on the following issues: 1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility? 2. Is the estimate of burden accurate? 3. Is there a way to enhance the quality, utility, and clarity of the information to be collected? 4. How can the burden of the information collection be minimized, including the use of automated collection techniques?	1) Improved definitions of changes to, and errors in, plant-specific PRA are necessary to establish mutually agreeable criteria that would trigger this reporting requirement, and those definitions should be provided in separate guidance. We support the NEI/EPRI RegTAC proposal to develop an NEI document that provides the criteria for corrective actions, reporting, and change management.
	XVIII. BACKFITTING AND ISSUE FINALITY ***Proposed* § *50.46c Rule*** (16136)	
64	The proposed rule would provide 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.	1) See comments on Item 24.

	Operating Licenses (16136)	
65	The proposed rule includes the option of allowing an applicant or licensee 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 this is a voluntary alternative to existing requirements as well the proposed requirements on ECCS, the inclusion of this option in the proposed rule is not backfitting or inconsistent with issue finality provisions in 10 CFR part 52. The proposed rule would also allow applicants and licensees who select the option of using the risk-informed approach for addressing the effects of debris on long-term cooling, to also use the same approach in demonstrating compliance with GDC–38 and GDC–41. Because this is a voluntary alternative with respect to a portion of the existing requirements in GDC–38 and GDC–41, inclusion of this option in the proposed rule is not backfitting as defined in § 50.109(a)(1).	No comments
	Draft Regulatory Guides (16138)	
66	The NRC also plans to issue regulatory guidance on the voluntary alternative for addressing the effects of debris on long-term cooling using a risk- informed approach. The NRC currently intends to issue the guidance in the form of one or more regulatory guides, and that the regulatory guides would be published in draft form for public comment before being issued in final form as part of a final § 50.46c rule.	1) The timing of publishing these draft regulatory guides, and their final approval is critical for those non-pilot plants that intend to use the risk-informed approach. Delay of these documents will result in delays of licensee amendment requests since the criteria may differ from the path that these licensees are currently pursuing. This represents significant regulatory uncertainty since it becomes very difficult for non-pilot plants (and potentially the BWR fleet) to adequately plan and implement this rule.

	PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES **§ 50.46c Emergency core cooling system performance during loss-of-coolant accidents (LOCA).** (16139)	
67	(b) *Definitions.* As used in this section: Debris evaluation model means the calculational framework used to quantify the impact of debris generation, transport, sump head loss, in-vessel effects, chemical precipitation, and other phenomena important to long- term cooling. It includes one or more computer programs and other information necessary for application of the calculational framework to a set of initiating events, the mitigation of which requires long term cooling via recirculation. It also includes mathematical models used, assumptions used by the programs, procedures for treating the program input and output information, specifications of those portions of analysis not included in computer programs, values of parameters, and all other information necessary to specify the calculational procedure. The debris evaluation model is used, along with the probabilistic risk assessment (PRA), to quantify the portion of core damage frequency and large early release frequency attributable to debris.	1) There should be clarity in the definition for Evaluation model as it pertains to the risk-informed approach. Maintaining the traditional definition will lead to substantial ambiguity on the part of both the applicants and the reviewers since an evaluation model for a risk-informed analysis is substantially different than that used for traditional core cooling considerations. How does the debris evaluation model interface with the traditional Evaluation model for core cooling? 2) The initial statement of the definition appears to be lacking in that it does not equate the impact to the plant risk as a function of debris. Stating that the impact is quantified could also be taken as the impact on the specific core cooling criteria. 3) Specifically stating that the model includes one or more computer programs may be somewhat misleading for some applicants. The range of calculational frameworks that could be used range from an Excel spreadsheet to a computer program as was used by STP for their pilot submittal. 4) A concern with including specific language for the definition in the rule, and not in the to be developed RG, is that it may be construed by some that the calculation framework that develops the conditional probabilities that are used for input to the PRA model are safety related. In most cases, this will not be true. 5) Recommendation: Maintain a high level definition in the rule and move the details of the definition to the RG. A proposed wording is: *Debris evaluation model means the calculational framework used to quantify the impact of debris generation, transport, sump head loss, in-vessel effects, and other phenomena important to long- term cooling. The debris evaluation model is used, along with the probabilistic risk assessment (PRA), to quantify the portion of core damage frequency and large early release frequency attributable to debris.*

