PRELIMINARY DRAFT

Enclosure 2

Public availability of this draft document is intended to inform stakeholders of the current status of the NRC staff's preliminary draft final rule package and associated documents for § 50.46c of Title 10 of the Code of Federal Regulations (10 CFR). These preliminary draft documents are in support of an October 22, 2015, Category 3 public meeting, and a November 2, 2015, Advisory Committee on Reactor Safeguards (ACRS) subcommittee meeting.

This draft document has not been subject to all levels of NRC management review. Accordingly, it is incomplete and may be in error in one or more respects. The document may be subject to further revision before the staff provides the final draft rule language package to the Commission (currently scheduled to be provided to the Commission in February 2016). In particular, the preliminary draft language in paragraph (e), ***Alternate risk-informed approach for addressing the effects of debris on long term core cooling****, is under current staff discussion with respect to the manner in which the risk-informed alternative may be used in the initial NRC approval of new reactor designs, and for modifications of both new reactor designs and currently operating nuclear power reactors.*

NRC Staff Responses to Public Comments on Proposed Rule:
"Performance-Based Emergency Core Cooling Systems Cladding Acceptance Criteria" and
Three Associated Draft Regulatory Guides
Federal Register 79 FR 16106 (March 24, 2014)

I. INTRODUCTION

This document presents the NRC's responses to written public comments received on the proposed rule, 10 CFR 50.46c, *"Performance-Based Emergency Core Cooling Systems Cladding Acceptance Criteria,"* published in the *Federal Register* (79 FR 16106, March 24, 2014). This document also provides the NRC's responses to written public comments received on three associated draft regulatory guides (DGs) referenced in the *Federal Register* notice: DG-1261, "Conducting Periodic Testing for Breakaway Oxidation Behavior" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML12284A324) DG-1262, "Testing for Post Quench Ductility" (ADAMS Accession No. ML12284A325), and DG-1263, "Establishing Analytical Limits for Zirconium-Based Alloy Cladding" (ADAMS Accession No. ML12284A323).

Public comments were also received on a fourth DG related to this rulemaking: DG-1322, "Risk-Informed Approach for Addressing the Effects of Debris on Post Accident Long-Term Core Cooling" (ADAMS Accession No. ML15023A025), in response to a separate *Federal Register* entry (80 FR 21658, April 20, 2015). Because this fourth DG was developed later than the other three, the NRC's responses to those public comments are in a separate document, which may be found at ADAMS Accession No. ML15252A131.

The NRC staff intends to issue the final version of Draft Guides 1261, 1262, and 1263 as Regulatory Guide (RG) 1.222, "Measuring Breakaway Oxidation Behavior," RG 1.223, "Determining Post Quench Ductility," and RG 1.224, "Establishing Analytical Limits for Zirconium-Alloy Cladding Material," respectively. Similarly, the NRC staff will issue the final version of DG-1322 as RG 1.229, "Risk-Informed Approach for Addressing the Effects of Debris on Post-Accident Long-Term Core Cooling,

II. OVERVIEW OF COMMENTERS AND COMMENTS

The 150-day public comment period for the proposed rule, DG-1261, DG-1262, and DG-1263 lasted from March 24, 2014 to August 21, 2014. The NRC received 35 comment submissions from 23 commenters during this time and one comment submission after the deadline. Of the 36 total submissions, 17 were from private citizens, and 19 were from members of the nuclear industry. Table 1 presents information on these comment submissions. The NRC received multiple requests for an extension of the public comment period, which the NRC granted. These extension requests are identified as NEI2, BEST/MATRR1, RT1 and IMP1 in the table below. The following represents a general breakdown of the percentage of comments received by topic:

- Risk-informed approach to addressing the effects of debris on long-term cooling: 38%
- Post Quench Ductility Draft Regulatory Guides: 20%
- Long-Term Cooling Criteria: 9%
- Implementation: 7%
- Cost-Benefit/Regulatory Analysis: 6%
- Post Quench Ductility Criteria: 4%
- Post Quench Ductility Reporting: 4%
- Breakaway Oxidation Testing/Reporting: 3%
- Crud: 2%
- Other Topics: 7%

Table 1.

Name	Affiliation	ADAMS Accession No.		Identifier
		Incoming	Annotated[1]	
Scott Bauer	STARS Alliance	ML14237A115	ML15281A086	STARS1
Gary Becker	NuScale	ML14237A380	ML15281A080	NS1
Gordon Clefton	Nuclear Energy Institute	ML14237A149	ML15281A085	NEI1
Gordon Clefton	Nuclear Energy Institute	ML14086A207[2]	N/A	NEI2
Jeffrey Deshon	Electric Power Research Institute	ML14234A340[3]	ML15281A100	EPRI1
James Gresham	Westinghouse	ML14233A400[4]	ML15281A090	WEC1
James Harrison	GE Hitachi	ML14237A338[5]	ML15281A082	GEH1
Tom Huber	Dominion	ML14237A110	ML15281A087	D1
Ata Istar	USNRC	ML14233A221	ML15281A091	AI1
Gretel Johnston Garry Morgan	Bellefonte Efficiency and Sustainability Team (BEST)/Mothers Against Tennessee River Radiation (MATRR)	ML14118A518	ML15281A110	BEST/ MATRR1
Paul Leonard	-	ML14237A188	ML15281A084	PL1
Marvin Lewis	-	ML14107A493[6]	ML15281A096	ML1
Mark Edward Leyse	-	ML14237A203	ML15281A083	MEL1
Robert Leyse	-	ML14098A491	ML15281A088	RL1
Robert Leyse	-	ML14115A463	ML15281A111	RL2
Robert Leyse	-	ML14195A504	ML15281A109	RL3
Robert Leyse	-	ML14219A539	ML15281A108	RL4
Robert Leyse	-	ML14223A668	ML15281A107	RL5
Robert Leyse	-	ML14226A647	ML15281A106	RL6
Robert Leyse	-	ML14233A199	ML15281A105	RL7
Robert Leyse	-	ML14233A204	ML15281A104	RL8
Robert Leyse	-	ML14237A094	ML15281A103	RL9
Robert Leyse	-	ML14219A582	ML15281A099	RL10
Ralph Meyer	-	ML14112A597	ML15281A095	RM1

[1]

[2] This comment was also logged in dockets NRC-2012-0041, NRC-2012-0042, NRC-2012-0043 as ML14090A087

[3] This comment was also logged in dockets NRC-2012-0041, NRC-2012-0042, NRC-2012-0043 as ML14234A341 and ML14234A342

[4] This comment was also logged in dockets NRC-2012-0041, NRC-2012-0042, NRC-2012-0043 as ML14239A036, ML14239A037 and ML14239A038

[5] This comment was also logged in dockets NRC-2012-0041, NRC-2012-0042, NRC-2012-0043 as ML14239A032, ML14239A033 and ML14239A034

[6] This comment was also logged in dockets NRC-2012-0041, NRC-2012-0042, NRC-2012-0043 as ML14122A017

Name	Affiliation	ADAMS Accession No.		Identifier
		Incoming	Annotated[1]	
Ralph Meyer	-	ML14125A494	ML15281A093	RM2
Michael Murray	South Texas Project	ML14231B210	ML15281A092	STP1
James Petro	FPL, NextEra	ML14237A486[7]	ML15281A113	FPL1
Chuck Pierce	Southern Nuclear Operating Co.	ML14237A361	ML15281A081	SNC1
Timothy Rausch	PPL Susquehana	ML14237A446	ML15281A079	PPL1
Cleveland Reasoner	Wolf Creek Nuclear Operating Corporation	ML14251A042	ML15281A098	WC1
Pedro Salas	Areva	ML14233A512[8]	ML15281A089	A1
Michael Scarpello	Indiana Michigan Power	ML14113A426	N/A	IMP1
Jack Stringfellow	Pressurized Water Reactor Owners Group	ML15194A144	ML15281A101	PWROG1
Ruth Thomas	Environmentalists, Inc.	ML14115A464	ML15281A094	RT1
James Gresham	Westinghouse	ML15191A326	ML15281A102	WEC2
James Barstow	Exelon Generation	ML14302A562	ML15281A112	EG1

The first comment for eleven of the commenters was a general endorsement of the industry comments provided by the Nuclear Energy Institute (NEI1): STP1, WEC1, A1, D1, STARS1, GEH1, SNC1, PPL1, EG1, PWROG1, and FPL1. The NRC response to NEI comments should be taken as responding to these comments as well, but these nine comments are not explicitly referenced in the next section for ease of reading.

Section III, “Specific Request for Comment,” provides a summary of the comments received in response to the specific requests for comment NRC provided as a part of the proposed rule. Section IV, “NRC Responses to Comments on the Proposed Rule,” provides the NRC’s detailed responses to comments on the proposed rule. Section V, “NRC Responses to Comments on Individual Draft Guides,” provides the NRC’s responses to comments on the three draft regulatory guides, DG-1261, 1262 and 1263. Section VI, “NRC Responses to Comments on Draft Regulatory Analysis,” provides NRC’s responses to comments on the draft regulatory analysis that was published with the proposed rule.

[7] This comment was also logged in dockets NRC-2012-0041, NRC-2012-0042, NRC-2012-0043 as ML14239A035, ML14241A382 and ML14245A017
[8] This comment was also logged in dockets NRC-2012-0041, NRC-2012-0042, NRC-2012-0043 as ML14233A462

III. SPECIFIC REQUEST FOR COMMENT

In the FRN for the proposed rule, the NRC provided specific requests for comment on twelve different topics. The major themes of the public comments associated with these specific requests and the NRC positions are summarized below. For more detailed responses, please see the Section IV, "Staff Responses to Comments on the Proposed Rule."

NRC Question 1. Performance-Based Peak Cladding Temperature Limit

The NRC requested comment on the retention of the prescriptive peak cladding temperature (PCT) criterion, rather than adopting a performance-based requirement. The NRC specifically asked whether established test procedures were available for demonstrating high temperature cladding performance. The NRC received specific responses regarding NRC Question 1 from AREVA, GEH, NEI, and WEC. All comments received on Question 1 expressed that maintaining the current prescriptive limit was inconsistent with the objective of a performance-based rule. Many industry commenters suggested that the peak cladding temperature limit be moved to regulatory guidance, allowing applicants wishing to request at PCT limit greater than 2,200 °F to address relevant degradation mechanisms. NEI noted that at present, there are no industry plans to immediately seek a PCT greater than 2,200 °F. No commenter identified test procedures that could be used to demonstrate high temperature cladding performance. The NRC's position is that there is not an adequate technical basis to extend peak cladding temperature beyond 2,200 °F. Further, the NRC does not believe there is a strong demand from licensees to outline a methodology to extend peak cladding temperature beyond 2,200 °F. The NRC did not change the rule due to these comments. See section IV. F for detailed comment responses.

NRC Question 2. Periodic Breakaway Testing

The NRC requested comment on the type of data that should be reported and the required frequency of testing for breakaway oxidation. The NRC expressed that the objective of periodic testing was to prevent affected fuel from being loaded into a reactor, without adding ineffective requirements or unnecessary burden. The NRC received specific responses regarding NRC Question 2 from AREVA, GEH, NEI, and WEC. The industry commenters generally expressed that the sample frequency should be reduced and be more flexible. The industry commenters also expressed that requiring licensees to report breakaway oxidation results was unnecessary and that the fuel cladding vendors should address the concerns regarding breakaway oxidation with their quality assurance programs. A few fuel cladding vendors proposed that periodic test program plans could be developed by the fuel cladding vendors and approved by the NRC. The NRC agreed that the periodic testing and reporting requirements could be revised in a way that adds flexibility, decreases cost and burden of breakaway oxidation testing, and still achieves the safety objective. The NRC agreed that the objective of the rule could be achieved with rule language that requires a fuel vendor to submit breakaway oxidation testing program for NRC review and approval and that the requirement for licensees to report breakaway oxidation results could be removed. The NRC changed the rule and associated regulatory guidance accordingly due to these comments. See section IV.F for detailed comment responses

NRC Question 3. Analytical Long-Term Peak Cladding Temperature Limit

The NRC sought comment on the new requirement in § 50.46c(g)(1)(v) of the proposed rule which stipulated that a long term cooling (LTC) peak cladding temperature analytical limit be established that preserved cladding ductility based upon an NRC-approved test program.

Specifically, the NRC requested input regarding this new performance requirement to determine whether (1)cladding ductility was the most suitable performance-based metric, (2)peak cladding temperature was the most suitable analytical limit, and (3) a technical basis existed for long-term cladding performance. No commenter supported the proposed new requirement. Several commenters questioned whether cladding ductility was the most appropriate performance-based metric. These commenters noted that different cladding degradation mechanisms may exist at different post-quench temperature regimes. Several commenters questioned the use of a single analytical limit on PCT, noting that time-at-temperature may be more appropriate to capture the degradation mechanisms. Not a single commenter identified an existing technical basis for long-term, post-quench fuel performance. Several commenters requested that the existing § 50.46 rule language be maintained.

As a result of the comments received, the NRC revised the LTC performance requirement. Specifically, if debris considerations prompt a post-quench reheat transient, then the applicant would need to demonstrate, using an NRC-approved analytical limit and experimental procedure, that no further cladding failure is predicted to occur. See Section IV.F for further details.

NRC Question 4. Acceptance Criteria for Risk-Informed Alternative

The NRC requested comment regarding whether detailed acceptance criteria for the risk-informed alternative approach permitted by draft § 50.46c(e) should be contained within the rule, or within the applicable regulatory guide. The NRC received specific responses regarding NRC Question 4 from GEH1, NEI1, PL1, PWROG1, and WEC1. There were other comments on this concept. All those commenting on this question stated that the detailed acceptance criteria should be in a regulatory guide and not the rule, which should be at a high level. Several commenters said that the guidance should refer to and be consistent with Regulatory Guide (RG) 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis.” One commenter suggested that industry should develop a guidance document for NRC endorsement and that the guidance should be piloted before final rulemaking.

The NRC position is that the rule is written at a high level and that the details are contained in RG 1.229. As no industry guidance document was received by NRC for possible endorsement, this suggestion has not been adopted. A pilot application of the alternative risk-informed approach was underway during this rulemaking activity and greatly influenced the development of RG 1.229. The NRC did not change the rule due to these comments. See section IV.E for detailed comment responses.

NRC Question 5. Regulatory Approach for Regulation

The NRC sought comment on whether the risk-informed alternative should (1) require meeting numeric-risk acceptance criteria, (2) allow risk-importance insights to establish measurable criteria or performance objectives, or (3) incorporate elements of (1) and (2), above. The NRC received specific responses regarding NRC Question 5 from GEH1, NEI1, PL1, and PWROG1. There were other comments on this concept. All of those commenting agreed that a “single selection” approach should not be specified, but rather the rule should allow use of core damage frequency (CDF) and large early release frequency (LERF), importance measures, or some other metrics. All stated that the rule should contain performance objectives rather than meeting specific numeric risk acceptance criteria. Two commenters suggested that § 50.48(c)

was a model for how this rule should be written. One commenter said the guidance, including the risk acceptance criteria, should be piloted before final rulemaking.

The NRC position is that numeric risk acceptance criteria for CDF and LERF are consistent with the current approach to risk-informed regulation as set forth in RG 1.174. These metrics are approved surrogates for the Commission's quantitative health objectives. The NRC did not find an adequate basis in the comment submissions to justify the use of risk importance measures or other metrics in lieu of the approved surrogates (CDF and LERF). The commenters did not provide examples of performance objectives for staff consideration. The NRC notes that the § 50.46c section on the alternative risk-informed approach contains less detail than § 50.48(c), but is consistent in terms of the risk-informed metrics, maintenance of defense-in-depth and safety margins, and other aspects. A separate pilot application of the risk acceptance criteria is not judged necessary, since a pilot application was underway during this rulemaking activity, and the risk-informed approach in the rule is consistent with RG 1.174 and past uses of risk information. The NRC did not change the rule due to these comments. See section IV.E for detailed comment responses.

NRC Question 6. Operational Modes Considered in Risk-Informed Alternative

The NRC requested comment on whether the risk-informed approach provided in § 50.46c(e) could generically exclude any plant operational modes (e.g., low power or shutdown) from consideration. The NRC received specific responses regarding NRC Question 6 from GEH1, NEI1, PL1, and PWROG1. There were other comments on this concept. Two commenters stated that the risk assessment should be limited to modes where Technical Specifications require recirculation and should be limited to design-basis accidents, not severe accidents. Two other commenters stated that the modes should be limited to those where high pressure jets could result in debris sufficient to impact the recirculation function. One commenter noted that there may be, on a case-by-case basis, some modes other than at-power where high pressure jets cold result in a debris issue, and noted the need to pilot the guidance on the alternate risk-informed approach.

The NRC position is that the risk assessment must consider all hazards and all operating modes. Some hazards and certain plant operating modes may be screened from further consideration using approaches as set forth in the American Society for Mechanical Engineers/American Nuclear Society (ASME/ANS) Probabilistic Risk Assessment (PRA) Standard as endorsed in RG 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities." Restricting the plant operating mode based on Technical Specifications or limiting the analysis to design-basis accidents is inconsistent with the risk-informed approach, which considers the risk from severe accidents. In addition, the NRC does not believe an additional pilot effort is necessary, as RG 1.229 was developed using insights from the pilot application underway during the rulemaking activity. The NRC did not change the rule due to these comments. See section IV.E for detailed comment responses.

NRC Question 7. Reporting Criteria for the Risk-Informed Alternative

The NRC requested comment on the reporting criteria contained in draft § 50.46c(m) regarding the reporting requirements associated with the risk-informed alternative. The NRC received specific responses regarding NRC Question 7 from GEH1, NEI1, PL1, and PWROG1. There were other comments on this concept. The commenters generally stated that the rule should be very high level regarding monitoring and reporting, and that the details should be in a regulatory

guide. By "high level," the commenters meant that the rule might only contain a requirement for a monitoring program and reporting, but not prescribe further specific requirements. Two commenters stated that the monitoring and reporting should be plant-specific – each licensee would propose its program in the license amendment request that the NRC would review and approve. These commenters suggested that thresholds for reporting would be graded – plants with higher risk could have more stringent reporting requirements than lower-risk plants, for example. One commenter said that corrective action and reporting should be no different than for current risk-informed applications. Regarding PRA updates, a commenter said that these should be event-triggered rather than calendar-based. In other words, PRA updates would result from plant or procedural modifications independent of the time since the last update. Finally, a commenter stated that the guidance on monitoring and reporting should be reviewed by industry and piloted.

The NRC position is that the rule must contain high-level requirements for performance monitoring, reporting, and corrective actions. The NRC's intent was to write the rule at a high level as suggested by the comments and to include detailed guidance for these requirements in the regulatory guides. The reporting and corrective action criteria in the rule have been modified to add clarity to the requirements by re-organizing the section. In addition, the NRC does not believe an additional pilot effort is necessary, as RG 1.229 was developed using insights from the pilot application underway during the rulemaking activity.

In response to the comments received, the NRC simplified paragraph (m)(4) of the final rule for added clarity. Paragraphs (m)(6), (m)(7), and (m)(8) now contain the requirements for risk-informed consideration of debris reporting, corrective action, and updates. See section IV.I for detailed comment responses.

NRC Question 8. Exemptions Needed to Implement the Risk-Informed Alternative

The NRC sought comment regarding whether conforming changes to other regulations (e.g., GDCs 35, 38, and 41) would be necessary to facilitate implementation of the risk-informed alternative without requesting additional exemptions. The NRC received specific responses regarding NRC Question 8 from GEH1, NEI1, PL1, and WEC1. Three commenters stated that they had identified no additional regulations for which exemption requests are expected to be necessary to support the implementation of the alternate risk-informed approach for addressing the effects of debris on core cooling. One commenter questioned whether an exemption from General Design Criterion (GDC) 19, "Control Room," would be needed and another suggested and exemption from 10 CFR 50.67, "Accident Source Term," might also be needed for debris effects, as the other regulatory criteria are also dependent upon success of the long-term recirculation criteria. There were other comments on this concept. *Placeholder for summary of NRC response.* See section IV for detailed comment responses.

NRC Question 9. Staged Implementation

The NRC sought comment on the staged implementation plan in § 50.46c(g)(1)(v) of the proposed rule. The staged implementation would have divided the existing fleet among three implementation tracks, based upon existing margin to the revised requirements, and anticipated level of effort to demonstrate compliance. No commenter supported the Table 1 plant-specific compliance dates in the proposed rule. Several commenters identified that ongoing licensing activities, planned plant modifications, potential fuel vendor and/or fuel cladding alloy changes, and other plant-specific activities may necessitate exemption requests due to the Table 1 assignments. A series of public workshops and webinars were held in 2015 to improve the

implementation plan. The industry provided a comprehensive, integrated schedule to illustrate the magnitude of effort and parallel and series work activities. This information informed a revision to the rule language. The rule was modified and Table 1 was removed and replaced with a requirement for licensees to submit an implementation plan within 6 months. Schedule requirements have been established within the rule for (1) submitting a license amendment request documenting compliance and (2) complying with the rule. The revised implementation plan is based upon an alternative implementation plan provided by several commenters. See Section IV.J for further details.

NRC Question 10. New Reactor Implementation

The NRC sought comment regarding the proposed implementation plan for new reactors. The NRC received specific responses regarding Question 10 from GEH1, NEI1, and WEC1. The commenters raised concerns about new reactors potentially loading fuel and coming on-line while being required to comply with the new rule at a faster pace than the operating reactor fleet. The NRC has rewritten paragraph (o)(9) of the proposed rule to place the new reactors on a time schedule for compliance that is consistent with the approach taken for the operating fleet. That is, a new reactor that is in the startup sequence aligned with the effective date of the rule must now comply with the requirements of the rule by the initial fuel loading or 84 months from the effective date of the rule, whichever is later. Thus, the compliance timing of a new reactor is consistent with that of the operating reactors. See section IV.J below for detailed comment responses.

NRC Question 11. Re-structuring 10 CFR Chapter I with respect to ECCS Regulations.

The NRC sought comment on the administrative changes of restructuring 10 CFR chapter I with respect to Emergency Core Cooling System (ECCS) regulations. In response to this request, the NRC received specific responses from GEH1, NEI1, PL1, and WEC1. All of these comments stated that the industry agrees with the NRC that there will be large costs to revise industry documentation to reflect the proposed restructuring discussed in this question. These costs include the complete renumbering of many licensing basis documents. The benefits of the proposed restructuring were perceived by these commenters to be small or non-existent from the standpoint of safety. The comments stated that, in light of the lack of perceived safety or other benefits of significance, the industry did not develop a cost estimate. The NRC did not change the rule due to these comments.

NRC Question 12. Cumulative Effects of Regulation

The NRC sought comment on the rule's implementation schedule in light of any existing cumulative effect of regulation (CER) challenges. In response to this request, the NRC received comments from NEI1, WEC1, and GEH1. The comments generally stated that the industry is concerned with the adequacy of industry resources that will be required to perform the work activities resulting from the rule. Further, comments stated that the rule's effective date, compliance date, and submittal dates do not provide sufficient time to implement the new requirements. To cope with the aforementioned challenges, comments suggested greater schedule flexibility. As a result of these public comments, the NRC hosted multiple public meetings in 2015 to discuss comments on implementation of the rule. The industry and NRC staff discussed the most effective and efficient means to implement § 50.46c. The industry provided a comprehensive, integrated schedule to illustrate the magnitude of effort and parallel and series work activities. This information informed a revision to the rule language. The revised implementation approach provides flexibility to address any plant-specific issues, such as

pursuing advanced cladding. The rule was modified with a requirement for licensees to submit an implementation plan within 180 days. Schedule requirements have been established within the rule for (1) submitting a license amendment request documenting compliance and (2) complying with the rule.

IV. STAFF RESPONSES TO COMMENTS ON THE PROPOSED RULE

Responses to comments on the proposed rule are organized in this section as follows:

A. Applicability of Rule
B. Definitions
C. Relationship to other NRC Regulations
D. ECCS Design
E. Alternate Risk-Informed Approach
F. Fuel Performance Criteria
G. NRC Approved Fuel
H. Corrective Actions and Reporting
I. Implementation
J. Appendix A to Part 50 – General Design Criteria
K. Appendix K to Part 50 – ECCS Evaluation Models
L. Miscellaneous Comments
M. Cumulative Effects of Regulation
N. Backfit

In each area, comments that raise similar or identical matters are "binned" into a single comment summary and an overall NRC response to the binned comments is provided.

