WOLF CREEK
NUCLEAR OPERATING CORPORATION

Cleveland Reasoner
Vice President Engineering

September 4, 2014

ET 14-0027

Secretary
U. S. Nuclear Regulatory Commission
Washington, DC 20555
ATTN: Rulemakings and Adjudications Staff

Reference: Federal Register Notice, 79 FR 16106 (Volume 79, No. 56), dated March 24, 2014

Subject: Comments on the NRC Proposed Rulemaking and Guidance for 10 CFR 50.46c, "Performance-Based Emergency Core Cooling Systems Cladding Acceptance Criteria," Docket ID NRC 2008-0332

Dear Secretary:

The Nuclear Regulatory Commission (NRC) has published a proposed rule to amend the current requirements governing emergency core cooling systems, per Federal Register Notice (FRN), Vol. 79, No. 56, dated March 24, 2014. 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 Generic Safety Issue (GSI)-191 and sump suction issues.

The purpose of this letter is to provide 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.

Wolf Creek Nuclear Operating Corporation (WCNOC) has 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 the risk associated with debris.

2. The reporting requirements for the Debris evaluation model, analysis changes, and errors should be deleted from the rule. Existing reporting processes including Part 21, §50.72, and §50.73 are sufficient. WCNOC would endorse development of an Nuclear Energy Institute (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 the enclosure to this document, it is also requested that NRC consider revision of RIS 2005-20 and NRC Inspection Manual Chapter 0326, "Operability Determinations and Functionality Assessments for Conditions Adverse to Quality or Safety," 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.

The enclosure 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.

This letter contains no commitments. If you have any questions concerning this matter, please contact me at (620) 364-4171, or Mr. Steven R. Koenig at (620) 364-4041.

Sincerely,

Cleveland Reasoner

COR/rlt

Enclosure

cc: M. L. Dapas (NRC), w/e
C. F. Lyon (NRC), w/e
N. F. O'Keefe (NRC), w/e
Senior Resident Inspector (NRC), w/e

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FEDERAL REGISTER

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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

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	V. PROPOSED REQUIREMENTS FOR ECCS PERFORMANCE DURING LOCAs ***B. Performance-Based Aspects of the Proposed Rule*** (16118)	
1	*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 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	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 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 decision making 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

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	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 decision making 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 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	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".

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	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	

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	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 decision	

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	making 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.	

XVIII. BACKFITTING AND ISSUE FINALITY		
Proposed* § *50.46c Rule (16136)		
Draft Regulatory Guides (16138)		
2	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)		
3	(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: *Risk-Informed assessment model means the 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 risk-informed assessment 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.*

4	(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?
5	(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.
6	(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?

7	(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?
8	(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.
9	(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".
10	(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, "Required Documentation."	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 longer using this term.

	(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.	

(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)

11	(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.
12	(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 1, which are applicable and related to this paragraph.
13	(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.
14	(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:	
15	(i) A description of the alternative risk-informed approach;	No comments

16	(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. 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.
17	(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.
18	(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.

19	(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)	
20	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. 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) 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)	

21	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.
22	(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 model of record (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?
23	(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 25.

24	(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 22 and 23). 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.
25	(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 °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 °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 23 and 24.

26	*(1) 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 23, 24, and 25. 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)	
27	(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 Generating Station
	Appendix A to Part 50 – General Design Criteria for Nuclear Power Plants (16145)	
28	*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 Generic Letter (GL) 2004-02 and should be appropriately factored into both the rule language and proposed RG.

29	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 GL 2004-02 and should be appropriately factored into both the rule language and proposed RG.
30	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 2004-02 and should be appropriately factored into both the rule language and proposed RG.