68	(c) *Relationship to other NRC regulations.* (16139) The requirements of this section are in addition to any other requirements applicable to an emergency core cooling system (ECCS) set forth in this part, except as noted in this paragraph. The analytical limits established in accordance with this section, with cooling performance calculated in accordance with an NRC approved ECCS evaluation model, are in implementation of the general requirements with respect to ECCS cooling performance design set forth in this part, including in particular Criterion 35 of appendix A to this part. If the effects of debris on long-term cooling are evaluated using a risk- informed method as described in paragraph (e) of this section, then this method and results can be relied upon to demonstrate compliance with other requirements of this part as allowed by this section and requested in the application.	1) This is an area that may need additional clarification. Since, by definition, ECCS does not include containment spray (GDC-38) and containment atmosphere control (GDC-41), are there other rules that may require change to justify use of a debris based risk-informed approach for meeting the applicable rule requirements, for example 50.67?
69	(d) *Emergency Core Cooling Design* (1) *ECCS performance criteria.* (16139) Each LWR must be provided with an ECCS designed to satisfy the following performance requirements in the event of, and following, a postulated LOCA. The demonstration of ECCS performance must comply with paragraph (d)(2) of this section: 1) Core temperature during and following the LOCA event does not exceed the analytical limits for the fuel design used for ensuring acceptable performance as defined in this section. 2) The ECCS provides sufficient coolant so that decay heat will be removed for the extended period of time required by the long-lived radioactivity remaining in the core.	1) There needs to be additional clarity and definition as to which aspects of the proposed rule language apply to licensees intending to implement the risk-informed approach for debris considerations. 2) The proposed RG will need to point to other proposed RGs for determination of the analytical limits that must be met. 3) The proposed RG will need to define “extended period of time”. The currently accepted value for GSI-191 is 30 days. 4) It is further recommended that a clarification of these requirements be made that the criteria applies to design basis events and not to beyond-design basis events. 5) Please clarify in the rule whether the limits will be approved on a plant specific basis or design specific basis (fuel vendor) and whether they will require NRC review.
70	(2) *ECCS performance demonstration.* (16139) ECCS performance must be demonstrated using an ECCS evaluation model meeting the requirements of paragraph (d)(2)(i) or (d)(2)(ii) of this section, and satisfy the analytical requirements in paragraphs (d)(2)(iii), (d)(2)(iv), and (d)(2)(v) of this section. Paragraph (e) of this section may be used for consideration of debris as described in paragraph (d)(2)(iii) of this section. The ECCS evaluation model must be reviewed and approved by the NRC.	1) It is unclear as to which aspects of a risk-informed approach apply to this section. An ECCS evaluation model that includes consideration of debris appears to be beyond current requirements. How are the two models separated?