A. Applicability of Rule

Comment: The draft rule language should be modified to state that if a certification of permanent cessation of operations has been submitted under 10 CFR 52.110, then the rule is not applicable. [NEI1-59]

NRC Response: The NRC agrees that 10 CFR 52.11(a)(1) should be added to the exclusion in § 50.46c(a), inasmuch as that section sets forth the license termination requirements for combined licenses issued under part 52, analogous to the 10 CFR 50.82 license termination requirements for part 50 operating licenses. The rule has been revised accordingly.

Comment: The language of the proposed rule should also allow boiling water reactors (BWRs) to adopt an alternative risk-informed approach for resolution of debris issues. [PL1-1, PL1-5]

NRC Response: The NRC agrees with this comment and notes that the alternative risk-informed approach in the proposed rule is not limited to a specific reactor type. No changes were made to the rule as a result of this comment.

Comment: In the Executive Summary - Purpose of the Regulatory Action, Generic Safety Issue (GSI)-191 is mentioned. Since BWRs are not currently required to resolve GSI-191, this paragraph should be revised to identify their special circumstance and the effort being undertaken to address the debris issue. [PL1-2] If the level of detail provided in II. Background - B. GSI-191 is necessary to describe the background for PWRs, then additional information should also be provided to reflect the current status of BWRs. [PL1-6]

NRC Response: The NRC disagrees that BWRs need to be mentioned in the Executive Summary or the Background section, as the alternative risk-informed approach in the rule is not limited to a specific reactor type. GSI-191 is mentioned in the Executive Summary because the

Commission direction in SRM-SECY-12-0034, "Proposed Rulemaking - 10 CFR 50.46c: Emergency Core Cooling System Performance During Loss-of-Coolant Accidents (RIN 3150-AH42)," and in SRM-SECY-12-0093, "Closure Options for Generic Safety Issue – 191, Assessment of Debris Accumulation on Pressurized-Water Reactor Sump Performance," were related to GSI-191. The rule does not limit use of the alternative risk-informed approach. No change was made to the rule as a result of this comment.

B. Definitions

Comment: The definition of "debris evaluation model" should be simplified and the wording associating the definition with deterministic methods should be eliminated. [NEI1-61] The definition of debris evaluation model does not need to be included in the proposed rule because there are other guidance documents that ensure the adequacy of the risk-informed methodology. [STP1-3] The lack of clarity in the definition of debris evaluation model could lead to the understanding that the debris evaluation model is part of the ECCS evaluation model. This could result in unintended documentation requirements for licensees. [STP1-4]

NRC Response: The NRC agrees that the definition of "debris evaluation model" was confusing. This definition has been removed from the final rule and the description of the alternative risk-informed approach (paragraph (e)) has been clarified.

Comment: The definition of "debris evaluation model" did not specifically tie the impact of debris to plant risk. The definition is too restrictive because it states that the model must include at least one computer code, and the calculational framework may be construed as having to be safety related, which is not necessarily the case for PRA model inputs. A high level definition is appropriate for the rule. [PL1-63, PL1-64, PL1-65, and PL1-66; WC1-17, WC1-18, WC1-19, and WC1-20]

NRC Response: The NRC agrees that the definition of "debris evaluation model" was confusing. The NRC disagrees with the need for this definition, as the "debris evaluation model" is part of the risk assessment described in paragraph (e). This definition has been removed from the final rule and the description of the alternative risk-informed approach (paragraph (e)) has been clarified.

Comment: The definition of "debris evaluation model" should be general enough to allow use of the debris evaluation model during the short-term post-LOCA period. [NEI1-61, STP1-2, PL1-24, PL1-62, WC1-16].

NRC Response: The NRC disagrees with the implication that a risk-informed method can be applied to the short-term post-LOCA period because the Commission specifically instructed the NRC staff to include a risk-informed alternative for long-term core cooling in SRM-SECY-12-0093. The Commission did not direct the staff to allow the short-term cooling period to be addressed using a risk-informed framework. No changes have been made to the rule as a result of this comment.

Comment: 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. [WC1-1]

NRC Response: The NRC agrees that the definition of "debris evaluation model" needs to be changed to improve clarity. This comment is related to other Wolf Creek comments (WC-16 through 20) and other industry comments on the definition of "debris evaluation model". This comment (WC1-1) is an overarching comment regarding the definition while the others are more specific comments on the same topic. In response to these comments the NRC determined that the definition for "debris evaluation model" should be removed from the rule. Also, to improve clarity, the requirements for submitting a risk-informed evaluation have been better defined in that section of the rule.

Comment: The definition of "debris evaluation model" applies only to models used in conjunction with the risk-informed evaluation approach. Lacking any reference to a deterministic debris evaluation model may lead to confusion. [A1-2]

NRC Response: The definition of "debris evaluation model" has been removed from the proposed rule. This comment is no longer relevant. See response to STP1-4.

Comment: The definition of the ECCS "evaluation model" should not include plant-specific inputs, which could be interpreted as "values of parameters, and all other information." [NEI1-60] The evaluation model does not include plant-specific input values that describe physical plant characteristics, such as operating pressure or high-pressure safety injection (HPSI) flow rates. [A1-1]

NRC Response: The NRC disagrees with the assertion that the ECCS evaluation model does not include plant-specific inputs. The definition of "evaluation model" contained in 10 CFR § 50.46c(b) remains largely unchanged from the one provided at 10 CFR 50.46(c)(2). In addition, NEI has, in the past, offered a similar interpretation (i.e., that an evaluation model should not be considered to include plant-specific input information) to the NRC, and the NRC has stated that it disagreed with NEI's interpretation. Refer to 65 FR 34918. Based upon (1) the fact that the new definition contained in 10 CFR 50.46c(b) is unchanged from that presently established at 10 CFR 50.46(c)(2), and (2) the NRC's long-standing interpretation that input information is considered a part of an evaluation model, the NRC has declined to revise the definition of "evaluation model" in response to the comment.

Comment: Remove redundant definition of "loss of coolant accident" (LOCA). [NEI1-63]

NRC Response: The NRC disagrees with this comment. Maintaining the definition of LOCA within § 50.46c ensures clarity with respect to ECCS performance requirements. No changes have been made as a result of this comment.

Comment: Add a definition for "crud". [NEI1-64]

NRC Response: The NRC agrees with this comment. The rule was modified to include a definition of "crud" in Paragraph (b).

Comment: Add a definition for "reload batch". [NEI1-65]

NRC Response: The NRC disagrees that a definition for "reload batch" is necessary. The proposed requirement for breakaway testing has been modified and no longer refers to a reload batch.

Comment: The NRC Glossary, http://www.nrc.gov/reading-rm/basic-ref/glossary/cladding.html, defines "cladding" as follows: The thin-walled metal tube that forms the outer jacket of a nuclear fuel rod. It prevents corrosion of the fuel by the coolant and the release of fission products into the coolant. Aluminum, stainless steel, and zirconium alloys are common cladding materials. However, 10 CFR Part 50.46(a)(1)(i) and 10 CFR Part 50.46(c) limit the cladding material to zircaloy or ZIRLO™ and "zirconium-alloy," respectively. The definition of "cladding" in the NRC Glossary may need to be revised according to the requirements of the rule by deleting Aluminum and stainless steel. [AL1-1]

NRC Response: The NRC disagrees with this comment. Relative to § 50.46, which was limited to zircaloy or ZIRLO, the applicability of § 50.46c has been expanded to all LWR fuel types. Applicants requesting approval for aluminum or stainless steel cladding would need to conduct research, identify all degradation mechanisms under LOCA conditions, define performance metrics, and define analytical limits and requirements. The final rule has not been modified, nor has the Glossary been revised, based on this document.

C. Relationship to other NRC Regulations

Comment: Paragraph (c) references GDC 35 but does not reference GDC 38 and 41. This appears to be an oversight, inasmuch as the proposed rule includes changes to GDC 38 and 41 which are analogous to the proposed changes in GDC 35. The paragraph should be changed to include references to GDCs 38 and 41 in the last sentence. [NEI1-66]

NRC Response: The NRC agrees that paragraph (c) should include conforming references to GDC 38 and 41, inasmuch as paragraph (c) was intended to ensure that no separate exemption is needed in order for licensees to voluntarily use a uniform method and results for showing compliance with both 10 CFR 50.46c and GDC 35, 38 and/or 41. The NRC does not intend that licensees must submit a request for and obtain an exemption from the NRC for any one or all of the three listed GDCs. The final rule has been revised to list GDC 35, 38, and 41. [*Placeholder for potential additional details.*]

Comment: Paragraph (c) of the proposed rule (addressing the relationship of the 10 CFR 50.46c regulation to other related NRC regulations), as well as other regulations not identified in the proposed rule, may need to be changed in order to allow the use of a debris based risk-informed approach for meeting the applicable rule requirements. For example, because ECCS does not include containment spray (GDC-38) and containment heat removal (GDC-41), a change to 10 CFR 50.67 (accident source term) may be needed. [PL1-25, PL1-67]

NRC Response: The NRC interprets the comments as suggesting that the NRC: (i) identify other regulations where the risk-informed provisions in the § 50.46c regulation for consideration of debris during long-term cooling could also be used as an alternative approach for demonstrating compliance with those regulations, such as 10 CFR 50.67, (ii) revise paragraph (c) of the proposed rule to identify those regulations, and (iii) make conforming changes to those regulations to enable the use of the risk-informed alternative without exemption.

[*Placeholder for NRC response*]

D. ECCS Design

a. *ECCS Performance Criteria*

Comment: Paragraph 50.46c(d) confuses ECCS design in accordance with GDC 35, with ECCS performance as demonstrated by meeting fuel analytical limits specified in 50.46c(g). [NEI1-67]

NRC Response: The NRC agrees in part with this comment. The recommended changes include (1) changing title from ECCS design to ECCS performance, (2) referring to GDC-35, and (3) referring to paragraph (g). The relationship to GDC-35 is defined in Paragraph (c) and does not need to be added here. Paragraph (g) defines analytical limits and requirements for uranium-oxide fuel within zirconium alloy cladding. Different fuel designs will have different requirements, which will be added to Paragraphs (h), (i), and (j). Therefore, Paragraph (d) should not refer solely to Paragraph (g).

Comment: Paragraph 50.46c(d)(1)(i) relates to fuel performance, not ECCS performance. [NEI1-68] Paragraph 50.46c(d)(1)(ii) should refer to the core cooling acceptance criterion. [NEI1-69]

NRC Response: The NRC disagrees with these comments. The recommended changes include referring to Paragraph (g). ECCS capability and capacity judged by its ability to deliver sufficient coolant to maintain fuel within acceptable temperature limits. Different fuel designs will have different requirements, which will be added to Paragraphs (h), (i), and (j). Therefore, Paragraph (d)(1) should not refer solely to Paragraph (g). No changes to the rule were made as a result of this comment.

Comment: There needs to be additional clarity and definition as to which aspects of the proposed rule change apply to licensees intending to implement the risk-informed approach for debris considerations. [PL1-68, WC1-22]

NRC Response: The NRC agrees with this comment. The risk-informed approach for debris considerations applies to long-term cooling requirements. The rule and statements of consideration (SOC) were clarified.

Comment: It is further recommended that a clarification of the requirements in § 50.46c(d) be made that the criteria apply to design basis events and not to beyond-design basis events. [PL1-71, WC1-25]

NRC Response: The NRC agrees, in part, with this comment. The deterministic aspects of § 50.46c, as well as § 50.46, requirements are applicable to design basis accidents. This may include consideration of GDC-2, but is not intended for beyond-design basis events. However, the risk-informed alternative approach, per 10 CFR 50.46c(e), does consider the entire spectrum of events, including beyond-design basis events. The rule and SOC were clarified.

Comment: The rule requires clarification regarding whether the limits will be approved on a plant specific basis or design specific basis (fuel vendor) and whether they will require NRC review [PL1-72, WC1-26]

NRC Response: The NRC disagrees with this comment. Paragraph (d) defines high-level performance requirements independent of fuel design. For uranium or mixed oxide pellets within cylindrical zirconium based cladding, paragraph (g) defines specific performance requirements, analytical limits, and analytical requirements. Paragraph (g) is clear with respect to requiring

NRC review for analytical limits. In general, the analytical limits and requirements will be design specific and documented and submitted for NRC review by the fuel vendors. However, a licensee may request approval of plant-specific analytical limits and requirements. No change to the rule was made based on this comment.

b. *ECCS Performance Demonstration*

Comment: The industry agrees with the inclusion of all zirconium-alloy claddings and mixed uranium-plutonium oxide fuel within the proposed rule. This change will facilitate the deployment of advanced materials without the burden of submitting exemption requests or additional future rulemaking. [NEI1-70]

NRC Response: The NRC agrees with this comment. No changes were proposed or required.

Comment: Paragraph (d)(2)(ii). In the context of the proposal to move Appendix K content to a new regulatory guide, we should no longer refer to an acceptable conservative model as "Appendix K," rather, call it the analog of realistic. [NEI1-72]

NRC Response: The NRC disagrees with this comment. Appendix K will remain in the regulation as it still provides a useful and acceptable method for evaluating ECCS performance. No changes to the rule were made as a result of this comment.

c. *Required Documentation*

Comment: In Paragraph (d)(3)(vi), Table 1 does not state what documentation is required to be submitted, so the proposed language must be changed to state that Table 1 only includes the compliance date. [NEI1-73] Also, there appears to be an editorial mistake in paragraph (d)(3)(vi): the words "of Table 1 in paragraph (o) of this section" from the end of 3rd line and in the 4th line of the paragraph seem mistakenly inserted. Recommendation: Remove the extra words. [GEH1-35]

NRC Response: The NRC agrees with this comment. Table 1 does not describe required documentation. Furthermore, Table 1 was removed from the rule. Paragraph (p) stipulates implementation schedule requirements. Paragraph (d)(3)(vi) was deleted.

Comment: Page 16140, 50.46c(d)(3)(i)(B) Required documentation, Statement in Rule: "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." Description of Concern: The required documentation being requested is unclear and could be misinterpreted. Basis for Concern: It is unclear if the NRC is requesting the source code or simply a list of program names and their executed versions. Proposal: Replace with "The source code for each computer program used in the ECCS evaluation model must be furnished to the NRC upon request." Basis of proposal: n/a [A1-3]

NRC Response: The NRC agrees with this comment. The recommended change was incorporated.

Comment: Page 16140, 50.46c(d)(3)(iii) Required documentation. Statement in Rule: "Appropriate sensitivity studies must be performed for each ECCS evaluation model, to evaluate the effect on the calculated results of variations in nodding, 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." Description of Concern: The application of the statement is not specified to the evaluation model: Realistic vs. Appendix K. Appendix K provides a prescriptive, conservative approached deemed to be acceptable to the NRC. Extensive sensitivity studies on the prescriptive Appendix K approach are not necessary. Basis for concern: This section could potentially require a large increase in sensitivity studies for deterministic, Appendix K, evaluation model analyses. Proposal: Modify the section as follows: Appropriate sensitivity studies must be performed for each Best Estimate ECCS evaluation model, to evaluate the effect on the calculated results of variations in nodding, 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. [A1-4]

NRC Response: The NRC disagrees with this comment. This requirement is consistent with Appendix K Section II.3 and will be maintained. No change to the rule was made as a result of this comment.

E. Alternate Risk-Informed Approach

a. *Clarify Risk-Informed versus Deterministic*

Comment: The rule language should be clarified to better distinguish between deterministic and risk-informed. [NEI1-71] It is not clear which paragraphs of the proposed 50.46c are applicable to (or not applicable to) the risk-informed approach. [NEI1-76, WC1-3, PL1-7] A risk assessment (PRA model) will result in scenarios that go to core damage; that is, "… scenarios for which compliance to (d)(1)(ii) cannot be demonstrated, although their risk contribution would be small." [STP1-5] How does paragraph (d)(2)(iv) on "LOCA analytical requirements" interface with the risk-informed alternative? [PL1-77, WC1-31] How does paragraph (d)(3) apply to the risk-informed approach for debris in the coolant? [PL1-79, WC1-33] It may not be possible to meet section (d)(2)(iii) with the risk-informed approach. [PL1-75, WC1-29]

NRC Response: The NRC agrees that it is important to clarify the distinction between "deterministic" and "risk-informed" approaches. One possible reason for the confusion indicated by the number of comments on this topic may be that the original language of the proposed rule was not clear on the following point: All licensees must demonstrate deterministically that paragraph (d) of the rule is met, either by including debris in the deterministic analysis or by assuming a debris-free plant for the deterministic analysis. In the latter case, the risk-informed alternative would need to be used to account for the impact of debris on long-term core cooling. The intent of the risk-informed approach is to use the principles of risk-informed regulation as set forth in RG 1.174 to inform the regulatory decision regarding the impact of debris on long term core cooling.

In order to clarify the deterministic and risk-informed approaches, the NRC has improved the rule language in paragraph d(2)(iii) as follows: 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. However, a licensee may evaluate effects of debris on long-term cooling using a risk-informed approach as specified in paragraph (e) of this section, in which case the ECCS evaluation model specified in

paragraph (d)(2)(i) or d(2)(ii) of this section need not include the effects of debris on long-term cooling.

The NRC disagrees that it may not be possible to meet (d)(2)(iii) or any of the other deterministic requirements with the risk-informed approach because the risk-informed approach is not used to demonstrate that those requirements are met. As clarified by the new rule language, the risk-informed approach only applies to the impact of debris and the deterministic analysis must also be performed, albeit without consideration of the impact of debris included in the risk-informed approach.

Comment: 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. [PL1-26]

NRC Response: The NRC disagrees that this part of the rule is a "deal breaker." The intent of the proposed rule is to allow a risk-informed alternative for assessing the impact of debris on long term cooling. A licensee choosing to apply the risk-informed alternative would assume no debris when applying its ECCS evaluation model, and then use the risk-informed approach to show that the presence of debris can be acceptable based on very small risk, adequate defense-in-depth and safety margins, and performance measurement strategies. In order to address this comment, the proposed rule was clarified by revising paragraph (d)(2)(iii); see response to NEI1-71.

Comment: It is unclear as to which aspects of a risk-informed approach apply to paragraph (d)(2). There needs to be additional clarity and definition as to which aspects of the proposed rule change apply to licensees intending to implement the risk-informed approach for debris considerations. [PL1-68, WC1-22] An ECCS evaluation model that includes consideration of debris appears to be beyond current requirements. How are the two models separated? [PL1-73, WC1-27] How and does the realistic ECCS model of paragraph (d)(2)(i) apply to the risk-informed approach for debris in the coolant? [PL1-74, WC1-28]

NRC Response: The NRC agrees that paragraph (d) should be clarified to clarify how it relates to the risk-informed approach. Text has been added in (d)(2)(iii) as follows:

> However, a licensee may evaluate effects of debris on long-term cooling using a risk-informed approach as specified in paragraph (e) of this section, in which case the ECCS evaluation model specified in paragraph (d)(2)(i) or d(2)(ii) of this section need not include the effects of debris on long-term cooling.

The NRC disagrees that an ECCS evaluation model that includes consideration of debris is beyond current requirements because the need to consider the effects of debris on ECCS performance is implicit in the current 10 CFR 50.46 rule. The explicit mention of debris here is to make clear that a new risk-informed approach is being provided as an alternate means of addressing debris.

b. *Analytical Limit and the Risk-Informed Approach*

Comment: Paragraph (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. The proposed RG for the alternate risk-informed approach will need to point to other proposed RGs for determination of the analytical limits that must be met. [PL1-69, WC1-23] [PL1-98, WC1-52, PL1-30] In paragraph (e)(2)(v) the word "cooling" should be "cladding". [NEI1-78, PL1-96, WC1-50]

NRC Response: The NRC agrees with this comment that the use of the term "analytical limit" was inconsistent in the proposed rule, and that "cooling" was the incorrect word. The NRC notes that the term is not applicable to the risk-informed alternative. The reference to an analytical limit has been removed from paragraph (e), resolving both comments.

Comment: Does the analytical limit on long-term peak cladding temperature for post-quench operation in the recirculation mode [referenced in paragraph (e)(2)(v) of the risk-informed alternative] need to consider a corresponding ductile-to-brittle transition when operating in the recirculation mode of core cooling? [PL1-97, WC1-51]

NRC Response: The NRC notes that the term "analytical limit" is not applicable to the risk-informed alternative. The reference to an analytical limit has been removed from paragraph (e).

Comment: Peak cladding temperature, as mentioned in paragraph (e)(2)(v) of the proposed rule, may not be the best analytical limit. [NEI1-79]

NRC Response: The NRC agrees that the PRA definition for core damage may be different than the proposed analytical limit for showing compliance with the deterministic portion of the rule. The NRC expects that the PRA would continue to use "state of practice" definitions of core damage consistent with the ASME/ANS PRA Standard, as endorsed by RG 1.200. However, if the plant is not at a "safe, stable end point" at the end of the PRA mission time selected for the risk assessment, then such sequences must be considered core damage as provided in the PRA Standard. Therefore, the reference to an analytical limit in the risk-informed portion of the rule has been removed.

Comment: The rule should not establish a PCT as a PRA success criterion, but allow the application of core damage success criteria established in the PRA (e.g., CDF and LERF). PCT may not be appropriate metric for long-term core cooling [for the PRA]. [STP1-6, PL1-100, WC1-54, PL1-103, NEI1-81, WEC1-20]

NRC Response: The NRC agrees that the rule should not establish PCT as a PRA success criterion and notes that the term is not applicable to the risk-informed alternative. The reference to an analytical limit has been removed from paragraph (e).

Comment: 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 nonrisk-informed aspects of this rule. [PL1-103, WC1-57]

NRC Response: As stated above, the NRC agrees that the rule should not establish PCT as a PRA success criterion and notes that the term is not applicable to the risk-informed alternative. The reference to an analytical limit has been removed from paragraph (e).

Comment: Does each entity that is pursuing the risk-informed approach have to 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. [PL1-104, WC1-58] Does paragraph [(m)(1)] specifically apply to the ECCS evaluation model or the Debris evaluation model, or both? [PL1-105, WC1-59]

NRC Response: The NRC agrees that the proposed rule language was not clear regarding what a licensee that elects to use the risk-informed alternative must do to comply with 10 CFR 50.46c. The rule language has been revised (paragraphs d(2)(iii) and (e)(1)) to make it clear that the risk-informed alternative applies only to debris effects and that compliance with the deterministic aspects of the rule must is still required, assuming no debris effects, if the risk-informed option is used. In addition, the rule language was revised to remove any reference to a "debris evaluation model." With these clarifications, the NRC believes that paragraph (m) does not require further revision, because it should be clear that all licensees must comply with (m)(1) and (m)(2) and that licensees using the risk-informed alternative must also comply with (m)(6) through (m)(8).

c. *Scope of Risk-Informed Approach (Including Methods)*

Comment: The risk-informed approach should be allowed for the impact of debris on core cooling regardless of time frame; e.g. short-term core cooling as well as long-term core cooling. [NEI1-31, NEI1-71, NEI1-74, NEI1-76, WEC1-16, NEI1-78, NEI1-79, NEI1-81]

NRC Response: The NRC does not agree that the risk-informed approach should be allowed for the demonstration of short-term cooling when debris is present that could impact the ability of the ECCS, containment spray, core spray, or other systems that provide safety functions for mitigation of a LOCA event. The NRC's PRA Policy Statement outlines expectations for increasing the use of PRA technology. Any new application must be supported by the state of the art and must support the NRC's traditional defense-in-depth philosophy. The NRC's position is that expanding the scope of the risk-informed alternative to include short term core cooling would violate those principles.

The NRC staff and industry has limited experience with evaluations that model the effects of debris on short-term core cooling and notes that such relatively new methods might have large uncertainty. Analysis of short term core cooling involves a number of sophisticated thermal hydraulic models needed to calculate hydrogen production, fuel embrittlement, entrainment of ECCS flow, and other complex phenomena. Even without consideration of debris, distinguishing between success and failure is challenging. The NRC does not believe that the effects of debris could be integrated into risk models in a credible fashion considering the present state of knowledge.

A key element of the defense-in-depth philosophy is that a reasonable balance is preserved amongst prevention of core damage, prevention of containment failure, and consequence mitigation. Although failure of long term core cooling as a result of debris may be assumed to cause core damage, decay heat loads and thermal hydraulic (T-H) conditions during this time are such that the challenge to containment would not be expected to be severe. Furthermore, "long term" by definition implies a period of time that would allow consequence mitigation such as EP actions and other mitigative measures. Therefore the balance between core damage prevention, prevention of containment failure, and consequence mitigation is maintained.