71	(i) *Realistic ECCS model.* (16139) A realistic model must include sufficient supporting justification to show that the analytical technique realistically describes the behavior of the reactor system during a loss-of-coolant accident. Comparisons to applicable experimental data must be made and uncertainties in the analysis method and inputs must be identified and assessed so that the uncertainty in the calculated results can be estimated. This uncertainty must be accounted for, so that when the calculated ECCS cooling performance is compared to the applicable specified and NRC-approved analytical limits, there is a high level of probability that the limits would not be exceeded.	1) How and does this apply to the risk-informed approach for debris in the coolant?
72	(iii) *Core geometry and coolant flow.* (16140) The ECCS evaluation model must address calculated changes in core geometry and must consider those factors, including debris, that may alter localized coolant flow in the core or inhibit delivery of coolant to the core. A licensee may evaluate effects of debris using a risk-informed approach to demonstrate long-term ECCS performance, as specified in paragraph (e) of this section.	1) As written, it may not be possible to meet this section with the risk-informed approach. Specifically, this sections states “A licensee may evaluate the effects of debris using a risk-informed approach.” The risk-informed approach evaluates the change in risk associated with debris in the coolant. The extent of evaluation of the effects of debris is to determine whether success criteria has been met when input to the PRA MOR, and whether the criteria of RG 1.174 can be met. 2) It is recommended that the definition of localized coolant flow be fully defined in a proposed RG since the performance of an evaluation for a risk-informed approach, a bulk analysis approach may be used. The acceptance should be based on adequate cooling of the core on a macroscopic scale rather than a microscopic scale.
73	(iv) *LOCA analytical requirements.* (16140) ECCS performance must be demonstrated for a range of postulated loss-of-coolant accidents of different sizes, locations, and other properties, sufficient to provide assurance that the most severe postulated loss-of-coolant accidents have been identified. ECCS performance must be demonstrated for the accident, and the post-accident recovery and recirculation period.	1) How does this interface with the requirements for a risk-informed debris evaluation model and accompanying plant PRA? 2) The term “assurance” is used in this paragraph. This should state “reasonable assurance”.
74	(3) *Required documentation.* (16140) Upon implementation of this section in accordance with paragraph (o) of this section, the documentation requirements of this paragraph apply and supersede the requirements in appendix K to this part, section II,	1) How and does this apply to the risk-informed approach for debris in the coolant? 2) Consider use of the term “practical” or “reasonable” versus “practicable”. Current consensus Code and standard language is no

	‘‘Required Documentation.’’ (i)(A) A description of each ECCS evaluation model must be furnished. The description must be sufficiently complete to permit technical review of the analytical approach, including the equations used, their approximations in difference form, the assumptions made, and the values of all parameters or the procedure for their selection, as for example, in accordance with a specified physical law or empirical correlation. (B) A complete listing of each computer program, in the same form as used in the ECCS evaluation model, must be furnished to the NRC upon request. (ii) For each computer program, solution convergence must be demonstrated by studies of system modeling or noding and calculational time steps. (iii) Appropriate sensitivity studies must be performed for each ECCS evaluation model, to evaluate the effect on the calculated results of variations in noding, phenomena assumed in the calculation to predominate, including pump operation or locking, and values of parameters over their applicable ranges. For items to which results are shown to be sensitive, the choices made must be justified. (iv) To the extent practicable, predictions of the ECCS evaluation model, or portions thereof, must be compared with applicable experimental information. (v) Elements of ECCS evaluation models reviewed will include technical adequacy of the calculational methods, including: For models covered by paragraph (d)(2)(ii) of this section, compliance with required features of section I of appendix K to this part; and, for models covered by paragraph (d)(2)(i) of this section, assurance of a high level of probability that the performance criteria of paragraph (d)(1) of this section would not be exceeded.	longer using this term.
(e) ***Alternate risk-informed approach for addressing the effects of debris on long-term core cooling.*** **(1)** ***Risk-informed approach acceptance criteria*** (16140)		
An entity may request the NRC to approve a risk- informed approach for addressing the effects of debris on long-term core cooling to demonstrate compliance with the requirements in paragraph (d)(1)(ii) of this section. The risk-informed approach must: (16140)		

75	(i) Provide reasonable confidence that any increase in core damage frequency and large early release frequency resulting from implementing the alternative risk-informed approach will be small;	1) This criteria needs to point to “small” as defined in RG 1.174.
76	(ii) Maintain sufficient defense-in- depth and safety margins;	1) It is assumed that the criteria for this paragraph will be provided in the RG. 2) Refer back to the comments on Item 9, which are applicable and related to this paragraph.
77	(iii) Consider results and insights from the probabilistic risk assessment (PRA); and	1) It is assumed that the criteria for this paragraph will be provided in the RG.
78	(iv) Utilize a PRA that, at a minimum, models severe accident scenarios resulting from internal events occurring at full power operation and reasonably reflects the current plant configuration and operating practices, and applicable plant and industry operational experience, is of sufficient scope, level of detail, and technical adequacy to support the alternative process, and is subjected to a peer review process that assesses the PRA against a standard or set of acceptance criteria that is endorsed by the NRC.	1) It is assumed that the criteria for this paragraph will be provided in the RG.
(2) *Contents of application* (16140) An entity seeking to use the risk-informed approach under paragraph (e)(1) of this section, must submit an application with the following information:		
79	(i) A description of the alternative risk-informed approach;	No comments