In stark contrast, a core damage event induced by short-term failure of the ECCS, when decay heat loads are high and no thermal energy has been removed from the RCS or containment, would lead to a severe challenge to the containment and would allow plant operational staff little or no time for consequence mitigation. Therefore, this shifts the balance by placing an increased importance on prevention of core damage, as protecting the containment and consequence mitigation are extremely difficult or impossible.

Since expanding the scope of the risk-informed alternative to include short term core cooling would violate the NRC's traditional defense-in-depth philosophy, no changes were made to the rule in response to these comments.

Comment: The risk-informed option should not be restricted to consideration of debris, but should be a comprehensive approach for risk-informing core cooling overall. [NEI1-19, D1-7, NEI1-24] Comment: NRC should include an option for a comprehensive risk-informed approach for long-term cooling. The proposed rule language restricts the use of a risk-informed approach to the consideration of debris. A more general risk-informed approach would provide the PWROG with a tool for evaluation of chemical effects and boric acid precipitation (BAP). [PWROG1-13]

NRC Response: The NRC does not agree with providing an option for using a risk-informed approach to demonstrating adequate core cooling during LOCAs. In order to be consistent with the defense-in-depth philosophy, the ECCS design must be able to mitigate design basis LOCA events with a high level of reliability and availability. Traditional engineering approaches, together with the single failure criterion and other applicable general design criteria, ensure that adequate safety margins and defense-in-depth are incorporated into the ECCS design. Licensees have the option of using the realistic approach as set forth in paragraph (d)(2)(i) of the proposed rule. No changes to the rule were made as a result of this comment.

Comment: Only design basis accident (DBA) events should be considered, not severe accidents. [PL1-28, PL1-35, PL1-47, PL1-87, WC1-41, NEI1-26]

NRC Response: The NRC disagrees that only DBA events should be considered if the alternate risk-informed approach is used to assess the impact of debris. This is because the risk-informed approach is intended to be realistic and therefore must consider the full spectrum of events or accident scenarios in determining the potential benefit from a debris-free containment and for which risk is increased by the presence of debris. This is consistent with the extant practice of crediting structures, systems, and components (SSCs) irrespective of their safety classification in PRA models and using expected ("realistic") success criteria. No changes to the rule were made as a result of this comment.

Comment: The scope of the risk-informed alternative should be restricted to only those modes of operation where recirculation would be required by Technical Specifications or modes of operation where recirculation is relied upon and the accident could cause high pressure jets that could result in debris generation and transport. Shutdown modes should not be in scope for these reasons. [PL1-33, PL1-46, PL1-89, WC1-43, GEH1-16] Since the debris "created" from a pipe break is a function of the area of jet impingement, it seems reasonable that for less-than-full power events (when the impact from the break would be less), less debris would be available to "clog" the sump. In general, at-power events (i.e., at Mode 1 or Mode 2) should be bounding. [PWROG1-7] External events should not be in scope unless the external event directly causes a DBA or directly affects mitigation of a DBA. [PL1-36, WC1-12] Paragraph (e)(2)(ii) appears to conflict with (e)(1). [PL1-86, WC1-40] Most plants do not have a PRA that

includes the external events guidance in revision 2 of RG 1.17 4; therefore, the rule should specify that plants meet the internal events criteria of RG 1.174, Revision 1 or later. [PL1-58, PL1-15]

NRC Response: The NRC does not agree with these comments. The NRC's position is that, consistent with RG 1.174, all modes and hazards should be addressed. The entity may be able to demonstrate that risk contributions from a specific mode or hazard are insignificant and would not alter the results of comparison with the risk acceptance guidelines, which includes both the plant's total risk as well as the change in risk associated with debris effects, and be able to screen out these modes and hazards from the risk-informed approach. The NRC's position is that it is the responsibility of each entity, not the NRC, to make this argument on a site-specific basis.

Comment: The words "including debris" in paragraph (d)(2)(iii) expand the scope of the rulemaking beyond the high-burnup research findings and the original goal stated in *Purpose of Regulatory Action.* Recommendation: The NRC should allow the industry to resolve the debris-related issues under the ongoing programs, such as GSI-191 resolution for pressurized water reactors (PWRs) and voluntary cooperation of BWROG. Once the concerns are addressed, there would be no need to permanently alter the LOCA methodologies (or standard evaluations). [GEH1-34]

NRC Response: The NRC agrees in part and disagrees in part with the comment's proposal that the nuclear power plant industry should be allowed to resolve the debris-related issues under ongoing activities such as GSI-191 resolution for PWRs and voluntary cooperation of the BWROG. Under the NRC's proposed rule, debris-related issues for ECCS function during the LOCA would continue to be addressed through GSI-191 for PWR licensees, and other regulatory actions for BWR licensees. Existing NRC-industry interaction on debris-related issues during long-term cooling would also continue under the proposed rule; the risk-informed alternative under paragraph (e) of the proposed rule provides a voluntary alternative for licensees. No change was made to the final rule as a result of this comment.

Comment: With a lack of clear guidance defining an acceptable method of evaluation, there is significant regulatory uncertainty. [PL1-95, WC1-49]

NRC Response: The NRC agrees that detailed guidance is needed and has developed a RG 1.229 to provide guidance for implementing the risk-informed portion of the rule.

d. *Level of Detail in Rule, Regulatory Guides, and Statement of Considerations*

There were many comments regarding the level of detail in the rule relative to what the commenters thought should be in regulatory guidance documents. The NRC understands that a performance-based rule should not prescriptively identify the means to achieve the desired performance. Therefore, the proposed rule does not specify "detailed" means for achieving compliance with respect to risk-informed consideration of debris effects on long-term cooling. However, the performance objectives during long term cooling must be specified with sufficient clarity (using objective standards to the extent technically supportable and practicable), so as to achieve regulatory stability and predictability. This is consistent with SRM-SECY-98-144, "*White Paper on Risk-Informed and Performance-Based Regulation* (March 1999). However, apart from the primary technical requirements expressed in a performance-based manner, the NRC notes that a regulation may have to specify some requirements that are not easily expressed in a performance-based manner. The NRC carefully considered which aspects of the proposed

rule are necessary to establish the requirements governing documentation, change control, and event reporting in the language of the regulation itself. The NRC response to these comments follows.

Comment: The details of the risk-informed alternative, including the reporting requirements, should not be part of the LOCA rule. The rule should only be changed to allow the alternative approach without the exemption requests. [GEH1-18]

NRC Response: The NRC disagrees with the comment. The NRC notes that a regulation may have to specify requirements on documentation, change control, and event reporting in order to achieve the NRC's regulatory objectives and/or facilitate effective NRC regulatory oversight. These kinds of requirements do not appear to be easily expressed in a performance-based manner. In addition, unless the documentation, change control, and event reporting requirements are specified in the regulation, the NRC would have to take licensee-specific action (in the form of an order) if a licensee were not meeting the NRC's documentation, change control, and event reporting expectations. This would be a resource intensive process, likely lead to differences in practices among licensees, and provide little regulatory predictability for both applicants and licensees. Therefore, the NRC disagrees with the comment with respect to the need to establish the requirements governing documentation, change control, and event reporting in the language of the regulation itself. No change to the rule was made as a result of this comment.

Comment: The rule language for the alternate risk-informed approach should use § 50.48(c)(4) as a model. [NEI1-75, NEI1-20, WEC1-19, NEI1-23, GEH1-15]

NRC Response: The NRC disagrees with the comment. The performance goals, performance objectives, and performance criteria referenced in 50.48(c)(4) are contained in NFPA 805 and incorporated into 50.48(c)(4) by reference (i.e., they are rule language). To use a parallel idea for § 50.46c, such performance attributes would need to be added to the rule; both deterministic and risk-informed attributes. The explicit requirements need to be in the rule, just like in § 50.48(c). No change was made to the final rule as a result of this comment.

Comment: Detailed acceptance criteria for the risk-informed approach should be in regulatory guides, not in the rule itself, and that consistency should be maintained with existing guidance and acceptance criteria (e.g. RG 1.174). [NEI1-20, NEI1-27, WEC1-7, WEC1-17, WEC1-18, GEH1-14, GEH1-43, PWROG1-3, PWROG1-4] Paragraphs (e)(1) through (e)(3) should be removed from the rule and included in the regulatory guide. [GEH1-13, GEH1-36] The rule should point to RG 1.174 for the risk-informed acceptance, including the definition of "small" and the criteria for adequate defense-in-depth and safety margins. [PL1-42, PL1-81, PL1-82, WC1-36] The criteria for using PRA risk insights and for meeting the PRA scope in (e)(1)(iv) should be included in a Regulatory Guide. [PL1-84, PL1-85, WC1-38, WC1-39]

NRC Response: The NRC agrees that detailed acceptance criteria should be contained in regulatory guides rather than the rule, and notes that this is achieved in the proposed rule as-written. For this reason e(1) through e(3) must be retained in the rule. High level attributes of an acceptable risk-informed approach are included in the rule, whereas the detailed acceptance criteria is contained in regulatory guides. As stated in the SOC, the acceptance guidelines of RG 1.174 and the guidance for PRA technical adequacy in RG 1.200 are incorporated into RG 1.229 for this section of the rule.

Comment: As an alternative to the NRC developing the draft RG, the industry could create its own guidance document, for which it would seek NRC endorsement through a regulatory guide. [PWROG1-2]

NRC Response: The NRC agrees that it is an option for industry to create a guidance document for possible NRC endorsement. As no industry guidance document was received by NRC, this suggestion has not been adopted. No change to the rule was made as a result of this comment.

Comment: The definition of localized coolant flow, as used in paragraph (d)(2)(iii), should be fully defined in a 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. [PL1-76, WC1-30]

NRC Response: The NRC disagrees with the comment, which appears to mix the risk-informed alternative of paragraph (e) with the deterministic requirements in paragraph (d). The sentence that includes the term localized coolant flow applies only to deterministic evaluations being conducted using approved ECCS evaluation models. ECCS evaluation models are not used for risk-informed long-term core cooling analyses. The NRC notes that, for the risk-informed approach, it is expected that probabilistic risk assessment models that are consistent with the current "state-of-practice" will be used for the risk assessment, subject to the requirements set forth in paragraph (e) of the rule. This expectation regarding the PRA model is included in RG 1.229. In addition, additional language has been added to paragraph (d)(2)(iii) to clarify the relationship of the risk-informed alternative to the ECCS evaluation model. No change was made to the final rule as a result of this comment.

Comment: The description in paragraph (e)(2)(ii) appears to be much more restrictive than the wording provided in the Section by Section Analysis [PL1-34, PL1-90, WC1-44]

NRC Response: The NRC disagrees with the comment, as the Section by Section Analysis addresses both paragraphs (e)(1)(iv) and (e)(2)(ii). While the risk assessment must consider all hazards and modes, the required PRA must at least address internal events at full power operation. As stated in the Section by Section Analysis, other approaches may be used to address hazards and modes not included in the PRA. However, the NRC agrees that it is important that the various explanations given in the Federal Register should serve to elucidate the rule language. The NRC reviewed the final rule language to ensure it was properly described in the Section by Section Analysis.

Comment: Paragraph (e)(2)(ii) should 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." [PL1-91, WC1-45]

NRC Response: The NRC disagrees with the proposed change in wording (see responses to comments PL1-86, PL1-87, WC1-41, PL1-88, WC1-42, PL1-89, WC1-43, and PL1-90, WC1-44). Consistent with past NRC practice, a risk-informed approach must consider all hazard groups and plant modes, although screening or bounding approaches may be used. No change to the rule language was made as a result of these comments.

Comment: The criteria for submitting the results of PRA review process in the license amendment to implement the risk-informed alternative would be provided in the RG. [PL1-92, WC1-46]

NRC Response: The NRC agrees that the details related to submittal content associated with the PRA review process should be provided in regulatory guidance documents. The guidance to which the comment refers is provided in RG 1.229, in conjunction with Regulatory Guides 1.174 and 1.200 as referenced.

Comment: The Commission directed that the proposed rule should allow licensees using the risk-informed informed alternative to address debris effects on long term cooling in the "the most simplified manner possible." This goal can be better accomplished by addition of a single paragraph stipulating that licensees selecting the risk-informed alternative need not "submit requests for exemption from specified regulation (*sic*.)." [GEH1-28]

NRC Response: The NRC agrees that the goal of the risk-informed alternative should be to address debris effects on long-term cooling in the simplest, most technically defensible manner consistent with NRC's regulatory needs of efficient and effective regulatory oversight, although the two SRMs directing the development and inclusion of the risk-informed alternative did not expressly direct this goal; see SRM-12-0034 (ML13007A478); SRM-SECY 12-0093 (ML12349AA378).

The NRC has evaluated what the regulation should specify in order to: (i) establish the performance requirement which a licensee seeking to use the risk-informed alternative must both demonstrate its capability to meet, and must meet during operation; and (ii) facilitate efficient and effective NRC regulatory oversight of a licensee who uses the risk-informed alternative. This oversight is necessary because changes in fuel design, ECCS design, operational practices, and many other factors could have a significant adverse impact on risk evaluations and results supporting the acceptability of the risk-informed alternative. Furthermore, any regulatory language that provides dispensation from compliance with an NRC regulation without an exemption must be clearly and precisely written. Such clarity and precision is needed so that all stakeholders understand the precise nature of the NRC's dispensation from compliance with the applicable NRC regulation, and the necessary conditions and attributes, which the licensee must continue to meet in order to remain within the bounds of the NRC dispensation. For these reasons, the NRC does not agree with the comment's assertion that a single paragraph is sufficient to allow the risk-informed alternative. No change was made from the proposed rule to the final rule in response to this comment.

e. *Risk-Informed Acceptance Criteria*

Comment: Paragraph (e)(1)(iv) states the risk-informed approach should "Utilize a PRA that, at a minimum, models severe accident scenarios resulting from internal events occurring at full power." Paragraph (e)(2)(ii) expands the scope of the risk evaluation to "...internal and external events initiated during full power, low power, and shutdown operation..." This rule language requires the applicant to evaluate all initial conditions without requiring those initial conditions to be an integral part of the PRA. This rule language may impose requirements above and beyond those necessary to demonstrate acceptable risk for those events leading to recirculation, and should not require consideration of those operating modes where the equipment supporting the recirculation function is not required by technical specifications. [NEI1-25] Is an internal events, at-power PRA sufficient to support the risk-informed alternative? As 10 CFR 50.46c applies to

loss of coolant accident (LOCA) issues, and the likelihood of an external hazard inducing a LOCA should be negligible, the licensee should not be required to expend significant resources for other than internal events. If external hazards are required to be considered, the guidance should address the use of a PRA for which there are no endorsed PRA standards, e.g., low power/shutdown PRA? [PWROG1-11]

NRC Response: The NRC does not agree that the rule imposes requirements greater than those necessary to demonstrate acceptable risk, nor does it agree that the analysis should be limited by technical specifications. This is because the risk-informed approach is intended to be realistic and therefore must consider any event or accident scenario that could benefit from a debris-free containment and for which risk is increased by the presence of debris. This is consistent with the extant practice of crediting SSCs irrespective of their safety classification in PRA models and using expected ("realistic") success criteria. The NRC notes, however, that current risk assessment practices allow screening out of modes, hazards, and scenarios that can be shown to be unimportant to the risk assessment, and guidance related to the scope of the risk assessment is contained in RG 1.229. No change to the rule language was made as a result of this comment.

Comment: Implementation guidance needs to address the following issue related to sections (e)(1)(iv) and (e)(2)(ii): The phrase/concept of "commensurate with the reliance on risk information" implies a risk-informed process; implementation guidance should define what metrics can be used to determine the reliance on risk information. [PWROG1-12]

NRC Response: The NRC disagrees that the supporting regulatory guide, RG 1.229, needs to establish criteria for what is meant by "commensurate with reliance on risk information." However, RG 1.229 and revised SOC language do describe the information that needs to be provided to support this review, which includes: 1) the peer review process to which the design/plant-specific PRA was subjected, 2) the reliance on other systematic evaluations to address areas not covered by the design/plant-specific PRA, and 3) the approach for demonstrating sufficient defense-in-depth and safety margins is maintained.

Comment: Implementation guidance needs to address the following issue related to sections (e)(1)(iv) and (e)(2)(ii): What is a systematic process with respect to the scope, level of detail, and technical adequacy of the PRA? It is inferred that for internal events at power, the systematic process is a peer-reviewed PRA. [PWROG1-10]

NRC Response: The NRC agrees that the regulatory guidance associated with the risk-informed alternative approach needs to clearly address the "systematic process." In this context, the PRA (including its scope, level of detail, and technical adequacy) is one aspect of the systematic process. Other aspects include the other techniques that might be used for scope (e.g., hazards and operating modes) not addressed by the PRA. The NRC has developed RG 1.229 accordingly.

Comment: The discussion of the adequacy of the systematic processes that evaluate internal and external events during shutdown operation [paragraph (e)(2)(ii)] is concerning. What is meant by shutdown operation is not clear. [PL1-88, WC1-42]

NRC Response: The NRC disagrees with the comment, which the NRC interprets as saying paragraph (e)(2)(ii) does not contain sufficient detail. The RGs related to the risk-informed alternative of this rule, RG 1.229, RG 1.174, and RG 1.200 have appropriate guidance on this topic. The NRC acknowledges that the term "shutdown operations," which is used often in the

discussion of nuclear power plants, may be confusing to a general reader. When a plant is shut down, it is not operating. However, the plant staff performs numerous tasks that can affect nuclear safety while the plant is shut down, including maintenance, surveillance testing, and refueling operations. Because the phrase "shutdown operations" is extensively used and understood by the NRC and the regulated entities, the rule language was not changed in this respect.

Comment: The approach should not be a single selection approach. Some plants may choose to utilize numeric-risk acceptance criteria 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. [NEI1-21, PL1-43, PWROG1-6]

NRC Response: The NRC disagrees because the risk assessment must show that any increase in risk is small and consistent with the Commission's Safety Goal Policy Statement. The current approved surrogates for the quantitative health objectives are core damage frequency and large early release frequency. The NRC agrees that risk-importance measures or other risk insights may be used in conjunction with estimating these surrogates. The NRC also disagrees that the rule language specifies a "single selection approach." Paragraph (e)(1)(i) says a risk assessment must be performed to show that any increase in core damage frequency and large early release frequency resulting from implementing the alternative risk-informed approach will be small. This could be a PRA result, a bounding analysis, or some other risk assessment. Paragraphs (e)(1)(iii) and (iv) require that results and insights from a PRA meeting the certain requirements must be considered. Paragraph (e)(2)(ii) requires entities to submit a description of the measures taken to assure that the scope, level of detail and technical adequacy of the <u>systematic processes</u> 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. The intent is that a risk-assessment be performed that considers all potential sources of risk attributable to debris from all modes and all hazards, where such consideration includes screening of modes, hazards and scenarios as appropriate. Any risk-informed approach must also address safety margins and defense-in-depth as set forth in (e)(1)(ii).

Comment: "Reasonable confidence" is used in § 50.46c(e)(1)(i) but is not defined. Previously mentioned is the notion that uncertainty can be quantified in terms of the mass of the risk that lies outside of the "small" or "very small" definitions of risk limits in RG1.174. In a similar way, "confidence" or "confidence interval" could be assigned quantifiable limits. Part of the "confidence" in the result is adequacy of the PRA as defined by the plant Model of Record. [STP1-9] The rule should clarify the difference between reasonable confidence and reasonable assurance. [PL1-29, WC1-14, PL1-17]

NRC Response: The NRC agrees that the term "reasonable confidence" is not defined. Paragraph (e)(1)(i) has been changed to say: A risk assessment must "Demonstrate any increase in core damage frequency and large early release frequency resulting from implementing the alternative risk-informed approach will be small." Removing the term "reasonable confidence" obviates the need to define it and should remove any confusion regarding NRC's statutory obligation to provide "reasonable assurance of public health and safety."

Comment: Performance objectives could provide some flexibility over that of numeric risk acceptance criteria. The referenced Maintenance Rule, § 50.65, provides an example of how this could be implemented. [NEI1-22, PL1-44] {This was in response to NRC Question in the FRN, regarding whether the risk-informed option in the rule should require the use of numeric risk criteria, other risk-informed approaches that use risk-importance insights to establish measurable criteria or performance objectives, or both?}

NRC Response: The NRC does not agree that performance measures should be used in place of the numeric risk acceptance guidelines for showing compliance with the risk-informed alternative set forth in paragraph (e). The risk-informed approach in the rule is based on the RG 1.174 approach for risk-informed changes to the licensing basis. However, the risk-informed approach has five key principles, one of which is performance measurement or monitoring to ensure that the desired outcome has been achieved and maintained and that no unintended consequences results. The NRC agrees that performance objectives would be appropriate for that purpose, and has included guidance on performance monitoring in RG 1.229.

Comment: A statement on the intent of the Commission's safety goal policy statement should be provided in the rule. [WC1-10, PL1-13]

NRC Response: The NRC does not agree that the rule should discuss the "intent" (purpose, objectives and expectations) of the Commission's safety goal policy statement. The "intent" of the safety goal policy statement is set forth in the policy statement itself, and the comment does not explain why a reiteration of the policy statement's intent in the statement of considerations (or the language of § 50.46c itself) is necessary or desirable. The safety goal policy is discussed in the statement of considerations for the proposed rule because that policy forms the basis for NRC's surrogate risk metrics and the associated acceptance guidelines, as published in RG 1.174. Paragraph (e)(1)(i) of the proposed rule states that any increase in core damage frequency and large early release frequency resulting from implementing the alternative risk-informed approach will be small. An acceptable way to meet this requirement is published in the associated regulatory guide for the risk-informed approach, RG 1.229, which references RG 1.174. No change was made to the final rule as a result of this comment.

Comment: The rule should point to "small" as defined in RG 1.174. [WC1-35]

NRC Response: The NRC does not agree that the rule should point to a regulatory guide, which is a lower-tier document, and which describes one method acceptable to the NRC for complying with the rule. The SOC discusses what "acceptably small" means, and points to RG 1.174, as does RG 1.229. No change to the final rule was made as a result of this comment.

Comment: The following statement in the Federal Register notice is not consistent with the language in the proposed rule: "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." 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. [PL1-9, PL1-83, WC1-6]

NRC Response: The NRC does not agree that the statement in the SOC is inconsistent with the proposed rule. This level of detail is not contained in the rule language itself; however, the paragraph referred to by the commenter is consistent with the NRC's current practice of

evaluating the impact of licensing basis changes on defense-in-depth, as set forth in RG 1.174. RG 1.174 provides seven elements as a way for licensees to structure their evaluation of the impact a proposed change would have on defense-in-depth. The NRC believes that this level of detail is more appropriate for a regulatory guide than the rule itself. The explanatory text in the Federal Register, at which this comment was directed, serves to publish the NRC's intent that the practices of RG 1.174 with respect to defense-in-depth would continue to apply for this new rule.

Regarding the aspects related to the design criteria and related aspects of defense-in-depth and safety margins, the NRC agrees that the rule and SOC do not provide detailed guidance on these topics. Specific guidance on these topics is provided in RG 1.229, which references existing risk-informed guidance (i.e., RG 1.174) as appropriate. The NRC believes that the guidance documents provide the necessary clarity and are the appropriate place for the level of detail presented.

Comment: "Sufficient" defense in depth and safety margins should be met if the risk measure that provides "high probability" is quantified as being "small" or "very small" as defined in RG1.174. "High probability" or "high confidence" would be demonstrated if the 95th percentile of the probability is below the acceptable limit. "Sufficiency" [of defense-in-depth and safety margin] should be viewed in a manner similar to other recommendations that rely on quantifiable risk measures with limits as defined in regulatory guidance (such as RG1.174). [STP1-10]

NRC Response: The NRC disagrees that sufficient defense-in-depth and safety margin safety margin can be shown by having a high confidence that the increase in risk meets the risk acceptance guidelines. Defense-in-depth and safety margin are key elements of risk-informed decision-making that are separate from the risk assessment. This separation tends to make the regulatory decision "risk-informed" rather than "risk-based." Risk-informed means using risk insights together with other information (including traditional engineering analyses) in regulatory decision-making; defense-in-depth and safety margin are key aspects of the "other information." The NRC notes that RG 1.174 provides guidance for determining whether defense-in-depth and safety margin would be maintained following a proposed change to the design or licensing basis of a nuclear power plant. Additionally, while parametric uncertainty analyses of PRA risk metrics are expected as part of the uncertainty analysis, it is the mean value of those metrics that is to be compared to the acceptance guidelines of RG 1.174. No change to the rule was made as a result of this comment.

Comment: By definition, any margin greater than 0 is acceptable. 10 CFR 50 contains 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. [WC1-9, PL1-12]

NRC Response: The NRC does not agree with this comment, which says that any margin greater than zero is acceptable, for several reasons. First, the concept of "margin" may refer to the deviation between a predicted parameter and its actual (known) failure point, or to an allowance for safety, as required, either by prudent engineering practices, or by regulations. The second reason is that this comment relates to the alternate risk-informed approach for assessing the impact of debris on long-term core cooling. The NRC's principles of risk-informed decision-making, as set forth in RG 1.174 and elsewhere, include an integrated evaluation of how a proposed change to the design or licensing basis impacts risk, defense-in-depth and

safety margin. Therefore, the licensee must evaluate the impact of debris to ensure safety margin is sufficiently maintained. No change to the rule was made as a result of this comment.

Comment: Much of the discussion regarding defense-in-depth is open to interpretation. For example, the meaning of the phrase "over reliance on programmatic activities to compensate for weaknesses in plant design" is in the eye of the beholder. As another example, "reasonable balance" is different to different people. [WC1-11, WC1-37, PL1-14]

NRC Response: The NRC agrees that the seven elements for assessing the impact of the alternative approach to defense-in-depth are subjective. These elements come from RG 1.174, where they are intended to provide a framework for licensees to evaluate the potential impact of a proposed change on defense-in-depth. As such, the elements must be subjective, to a certain extent. The RG for the risk-informed alternative of the rule provides the application-specific guidance for each of the seven elements related to maintaining the philosophy of defense-in-depth.

Comment: In Section F of the Federal Register Notice, relating to paragraph (e)(2)(i) of the rule, applicants are required to follow established regulatory guidance or discussion of the information required if a different approach is chosen. However, the rule language does not require this. 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. [PL1-31, PL1-32, PL1-94, WC1-48]

NRC Response: The NRC agrees that the FRN Section F was incorrect. The rule language is correct. Licensees must follow the rule, and NRC publishes guidance documents that set forth approaches acceptable to the NRC for compliance with the rule. The NRC does not believe that regulatory uncertainty will be created when this rule is issued, because the NRC is issuing RG 1.229 at the same time as the final rule. The draft version, DG-1322, was provided for public comment in advance of the final rule to allow NRC consideration of stakeholder comments. Section F of the SOC was revised as a result of this comment.

Comment: The use of FLEX equipment and strategies should also be identified as acceptable defense-in-depth strategies. [PL1-52]

NRC Response: The NRC does not agree that the rule should specify any specific defense-in-depth strategy, such as use of FLEX equipment and strategies. The NRC believes that RG 1.229 is a better place for the details of adequate defense-in-depth and safety margins than the rule language. If a licensee wanted to credit FLEX equipment and strategies as defense-in-depth measures, that strategy would need to be justified in the license application. No change to the rule was made as a result of this comment.

F. Fuel Performance Criteria

a. General

Comment: A definition for cladding should be added to the rule. [NEI1-62]

NRC Response: The NRC agrees with the comment; a definition for cladding within the rule language would clarify the intent of the rule. The following definition has been added in section

(b) Definitions: Cladding means the material structure containing the fissile material and providing a barrier to prevent fission product transport or release to the coolant.

Comment: M5 is a registered trademark of AREVA and should always be represented as M5®. [A1-11]

NRC Response: NRC agrees with this comment. The Statements of Consideration has been revised to use M5® and include a footnote at the end of the main document as "M5® is a registered trademark of AREVA NP."

b. Peak Cladding Temperature Rule Language

Comment: The wording to describe the use of a PCT lower than 2200 °F in paragraph (g)(1)(ii) could be improved to avoid misunderstanding. It would be more clear to state, "if the peak cladding temperature resulting from the integral time at temperature analytical limit, established to preserve cladding ductility is lower than the 2200 °F limit specified in paragraph (g)(1)(i) of this section, then the lower temperature shall be the applicable limit corresponding to the integral time at temperature analytical limit." [GEH1-38]

NRC Response: The NRC agrees with the comment that paragraph (g)(1)(ii) could be improved to avoid misunderstanding. The rule language has been revised to reflect this comment.

Comment: The proposed language could be interpreted as requiring use of a lower PCT analytical limit for all fuel assemblies, even if different analytical limits are applicable to various groups of fuel assemblies. The proposed rule should be revised to read, "… shall be used in place of the 2200 °F limit for the cladding that credits the lower temperature" at the end of (g)(1)(ii). [NEI1-85]

NRC Response: The NRC agrees with the comment. It is the NRC's intention to allow separate embrittlement analytical limits to be used for various groups of fuel assemblies when supported by ECCS analysis. Language was added to RG 1.224 to clarify that separate PCT limits can be applicable to separate groups of fuel assemblies.

Comment: Prescriptive limits are not compatible with a performance-based rule [NEI1-83, WEC1-5, GEH1-2, GEH1-37], and the requirements in § 50.46c(g)(1)(i) are redundant to Section (g)(1)(ii) [A1-6]. The language regarding peak cladding temperature limits should be moved to DG-1263, where language could be added to identify other considerations that may degrade the fuel and need additional testing beyond post-quench ductility (PQD) testing [A1-12, WEC1-7].

NRC Response: The NRC disagrees with these comments. The rule language must establish legally enforceable criteria. This can be in the form of prescriptive limits or specified performance-based requirements. At this time, the NRC believes that a comprehensive set of performance-based requirements cannot be established. If performance-based requirements cannot be specified, than the prescriptive limit must remain. No change was made to the final rule in response to this comment.

Comment: If the industry desires to extend beyond 2200 °F, each fuel vendor ECCS evaluation model will propose a new upper limit for peak cladding temperature. The NRC will then have an opportunity to review the proposed criterion and testing basis. [NEI1-11] DG-1263 should stipulate that the applicant address high temperature ductile failure and autocatalytic oxidation if requesting a PCT limit above 2200 °F. [WEC1-7] GEH/GNF does not believe developing test procedures to develop a PCT limit higher than 2200 °F should be considered high-priority because the current criterion provides adequate assurance for safety in case of a postulated LOCA. [GEH1-3]

NRC Response: The NRC agrees in part with these comments. At this time, the NRC does not believe there is an adequate technical basis to extend peak cladding temperature beyond 2200 °F or a technical basis to develop a methodology to do so. Further, the NRC does not believe there a strong demand from licensees to outline a methodology to extend peak cladding temperature beyond 2200 °F. No change was made to the rule in response to this comment.

Comment: The proposed language is not compatible with realistic ECCS evaluation models where there is only a statistical probability that 2200 °F will not be exceeded. [NEI1-84]

NRC Response: The NRC disagrees with this comment. The phrase “calculated maximum fuel element cladding temperature shall not exceed 2200 °F” is identical to the existing requirement in § 50.46(b)(1). It is understood that within a statistical approach, a small probability of exceeding 2200 °F exists. No change was made to the final rule in response to this document.

Comment: While the proposed rule seeks to maintain the level of protection contained in the current regulation by requiring that new technical matters be addressed, the level and complexity of testing associated with licensing a new cladding alloy under the proposed rule will have a detrimental effect on the introduction of improved cladding materials that would benefit public health and safety. [WEC1-2]

NRC Response: The NRC disagrees with this comment. The additional burden of testing new cladding alloys under § 50.46c, relative to existing § 50.46, is not significant. The associated RGs for testing PQD and breakaway and establishing analytical limits should help to streamline the process and reduce regulatory uncertainty. No change was made to the final rule in response to this comment.

Comment: Lack of material properties, specifically temperature dependent creep and oxidation rates, at temperatures above 2200 °F are the real issue limiting a technical basis to have a peak cladding temperature above 2200 °F. Testing protocols to expand the material database can be developed from existing industry standards. [NEI1-12]

NRC Response: The NRC disagrees with these comments. At this time, the NRC believes that a comprehensive set of material properties and their respective performance-based requirements have not been established. If performance-based requirements cannot be specified, than the prescriptive limit must remain. No change was made to the final rule in response to this comment.

Comment: The NRC should study the PHEBUS B9R-2 test, an integral experiment conducted with pre-oxidized fuel cladding. [MEL1-3] Preventing thermal runaway could be a more important safety issue than preventing excessive cladding embrittlement. [MEL1-4] The results of the PHEBUS B9R-2 test should be reviewed to determine if the peak cladding temperature needs to be lower than 2200 °F. [MEL1-5]

NRC Response: The NRC partially agrees with the comment. The NRC has studied PHEBUS B9R-2 as part of the review of PRM-50-93 and considered the experiment in the context of the § 50.46c rulemaking. The Commission's finding for PRM-50-93 will include additional discussion. In NRC's investigation of data from numerous experimental programs, the staff has concluded that thermal runaway only occurs at temperatures above 2200 °F. The NRC agrees that preventing thermal runaway is an important safety issue and it is for this reason that the NRC has instituted a peak cladding temperature limit of 2200 °F. The claim that the test results of integral experiments may indicate that the 2200 °F peak cladding temperature limit needs to be lowered is the subject of PRM-50-93. This petition is pending resolution and the commenter is referred to the forthcoming Commission's finding for the staff's evaluation of this claim. No change was made to the rule as a result of this comment.

Comment: It is unlikely that a limiting curve much higher than the curve obtained from testing at 1200 °C [approximately 2200 °F] could be found at a lower temperature. [RM1-3] Scientifically, this has not been proven and there may be some small effects, but as a regulatory policy it seems wrong to imply that significant effects might exist and to provide regulatory guidance to obtain benefit from them. It would be better to put the bounding limit from testing at 1200 °C directly into the rule as a fixed limiting curve. [RM1-4] The limiting curve obtained from testing at 1200 °C is performance-based because a manufacturers cladding that picks up less hydrogen would get a higher limiting value and putting the embrittlement limit directly into the rule in paragraph 50.46c(g)(1)(ii) would not reduce the rule's performance-based character in any significant way. [RM1-6]

NRC Response: The NRC disagrees with these comments. The NRC believes that the combination of rule language that requires analytical limits to be developed based on the performance criteria of maintaining ductility and the regulatory guidance that provides a methodology to develop these analytical limits is technically adequate. The NRC also believes that this approach best meets the Commission's direction to the staff to create performance-based regulations. No change to the rule language was made in response to this comment.

Comment: The proposed rule reaffirms the use of the Baker-Just correlation and the 2200 °F PCT limit. The very complex proposed rule and the three draft regulatory guides avoid experiments with multi-zirconium-rod assemblies. If such experiments were performed, the necessity for a much lower PCT limit than 2200 °F would be confirmed. [RL8-1]

NRC Response: The NRC disagrees with this comment. The NRC does not agree that experiments with multi-zirconium-rod assemblies would produce results indicating that a PCT limit lower than 2200 °F is necessary. No change to the rule was made in response to this comment.

Comment: The proposed rule is providing a path for moving the 2200 °F PCT limit into another regulatory guide. [RL8-2]

NRC Response: The NRC disagrees with this comment. The NRC does not agree that the proposed rule is providing a path for moving the 2200 °F peak cladding temperature limit to a regulatory guide. The NRC staff considered whether the 2200 °F PCT criteria could be replaced with performance-based criteria combined with regulatory guidance. The NRC determined that, at this time, a comprehensive set of performance-based requirements has not been established for cladding temperatures above 2200 °F. If performance-based requirements cannot be

specified, than the prescriptive limit of 2200 °F must remain in the rule. No change was made to the final rule in response to this comment

c. *Embrittlement criteria*

Comment: The performance criterion in§ 50.46c(g)(1)(ii) should be titled "Integral Time at Temperature" rather than "cladding embrittlement" since peak cladding temperature and breakaway oxidation (criteria i and ii) are also measures to protect against embrittlement. [A1-5]

NRC Response: The NRC agrees with the comment. The title for § 50.46c(g)(1)(ii) was changed to "Post-quench ductility." The revised title reflects the NRC's intentions and will provide greater clarity.

Comment: Testing to determine performance-based criteria for peak cladding temperature, integral time at temperature and breakaway oxidation to ensure post quench ductility should not be required for LWR designs where LOCA events do not result in core uncovery or any significant clad heat up. A lower peak clad temperature threshold (650 °C) should be specified below which testing is not required. [NS1-1]

NRC Response: NRC disagrees with this comment. The NRC believes that testing to determine the appropriate criteria for all fuel loaded the reactor is necessary. PQD testing is not required for the currently approved alloys listed in RG 1.224. And for the situation described where there is no core uncovery, it would be relatively simple to demonstrate compliance to the default PQD analytical limit. Breakaway susceptibility begins at lower temperatures, as such, testing is required. No change was made to the rule language in response to this comment.

Comment: It is better to have a specific cladding embrittlement limit, or limiting curve, § 50.46c(g)(1)(ii), rather than in the regulatory guides. With a specific limit, the embrittlement limit is not subject to interpretation and costly review. [RM1-1] Further, the research found no effect of alloy composition on embrittlement and there is no reasonable expectation that a limiting curve should be found at 1200 °C for another zirconium alloy that would be different from the referenced figure. [RM1-2]

NRC Response: The NRC disagrees with these comments. The NRC believes that the combination of rule language that requires analytical limits to be developed based on the performance criteria of maintaining ductility and the regulatory guidance that provides a methodology to develop these analytical limits is technically adequate and that this approach best meets the Commission's direction to the staff to create performance-based regulations. No change to the rule language was made in response to this comment.

Comment: Extra attention is needed on the calculation of limiting oxidation levels (especially for double-sided oxidation). Prior to the recognition of lowered oxidation limits for high-burnup fuel, the fixed 17% was so high that PCT was usually limiting and careful scrutiny of the non-limiting oxidation calculations was not needed. With high-burnup fuel, the situation is reversed and calculated oxidation may be limiting. [RM1-13]

NRC Response: The NRC agrees with this comment in part. The NRC agrees that the finding of the NRC's LOCA research program that high-burnup fuel has lowered oxidation limits, and the resulting proposed rule requirements, mean that extra attention is needed on the calculation of limiting oxidation levels. The NRC believes that the rule language and implementation

schedule have been developed to adequately address the extra attention that is needed. No change to the rule language was made in response to this comment.

d. Breakaway Oxidation Rule Language

Comment: The proposed requirements for periodic measurements and reporting of the time to reach breakaway oxidation for batches of manufactured cladding material are excessively burdensome and unnecessary and should be removed. [NEI1-102] The 10 CFR 50 Appendix B Quality Assurance Programs for each cladding vendor are sufficient to assure that requirements on the time to breakaway oxidation are maintained [WEC1-3, WEC1-11]. The requirement to measure and report breakaway oxidation for each reload batch is unnecessary when breakaway oxidation is addressed as part of fuel supplier's QA programs and considering the margin to breakaway oxidation that exists for BWR LOCAs. The proposed reporting requirement in paragraph (m)(3) will therefore cause an undue burden to the holder of an operating license or combined license and provide no safety benefit. [GEH1-42]

NRC Response: The NRC disagrees with the comment that the quality assurance programs defined by 10 CFR Appendix B are sufficient to assure that requirements on the time to breakaway oxidation are maintained. However, the NRC agrees that it is possible to revise the periodic testing and reporting requirements in a way that adds flexibility, decreases cost and burden of breakaway oxidation testing and still achieves the safety objective. The NRC agrees that the objective of the rule can be achieved with rule language that requires a fuel vendor to submit breakaway oxidation testing program for NRC review and approval. The rule language has been revised in response to this comment.

Comment: It is proposed that a periodic test program be developed by each vendor and approved by the NRC. [A1-13, GEH1-4] The objective of the rule can be achieved with rule language that simply requires a fuel vendor to submit a breakaway oxidation test program for NRC review and approval. Each licensee would then reference an NRC-approved vendor program. [NEI1-13] Regarding the frequency of testing, it is recommended that information about the frequency of testing be included in the draft regulatory guide rather than in the proposed rule. [WEC1-9] The test frequency should be set as part of the quality assurance program built on statistical confidence level based on test data, rather than as set as part of the rule. [GEH1-6, GEH1-9]

NRC Response: The NRC agrees with these comments. The NRC agrees that it is possible to revise the periodic testing and reporting requirements in a way that adds flexibility, decreases cost and burden of breakaway oxidation testing and still achieves the safety objective. The NRC agrees that the objective of the rule can be achieved with rule language that requires a fuel vendor to submit breakaway oxidation testing program for NRC review and approval. The rule language has been revised in response to this comment. The NRC revised RG 1.224 to include discussion of periodic testing frequency.

Comment: The two most significant factors that can result in early onset of breakaway oxidation are the use of the electrolytic process for extracting Zr and the use of a HF-based pickling process as the last surface finish step in cladding manufacturing. These factors are not applicable to the manufacturing process used by fuel vendors in the US and therefore the likelihood of affected fuel being loaded into a reactor is very low. [GEH1-7] Although surface scratches can have a small effect on breakaway oxidation onset, the presence or extent of surface scratches can be readily controlled using the normal manufacture quality control and

assurance process, without a specific need for periodic testing for breakaway oxidation. [GEH1-8]

NRC Response: The NRC disagrees with this comment. The NRC disagrees that all factors that can result in early onset of breakaway are readily identified and understood. Further, the NRC believes that there is no legal requirement in place to ensure that the known factors that can result in early onset of breakaway are controlled. The NRC believes that the most effective approach to ensure that any factor that can result in early onset of breakaway oxidation has affected fuel being loaded into a reactor is through periodic testing. However, the NRC has revised the rule language to decrease the burden of the periodic testing requirement and allow for vendor-developed breakaway oxidation test programs.

Comment: Paragraph 50.46c(g)(1)(iii) is unnecessary and could be eliminated. Screening tests for breakaway oxidation should be adequate and could be reviewed in annual reports or licensing topical reports for new cladding varieties. [RM1-7] The requirement for periodic testing could be eliminated and the regulatory guide [1.222] could be used for screening tests. [RM1-8, RM1-12]

NRC Response: The NRC agrees with this comment in part. The NRC agrees that the requirement for periodic testing could be revised and that the RG 1.222 could be used for screening tests. The periodic testing and reporting requirements in the rule have been revised in a way that adds flexibility, decreases cost and burden of breakaway oxidation testing and still achieves the safety objective. However, the NRC believes that without regulatory requirements for breakaway oxidation testing, the NRC would have no legal authority to request and review results of breakaway oxidation testing in licensing topical reports for new cladding varieties. No change to the rule language was made in response to this comment.

Comment: Regarding the type of data to be reported, it is proposed that cladding samples be tested during production to confirm that production alloy batch exceeds the established analytical limit. The time to breakaway does not need to be reported, only that the material met the requirement. [WEC1-8, A1-14]. The type of data generated from each test is expected to be a pass or fail relative to an NRC-approved time, as opposed to a numeric value for breakaway onset time. [GEH1-5] For an example time frame of 5000 seconds, cladding would be tested at sufficient frequency to provide assurance that only cladding that does not develop breakaway oxidation at 5000 seconds would be used for fuel manufacture. [GEH1-10]

NRC Response: The NRC agrees with this comment. The intention of the requirement for periodic testing of breakaway performance is to confirm that slight composition changes or manufacturing changes have not inadvertently altered the cladding's susceptibility to breakaway oxidation. The NRC agrees that this intent can be fulfilled by demonstrating, on a periodic basis, that a cladding does not experience breakaway oxidation in a time period less than the established analytical limit. The final version of RG 1.222 has been modified to clarify that periodic testing may be performed for the period of time defined by the analytical limit and that it is not necessary to continue testing for longer time periods and until breakaway oxidation is observed for periodic demonstration.

Comment: Regarding the frequency of testing, it is suggested that the requirement to perform periodic testing for breakaway oxidation be removed from the rule and replaced with a requirement to account for breakaway oxidation. [WEC1-10]

NRC Response: NRC disagrees with this comment. The rule language must establish legally enforceable criteria. The commenter provided no explanation for a "requirement to account for breakaway oxidation", and the NRC is not clear how such a requirement could be legally enforceable. No change was made to the final rule in response to this comment.

Comment: Regarding § 50.46c(m)(3), annual and reload batch reporting is inappropriate. The testing result is being reported, rather than the ECCS evaluation result. [A1-10]

NRC Response: The NRC agrees with this comment. The intention of the requirement for periodic testing of breakaway performance is to confirm that slight composition changes or manufacturing changes have not inadvertently altered the cladding's susceptibility to breakaway oxidation. The reporting requirement in § 50.46c(m)(3) has been removed.

Comment: Fuel assemblies with cladding manufactured prior to the implementation of the new rule should be grandfathered with respect to breakaway oxidation test requirements. [A1-15]

NRC Response: The NRC disagrees with this comment. Maintaining § 50.46 requirements for legacy fuel and § 50.46c requirements for future fuel would lead to confusion and errors. The NRC recognizes that source material from legacy alloys may not be available for testing. Guidance will be added to RG 1.224 regarding legacy fuel assemblies. In summary, legacy alloys will use the acceptable allowable Cathcart-Pawel equivalent cladding reacted (CP-ECR) versus cladding hydrogen content curve in RG 1.224 for PQD along with a defined breakaway oxidation analytical limit. No change was made to the final rule in response to this document.

e. Maximum Hydrogen Generation Rule Language

Comment: Use of a specific numerical value (i.e.0.01) for the hydrogen generation limit is not consistent with the goal of a performance-based rule. Analytical limits are properly within the scope of regulatory guides. [NEI1-86]

NRC Response: The NRC disagrees with this comment. The core average oxidation limit protects against excessive hydrogen generation and combustion. The current limit has existed for decades and there is no new research driving its change. No change was made to the final rule in response to this document.

f. Long-term Cooling Rule Language

Comment: Sufficient research has not been completed to establish the technical basis for an analytical limit on peak cladding temperature (or any other parameter) for long-term cooling. Until sufficient research has been completed the proposed rule language should not be implemented. No "NRC-approved experimental technique" currently exists. [NEI1-4, NEI1-10, NEI1-87, STARS1-4] The proposed rule is inadequate for determining the impacts to long term cooling. Regulatory guidance has not been developed and research findings have not been provided; consequently, specifics for evaluations, acceptance criteria, and test methods to establish these criteria are not presently available. [D1-5]

NRC Response: The NRC agrees with this comment. A comprehensive technical basis for fuel performance during a debris-induced post-quench reheat transient does not exist. Fuel degradation mechanisms, performance metrics, and analytical limits have not been defined for the post-quench, long-term period. The rule was modified to remove the proposed cladding

ductility performance metric and PCT analytical limit. The final rule establishes an LTC performance metric, requiring no further cladding failure. If an applicant predicts a debris-induced, post-quench reheat transient, the applicant would bear the burden of conducting research, identifying degradation mechanisms, and establishing analytical limits that ensure cladding integrity. Absent a significant debris-induced, post-quench reheat transient, no research is necessary and the existing analysis-of-record remains acceptable.

Comment: The industry does not support a rule change to specify an analytical limit on long-term peak cladding temperature, and this limit should be removed from the proposed rule. Numerical limits are not appropriate in a performance-based rule. [NEI1-14] Maintaining the PCT criterion in the rule is inconsistent with the objective of performance-based criteria. [WEC1-14] The proposed wording of the rule at § 50.46c(g)(1)(v) does not provide an option of utilizing anything other than 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 these options need to be identified within the rule. [PL1-41]

NRC Response: The NRC agrees with this comment. Establishing a prescriptive temperature limit is not performance-based. The rule has been modified to remove the proposed cladding ductility performance metric and PCT analytical limit, and instead establishes an LTC performance metric. See response to comments NEI1-4, NEI1-10, NEI1-87, STARS1-4, and D1-5, earlier in this section.

Comment: 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 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. [PL1-40]

NRC Response: The NRC agrees with this comment. The rule has been modified to remove the proposed cladding ductility performance metric and PCT analytical limit, and instead establishes an LTC performance metric. See response to comments NEI1-4, NEI1-10, NEI1-87, STARS1-4, and D1-5, earlier in this section.