80	(ii) A description of the measures taken to assure that the scope, level of detail and technical adequacy of the systematic processes that evaluate the plant for internal and external events initiated during full power, low power, and shutdown operation (including the PRA, margins-type approaches, or other systematic evaluation techniques used to evaluate severe accidents) are commensurate with the reliance on risk information;	1) It is unclear as to what extent external events need to be modeled in the PRA MOR. If the external event does not contribute to an increase in debris that could impact the necessary cooling capabilities, then why would this have to be modeled? Also, this section appears to conflict with (e)(1) in that it requires consideration of external events in addition to full power internal events. 2) To what extent do severe accidents have to be evaluated since the purpose of 50.46 is to prevent severe accidents. Severe accidents are not in the scope of DBA and should not be referred to. Without additional information, this section is problematic. 3) An additional concern is the discussion of the adequacy of the systematic processes that evaluate internal and external events during shutdown operation. What specifically is meant by shutdown operation? 4) Why would shutdown modes be included since events during this condition do not generate debris, and for most if not all licensees, Technical Specifications do not require operability of the containment recirculation function during Modes 5 and 6. 5) The wording in this paragraph appears to be much more restrictive than the discussion in the Section by Section Analysis (See Item 30). 6) It is recommended that this paragraph be modified to state: *A description of the processes used to evaluate the plant for internal events and any external events that could result in debris generation, for those plant modes that could require recirculation.* The remaining detail could be described in the proposed RG.
81	(iii) Results of the PRA review process conducted to satisfy the requirements of paragraphs (e)(1)(iii) and (iv) of this section;	1) It is assumed that the criteria for this paragraph will be provided in the RG.
82	(iv) A description of, and basis for acceptability of, the evaluations conducted to demonstrate compliance with paragraphs (e)(1)(i) and (ii) of this section; and	1) It is assumed that the criteria for this paragraph will be provided in the RG. 2) As written, (e)(2)(i) does not require applicants to follow established regulatory guidance or provide discussion of the information required if a different approach is chosen. 3) With a lack of clear guidance defining an acceptable method of evaluation, there is significant regulatory uncertainty.

83	(v) The analytical limit on long-term peak cooling temperature as established in paragraph (g)(1)(v) of this section.	1) This should state peak cladding temperature instead of peak cooling temperature. 2) Does the long-term peak cladding temperature limit for post-quench operation in the recirculation mode need to consider a corresponding ductile-to-brittle transition when operating in the recirculation mode of core cooling? 3) (e)(2)(v) requires an analytical limit that is defined in another part of the rule that appears to be related to an ECCS evaluation model independent of debris.
(3) *NRC approval* (16140)		
84	If the NRC determines that the application demonstrates that the requirements of paragraph (e)(1) of this section are met, and the application establishes an acceptable long-term peak cladding temperature limit, then it may approve the use of the risk-informed approach for addressing debris effects on long- term cooling when issuing the license, regulatory approval or amendments thereto. The NRC's approval must specify the circumstances under which the licensee or design certification applicant, as applicable, shall notify the NRC of changes or errors in the risk evaluation approach utilized to address the effects of debris on long-term cooling.	1) The magnitude of changes or errors needs to be better defined to prevent unnecessary reporting and should be in a separate document (outside of the rule). 2) The long-term peak cladding temperature limit appears to not have any bearing on the risk-informed approach. Refer also to the comments on Items 34 and 35. 3) It is highly recommended that the magnitude of changes or errors that would require reporting be specifically described and not so restrictive as to not enable changes that result in minimal changes from being implemented at a plant without having to enter the reporting or application process. 4) In Item 34 (the statement and considerations paragraph applicable to this rule paragraph) identifies that a license condition will be the implementation methodology. Is this really necessary or should approval of the change in the licensing basis be the methodology? 5) Under what methodology would an acceptable long-term peak cladding temperature be established that ensures the ductile-to-brittle transition for the zirconium-alloy cladding material using an NRC-approved experimental technique? This is beyond the current scope of the risk-informed approach and is more appropriate for the non-risk-informed aspects of this rule.
(m) *Corrective actions and reporting.* (16141)		