Comment: It is not clear at this time that a single PCT criterion is appropriate for both BWRs and PWRs. It is also not clear that a single criterion is appropriate to the entire time frame of "long term." [NEI1-15] The long-term cooling (LTC) requirement is based on demonstrating PCT is below the ductile-to-brittle transition, but the scenario for determining the PCT is not defined. [WEC1-12] GEH/GNF concurs with the objective of preserving ductility; however, a single metric of peak cladding temperature is not considered to be a useful way to achieve the goal of preserving cladding ductility for the purpose of long-term cooling up to 30 days. [GEH1-11, GEH1-12] A single peak cladding temperature is not appropriate for the long-term cooling ductile-to-brittle transition or additional degradation mechanisms possible in the long-term. Proposal: The criterion should be modified as follows: "An analytical limit that corresponds to the long-term cladding degradation phenomena shall be established and approved by the NRC." Basis of proposal: The proposed wording allows for the identification of all the potential degradation mechanisms and the appropriate establishment of a requirement. [A1-7, A1-17]

NRC Response: The NRC agrees with this comment. A single criterion, such as PCT, may not be appropriate to ensure acceptable fuel behavior. The NRC also agrees that additional degradation mechanisms (beyond ductile-to-brittle transition) are possible during the long-term period. The rule has been modified to remove the proposed cladding ductility performance

metric and PCT analytical limit and instead establishes an LTC performance metric. See response to comments NEI1-4, NEI1-10, NEI1-87, STARS1-4, and D1-5, earlier in this section.

Comment: The industry proposes that the NRC should continue to use the current language in 10CFR50.46 that refers to the use of an acceptable analysis or ECCS evaluation model vice the proposed language of an approved ECCS evaluation model. [NEI1-16] In addition, the proposed rule requires any associated evaluation model specifically be NRC-approved, rather than acceptable. [D1-5] The scope and cost associated with the new requirement that LTC evaluation models be reviewed and approved has not been properly accounted for. [NEI1-17, NEI1-18]

NRC Response: The NRC agrees with this comment. The rule has been modified to remove the requirement that evaluation models be NRC reviewed and approved. The rule states that acceptable evaluation models shall be used to demonstrate ECCS performance.

Comment: For plants that can demonstrate continued and sustained fuel quench, or for plants with very small long-term fuel cladding heat-ups, long-term fuel cladding performance testing is unwarranted. [WEC1-15]

NRC Response: The NRC agrees with this comment in part. A comprehensive technical basis for fuel performance during a debris-induced post-quench reheat transient does not exist. Fuel degradation mechanisms, performance metrics, and analytical limit have not been defined for the post-quench, long-term period. As such, what constitutes an acceptable reheat temperature is not defined. The rule has been modified to remove the proposed cladding ductility performance metric and PCT analytical limit, and instead establishes an LTC performance metric. See response to comments NEI1-4, NEI1-10, NEI1-87, STARS1-4, and D1-5, earlier in this section.

Comment: Dominion recommends maintaining the current rule language for long term cooling, which will allow the technical issues to be fully characterized and addressed separate from the rule. [D1-6]

NRC Response: The NRC disagrees with this comment. The existing rule does not define a performance metric for acceptably low temperature. Furthermore, at the time when the rule was promulgated, the potential for a debris-induced, post-quench reheat transient was not recognized. The rule has been modified to remove the proposed cladding ductility performance metric and PCT analytical limit, and instead establishes an LTC performance metric. See response to comments NEI1-4, NEI1-10, NEI1-87, STARS1-4, and D1-5, earlier in this section.

Comment: In paragraph (g)(1)(v), the rule should recognize that the performance-based metric does not necessarily require an analytical limit that corresponds to the ductile-to-brittle transition as long as the established temperature limit preserves ductility. In other words, the ductile-to-brittle transition might not be the sole criterion. [GEH1-39]

NRC Response: The NRC agrees with this comment. A single criterion, such as PCT, may not be appropriate to ensure acceptable fuel behavior. The NRC also recognizes that additional degradation mechanisms (beyond ductile-to-brittle transition) are possible during the long-term period. The rule has been modified to remove the proposed cladding ductility performance metric and PCT analytical limit, and instead establishes an LTC performance metric. See response to comments NEI1-4, NEI1-10, NEI1-87, STARS1-4, and D1-5, earlier in this section.

g. Fuel System Modeling Requirements Rule Language

Comment: The embedded definition of crud in sub-paragraph (ii) should be moved to paragraph (b). [NEI1-88]

NRC Response: The NRC agrees with this comment. The rule was modified as recommended.

Comment: The rule language should not imply any additional crud inspections. [NEI1-89]

NRC Response: The NRC agrees with this comment. The rule language implies that licensees may need to perform additional crud inspections. However, licensees must maintain a technical basis for the crud level assumed in the LOCA analysis. Apart from additional crud inspections, this basis could be derived from historical levels of observed crud. No change to the rule was made as a result of this comment.

Comment: If oxygen is present on the cladding inside surface, subparagraph (i) requires that it must be considered in the evaluation model. The "If" in this paragraph is problematic and invites expensive testing and costly review of phenomena that can be partly stochastic. Surprisingly, oxygen penetration from the inside surface could be required at all times without unduly penalizing a licensee – and with a subtle benefit….. The inclusion of double-sided oxygen penetration everywhere in the cladding would thus provide a reasonable minimum value in cases where a ballooning model gives an under prediction. This is a critical consideration because limiting oxidation level is almost always found in a balloon. Simple word changes in this paragraph of the proposed rule could achieve the improvement. [RM1-9]

NRC Response: The NRC disagrees with this comment. While the commenter's proposed changes would simplify the LOCA analysis, licensees should maintain the ability to model these separate phenomena separately. Licensees have several options in this regard. For example, a licensee may gather the technical basis to support a burnup threshold at which an oxygen source is present, and seek NRC review and approval for use of that threshold. A licensee may also use the acceptable threshold provided in RG 1.224. No change was made to the final rule in response to this document.

Comment: Paragraph (g)(2)(ii) must be augmented as follows: (ii) The thermal effects of curd and oxide layers that accumulate on the fuel cladding during plant operation must be evaluated. The thermal effects of crud and oxide layers must be evaluated based the observed crud and oxide layers that are present on the fuel cladding at the start of the forthcoming operating cycle, and in addition, the projected changes in the crud and oxide layers during the course of the forthcoming operating cycle must be included in order to provide an accurate evaluation. For the purposes of this paragraph, crud means any foreign substance deposited on the surface of fuel cladding prior to initiation of a LOCA. [RL2-1] Paragraph (g)(2)(ii) needs to be augmented with additional instructions, explaining that licensees are required to conservatively evaluate the thicknesses and thermal conductivites of crud and/or oxide layers for each fuel cycle. [MEL1-1]

NRC Response: The NRC disagrees with this comment. The rule requires that applicants account for the thermal effects of crud and oxide layers. Further details within the rule language are unnecessary. The details as to how each applicant accounts for these items will be addressed in the staff's review of the evaluation model..

Comment: Licensees have not been evaluating the thermal impact that crud would have in a LOCA. The NRC should issue an order regarding information relevant to regulatory activities requiring licensees to evaluate how crud would impact a LOCA. [RL4-1]

NRC Response: The NRC disagrees with this comment. The NRC is pursuing rulemaking in lieu of an order to explicitly add a requirement that the thermal effects of crud be considered. No change was made to the final rule in response to this document.

Comment: The NRC should also require that the impact of crud be included in the reporting of core operating limits: [Core] operating limits shall be established and documented in the [CORE] OPERATING LIMITS REPORT before each reload cycle or any remaining part of a reload cycle. [RL4-2]

NRC Response: The NRC agrees with this comment in part. The COLR contains limits on fuel rod power based upon the initial conditions assumed in the LOCA analysis (i.e., LOCA LHGR or MAPLHGR). These fuel rod power limits are based upon the ECCS performance demonstration and the approved evaluation model. The evaluation model, referenced in the COLR, will document how the thermal effects of crud are being addressed. No change was made to the final rule in response to this document.

Comment: Such models need to be used to predict the thicknesses of crud deposits—for both outer loose, fluffy layers and inner tenacious layers—that would be present on the fuel cladding during each fuel cycle. And such models need to be used for both PWRs and BWRs. Clearly, the thermal effects of crud—for fluffy layers and tenacious layers—and oxide layers need to be evaluated in LOCA analysis; and the thicknesses and thermal conductivities of such layers need to be modeled conservatively. [MEL1-2]

NRC Response: The NRC agrees with this comment. The proposed rule added a specific requirement that the thermal effects of crud and oxide layers be evaluated. As a result of this analytical requirement, applicants must demonstrate the ability to accurately account for the thermal effects, which will be dependent on crud deposition rate, crud thickness, crud morphology, and ultimately crud thermal conductivity. Similar is true for oxide layers. The rule, itself, does not prescribe the exact treatment and applicants are free to justify crud and oxide models; provided they are validated. No change to the rule was made as a result of this comment.

G. <u>NRC Approved Fuel</u>

Comment: The industry recommends that irradiated and unirradiated fuel assemblies that are procured within 60 months of the effective implementation date be permanently grandfathered. This will allow existing inventories of fuel to be used for power generation. [NEI1-90]

NRC Response: The NRC agrees with this comment. Guidance has been added to RG 1.224 regarding legacy fuel assemblies. In summary, legacy alloys will use the acceptable allowable CP-ECR versus cladding hydrogen content curve in RG 1.224 for PQD along with a defined 3,500 second breakaway oxidation analytical limit. No change was made to the final rule in response to this comment; however, guidance was added to RG 1.224 in response to this comment.

Comment: The terminology "NRC-approved" may be problematic depending on the licensing history of the commercial fuel designs. [NEI1-91]

NRC Response: The NRC disagrees with this comment. Fuel designs are approved using several regulatory vehicles, such as approved topical reports or license amendment requests and modifications made under an approved fuel design change process or § 50.59. The rule recognizes the use of unapproved fuel design features under the lead use program. No change was made to the final rule in response to this document.

Comment: It appears that "paragraph (d)" should be "paragraph (g)", since that is where the fuel requirements are specified. [NEI1-92]

NRC Response: The NRC agrees with this comment. The rule was modified to refer to paragraph (g) for current zirconium alloy fuel designs.

H. Corrective Action and Reporting

a. ECCS Models

Comment: The (m)(1) and (m)(2) reporting and corrective action requirements associated with ECCS evaluation model and analysis changes and errors should be deleted from the rule. The industry proposes to develop an NEI guidance document to standardize reporting in the industry. [NEI1-93, STARS1-3] The final rule should rely on reporting requirements of 10 CFR 50.72, 50.73 and 10 CFR 21, rather than establishing separate reporting requirements. [SNC1-4]

NRC Response: The NRC agrees in part with this comment. The NRC encourages industry efforts to standardize actions, because doing so improves consistency and reduces the expenditure of unnecessary effort required for compliance. The NRC would also consider reviewing and endorsing, or approving for use, as appropriate, an industry document providing standardized reporting practices. However, the NRC disagrees that the reporting requirements should be deleted from the rule, or that the rule should rely instead on reporting requirements separate from this section. ECCS evaluation models are complex systems of computer codes and their application requires concatenation of a large quantity of inputs and modeling parameters. Timely reporting, commensurate with the safety significance of any error or change, is required so that the Commission may make a determination of the safety significance and continued applicability of the evaluation model as a whole. The necessity for this requirement remains unchanged from the 1988 promulgation of this rule (53 FR 36004, Sept. 16, 1988). Based upon the need for the Commission to make a timely determination of the safety significance of any reported error or change, the NRC has not changed the final rule with regard to this requirement.

Comment: The language "or the application of such a model" appears to be missing from (ii) and (iii) and is assumed to be an editorial problem. [NEI1-94]

NRC Response: The NRC agrees with this comment. Based upon consideration of the comment and an editorial review, the NRC has revised the rule language to include the noted clause in all sentences included in § 50.46c(m)(1).

Comment: The language "or resulting noncompliance with the acceptance criteria in this section" is assumed to be an editorial problem. [NEI1-95]

NRC Response: The NRC agrees with this comment. Based upon consideration of the comment and an editorial review, the NRC has revised the rule language by deleting the phrase.

Comment: The Commission's use of the phrase "predicted response" with regard to reporting of changes or errors is subject to misinterpretation. [NEI1-96]

NRC Response: The NRC disagrees with this comment. The current rule language contained in 10 CFR 50.46(a)(3) states, "estimated effect on the limiting ECCS analysis…" but relates more specifically to estimated effect on PCT. The Commission has chosen to adopt language "predicted response," to broaden the requirement to include effects on predicted ECR and to simplify the language in the rule. Aside from including estimated effects of ECR in the reporting requirements, the Commission does not intend to be interpreted any differently than the current language. Based upon the need to include estimated effects of ECR in reporting requirements and the desire to maintain simplified language in the rule, the NRC has not changed the final rule language in response to this comment.

Comment: The proposed language introduces the concept of "operation inconsistent with the ECCS evaluation model" or "operation" which is vague and also unnecessary, as the existing language "changes, errors" remains sufficient. Operation that is inconsistent with the analyses is considered to be an unanalyzed condition, and as such should be considered for reportability under § 50.72 not § 50.46c. [NEI1-97, GEH1-40]

NRC Response: The NRC agrees with this comment. Based upon the fact that 10 CFR 50.72 requires reporting of unanalyzed conditions, and "operation inconsistent with the ECCS evaluation model" would be considered an unanalyzed condition, the NRC has revised the rule language to omit the phrase.

Comment: Revise the 30-day reporting period to 60 days for consistency with other similar regulations. [NEI1-98]

NRC Response: The NRC agrees in part with the comment. While changing the requirement to report significant changes or errors that do not jeopardize facility compliance with the § 50.46 acceptance criteria would be more consistent with the 10 CFR requirements identified by the commenters, the Commission still believes that 30 days remains appropriate for conditions in which the § 50.46 acceptance criteria are exceeded. Based upon these considerations, the NRC has revised § 50.46c(m)(ii) to require reporting within 60 days, but retained the 30-day requirement in § 50.46c(m)(iii).

Comment: The proposed rule language does not allow for the existing rule language "or taking other action as may be needed" as an alternative to submitting a reanalysis for errors or changes that are significant. Requiring a reanalysis will impose a significant cost with no obvious impact on public health and safety. [NEI1-99]

NRC Response: The NRC disagrees with this comment. The existing language contained in 10 CFR 50.46(a)(3)(ii) requires that licensees/applicants include, with a report describing a significant change or error in an ECCS evaluation model, or in an application thereof, "a proposed schedule for providing a reanalysis or taking other action as may be needed to show

compliance with § 50.46 requirements." The NRC is aware that, in the past, licensees have interpreted the "or taking other action" clause to mean that providing an estimate that indicates that the predicted PCT remains below 2200 °F satisfies the requirement. However, the NRC did not identify any instances in which the Commission agreed with this interpretation, and has in the course of licensing correspondence, explicitly disagreed with it. In addition, the NRC issued Information Notice 97-15, Supplement 1, (ML031050356) to clarify its position on this matter. Thus, the NRC has determined that this comment is based on a misinterpretation of the language in the current rule, which is being changed for added clarity. Furthermore, the NRC is also aware that the effects of errors and changes in ECCS evaluation models, and in the applications thereof, may be estimated using first principles and engineering judgment, with the predicted results becoming incorporated into the facility licensing basis as a means to demonstrate compliance with 10 CFR 50.46 acceptance criteria and subsequently forming the basis for core operating limits. Since such estimates are not required to be performed using explicit analyses in accordance with an acceptable evaluation model, it may not be possible to have the same high probability and confidence results that the rule requires. Therefore, the NRC has determined that reliance on estimated effects of changes and errors in ECCS evaluation models and applications thereof cannot be used to show compliance with the acceptance criteria as the comment suggests. Finally, the NRC has determined, through past review activity, that licensees and applicants frequently estimate the effects of significant errors and changes by re-executing the acceptable evaluation model with the change or error correction incorporated, such that the requirement to provide a re-analysis is inherently satisfied and not unduly burdensome. The NRC also notes that the rule language states that the licensee must propose a schedule to provide a reanalysis, rather than submit the reanalysis for NRC staff review and approval. Based upon (1) the commenters' misinterpretation of existing requirements, (2) the need to use an acceptable evaluation model to determine licensing basis ECCS performance results and show compliance to 10 CFR 50.46 acceptance criteria, and (3) the NRC's disagreement that the revised requirement would be as burdensome as the commenters suggest, the NRC has declined to revise the requirements in response to this comment.

Comment: Pages 16141 to 16143, § 50.46c(m) and associated sub-sections. Statement in Rule: The proposed Rule states that "Each <u>entity</u> [emphasis added] subject to the requirements of this section must comply with paragraphs (m)(1) through (3) of this section. Each <u>entity</u> [emphasis added] 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." Description of Concern: Entity is too broad a category. Basis for concern: The responsibility for error-reporting is unclear with this term. Proposal: "Entity" should be replaced with "licensee or licensee-applicant" or clarified as appropriate, throughout the rule. Basis of proposal: § 50.46c(a) uses entities as those who design, construct, or operate a light water reactor. The broad term "entity" could lead to misinterpretation of intent. For example, if misinterpreted, the plant designers would maintain responsibility for reporting throughout the plant's lifetime. Furthermore, individuals and organization other than the licensees would be required to set schedules for the licensees. [A1-8]

NRC Response: The NRC disagrees that the term, "entity," is too broad. The revised language in § 50.46c(a) clearly defines the entities to which the regulation applies. Based upon the definition provided in § 50.46c(a), the NRC has made no change to the final rule in response to this comment.

Comment: Page 16141, § 50.46c(m)(2) Significant change or error in the ECCS evaluation model Statement in Rule: "a significant change or error in an ECCS evaluation model is one that

results in a calculated [emphasis added] (i) Peak fuel cladding temperature different by more than 50 °F…" Description of Concern: The word "calculated" could be misinterpreted as requiring the analysis to be reperformed. Basis for concern: n/a Proposal: Use "estimated" which is consistent with Supplementary Information Section V.C. "Corrective Actions and Reporting Requirements." Basis of proposal: First principles and engineering judgment are appropriate for use in determining the effect of a change or an error. [A1-9]

NRC Response: The NRC disagrees with the comment. "Calculated" exists in the current regulation and the Commission is not aware that its use has been the subject of misinterpretation. Since the requirement is to estimate the effects of the change error or operation, it is understood that "calculated" includes the results provided from the evaluation model, augmented to include the estimated effect(s). Based upon the similarity between the language in the current reporting requirement, and the new rule, the NRC has made no change to the final rule in response to this comment.

Comment: In the current rule, an estimate for the impact of a change or an error in the evaluation model is necessary. In the proposed rule, a demonstration that the error, change, or operation is not significant is required. Clarification is needed that, similar to impact estimate, the demonstration can be based on first principles, known sensitivities, code calculations, and/or engineering judgment. [GEH1-41]

NRC Response: The NRC disagrees with the comment. In the current rule, annual reporting inherently provides such a demonstration by including the estimated effects of all changes, errors, etc. Therefore, the adoption of the "demonstration" language does not represent a change from existing reporting requirements. As suggested in the NRC's response to other comments, such a demonstration may be based on first principles, known sensitivities, code calculations, and/or engineering judgment. Based upon the consideration that adding the "demonstration" language does not alter the meaning of the rule, the NRC has made no change to the final rule in response to this comment.

Comment: The proposed LOCA analysis reporting requirements need to be more performance-based. [NEI1-100]

NRC Response: The NRC disagrees with the comment. To the extent that (1) the reporting requirements establish a threshold of significance and require timelier reporting of significant errors, changes, etc., and (2) various corrective actions are required depending on the effect that errors, changes, etc., have on the calculated performance with respect to the acceptance criteria; the NRC determined that the rule is adequately performance-based. Based on this consideration, the NRC did not revise the requirements in response to this comment.

Comment: The proposed rule requires that the magnitude of change or error be "calculated" which may be interpreted as running the ECCS evaluation model. The licensees need to be allowed to estimate PCTs and ECRs to avoid excessive cost to the industry. [NEI1-101]

NRC Response: The NRC disagrees with the comment. The existing reporting requirements provide the same definition of a significant change or error, and the NRC is not aware that this language has been subject to significant misinterpretation. Further, the definition states that a significant change or error is one that results in peak fuel cladding temperature, or integral time at temperature, different by a significant amount from the temperature calculated for the limiting transient. The word "calculated" is intended to refer to the results of the existing analysis of record, and not the process used to estimate the effects of a change or error. Based on the

facts that (1) this definition is consistent with the existing requirement, (2) the NRC is not aware that this requirement has been frequently misinterpreted, and (3) the word "calculated" correctly modifies the temperature and oxidation results that should be calculated, and not the effects of a change or error, which should be estimated, the NRC did not revise the requirements in response to this comment.

Comment: The error level of 0.4 percent in subparagraph (ii) should be increased to 2 percent. On page 16120 of the FRN it says that 0.4 percent ECR would be equivalent to a change in calculated ECR for a 50 degree Fahrenheit change in cladding temperature. This statement is not correct. Using the Cathcart-Pawel correlation, which is the basis for analysis of the current work, an increase of 50 degrees Fahrenheit for a particular oxidation period produces an increase in oxidation level of about 2 percent. Further, ANL's claimed uncertainty in Fig. 1 is 1 percent, and it is not reasonable to require more precision in the analysis than there is accuracy in the data. [RM1-10, RM1-11]

NRC Response: The NRC disagrees with this comment. The NRC recognizes that determining the threshold for a significant change in ECR is somewhat subjective. For example, it would be possible to perform the preceding conversion using an absolute temperature scale, such as Kelvin, and obtain a lower value of ECR that would be significant. It is also possible to use the difference between peak cladding temperature and an approximate normal operating temperature for reactor coolant, and if so, the equivalent value of a significant ECR would be higher. The NRC believes that the chosen threshold is sufficiently large to screen the code error corrections and changes that have little safety significance while providing a mechanism for timely reporting of more serious errors and changes. Based upon the preceding discussion, the NRC has not revised the rule language.

Comment: Assuming the debris evaluation model falls under these requirements, what would be the purpose of this annual report? To what end would the NRC use this information. [PL1-108, WC1-62]

NRC Response: The NRC agrees with this comment. Paragraph (m)(1) and (m)(2) do not apply to a deterministic debris LTC model. Therefore, no annual report is necessary. However, the requirements to take corrective action and report in Paragraph (m)(3) do apply to deterministic LTC models. Requirements associated with a risk-informed debris model are described in Paragraph (m)(4). No changes to the final rule have been made in response to this comment.

b. Alternate Risk-Informed Approach

Comment: The appropriate reporting criteria are dependent on how the staff specifies the "circumstances" or the "values for changes." The parameters defining accidents should not be so sensitive that the reporting process becomes burdensome to the licensee. [PWROG1-8]

NRC Response: The NRC agrees that the reporting criteria depend on the staff definition of the circumstances, or values of change, that trigger the need to report. The NRC also agrees that this definition should not be burdensome. The rule clearly states the conditions when reporting is needed for each affected entity. The SOC and the RG 1.229 further clarify the specific conditions and values, for which such reports are needed. No change to the rule was made in response to this comment.

Comment: Section 50.46c(m)(4)(vii) would require that the PRA (among other items) needs to be reviewed no later than 48 months after the previous review. The PWROG suggests that instead of using a time-based criterion for triggering a PRA review, PRA reviews should be triggered by changes to the plant facility and/or procedures with criteria that include the aggregate impact of changes since the last PRA model update. This is a more meaningful criterion, and not as arbitrary as a specific calendar periodicity (during which there may be no substantial change to the plant or procedures). [PWROG1-9]

NRC Response: The NRC disagrees that the periodic update should only be tied to facility or procedure changes. The rule establishes that, at least every 48 months, the systematic evaluation must be updated to confirm the results remain valid. This periodic update recognizes that there may be industry experience, model/analysis errors or changes, and other information identified separate from plant-specific changes that could result in changes to the evaluation results. The rule also establishes the need for a monitoring program that would capture these additional potential changes, as well as the plant-specific changes. No change to the rule was made in response to this comment.

Comment: New change or error reporting requirements for the risk-informed alternative should not be included in the rule. (1) Add a new paragraph (e)(1)(vi) for the risk-informed license amendment request (LAR) to include a monitoring program and a process for notifying NRC of changes and errors. (2) delete paragraph (m)(4) in its entirety. Licensees could then take advantage of existing programs and procedures, such as their corrective action programs, design control procedures, reporting procedures, Maintenance Rule implementing procedures, etc. [NEI1-80, NEI1-82, NEI1-103, STP1-7, GEH1-44, WC1-2]

NRC Response: The NRC agrees in part and disagrees in part with this comment. The NRC agrees that the risk-informed alternative should include a requirement that licensees implement a monitoring program to track the continued validity of the assumptions and results of the risk assessment. The NRC has added this requirement in new paragraph (e)(1)(v). The NRC disagrees that existing requirements or licensee programs fully cover the new reporting requirement, which was therefore retained in the rule.

Comment: 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. [PL1-19, PL1-59]

NRC Response: The NRC agrees that improved clarity is important and has provided additional guidance. Guidance on an acceptable approach for performing the risk-informed analysis is provided in RG 1.229. The rule language and SOC have been clarified to provide additional guidance on errors and changes in the analysis.

Comment: There needs to be a more explicit definition as to what constitutes a change or error. [PL1-112, WC1-66] The magnitude of changes or errors that would require reporting should be specifically described to prevent unnecessary reporting, and that minimal changes should not have to be reported. Changes to the PRA model should only need to be reported if the impact on the results exceeds some threshold. A better definition of *significant* is needed. [PL1-38, PL1-99, WC1-53, PL1-101, WC1-55, PL1-107, PL1-109, WC1-61, WC1-63] NRC should endorse in a regulatory guide an industry document that provides the criteria for corrective actions, reporting, and change management. [PL1-60, PL1-110, PL1-114, WC1-64, WC1-68] The reporting guidance should be in a separate document (outside of the rule). [PL1-99, WC1-53]

NRC Response: The NRC agrees in part and disagrees in part with the comment. The NRC agrees that changes or errors that do not exceed the threshold for risk increase, or that do not result in reductions in defense-in-depth or safety margins, do not need to be reported. However, § 50.46c(e)(1) establishes these thresholds. The NRC disagrees that a definition of significant is needed, because the rule language is clear that changes or errors that result in failing to meet the risk-informed acceptance criteria needed to be reported. The NRC notes that RG 1.174 provides the necessary guidance on the risk-informed acceptance criteria outside the rule itself. The NRC is issuing RG 1.229, which provides additional detail regarding how to assess defense-in-depth and safety margins. No change to the rule was made in response to these comments.

Comment: 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, the respective reporting and actions shall be taken. [NEI1-28, PL1-48]

NRC Response: The NRC disagrees that monitoring of the cumulative impact of errors or changes in the risk-informed analysis is necessary. The rule was written such that the risk-informed acceptance criteria must continue to be met rather than requiring tracking of cumulative impacts over time, which would be more burdensome and not necessary to achieve the regulatory goal. No change to the rule was made in response to this comment.

Comment: The corrective actions and reporting criteria specific to the risk-informed approach for addressing the effects of debris on long-term cooling should not be any different than current requirements that are applicable to probabilistic evaluations that are acceptable today. [GEH1-17]

NRC Response: The NRC disagrees that the corrective actions and reporting criteria associated with the alternate risk-informed approach should be the same as those applicable to other risk-informed licensing actions. For many risk-informed changes to the licensing basis of a nuclear power plant, there are no specific requirements for corrective action or reporting. For example, many risk-informed applications (e.g., Technical Specification completion time extensions; notice of enforcement discretion) allow *temporary* entry into a plant configuration or relaxation of a test interval.

Conversely, § 50.46c would allow a *permanent* change in plant operations with potential new challenges to risk-significant safety systems (ECCS and CS). Furthermore, risk related to debris is driven by unique factors (e.g., chemical composition of paint chips, quantity of latent debris), rather than traditional risk drivers such as equipment availability and reliability. Therefore, the rule contains specific requirements for corrective action and reporting.

The rule language does not prevent licensees from relying on existing programs in order to meet the requirements in (m)(6); however, the NRC believes that specific provisions in the rule for changes and reporting of errors are necessary due to the somewhat unique nature of the rule. No changes were made to the rule in response to this comment.

Comment: Section V of the Federal Register Notice, under B, “Performance-Based Aspects of the Proposed Rule,” lists "incorporate monitoring and performance measurement strategies" as a key principle of risk-informed regulation that is applicable to the risk-informed alternative set

forth in the proposed rule, but this principle is not included in the proposed rule language. [WC1-5, PL1-8]

NRC Response: The NRC agrees with the comment, and has added this principle explicitly in new paragraph (e)(1)(v) of the rule. The NRC also notes that paragraph (m) has been re-written to more clearly distinguish among reporting, corrective actions and updating; this entailed the removal of confusing references to monitoring in paragraph (m).

Comment: There should be discrete reporting criteria developed for each applicant based on their risk values. [NEI1-28, PL1-48]

NRC Response: The NRC disagrees with the comment. The NRC initially explored the concept of tiered reporting criteria (i.e., more stringent criteria for plants with higher baseline risk values) but ultimately determined that a single set of criteria tied to the RG 1.174 acceptance guidelines would be simpler, would provide NRC with sufficient information regarding implementation of the alternate risk-informed approach, and would impose a lower regulatory burden on the industry. No change to the rule was made in response to this comment.

Comment: Since the reporting 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. [PL1-50]

NRC Response: The NRC partially agrees with this comment. Paragraph (m)(6) states that the acceptance criteria for evaluating changes or errors in the risk assessment are the same as stated in paragraph (e)(1). The RG includes specific details regarding how to assess the acceptance criteria. No change was made to the rule as a result of this comment.

Comment: Regarding the following statement in paragraph (m)(6)(vii) of the proposed rule: "… then the licensee shall take action in a timely manner to bring the facility into compliance." The same tools that were used to assess the impact of debris should 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. [PL1-113, WC1-67]

NRC Response: The NRC disagrees in part with the comment. The NRC and the industry already have guidance that addresses timeliness of corrective action when there is non-compliance with a regulatory requirement. These include requirements in license conditions, completion times contained in Technical Specifications, and industry commitments. The tools for assessing the impact of debris may provide information that would enable or facilitate good implementation of the risk-informed approach governing timing of corrective action, but such a process needs to be implemented in accordance with the industry/NRC-approved guidance.

Comment: Paragraph (m)(4)(vii) of the proposed rule does not include the situation where following the identification of a change or an error that causes the acceptance criteria to not be met, that the plant condition is restored to within the licensing basis, and therefore an LAR should not be required. [NEI1-104, STP1-8]

NRC Response: The NRC agrees with the comment. The NRC determined that existing NRC change control requirements such as 50.59, coupled with the change controls imposed by paragraph (m)(8) of the final rule, are together sufficient to ensure adequate NRC regulatory oversight of licensees using the risk-informed alternative. Accordingly, paragraph (m)(7) of the final rule (paragraph (m)(4) in the proposed rule) has been revised to remove the requirement that a licensee submit a license amendment to obtain approval of corrective actions where a change or error is corrected and a plant restored to compliance with its licensing basis.

Comment: For licensed defense-in-depth and safety margins, if not currently part of the licensed risk analysis, and not falling under Technical Specification requirements, any reduction in these margins should be reported in an 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. [NEI1-29, PL1-49]

NRC Response: The NRC disagrees that a two-tier reporting framework for reduction in the amount of defense-in-depth or safety margin is needed. As described in the proposed rule, licensees would need to clearly identify these features that provide defense-in-depth and safety margin in the application so that they can be assessed in an integrated fashion along with the calculated risk numbers. If a condition were identified, in which insufficient defense-in-depth and safety margin existed, then the licensee must make a report as required by paragraph (m)(6). Otherwise, a report is not needed (e.g., an annual report). No change to the rule was made as a result of this comment.

Comment: The very prescriptive language that is present in § 50.46c(m)(4) of the proposed rule is counterproductive, especially, while the regulatory effort between stakeholders is still In progress. [GEH1-19]

NRC Response: The NRC disagrees with this statement that the rule language is prescriptive. Consistent with the principles of performance-based regulation, the rule specifies only that changes and errors need to be addressed but does not prescribe a method for addressing them. Regarding the interactions between NRC and its stakeholders, the rule language was "proposed" in order to elicit comments and make any changes that are deemed appropriate. The final rule is being issued after completion of the "regulatory effort" referred to in the comment. As noted in response to other comments, appropriate changes to the reporting and corrective action requirements contained in the rule have been made.

Comment: NUREG-1022 should be revised to include the newly defined reporting requirements for the risk-informed alternative, and RIS 2005-20 (and associated inspection guidance) be revised to allow for use of risk-informed methodologies for evaluation on non-conformances and degraded conditions. [PL1-51, WC1-4]

NRC Response: The NRC agrees in part and disagrees in part with the comment. The NRC agrees that it should consider revising NUREG-1022 to include reporting required in paragraph (m) of the rule, and to consider conforming changes as necessary to other affected documents. In addition, the rule allows a licensee to use its approved risk-informed approach to evaluate changes and errors to determine whether action is necessary to meet the acceptance criteria of paragraph (e)(1), and whether a report to the NRC is required. The NRC does not agree that the risk-informed approach may be used to determine operability of SSCs as defined in technical specifications. Currently, the NRC's inspection guidance associated with RIS 2005-20 (i.e., IMC Part 9900) does not allow the use of risk to assess operability. Operability is a

function only of whether an SSC can perform its intended safety function, not whether the SSC is important from a risk perspective. This consideration ensures that risk insights are not inappropriately used as a basis for allowing degraded system performance. Furthermore, the risk numbers that might be used in such an argument could be based on the assumption that SSCs are maintained in a manner that ensures their reliable operation. Allowing degraded or inoperable SSCs based on risk numbers that assume operable SSCs would be inappropriate. No change to the rule was made in response to this comment.

I. Implementation

a. Implementation of Deterministic …

Comment: Paragraph (e), the alternate risk-informed approach to debris, is optional. Because it is optional it is inferred that paragraph (o) is not applicable to paragraph (e) as it would not make sense to establish a compliance schedule requirement for something that is optional. [NEI1-105]

NRC Response: The NRC agrees with this comment. The rule has been modified to clearly state that the implementation plan does not apply to the optional risk-informed approach to debris.

Comment: The implementation plan should be replaced by a requirement for licensees to submit within 180 days of the effective date of the rule a plan for compliance. The NRC would review and approve the plan and manage it outside of the rule. [NEI1-106, NEI1-32, WEC1-23, D1-2, D1-4, SNC1-2]

NRC Response: The NRC agrees with this comment. The rule has been modified and Table 1 has been removed and replaced with a requirement for licensees to submit an implementation plan within 180 days. Schedule requirements have been established within the rule for (1) submitting a license amendment request documenting compliance and (2) complying with the rule.

Comment: The current implementation plan has only one compliance date for each track. A phased implementation plan that allows different dates for different rule requirements is more appropriate. As a minimum a separate date is required for compliance with the long-term cooling requirements. [NEI1-107] A separate compliance schedule for debris effects on core cooling requirements is definitely needed by industry due to the regulatory uncertainty on this subject. [NEI1-32] The proposed § 50.46c(g)(1)(v) has ramifications to the ongoing GSI-191 efforts of the owners groups. Specifically with respect to the timing of test scope definition, completion, and ultimately, supporting ECCS rulemaking implementation. This needs to be considered as part of a multiple path compliance effort. [NEI1-40, WEC1-22]

NRC Response: The NRC agrees with this comment. The rule has been modified to separate debris-related LTC performance demonstration (either deterministic or risk-informed approach) from the non-debris short-term and long-term compliance schedule. No implementation plan has been described for the debris-related activities, as these are being managed outside of § 50.46c.

Comment: Table 1 was developed based on best-estimate assessments. There is currently no way to know what the outcome of “Licensing Basis” calculations will be simply because there

are too many unknowns at this time. The presence of Table 1 in the rule language has the potential to cause avoidable regulatory problems. Compliance via existing regulatory processes, outside of rule language, should be adequate. [NEI1-108] As a bare minimum, delete plant names from Table 1 to allow future plant reassignment consistent with a performance-based approach, and to allow regulatory flexibility without exemption requests. [NEI1-109]

NRC Response: The NRC agrees with this comment. See response to Comments NEI1-106, NEI1-32, WEC1-23, D1-2, D1-4, and SNC1-2, earlier in this section.

Comment: The NRC assumes plants assigned to Track 1 can demonstrate compliance via submittal of a letter report not involving a LAR as technical specification changes or licensing basis changes would not be required. The industry perspective is the fuel vendors will be developing LTR's, for NRC review and approval, of new hydrogen pickup models, and new debris effects on core cooling evaluation methodology. Both of these would require a licensee to revise the list of methodology reports, which would necessitate submitting a LAR. [NEI1-33] The industry would appreciate working with NRC to explore a compliance approach for the Track 2 and 3 plants that does not require revising the ECCS evaluation model topical report. The technical content would be submitted with an LAR on a plant-specific basis. [NEI1-34] The rule does not speak to the schedule for completion of the NRC review activities or the schedule for formal LOCA analyses using the revised or new ECCS evaluation models following NRC approval. [NEI1-35]

NRC Response: The NRC agrees with this comment. During multiple 2015 public workshops, the industry and staff discussed the most effective and efficient means to implement § 50.46c. The industry provided a comprehensive, integrated schedule to illustrate the magnitude of effort and parallel and series work activities. This information informed a revision to the rule language. See response to Comments NEI1-106, NEI1-32, WEC1-23, D1-2, D1-4, and SNC1-2, earlier in this section.

Comment: The industry maintains that grandfathering of fuel assemblies/bundles and cladding manufactured under the existing regulations is necessary. [NEI1-36, D1-3, STARS1-2, SNC1-5]

NRC Response: The NRC disagrees with this comment. Maintaining § 50.46 requirements for legacy fuel and § 50.46c requirements for future fuel would lead to confusion and errors. The NRC recognizes that source material from legacy alloys may not be available for testing. Guidance will be added to RG 1.224 regarding legacy fuel assemblies. In summary, legacy alloys will use the acceptable allowable CP-ECR versus cladding hydrogen content curve in RG 1.224 for PQD along with a defined breakaway oxidation analytical limit. No change was made to the final rule in response to this document.

Comment: The NRC should develop a Review Standard (RS) for § 50.46c submittals. [NEI1-37] The industry requests that a Regulatory Information Summary (RIS) be developed to support rule implementation. [NEI1-39] These processes can be used together to effectively and efficiently standardize submittals that can be reviewed within a short period of time by the NRC staff and reduce the number of RAIs with such a complicated issue. [D1-10]

NRC Response: The NRC agrees with this comment. During multiple 2015 public workshops, the industry and staff discussed the most effective and efficient means to implement § 50.46c. The industry provided a comprehensive, integrated schedule to illustrate the magnitude of effort and parallel and series work activities. The NRC staff and stakeholders agreed to conduct future

workshops aimed at establishing implementation guidance and LAR templates. No change was made to the final rule in response to this document.

Comment: The implementation requirements and schedule should not discourage licensees from pursuing the hardware fix of implementing advanced cladding. [NEI1-38, GEH1-24]

NRC Response: The NRC agrees with this comment. During multiple 2015 public workshops, the industry and staff discussed the most effective and efficient means to implement § 50.46c. The industry provided a comprehensive, integrated schedule to illustrate the magnitude of effort and parallel and series work activities. This information informed a revision to the rule language. The revised implementation approach provides flexibility to address any plant-specific issues, such as pursuing advanced cladding. Regarding the implementation schedule, see response to Comments NEI1-106, NEI1-32, WEC1-23, D1-2, D1-4, and SNC1-2, earlier in this section.

Comment: There is no safety benefit associated with revision of legacy documentation which currently references § 50.46(b) simply to reference the proposed rule. Changes to existing documentation should not be required unless modification is needed to address requirements of the proposed rule. [WEC1-4]

NRC Response: The NRC disagrees with this comment. There are new requirements which need to be addressed. Furthermore, there is the compliance issue. Licensees need to reference approved methods. Any legacy methods that reference § 50.46 may not capture the new requirements in § 50.46c or be suitable for use to demonstrate compliance to § 50.46c. NRC approval explicit to § 50.46c is required for previously approved methods that will continue to be used after the licensee has migrated from § 50.46 to § 50.46c. No change was made to the final rule in response to this document.

Comment: 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. [PL1-22]

NRC Response: The NRC disagrees with this comment. The NRC's attempt to promulgate 50.46a (transition break size rulemaking) has been delayed. There is currently no schedule for issuance of this rule. Furthermore, similar to the risk-informed treatment of debris, 50.46a is optional and no implementation schedule will be dictated. The NRC agrees that staff resources may be an issue should multiple project schedules intersect. No change was made to the final rule in response to this document.

Comment: Also since some NRC staff are supporting both the § 50.46 rulemaking and review of current Risk-Informed applications, how is NRC managing the resources? 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? [PL1-23]

NRC Response: The NRC disagrees with this comment. As described in the comment responses above, the § 50.46c implementation plan (absent debris consideration) has been separated from the resolution of LTC debris issues (e.g. GSI-191). The implementation plan allows licensees to submit an implementation plan. The NRC intends to coordinate review

activities and balance workload via licensee schedule commitments. Regulatory guidance documents have been developed for both the short-term aspects (e.g., PQD, breakaway) and the risk-informed alternative. These RGs along with ongoing corporative efforts to develop review standards and LAR templates should help ensure timely, consistent reviews.

Comment: 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 non-pilot plants. [PL1-54] 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 month from effective date of rule category: Calvert Cliffs, Diablo Canyon, Palisades, Point Beach, St. Lucie, Seabrook, Turkey Point, Wolf Creek. [PL1-116, WC1-70]

NRC Response: The NRC agrees with this comment. As described in the comment responses above, the § 50.46c implementation plan (absent debris consideration) has been separated from the resolution of LTC debris issues (e.g. GSI-191). The implementation plan allows licensees to submit an implementation plan. Table 1 prescriptive schedule requirements have been removed from the rule. As a result, individual plants may coordinate debris related and non-debris related activities. However, no strict schedule for compliance with debris-related activities will be defined within § 50.46c.

Comment: The timing of publishing these draft RG, 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. [PL1-61] 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. [WC1-15]

NRC Response: The NRC agrees with the comment that timely issuance of the draft regulatory guide and its finalization is critical to timely implementation of the risk-informed aspect of the rule. The draft regulatory guide was issued for public comment on April 20, 2015, and comments have been dispositioned to support issuance of the final regulatory guide at the same time as issuance of the final rule. This coordination should support timely implementation of the rule.

Comment: A staged implementation of the proposed rule is an efficient approach. However, listing of the plant names in the track assignments could be problematic if the conditions that had resulted in particular assignment changes for a given plant. A better approach would be setting forth the criteria for compliance timetable in the rule. The criteria could be similar to the one used in the current proposed rule. The licensees then can provide their plan for compliance with the revised rule within a predetermined timeframe. The expectations of the content of the plan could be included in the rule. The plan should include the method (e.g. demonstration of existing analysis against new limits, a new analysis using existing evaluation model, or a new analysis with a new methodology), and submittal date. [GEH1-23]

NRC Response: The NRC agrees with this comment. See response to Comments NEI1-106, NEI1-32, WEC1-23, D1-2, D1-4, and SNC1-2, earlier in this section. While the NRC did not prescribe criteria for a compliance timetable, the NRC staff intends to coordinate review activities and balance workload via licensee schedule commitments.

Comment: Depending on the final rule, the licensees might need to do more analysis to comply with requirements associated with debris and crud. Compliance with the breakaway oxidation requirements will also take additional effort. Therefore it is not clear from the rule and the proposed staged implementation plan how the Track 1 plants can comply with the new rule in 24 months. Given the variety of issues that need to be addressed, additional time in the rule might be needed to avoid exemptions. [GEH1-25]

NRC Response: The NRC agrees with this comment. During multiple 2015 public workshops, the industry and staff discussed the most effective and efficient means to implement 50.46c. The industry provided a comprehensive, integrated schedule to illustrate the magnitude of effort and parallel and series work activities. This information informed a revision to the rule language. See response to Comments NEI1-106, NEI1-32, WEC1-23, D1-2, D1-4, and SNC1-2, earlier in this section.

Comment: The final rule should carefully examine the requirements of 10 CFR 50.59 in considering what will be required in terms of NRC approvals in order for plants to comply with the new requirements. [SNC1-3]

NRC Response: The NRC agrees with this comment. During multiple 2015 public workshops, the industry and staff discussed the most effective and efficient means to implement 50.46c. The industry provided a comprehensive, integrated schedule to illustrate the magnitude of effort and parallel and series work activities. During these meetings, it was agreed that the most effective implementation and compliance plan involves each licensee submitting a LAR and subsequently receiving NRC approval. This information informed a revision to the rule language. See response to Comments NEI1-106, NEI1-32, WEC1-23, D1-2, D1-4, and SNC1-2, earlier in this section.

Comment: With respect to the BWROG's voluntary initiative related to debris, the envisioned testing and evaluation programs extend beyond the dates proposed in the final rule. [GEH1-21] The schedule for the BWROG program to investigate debris blockage does not appear to be in sync with the proposed rule implementation schedule. [WEC1-13]

NRC Response: The NRC agrees with this comment. Resolution of debris related issues is not a new requirement in § 50.46c and ongoing programs will continue on previously agreed upon schedules. The rule has been modified to explicitly exclude debris considerations from the implementation schedule.

Comment: With respect to the BWROG's voluntary initiative related to debris, the rule should allow for a risk-informed approach for debris without specifics on implementation and reporting. [GEH1-22]

NRC Response: The NRC agrees with this comment in part. Resolution of debris related issues is not a new requirement in § 50.46c and ongoing programs will continue on previously agreed upon schedules. The rule has been modified to explicitly exclude debris considerations from the implementation schedule. However, certain aspects of an acceptable risk-informed approach need to be defined. The risk-informed reporting requirements are being modified

based upon several other comments. However, reporting requirements will remain within § 50.46c. No change was made to the final rule in response to this comment.

Comment: In Appendix D of the their comment package (WEC1), Westinghouse provided recommendations for a future LTC regulatory guide which would clarify current requirements and provide acceptable attributes for LTC models. These recommendations are labeled WEC1-64 through WEC1-81. The recommended guidance included specific comments similar to those discussed for LTC and implementation above. For example, (1) the rule should not specify a LTC PCT analytical limit, (2) a schedule for compliance should not be established until guidance has been issued, and (3) LTC models should be allowed to use realistic assumptions.

NRC Response: The NRC agrees with this comment. As described in the comment responses above, the § 50.46c implementation requirements have been modified. The revised rule language allows licensees to submit an implementation plan. No strict schedule for compliance with debris-related activities has been defined within § 50.46c. Absent debris consideration, no new requirements have been established relative to long-term cooling (i.e., LTC PCT limit removed from rule). During a public workshop on § 50.46c implementation in May 2015, industry representatives described an ongoing task to develop LTC guidance. The NRC supports these industry initiatives and will work with the industry to finalize guidance specific to LTC ECCS performance.

Comment: Many meetings and PRMs are going forward at this time without the reasonable and required need to await parts of this PRM herein that will affect those meetings and PRMs. Scheduling is inadequate to address many issues that are moving thru the NRC which will be affected when this PRM issues. I request that all actions on PRMs and licensing await the conclusion of this PRM before proceeding. [ML1-2]

NRC Response: The NRC interprets this comment as a request to delay this rulemaking until petitions for rulemaking PRM-50-93 and PRM-50-95 are resolved by the NRC. The NRC declines this request. If the NRC determines that rulemaking is necessary to address the issues raised in these petitions, then the NRC can initiate the rulemaking process and address the issues regardless of the status of this rulemaking. For the status of the NRC's evaluation of PRM-50-93 and PRM-50-95, see ADAMS Accession No. ML15174A100. No change was made to the rule as a result of this comment.

Comment: The NRC is proposing that new reactors per (o)(9) may operate for the initial fuel cycle without meeting the proposed new rule requirements. There can be a conflict between the compliance date for new plants and the completion of the first fuel cycle. The license approval date, the rule effective date, and the track compliance date can combine to create an unanticipated complication for new plants. The language should not require new plants to meet the rule in less time than the Track 1, 2, and 3 compliance requirements if the rule implementation is delayed. It would be possible for the initial cycle to conclude prior to Track timing requirements if the rule making is delayed. [NEI1-41, NEI1-110]

NRC Response: The NRC agrees with this comment. The rule language previously in (o)(9) has been rewritten in such a manner as to address the concern expressed in this comment. The rule language now reads:

> Combined licenses issued under Part 52 of this chapter, before [EFFECTIVE DATE OF RULE] and combined licenses issued after [EFFECTIVE DATE OF RULE] whose applications were docketed before [EFFECTIVE DATE OF RULE] must comply with this

> section by initial fuel loading or [84 MONTHS FROM EFFECTIVE DATE OF RULE] whichever is later.