85	Each entity subject to the requirements of this section must comply with paragraphs (m)(1) through (3) of this section. Each entity demonstrating acceptable long-term core cooling under the provisions of paragraph (e) of this section shall also comply with the requirements of paragraph (m)(4) of this section.	1) Does this mean that each entity that is pursuing the risk-informed approach must address paragraphs (m)(1) through (3) as part of their risk-informed application? It appears that (m)(1) through (3) are part of the ECCS evaluation model and not part of the Debris evaluation model.
86	(1) *Categories of changes, errors, or operation inconsistent with the ECCS evaluation model.* (i) If an entity identifies any change to, or error in, an ECCS evaluation model or the application of such a model, or any operation inconsistent with the ECCS evaluation model or resulting noncompliance with the acceptance criteria in this section, that does not result in any predicted response that exceeds any acceptance criteria specified in this section and is itself not significant, then a report describing each such change, error, or operation and a demonstration that the error, change, or operation is not significant must be submitted to the NRC no later than 12 months after the change or discovery of the error, or operation.	1) Does this paragraph specifically apply to the ECCS evaluation model or the Debris evaluation model, or both? 2) If the Debris evaluation model is considered to be part of this paragraph, then the criteria that is developed should be part of the proposed RG. 3) There are many factors that drive changes to the PRA MOR. As currently written, this section implies that for any change to the PRA MOR, even if there is not a significant impact on the results used to establish the licensing basis, then an annual report documenting all changes must be made. There should be more discrete criteria that would require this annual report. 4) What would be the purpose of providing this annual report, assuming the Debris evaluation model is considered as falling under these requirements? To what end would the NRC use this information?
87	(ii) If an entity identifies a change, error, or operation inconsistent with the ECCS evaluation model that does not result in any predicted response that exceeds any of the acceptance criteria but is significant, then a report describing each such change, error, or operation, and a schedule for submitting a reanalysis and implementation of corrective actions must be submitted within 30 days of the change, discovery of the error, or operation.	1) As with (i), more discrete criteria needs to be developed identifying the threshold upon which the actions of this section should be taken. For example, if a change is made to the plant that results in a change in the ΔCDF that exceeds X% of the value upon which the licensing basis was established, then this section would apply. In other words, better definition of significant is needed to ensure needed reporting is made, and unnecessary reporting is not made, for the risk-informed approach. 2) Refer also to Item 89.

88	(iii) If a licensee of a facility licensed to operate identifies a change, error, or operation inconsistent with the ECCS evaluation model that results in any of the acceptance criteria specified in this section to be exceeded at the facility, then the licensee shall report the change, error, or operation under §§ 50.55(e), 50.72, and 50.73, as applicable, and submit a report describing each such change, error, or operation and a schedule for submitting a reanalysis and implementation of corrective actions within 30 days of the change, discovery of the error, or operation.	1) See the comments on (i) and (ii) above (Items 86 and 87). 2) It is recommended that the rule language be significantly modified to state that reporting criteria, corrective actions, and configuration management be established to ensure compliance with the rule. One method to accomplish this would be to develop industry guidance that would be endorsed by the NRC as described in the supporting RGs.
89	(2) *Significant change or error in the ECCS evaluation model.* For the purposes of paragraph (m)(1) of this section, a significant change or error in an ECCS evaluation model is one that results in a calculated– 1) Peak fuel cladding temperature different by more than 50 ^{o}F from the temperature calculated for the limiting transient using the last NRC-approved ECCS evaluation model, or is a cumulation of changes and errors such that the sum of the absolute magnitudes of the respective temperature changes is greater than 50 ^{o}F; or 2) Integral time at temperature different by more than 0.4 percent ECR from the oxidation calculated for the limiting transient using the last NRC- approved ECCS evaluation model, or is a cumulation of changes and errors such that the sum of the absolute magnitudes of the respective oxidation changes is greater than 0.4 percent ECR.	1) The definition of significant in this section has traditionally applied to ECCS evaluation models. Additional definition needs to be developed to address the risk-informed coolant debris considerations. It is not anticipated that all licensees will develop full evaluation models that will identify the specific changes in cladding temperature but rather will develop risk-informed debris evaluation models that will identify if changes will continue to meet the success criteria as defined by RG 1.174, as given in their license amendment request and subsequent license amendment. 2) Refer also to the discussion in Items 87 and 88.