Comment: Section VI.K of the Statements of Consideration for the proposed rule states that "Paragraph (o)(6) would require standard design certifications under 10 CFR Part 52 issued before the effective date of the rule to comply no later than the time of renewal of certification." Depending on when the final rule is made effective, a conflict could arise between the compliance date and submittal of the certification renewal application for the AP1000® Pressurized Water Reactor (PWR) plant design certification, which by regulation, must be submitted between February 2018 and February 2020. For example, the date of rule could coincide with intended certification renewal submittal. This could create unintended issues for both vendors and Combined Operating License applications. It is recommended that the compliance timing requirements be elaborated on and/or a "grandfather clause" be added to prevent unanticipated and costly unintended consequences. [WEC1-24]

NRC Response: The NRC does not agree with this comment. The intention of paragraph (o)(6) was to not place a burden on a certified design until the design should be renewed. Compliance with the requirements of 10 CFR 50.46c would not be required until completion of the renewal process for a certified design rather than at the time of submittal of the application for renewal.

Comment: Section VI.K of the Statements of Consideration for the proposed rule states that "Those entities that are issued combined licenses prior to the effective date of the rule must comply with the rule no later than the first refueling outage after initial fuel load." Depending on when the final rule is made effective, a conflict could arise between the compliance date and the first refueling. For example, the date of rule could immediately precede the first refueling. This may not allow sufficient time for reanalysis efforts which could in turn necessitate licensing basis modifications. Additionally, if any of the licensing basis changes require prior NRC approval, additional time will be needed to comply. It is recommended that the compliance timing requirements be elaborated on and/or a "grandfather clause" be added to prevent unanticipated and costly complications. [WEC1-25]

NRC Response: The NRC agrees with this comment. The rule language previously in (o)(9) has been rewritten in such a manner as to address the concern expressed in this comment. The rule language now reads:

> Combined licenses issued under Part 52 of this chapter, before [EFFECTIVE DATE OF RULE] and combined licenses issued after [EFFECTIVE DATE OF RULE] whose applications were docketed before [EFFECTIVE DATE OF RULE] must comply with this section by initial fuel loading or [84 MONTHS FROM EFFECTIVE DATE OF RULE] whichever is later.

Comment: It is logical to expect new applications to comply with the rule that is then current. However, there is no need to urge the new reactor designs to comply with all requirements of the rule faster than the current operating plants, especially when their LOCA response is typically more favorable compared to current technology. NRC should consider giving similar grace periods after the final rule date, since none of these issues pose a safety concern. [GEH1-26]

NRC Response: The NRC agrees with this comment. The rule language previously in (o)(9) has been rewritten in such a manner as to address the concern expressed in this comment. The rule language now reads:

> Combined licenses issued under Part 52 of this chapter, before [EFFECTIVE DATE OF RULE] and combined licenses issued after [EFFECTIVE DATE OF RULE] whose applications were docketed before [EFFECTIVE DATE OF RULE] must comply with this section by initial fuel loading or [84 MONTHS FROM EFFECTIVE DATE OF RULE] whichever is later.

b. Implementation of Alternate Risk-Informed Approach

Comment: As elements of the guidance are developed, they should 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 NRC. [PL1-18] 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. [PL1-45]

NRC Response: The NRC agrees with these comments. Several public meetings have been held with industry representatives, including representatives from non-pilot plants. The draft guide was issued for public comment and a public meeting was held to obtain input from interested stakeholders.

Comment: There should be an industry/NRC pilot program prior to the final rulemaking. This pilot would help to ensure that the process that is developed would be viable for both the industry (execution) and the NRC (regulatory review). As the current STP submittal is the basis for the guidance document accompanying the rulemaking language, an independent application, which tests the actual rule language and guidance, should be performed with a pilot plant other than STP. [PWROG1-5, PWROG1-6, PWROG1-7, PWROG1-8]

NRC Response: The NRC disagrees that additional piloting of the risk-informed approach is necessary. A pilot application of the alternative risk-informed approach was underway during this rulemaking activity and greatly influenced the development of the associated regulatory guide. The alternate risk-informed approach is consistent with past risk-informed changes to the licensing basis ad with RG 1.174. No change to the rule language was made as a result of this comment.

Comment: Although the section on implementation states that licensees could submit a request to use the risk-informed alternative in advance of achieving full compliance with the requirements related to the embrittlement research findings, it is also possible that such submittals could occur 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 NRC. [PL1-21]

NRC Response: The NRC agrees that under the proposed rule, licensees may submit a request to use the risk-informed alternative (in the form of a license amendment) either before or after the compliance dates in paragraph (o) of the proposed regulation. Thus, the NRC agrees that requests for use of the risk-informed alternative may pose significant resource

challenges to the NRC. In particular the following situations are of concern to the NRC: (1) requests for use of the risk-informed alternative that are submitted at the same time as any license amendment requests needed to adhere to the compliance dates in paragraph (o) of the proposed rule (note that the implementation discussion is in paragraph (p) of the final rule), and (2) closely-spaced requests to use the risk-informed alternative which are submitted after the paragraph (o) compliance dates.

To address these concerns, the final rule has been modified.

Comment: In FRN section V.B.6, "codes and standards" are mentioned in the context of maintaining adequate safety margins. 10 CFR 55a is currently being revised – what version of the codes referenced therein apply? Licensees only update to these new requirements on a periodic basis. Could plants update to later editions and credit reduced probability of failures? [WC1-13, PL1-16]

NRC Response: The NRC agrees that codes and standards may be periodically updated. However, a specific licensee is generally committed to specific codes and standards as set forth in the licensing basis for the plant. Updating license commitments to codes and standards is outside the scope of this rule. The reference to codes and standards was in the context of maintaining adequate safety margin, and not related to failure probabilities. No change to the rule language was made as a result of this comment.

Comment: Regarding the discussion in the section-by-section analyses of paragraph (e)(2)(v), regarding implementation of the risk-informed alternative: Is a license condition necessary? [PL1-39, PL1-102, WC1-56]

NRC Response: The NRC disagrees with the comment, which the NRC understands to say that a license condition may not be necessary when implementing the risk-informed alternative. When the NRC issues a license amendment approving a request to use the risk-informed alternative for addressing long-term core cooling, the NRC's safety evaluation will be based on the specific approaches, methods, and data submitted. The results of the risk analysis will be evaluated against the risk-acceptance guidelines, and the NRC will determine whether sufficient safety margins and defense-in-depth are maintained. A license condition or equivalent obligation will be necessary to ensure that the licensee's monitoring program continues to use the approaches, methods, and data that the NRC used to make its safety determination. This will ensure that changes in the scope, methods, data, approaches, assumptions, etc. used in the risk-informed alternative will be submitted for NRC review and approval. No change to the rule was made as a result of this comment.

J. <u>Appendix A to Part 50 – General Design Criteria</u>

Comment: Paragraph 1 of 10 CFR part 50, Appendix A, Criterion 35 (GDC 35) should be rewritten to place emphasis on ECCS performance on fuel performance, because ECCS performance can only be assessed in the context of fuel performance. Thus, GDC 35 should be re-written in a manner analogous to GDC 10. This revision would make clear that 10 CFR 50.46c(g) is a direct implementation of the high level requirements in GDC 35. [NEI1-111]

NRC Response: The NRC does not agree with the comment. The focus of GDC 35 is on the design of the ECCS system. Although the comment is correct that the acceptability of ECCS design under GDC 35 involves the fuel system design, it is nonetheless true that the regulatory

requirement in GDC 35 applies to the ECCS. There are other GDC, *viz*., GDC 1, GDC 4, and GDC 10, which are applicable to the design of the fuel system. The suggested revision of GDC 35 would obscure the true nature of the regulatory requirement. No change was made to the rule language as a result of this comment.

Comment: The proposed changes to the GDC are not needed to allow the use of the risk-informed alternative without a corresponding exemption. [GEH1-45, 46, 47]

NRC Response: The NRC agrees that the proposed changes to the GDC are not needed to allow the use of the risk-informed alternative without a corresponding exemption. However, obviating the need for exemptions was not the primary purpose of the NRC-proposed changes to the GDC. The NRC intended the proposed changes to the language of the GDC to allow the applicant/licensee to use risk information and risk-informed methods, which would satisfy the risk-informed, long-term cooling provision in § 50.46c, to satisfy also the requirements of each of the revised GDCs, if the applicant/licensee so chooses. No change was made from the proposed rule to the final rule as a result of this comment.

Comment: 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? [WC1-21]

NRC Response: Placeholder

Comment: Is GDC 19 a potential candidate for using a risk-informed approach for consideration of debris during long-term cooling? Other regulatory criteria are dependent upon the success of the recirculation function to satisfy those criteria. [PL1-53]

NRC Response: Placeholder

Comment: GDC's are high level criteria. As such there is no need for them to make specific pointers to lower level rules. [NEI1-112, NEI11-113, NEI1-114]

NRC Response: The NRC disagrees with this comment. The NRC-proposed changes to the language of the GDCs were not intended solely to provide "pointers" to "lower-tier" regulations. Instead, the NRC intended the proposed changes to the language of the GDCs to allow the applicant/licensee to use risk information and risk-informed methods, which would satisfy the risk-informed long-term cooling provision in § 50.46c, to satisfy also the requirements of each of the revised GDCs, if the applicant/licensee so chooses. No change was made from the proposed rule to the final rule as a result of this comment

Comment: 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 request for additional information (RAI) set received by STP, it is not expected that the proposed language would significantly change the course of the review by the staff. [PL1-117, WC1-71]

NRC Response: The NRC disagrees with the comment that there are significant questions as to how these specific GDCs are addressed in the risk-informed, alternative approach. Subsequent to the issuance of the draft rule, the NRC issued DG-1322, associated with this aspect of the rule, for public comment. The final version of RG 1.229, in concert with the rule establishes sufficient guidance on how the subject GDCs are addressed for the risk-informed

alternative. Note that both RG 1.229 and the alternative risk-informed approach in the final rule have been informed by the STP pilot application.

Comment: 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. [PL1-118, WC1-72]

NRC Response: The NRC agrees with the comment that the risk-informed approach in this rule is consistent with the determination of reasonable assurance. This includes the reliance on the risk-informed approach to addressing debris for the subject GDCs.

Comment: The risk-informed approach is consistent with the “holistic” approach advocated by the NRC since the issuance of the generic letter (GL) and should be appropriately factored into both the rule language and proposed RG. [PL1-119, WC1-73]

NRC Response: The NRC agrees that the risk-informed approach, as factored into the rule language and associated regulatory guide, is consistent with Generic Letter 2004-02 regarding addressing the effects of debris on ECCS performance. No change to the rule was made as a result of this comment.

K. Appendix K to Part 50 – ECCS Evaluation Models

Comment: The detailed technical content of Appendix K is more suited to a regulatory guide. [NEI1-43, NEI1-115, GEH1-29]

NRC Response: The NRC interprets these comments as requesting that Appendix K be revised to remove "detailed technical content." The NRC has decided that this rulemaking should include only those changes to Appendix K need to support adoption of risk-informed, performance-based, technology-neutral (e.g., without reference to specific fuel cladding compositions) ECCS requirements, or to enable the risk-informed alternative for addressing debris effects during long-term cooling. Removing technical content because it is believed to be more appropriate for a regulatory guide does not meet this criterion. For this reason, the NRC decided not revise Appendix K to accomplish the goal specified by the commenters. No change was made to the final rulemaking as a result of these comments.

Comment: Allow the Cathcart-Pawel correlation to be used with Appendix K ECCS evaluation models. [NEI1-116]

NRC Response: The NRC has decided that this rulemaking should include only those changes to Appendix K need to support adoption of risk-informed, performance-based, technology-neutral (e.g., without reference to specific fuel cladding compositions) ECCS requirements, or to enable the risk-informed alternative for addressing debris effects during long-term cooling. Allowing the Cathcart-Pawel correlation to be used with Appendix K ECCS evaluation models does not meet this criterion. For this reason, the NRC decided not revise Appendix K to accomplish the goal specified by the commenters. No change was made to the final rulemaking as a result of these comments.

Comment: Add a long-term decay heat model to Appendix K. [NEI1-117]

NRC Response: The NRC has decided that this rulemaking should include only those changes to Appendix K need to support adoption of risk-informed, performance-based, technology-neutral (e.g., without reference to specific fuel cladding compositions) ECCS requirements, or to enable the risk-informed alternative for addressing debris effects during long-term cooling. Adding a long-term decay heat model to Appendix K does not meet this criterion. Furthermore, such an addition would likely require re-noticing of this rulemaking, resulting in delays in the schedule for completion. For these reasons, the NRC decided not revise Appendix K to accomplish the goal specified by the commenters. No change was made to the final rulemaking as a result of these comments.

L. Miscellaneous Comments

Comment: The NRC should re-notice the proposed rule and provide a second opportunity for public comment after making changes to the proposed rule in response to comments submitted. There are significant issues with a very complex proposed rule, and it is unclear how the NRC may resolve these issues in a final rule. Accordingly, an additional opportunity for public comment would help lead to an effective, smooth implementation of the final rule. [NEI1-5, NEI1-8]

NRC Response: The NRC agrees in part with this comment. The NRC has held a number of public meetings to allow for additional opportunities for public stakeholders to present their views, and to have an interchange of information with respect to possible approaches for addressing issues raised by the public stakeholders. On March 17-19, 2015, the NRC

conducted a public meeting to seek clarification regarding comments previously received on implementation and the regulatory analysis associated with the proposed rule. As a result of this public meeting, the NRC held a series of three follow-on public meetings to further discuss a draft preliminary implementation plan that would represent an alternative to that in the proposed rule. These follow-on meetings were held on April 23, 2015, May 7, 2015, and June 4, 2015. Additionally, on April 29-30, 2015, the NRC conducted a public meeting at Oak Ridge National Laboratory to discuss specific comments received on draft regulatory guides (DG) DG-1261, "Conducting Periodic Testing for Breakaway Oxidation Behavior," DG-1262, "Testing for Post Quench Ductility," and DG-1263, "Establishing Analytical Limits for Zirconium-Based Alloy Cladding." On June 9, 2015, the NRC conducted a public meeting to discuss the long-term cooling provision in the proposed rule. Therefore, as a result of the extensive public outreach, the NRC has not re-noticed the proposed rule in response to this comment.

Comment: The regulation should have a single standard by which acceptance criteria are weighed: *reasonable assurance*. Providing gross conservatism in the rule to achieve excessive retained margin is not consistent with performance-based or risk-informed rulemaking. The proposed rule has a variety of standards which are inconsistent, *viz*., adequate protection, maintain ductility before quench; prevent; maintain a measure of; ensure; reasonable assurance; and adequate margin. As an example, one sentence in the statement of considerations (79 FR 16106, at 16136; March 24, 2014) for the proposed rule uses three different standards in the same sentence:

> In sum, the NRC believes that imposing the requirements of the proposed rule is necessary to *prevent* embrittlement of fuel cladding and to *ensure* that the rule maintains *reasonable assurance* of adequate protection to public health and safety….

[NEI1-6]

NRC Response: The NRC agrees in part of the comment. Reasonable assurance of adequate protection is the overall safety standard which must be provided by the NRC, in accordance with the applicable provisions of the Atomic Energy Act of 1954, as amended. The NRC also believes that "excessive" margin and "gross conservatism" – which the NRC equates to unjustified conservatism – should not be the goal or the requisite level of performance under performance-based or risk-informed regulation. Finally, the NRC also agrees that acceptance criteria of the same "hierarchical level" or "regulatory character" should use consistent (if not identical) standards. The NRC agrees that quoted language from the statement of considerations for the proposed rule contains an inconsistent standard when it states the requirement is necessary to "ensure that the rule maintains reasonable assurance…." This would be better expressed as, "…thereby providing reasonable assurance…."

However, it is not inconsistent for the regulation (and the statement of considerations) to express different standards for acceptance criteria of different hierarchical levels or regulatory character. The quoted language from the statement of considerations for the proposed rule, uses the standard of "prevent" for the acceptance criterion addressing the technical matter of embrittlement. Thus, the fuel cladding embrittlement is of a different (*i.e*., lower) "hierarchical level," and a different "regulatory character" (cladding embrittlement, versus overall concept of safety), as compared with the overarching hierarchical character of the adequate protection standard.

Changes were made to the statement of considerations consistent with the discussion above, A review of the remaining rule language did not disclose any redundant and inconsistent standards for identical acceptance criteria and acceptance criteria of the same "hierarchical level" or "regulatory character." Therefore, no change to the language of the final regulation was made as a result of this comment, although changes to the language of acceptance criteria were made for other reasons (e.g., clarity, or to focus on the appropriate figure of merit).

Comment: It strange that Baker-Just is deployed in the Federal Register in the following instance, because neither Baker-Just or BJ is used elsewhere in the entire document: "For this case, appendix K to 10 CFR part 50 ECCS evaluation models would continue to use the Baker-Just (BJ) weight gain correlation for estimating the rate of energy release and hydrogen generation from the metal/water reaction." [RL1-1]

NRC Response: NRC disagrees with this comment. The Baker-Just correlation can continue to be used for Appendix K LOCA methodologies, only for calculation of the metal-water reaction heat generation rate. No change was made to the rule as a result of this comment.

Comment: The NRC should consider dividing this rulemaking into two or more rulemakings. If this approach is followed, then the current rulemaking should proceed by addressing only the items necessary to achieve adequate protection of public health and safety:

- PQD as a function of cladding hydrogen content
- Short term breakaway oxidation
- Interior cladding oxidation
- Crud effects

All issues related to risk-informed aspects, such as the currently-withdrawn regulation on risk-informed large break LOCA consideration, would be deferred to other rulemakings. [NEI1-9]

NRC Response: The NRC disagrees with the comment. The comment, as submitted, suggested that the industry does not know if such a rulemaking path would be more cost-effective in the long run. The NRC believes that the proposed rule, as revised to reflect public comments, represents an integrated regulation that addresses both the matters deemed necessary by the comment, as well as the risk-informed matters involving consideration of debris in long term cooling. In addition, the technical considerations debris in long-term cooling are neither identical to nor inextricably tied to the currently-withdrawn regulation on risk-informed large break LOCA consideration. Therefore, no purpose would be served by dividing this rulemaking into two parts and setting them on separate schedules. No change was made to the final rulemaking as a result of this comment.

Comment: Risk-Informed regulation is not necessarily the same thing as a risk-informed rule. Risk-informed regulation has an expectation that all rules would adhere to a common way of treating issues surrounding the PRA. The direction of the proposed rulemaking adds to the perception that the agency is going down a path of application specific control. In order for a PRA to provide consistently useful information, we need to avoid application specific control of PRA inputs. [NEI1-7]

NRC Response: This comment expresses an opinion but does not provide any actionable suggestion to improve the proposed rule language. No change was made to the rule as a result of this comment.

Comment: Consider use of the term “practical” or “reasonable” versus “practicable”. Current consensus Code and standard language is no longer using this term. [PL1-80, WC1-34]

NRC Response: The NRC disagrees with the comment. The NRC believes that the term, “practicable,” which means that something is capable of being done or put into practice, is the appropriate criterion for use in this regulation. By contrast, “practical” refers to something actually in use or action, which would appear to be too stringent a limitation for this rulemaking. The term, “reasonable,” is implicit in the term, practicable. However, practicable more clearly implies the need for a matter to be capable of actually being accomplished. That voluntary consensus standards bodies may not use the term, “practicable,” does not necessarily mean that it is inappropriate for the NRC, *acting as a regulator*, to employ that term in a regulation if appropriate. No change was made to the rule language as a result of this comment.

Comment: In the Executive Summary - Costs and Benefits: "As a more general matter, adopting a performance-based approach to demonstrating ECCS adequacy may afford applicants ... This may result in reduced ..." The use of the word "may" suggests that the necessary rigor was not applied in performing the cost benefit analysis. [PL1-3]

NRC Response: The NRC disagrees with this comment. As noted in the comment and response to PL1-4, the performance-based rule, including a risk-informed alternative to address the effects of debris on long-term core cooling, will result in greater flexibility for compliance, which will result in reduced costs for compliance. No change was made to the rule as a result of this comment.

Comment: The ACRS erroneous statement in May 23, 2007 letter (ADAMS MLXXXXXXXXX), that the “correlation specified for the rates of steam reaction with the claddng is viewed by the technical community as an anachronism,” is not true. Both the NRC staff and NEI “defends” the Baker-Just correlation for the rates of steam reaction. [RL9-1A]

NRC Response: Out of scope. No response is necessary. No changes to the rule language were made as a result of this comment.

Comment: The ACRS erroneous statement (that the Baker-Just correlation on rates of steam reaction is a “technical anachronism “) was intended by the ACRS to “augment its recommendation to relocate the requirements in Appendix K to a regulatory guide, which would be unenforceable.” [RL9-1B]

NRC Response: The comment addresses the intent of the ACRS, which is an independent advisory committee. Furthermore, the veracity of the comment is not relevant to the technical issues relevant to the proposed rule. Thus, no additional NRC response is necessary to address the substance of the comment.

Comment: The proposed rule will afford greater flexibility for compliance. [PL1-4]

NRC Response: The NRC agrees with this statement.

Comment: Regarding V.B.6 in the FRN, Much of the language, taken from RG 1.174, is not in the rule itself. Consider better defining the relationship of RG 1.174 to the rule, but do not codify the RG. [PL1-10]

NRC Response: The NRC disagrees that RG 1.174 should be explicitly mentioned in the rule, as it is a lower-tier document that provides guidance on approaches acceptable to the NRC for complying with portions of the rule. The Regulatory Guide developed for the alternate risk-informed approach references and depends upon RG 1.174. No change was made to the rule as a result of this comment.

Comment: 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. [PL1-11]

NRC Response: The NRC disagrees that the rule language is more demanding than the discussion in the statement of considerations. However, this aspect of the rule (i.e., paragraph (m)) has been revised to be clearer and the associated discussions in the statement of considerations has similarly been revised to be consistent with the rule.

Comment: The table on p. 16100 of the Federal Register notice of Proposed Rulemaking, at 79 FR 16105 (March 24, 2014) minimizes and trivializes the history of Robert and Mark Leyse's attempts to bring the Commission's attention to the very subjects now admitted to in this rulemaking on Page 16110 thru 16115. [ML1-1, RT1-2]

NRC Response: The NRC disagrees. The NRC prepared the table to concisely present information on the Leyses' concerns brought to the attention of the NRC and the Advisory Committee on Reactor Safety (ACRS) which are directly or tangentially relevant to the topics in this rulemaking. No change was made to the table or the statement of considerations for the final rule as a result of this comment.

Comment: The NRC should require that all licensees and subcontractors be required to be as open to the public, in the same manner as NRC has been to the general public. The Fukushima experience shows that employees and independent contractors of a licensee tend to "translate" data in light favorable to the licensee. [ML1-3]

NRC Response: The NRC interprets the comment as a request that the NRC adopt regulations requiring nuclear power plant applicants and licensees to make information relevant to their NRC license publicly available to the same extent that the NRC is required under applicable law. The NRC considers this comment to be outside the scope of this rulemaking, because the comment's proposal does not address the information collection and reporting provisions for this ECCS rulemaking. No change was made to the regulatory language, statement of considerations, or the applicable regulatory guidance for this rule as a result of this comment.

Comment: The NRC should provide an extension beyond April 23, 2014, for submitting comments on the information collection aspects of the proposed rule, the rule, and draft guidance. [NEI2, IMP1, RT1-1, BEST/MATRR-1]

NRC Response: The NRC agreed that an extension of the comment period was reasonable under the circumstances. Accordingly, the NRC extended the comment period by 120 days to August 21, 2014. 79 FR 22456 (April 22, 2014).

Comment: The NRC should adopt the recommendation in the report, "High Burnup Nuclear Fuel - Pushing the Safety Envelope," by Marvin Resnikoff and Donna Gilmore, January 2014 - http://sanonofresafety.org/2014/01/08/high-burnup-fuel-fact-sheet-2/, that "the NRC should stop use of high burnup fuel and make solving high burnup fuel storage problems of its highest priorities." [RT1-3]

NRC Response: The NRC considers the subjects of the high burnup fuel use and high burnup fuel storage problems to be outside the scope of this rulemaking. The comment did not present any information or rationale why this rulemaking, which focuses on emergency core cooling system design, must also address the use of high-burnup fuel and alleged high burnup fuel storage problems. No change was made to the final rule, the regulatory guidance, or the statement of considerations for the final rule as a result of this comment.