90	*(4) Updates to risk-informed consideration of debris in long-term cooling.* (vii) *Operating licenses and combined licenses after finding under § 52.103(g) of this chapter—updating and corrections.* (16142, 16143) The licensee shall review the analyses, evaluations, and modeling performed under paragraph (e) of this section for changes and errors and incorporate changes to the design, plant, operational practices, and applicable plant and industry operational experience. As appropriate, the licensee shall update the debris evaluation model and the PRA and its supporting analyses, and re-perform the evaluations of risk, defense-in-depth, and safety margins to confirm that the acceptance criteria identified in paragraph (e)(1) of this section continue to be met. The licensee shall perform this review in a timely manner after a change or error is identified in the analyses, evaluations, and modeling or a change is identified in the design, plant, operational practices, or applicable plant and industry operational experience. The licensee shall perform this review even if no changes or errors are identified, by no later than 48 months after the last review. If the licensee, at any time, determines that any acceptance criterion of paragraph (e)(1) of this section is not met, then the licensee shall take action in a timely manner to bring the facility into compliance with the acceptance criteria of paragraph (e)(1) of this section. The licensee shall also report the failure to meet the long-term cooling acceptance criterion in paragraph (e)(1) of this section. The report must be prepared and submitted in accordance with, §§ 50.72, and 50.73, as applicable. Thereafter, the licensee shall submit, in a timely fashion, an application for amendment of its license, including necessary changes to its updated final safety analysis report. The amendment application must demonstrate that the acceptance criteria of paragraph (e)(1) of this section are met, and must describe any changes to the analyses, evaluations and modeling needed to support that conclusion. The amendment application for a combined license must, if applicable, include a request for exemption from a referenced design certification rule, but need not address the criteria for obtaining an exemption. The NRC need not address either the backfitting criteria in § 50.109 or the issue finality criteria in §§ 52.63, 52.83, and 52.98 of this chapter when acting on this amendment and shall, as part of any approved amendment, issue any necessary exemption upon a finding that the exemption is authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.	1) There is uncertainty with the way this section is worded with regard to the criteria to be used to determine if changes or errors have occurred. There needs to be more explicit definition as to what constitutes a change or error. 2) With regard to the statement ".then the licensee shall take action in a timely manner to bring the facility into compliance.", it is recommended that the same tools that were used to assess the impact of debris also be used to assess the necessary timing of the action that needs to be taken. If an issue is identified, it will most likely require some physical change to the plant that may have the potential to require a refueling outage to accomplish. If the issue can be shown, through the use of PRA, that the potential impact is manageable through compensatory or other actions, then allowances for the necessary time to effect the required changes should be provided. 3) Refer also to the discussion in Items 87, 88, and 89. 4) It is recommended that this section be made consistent with the changes proposed by the NEI/EPRI RegTAC to develop a separate NEI document to provide the necessary and consistent criteria for corrective actions, reporting, and change management. 5) It is unclear as to why language is placed in this section which allows the NRC to exempt themselves from the backfitting criteria in § 50.109 or the issue finality criteria in §§ 52.63, 52.83, and 52.98. Is there going to be comporting changes to these regulations in support of the proposed changes to § 50.46?

(o) *Implementation* (16143)		
91	(4) Operating licenses issued under this part as of [EFFECTIVE DATE OF RULE] must comply with the requirements of this section by no later than the applicable date set forth in Table 1 in paragraph (o) of this section. Until such compliance is achieved, the requirements of § 50.46 continue to apply.	3) Some plants pursuing risk-informed debris approach may not be in full compliance by the dates published in Table 1 since their amendment requests may still be in NRC review. Plants in the no later than 24 months from effective date of rule category: Calvert Cliffs Diablo Canyon Palisades Point Beach St. Lucie Seabrook Turkey Point Wolf Creek
Appendix A to Part 50 – General Design Criteria for Nuclear Power Plants (16145)		
92	*Criterion 35—Emergency core cooling.* A system to provide abundant emergency core cooling shall be provided. The system safety function shall be to transfer heat from the reactor core following any loss of reactor coolant at a rate such that 1) fuel and clad damage that could interfere with continued effective core cooling is prevented and 2) clad metal-water reaction is limited to negligible amounts. Suitable redundancy in components and features, and suitable interconnections, leak detection, isolation, and containment capabilities shall be provided to assure that for onsite electric power operation (assuming offsite power is not available) and for offsite electric power system operation (assuming onsite power is not available) the system safety function can be accomplished, assuming a single failure. The effects of debris on system safety function with respect to long-term cooling may be evaluated in accordance with all requirements applicable to the risk-informed approach in § 50.46c.	1) The chosen language currently appears to leave significant questions as to how this would be addressed in a licensee's application. Based on the initial RAI set received by STP, it is not expected that the proposed language would significantly change the course of the review by Staff. 2) There is conflict that needs to be addressed – assurance is "reasonable assurance" not "absolute assurance" as is implied by the GDC and as some NRC Staff interprets. The new tool, i.e., Risk-informed approach, allows a method consistent with determination of reasonable assurance. 3) The risk-informed approach is consistent with the "holistic" approach advocated by the NRC since the issuance of the GL and should be appropriately factored into both the rule language and proposed RG.

93	Criterion 38—Containment heat removal system. A system to remove heat from the reactor containment shall be provided. The system safety function shall be to reduce rapidly, consistent with the functioning of other associated systems, the containment pressure and temperature following any loss- of-coolant accident and maintain them at acceptably low levels. Suitable redundancy in components and features, and suitable interconnections, leak detection, isolation, and containment capabilities shall be provided to assure that for onsite electric power system operation (assuming offsite power is not available) and for offsite electric power system operation (assuming onsite power is not available) the system safety function can be accomplished, assuming a single failure. The effects of debris on safety system function with respect to the maintenance of containment pressure and temperature may be evaluated in accordance with all requirements applicable to the risk-informed approach in § 50.46c.	1) The chosen language currently appears to leave significant questions as to how this would be addressed in a licensee's application. Based on the initial RAI set received by STP, it is not expected that the proposed language would significantly change the course of the review by Staff. 2) There is conflict that needs to be addressed – assurance is "reasonable assurance" not "absolute assurance" as is implied by the GDC and as some NRC Staff interprets. The new tool, i.e., Risk-informed approach, allows a method consistent with determination of reasonable assurance. 3) The risk-informed approach is consistent with the "holistic" approach advocated by the NRC since the issuance of the GL and should be appropriately factored into both the rule language and proposed RG.
94	Criterion 41—Containment atmosphere cleanup. Systems to control fission products, hydrogen, oxygen, and other substances which may be released into the reactor containment shall be provided as necessary to reduce, consistent with the functioning of other associated systems, the concentration and quality of fission products released to the environment following postulated accidents, and to control the concentration of hydrogen or oxygen and other substances in the containment atmosphere following postulated accidents to assure that containment integrity is maintained. Each system shall have suitable redundancy in components and features, and suitable interconnections, leak detection, isolation, and containment capabilities to assure that for onsite electric power system operation (assuming offsite power is not available) and for offsite electric power system operation (assuming onsite power is not available) its safety function can be accomplished, assuming a single failure. The effects of debris on system safety function following occurrence of the postulated accidents may be evaluated in accordance with all requirements applicable to the risk-informed approach in § 50.46c.	1) The chosen language currently appears to leave significant questions as to how this would be addressed in a licensee's application. Based on the initial RAI set received by STP, it is not expected that the proposed language would significantly change the course of the review by Staff. 2) There is conflict that needs to be addressed – assurance is "reasonable assurance" not "absolute assurance" as is implied by the GDC and as some NRC Staff interprets. The new tool, i.e., Risk-informed approach, allows a method consistent with determination of reasonable assurance. 3) The risk-informed approach is consistent with the "holistic" approach advocated by the NRC since the issuance of the GL and should be appropriately factored into both the rule language and proposed RG.