Comment: Fuel failure and cladding issue meetings should be included in NRC notices about Browns Ferry, since fuel failures and cladding corrosions have had a significant effect on Browns Ferry performance [BEST/MATRR1-2]

NRC Response: The NRC interprets this comment as requesting that the NRC publish in the *Federal Register*, notices of meetings on fuel failure and cladding which are held to support this rulemaking, under the caption of the *Browns Ferry* plant. These meeting notices would be in addition to the meeting notices published in the *Federal Register* under the caption of the 10 CFR § 50.46c rulemaking.

The NRC disagrees with this comment. The § 50.46c rulemaking is a separate activity from any licensing actions involving *Browns Ferry* – or indeed, any other nuclear power plant. There is nothing special about the § 50.46c rulemaking that makes it uniquely applicable to, or otherwise directed at, the *Browns Ferry* plant. The comment's assertion that fuel failures and cladding corrosions have had a significant effect on *Browns Ferry* performance (a matter for which the comment provides no supporting documentation), even if true, does not appear to be a basis for publishing a parallel notice for § 50.46c rulemaking meetings under the *Browns Ferry* licensing caption. Furthermore, there are many rulemaking actions which, arguably, have an "effect on" *Browns Ferry* and many other operating nuclear power plants. Adopting the comment's suggestion, if followed consistently by the NRC, would result in hundreds of parallel *Federal Register* notices being published. This would be costly to the NRC, and will not appreciably increase public transparency. Finally, publication of parallel notice as suggested by the comment is inconsistent with the legal purpose of the Federal Register as established by Congress: to provide a single source of Federal agency notices for which publication constitutes legal notice to the public. No change to the rule was made as a result of this comment.

Comment: The NRC should be aware of a report in ADAMS, prepared by author, with respect to loss of coolant accidents, which may be useful to the NRC staff responsible for this rulemaking. The report is *Fuel Behavior under Abnormal Conditions* (R.O. Meyer), NUREG/KM-0004, January 2013, ADAMS Accession No. ML13028A421 [RM2-1]

NRC Response: No response necessary.

Comment: A report, originally prepared for the Columbia Generating Station, describes crud-related problems at that nuclear power plant with respect to the main condenser. [RL3-1]

NRC Response: The comment did not provide a discussion of the relevance of this report to the portion of the proposed rule which would require consideration of crud. No changes were

made to the final rule, statement of considerations or implementing guidance as a result of this comment.

Comment: The NRC is considering relocating the information in 10 CFR Part 50, Appendix K to an NRC regulatory guide. It is pertinent history that: the commenter pursued the underlying documentation ("roots") of the Baker-Just correlation, that those roots were not available in NRC files when it evaluated PRM-50-76 as they had not been transferred to NRC when the agency was created in 1974, the NRC finally acquired and placed those roots in ADAMS during April 2010, at which time the NRC promptly informed Leyse of their availability in ADAMS. [RL5-1]

NRC Response: The comment did not explain why the alleged historical sequence of events, as described in the comment, is relevant to consideration of any element of the proposed rule. No changes were made to the final rule, statement of considerations or implementing guidance as a result of this comment.

Comment: The ACRS has not sufficiently addressed crud issues raised in PRM-50-84, based upon a statement by one member of the ACRS that he "missed" the proposed regulatory requirement in 50.46c for consideration of crud. [RL6-1]

NRC Response: The NRC disagrees with the comment. That one member of the ACRS failed to identify the regulatory provision in the proposed rule does not mean that the ACRS, as a body comprised of 13 members, did not consider and understand how the proposed rule addressed crud and the underlying PRM. No changes were made to the final rule, statement of considerations or implementing guidance as a result of this comment.

Comment: The commenters endorse the comments submitted by NEI [STP1-1, WEC1-1, A1-80, D1-1, STARS1-1, GEH1-1, SNC1-1, PPL1-1, EG1-1 and FPL1-1]

NRC Response: No response necessary.

Comment: An individual, R. Meyer, did not address the impact of crud or runaway [oxidation], the impact of crud on RIAs (which are difficult to model and should be determined empirically by testing), or the need for experiments with multirod assemblies in LOCA investigations. Meyer also does not reference a particular portion of a report, ANL-7609. [RL7-1, RL7-2, RL7-3, RL7-4]

NRC Response: The NRC interprets the comment as referring to NUREG/KM-0004, which is a report authored by Mr. Meyer while he was employed by the NRC. (That report is referenced by Mr. Meyer in his own comment on this rulemaking, RM1-1 above, and is available through ADAMS: ML13028A421).

No specific response to the comment is necessary, inasmuch as NUREG/KM-0004 is not relied upon by the NRC as part of the technical basis for this rulemaking. However, the NRC notes that any lack of consideration of crud effects on ECCS performance in NUREG/KM-0004 is of no relevance to this rulemaking, inasmuch as the proposed rule expressly requires consideration of crud in ECCS analyses. With respect to consideration of crud on RIAs, this is out of scope of this rulemaking. Finally, with respect to the need for multirod assembly testing, the staff addresses this topic in the NRC's response to RL8-1.

No changes were made to the final rule, statement of considerations or implementing guidance as a result of this comment.

Comment: A requirement for monitoring and performance measurement strategies under the risk-informed alternative, as reflected in the fourth bullet on p. 16118 of the Federal Register notice of proposed rulemaking, is not contained in the proposed regulatory language. To be a mandatory requirement, the requirement must be in the rule language. Guidance on implementing the requirement should be in a regulatory guide. [WC1-5]

NRC Response: The NRC agrees that the proposed rule language did not contain requirements for monitoring and performance measurement strategies for the risk-informed alternative. Paragraph 50.46c(e)(1)(v) of the final rule explicitly requires that a monitoring program be established. The final rule has been modified accordingly.

Comment: The title of Sub-Paragraph (1) is not consistent with the content as items (iii) and (iv) are not acceptance criteria [NEI1-77]

NRC Response: The NRC agrees with the comment. The NRC changed the title of (e)(1) from "(1) *Risk-informed approach acceptance criteria.*" To "*Attributes of an acceptable risk-informed approach.*"

Comment: The definition of *significant* in this paragraph (m)(2) of the proposed rule has traditionally applied to ECCS evaluation models, and that additional definition needs to be developed to address the risk-informed coolant debris considerations. [PL1-111, WC1-65]

NRC Response: The NRC agrees that paragraph (m)(2) applies to the ECCS evaluation model, which is defined in the rule. Paragraphs (m)(6) through (m)(8) address changes or errors in the risk-assessment or other aspects of the risk-informed approach, as well as associated reporting requirements. That paragraph states that the acceptance criteria for evaluating changes or errors in the risk assessment are the same as stated in paragraph (e)(1). The RG includes specific details regarding how to assess the acceptance criteria. No change was made to the rule as a result of this comment.

Comment: The rule language appears to be "much more demanding" than discussed in Federal Register Section V., "Proposed Requirements for ECCS Performance during LOCAs," Part B, "Performance-Based Aspects of the Proposed Rule," paragraph 6, " Use of Risk-Informed Approaches to Address Debris for Long-Term Cooling," which states: "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." [WC1-8]

NRC Response: The NRC agrees that the rule language has much more detail regarding corrective action and reporting than the Federal Register section referred to in this comment. The comment was about descriptive text in the Federal Register that talks in general about the performance-based aspects of the proposed rule. The NRC believes that this level of presentation is appropriate for that section of the Federal Register and, therefore, did not revise the explanatory material as a result of this comment. However, NRC has provided additional detail to the section by section portion of the FRN to further explain the corrective action and reporting requirements for the risk-informed approach.

Comment: The SOC description of proposed rule paragraph (e) states that the NRC intends to use review guidance. When will that guidance be available to licensees to better inform their applications? [PL1-37]

NRC Response: The NRC will issue the regulatory guide for the risk-informed alternative at the same time that the final rule is issued. The draft regulatory guide was provided for public comment in advance of the final rule to allow NRC consideration of stakeholder comments.

Comment: 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. [PL1-27]

NRC Response: The NRC disagrees that partial or full blockage of the core are not considered in the current rule, if such could occur. The explicit mention of these phenomena in the new rule is therefore not a new requirement.

Comment: Will the criteria for paragraph (e)(2)(iv), which is to provide a description of, and basis for acceptability of, the evaluations to show compliance with (e)(1)(i) and (ii), be provided in the associated regulatory guide? [PL1-93, WC1-47]

NRC Response: The NRC notes that the subject guidance is contained in the associated regulatory guide.

Comment: In Section V of the Federal Register Notice, under B, “Performance--Based Aspects of the Proposed Rule,” it states that 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. This is not discussed in the proposed rule language. This probably does not belong in the rule and would be more appropriate for the proposed regulatory guide. [PL1-20]

NRC Response: The NRC agrees that updating the FSAR is a level of detail that does not need to be in the rule itself. 10 CFR 50.71 already requires periodic updating of the FSAR to include, in part, all safety analyses and evaluations performed by the applicant or licensee in support of approved license amendments. Therefore, no change to rule language or the referenced text was made as a result of this comment.

Comment: If the debris evaluation model is considered to be part of [in scope of] paragraph (m)(1), then the criteria that is developed should be part of the proposed RG. [PL1-106, WC1-60]

NRC Response: The NRC has removed the term “debris evaluation model” from the rule language, which addresses this comment by rendering it moot. Reporting requirements associated with supporting analyses for the alternate risk-informed approach are covered in paragraphs (m)(6) through (m)(8).

Comment: The NRC understands the comment as questioning: (i) why the NRC should be allowed to exempt themselves from the backfilling criteria in § 50.109 or the issue finality criteria in §§ 52.63, 52.83, and 52.98, as provided for in proposed paragraphs (m)(4)(vi) and (vii); and

(ii) if the NRC is going to adopt conforming changes to §§ 52.63, 52.83, and 52.98. [PL1-115, WC1-69]

NRC Response: The NRC disagrees with the comment. With respect to the need for making conforming changes to §§ 52.63, 52.83, and 52.98, the NRC has decided that such changes are not needed. The proposed rule did not include a conforming change to 10 CFR 50.109 because it was felt that the best place for addressing the lack of applicability of the backfit rule would be within § 50.46c. Therefore, to be consistent with that decision, the NRC decided that no conforming changes to §§ 52.63, 52.83, and 52.98 should be made. The comment did not present any reasons why the NRC's decision would constitute a problem. Therefore, the NRC has decided that the final rule should reflect the same approach as the proposed rule. No change was made to the final rule as a result of this comment.

Comment: The term "assurance" as used in paragraph 50.46c(d)(2)(iv) should read "reasonable assurance." [PL1-78], [WC1-32]

NRC Response: The NRC disagrees with this comment. The words in the proposed rule are taken directly from the existing rule. The commenters did not provide adequate justification for changing the rule language. The NRC has not experienced difficulty with the implementation of the rule language as currently written. Therefore, no change to the proposed language will be made.

Comment: The industry has not identified any additional regulations for which exemption requests are expected to be necessary to support the implementation of the alternate risk-informed approach for addressing the effects of debris on core cooling. [NEI1-30, GEH1-20, WEC1-21]

NRC Response: No response necessary.

M. Cumulative Effects of Regulation

Comment: The industry agrees with the NRC that there will be large costs to revise industry documentation to reflect the proposed restructuring in question. These costs include the complete renumbering of many licensing basis documents. The benefits of the proposed restructuring to be small or non-existent from the standpoint of safety. In light of the lack of perceived safety or other benefits of significance, the industry has not developed a cost estimate. [NEI1-42, WEC1-26, A1-18, PL1-55, PL1-56, PL1-57, GEH1-27]

NRC Response: No responses necessary.

Comment: The proposed rule only includes compliance dates for licensee submittals. There are no schedules for the NRC review activities, and consequently licensees will not be able to plan the downstream work activities. The industry will need NRC agreement to grandfather the existing fuel assembly/bundle designs and cladding materials well into the future to allow the post-submittal activities to be completed. It will not be possible for licensees to make any decisions or plans in this uncertain situation. There are major concerns with both industry and NRC technical resources to support the implementation of the rule. [NEI 1-44] [WEC 1-27]

Response: The NRC agrees with this comment in part. The implementation rule language has been revised; see responses to comments NEI1-106, NEI1-32, WEC1-23, D1-2, D1-4, SNC1-2, and NEI1-35 in Section III.K. above. The NRC does not agree with the comment to grandfather existing fuel assembly designs. Maintaining § 50.46 requirements for legacy fuel and 50.46c requirements for future fuel would lead to confusion and errors. See responses to comments NEI1-36, D1-3, STARS1-2, SNC1-5] in Section III K. above.

Comment: The rule's effective date, compliance date, and submittal dates do not provide sufficient time to implement the new proposed requirements, including changes to programs, procedures, in light of other CER challenges. As illustrated by the owners' group reports on margin assessment and the agency's own evaluation, the high-burnup fuel research findings do not pose a safety concern. [GEH1-30]

Response: The NRC agrees with this comment in part. The implementation rule language has been revised with a requirement for licensees to submit an implementation plan within 180 days. Schedule requirements have been established within the rule for (1) submitting a license amendment request documenting compliance and (2) complying with the rule. See responses to comments NEI1-106, NEI1-32, WEC1-23, D1-2, D1-4, SNC1-2, and NEI1-35.

Comment: Another major issue is the NRC's intent to adopt a limit on cladding temperatures related to long-term cooling prior to preparing a regulatory guide that captures the research and proposes a methodology that is acceptable to the NRC. This is contrary to the NRC approach on cladding embrittlement and breakaway oxidation that was accompanied by regulatory guides. [NEI 1-45]

Response: The NRC agrees with this comment. See the response to comment D1-5. The rule will be modified to remove the proposed cladding ductility performance metric and PCT analytical limit. In its place, the rule will establish a LTC performance metric requiring no further cladding failure.

Comment: The same situation exists with the alternate risk-informed approach for addressing the effects of debris on long-term cooling - the rule precedes the regulatory guide. [NEI 1-46]

Response: The NRC agrees with this comment in part. The NRC received explicit Commission approval to provide the proposed rule prior to development of the regulatory guide in response to COMSECY-13-0006. The draft regulatory guide, DG-1322, "Alternate Risk-Informed Approach for Addressing the Effects of Debris on Post-Accident Long-Term Core Cooling," was published on April 20, 2015, (RIN 3150-AH42) for 75-day comment period. The rule will be modified to explicitly exclude debris considerations from the implementation schedule. See response to WEC1-13.

Comment: There should be more implementation schedule flexibility. This can be accomplished by allowing licensees to develop their own plan for compliance based on the principles laid out in the regulation. NRC can then evaluate the proposed implementation plans on a case-by-case basis. [GEH1-31]

Response: The implementation rule language has been revised with a requirement for licensees to submit an implementation plan within 180 days. Schedule requirements have been established within the rule for (1) submitting a license amendment request documenting compliance and (2) complying with the rule. See responses to comments NEI1-106, NEI1-32, WEC1-23, D1-2, D1-4, SNC1-2, and NEI1-35.

Comment: One possible unintended consequence of the proposed rule is that vendors and licensees may choose not to pursue advanced cladding and fuel assembly designs due to the associated increased cost of performing LOCA analyses for a range of fuel exposures, due to the cladding embrittlement analytical limits being exposure-dependent. Also, the cost of testing of new cladding materials will increase with the proposed testing requirements, in particular if testing of irradiated materials is required rather than allowing testing of hydrogen-charged materials as a surrogate. [NEI 1-47]

Response: The NRC agrees with this comment in part. During multiple 2015 public workshops, the industry and staff discussed the most effective and efficient means to implement § 50.46c. The industry provided a comprehensive, integrated schedule to illustrate the magnitude of effort and parallel and series work activities. This information informed a revision to the rule language. The revised implementation approach provides flexibility to address any plant-specific issues, such as pursuing advanced cladding. The rule will be modified and Table 1 will be removed and replaced with a requirement for licensees to submit an implementation plan within 180 days. Schedule requirements have been established within the rule for (1) submitting a license amendment request documenting compliance and (2) complying with the rule.

Comment: Another possible unintended consequence is that the NRC review of the industry submittals will expand into technical areas unrelated to the rule (e.g. the fuel fragmentation, relocation, and dispersal issue currently in the discovery phase). Should this occur the progress with reviewing the large volume of submittals will be slow, which will eventually challenge plant operation decisions. [NEI 1-48]

Response: The NRC agrees with this comment in part. During multiple 2015 public workshops, the industry and NRC staff discussed the most effective and efficient means to implement 50.46c. The industry provided a comprehensive, integrated schedule to illustrate the magnitude of effort and parallel and series work activities. The industry and NRC staff agreed on future workshops aimed at establishing implementation guidance and LAR templates. No change was made to the final rule in response to this document. For a similar comment and response, see NRC response to [D-10].

Comment: Another possible unintended consequence relates to the proposal regarding long-term cooling. If an ECCS demonstration is required for some explicitly definable time period, it has the potential to increase the number of systems which fall under the new rule because they may be relied upon, even though they are not formally identified as being safety related ECCS systems. We don't want to create a situation where equipment which is not seismically qualified might need to be credited on a long term basis, and thus fall into a trap that did not previously exist (potential GDC2 issue). [NEI 1-49]

Response: The NRC agrees with this comment. The rule will be modified to remove the proposed cladding ductility performance metric and PCT analytical limit. In its place, the rule will establish a LTC performance metric requiring no further cladding failure. See responses to PL1-40 and PL1-41.

Comment: Another problem with the long-term cooling proposal is from the perspective of what is a design basis accident. Explicitly defining a cooling period which must be demonstrated using reviewed and approved methods and acceptance criteria would invariably lead to an expansion of what constitutes a design basis LOCA. A related issue then presents itself. When

defining a long-term cooling accident, when exactly does the postulated accident/DBA end? [NEI 1-50]

Response: The NRC agrees with this comment. The rule will be modified to remove the proposed cladding ductility performance metric and PCT analytical limit. In its place, the rule will establish a LTC performance metric requiring no further cladding failure. See responses to PL1-40 and PL1-41.

Comment: The breakaway periodic testing requirement does not support the revised rule's goal of providing adequate protection. After the initial testing, process control of fuel manufacturing would sufficiently ensure no early onset of breakaway oxidation….[GEH1-32]

Response: The NRC agrees that it is possible to revise the periodic testing and reporting requirements in a way that adds flexibility, decreases cost and burden of breakaway oxidation testing and still achieves the safety objective. The NRC agrees that the objective of the rule can be achieved with rule language that requires a fuel vendor to submit breakaway oxidation testing program for NRC review and approval. The rule language has been revised in response to this comment. See response to GEH1-42.

Comment: Based on the statement in the regulatory analysis, using the "adequate protection justification" as a basis for not entering the backfit analysis provision per 10 CFR 50.109(a)(4)(ii), industry does not agree that the entire content of the proposed rulemaking meets the backfit requirements. [NEI 1-51 part A]

NRC Response: The NRC disagrees with the comment. No valid argument was provided in the comment explaining why the rulemaking as a whole either: falls within the definition of backfitting in 10 CFR 50.109(a)(1); or constitutes a violation of any applicable issue finality provision in 10 CFR Part 52. No change was made to the regulatory analysis, backfitting and issue finality discussion or the language of the regulation as a result of this comment.

Comment: Industry believes NRC should perform a realistic review of the cost of the proposed rule and consider the inaccuracies identified in the regulatory analysis. The overall perception by the industry is that the NRC's cost estimates for industry activities is substantially below current estimates. This perception has been confirmed by both the industry review and in a recent NEI study comparing actual vs. estimated cost for previous regulatory issues (see Figure 4.1), showing a consistent, significant, under estimation of actual costs. Refer to Chapter 5 of this report for the detailed industry comments. [NEI 1-51 part B]

Response: The NRC agrees with the general principle which apparently underlies the comment, *viz*., that the NRC must perform regulatory analyses and backfitting analyses which do not deliberately or systematically underestimate the costs of compliance by regulated entities, and which are based upon best available cost data or realistic estimates of costs. The NRC also acknowledges that an industry review and an NEI study showed that an industry-selected set of NRC's regulatory analyses showed significant, under-estimation of actual costs. To ensure that NRC decisionmakers have the best information available to help inform their regulatory decisionmaking, and to enhance public confidence in the NRC's regulatory decisions for this rulemaking, the NRC has held multiple public meetings to discuss the inputs and the bases for estimating costs for this rulemaking and to provide the opportunity for industry to inform these estimates. Changes were made to the regulatory analysis consistent with the discussion above and the industry cost information provided during these meetings.

N. Backfit

Comment: This rulemaking should not rely on the "adequate protection" justification for not preparing a backfit analysis for the § 50.46c rulemaking. The rulemaking requires licensees to provide "extra-adequate" protection. The Backfit Rule, 10 CFR 50.109 provides that if there are more than one way to achieve adequate protection, then consideration of costs to the industry may be considered when selecting among those alternatives ways of providing adequate protection. [NEI1-3]

NRC Response: The NRC agrees that under the Backfit Rule, if there is more than one way to achieve adequate protection, then consideration of costs to the industry may be considered when selecting among those alternatives ways of providing adequate protection. The NRC utilized this approach when selecting among alternative ways of addressing, for example, breakaway oxidation. This concept also provides part of the rationale for including the voluntary alternative for addressing the effects debris during long term cooling in a risk-informed manner (paragraph (e) of the regulation). Finally, the NRC adopted a different approach in implementing the requirements of the rule, in response to concerns (including cost) raised by current holders of operating licenses. In sum, the requirements in the final rule were selected to ensure that the most cost-effective approach (from the standpoint of both the applicants and licensees subject to the rule's requirements, as well as the NRC) was selected in achieving the reasonable assurance of adequate protection.

The NRC does not agree that there are aspects of the regulation that go beyond what is needed for adequate protection to public health and safety ("extra-adequate" protection). Neither this comment, nor other comments submitted by the commenter, identified particular provisions of the rule which are unnecessary to provide reasonable assurance of adequate protection (and any rationale for such a position).

For these reasons, no change was made to the rule language as a result of this comment, although the final rule was revised to address many substantive comments presented by commenters.

V. NRC RESPONSES TO COMMENTS ON INDIVIDUAL DRAFT GUIDES

Comments on the DGs are grouped according to the DG as follows:

A. DG-1261, "Conducting Periodic Testing for Breakaway Oxidation Behavior"
B. DG-1262, "Testing for Post Quench Ductility"
C. DG-1263, "Establishing Analytical Limits for Zirconium-Based Alloy Cladding"

A. DG-1261, "Conducting Periodic Testing for Breakaway Oxidation Behavior"

a. Periodic Testing Requirements

Comment: Draft Regulatory Guide-1261 should only describe the testing protocol for breakaway oxidation and should not use the phrase "analytical limit" relative to the periodic testing described in the guide. DG-1263 should establish the analytical time limit based on the results of the testing**.** [A1-20]

NRC Response: NRC agrees with this comment. The NRC agrees that RG 1.222 should only refer to testing protocol and that RG 1.224 should discuss how to establish an analytical limit. Because RG 1.222 discusses protocol for periodic testing and because periodic testing is focused on confirmation of the established analytical limit, there are a few instances where RG 1.222 makes reference to the analytical limit. However the final Regulatory Guides have been revised in an effort to reduce confusion for the users of each regulatory guide.

Comment: The draft regulatory guide states, "It is acceptable to measure the onset of breakaway oxidation for each reload batch…" This phrase indicates that the exact timing for breakaway oxidation must continually be determined. The onset of breakaway oxidation is not necessary for the continued demonstration that a previously determined limit for breakaway oxidation is not challenged. [A1-21] The "reporting results of periodic testing" section should be removed or modified to state "a record of the testing should be maintained by the testing organization and available for NRC audit. It is acceptable to report only test results that affect the established analytical limit for breakaway oxidation." [A1-22]

NRC Response: The NRC agrees with this comment. The intention of the requirement for periodic testing of breakaway performance is to confirm that slight composition changes or manufacturing changes have not inadvertently altered the cladding's susceptibility to breakaway oxidation. The staff agrees that this intention can be fulfilled by demonstrating, on a periodic basis, that a cladding does not experience breakaway oxidation in a time period less than the established analytical limit. In fact, RG 1.224 reflects this position, even though it was not clear in RG 1.222. The final Regulatory Guide has been modified to clarify that periodic testing may be performed for the period of time defined by the analytical limit and that it is not necessary to continue testing for longer time periods and until breakaway oxidation is observed for periodic demonstration.

Comment: Initial scoping test results may show that there are no temperatures for which the cladding demonstrated breakaway oxidation before 5000 seconds. There are several places in DG-1261 where only "the temperature at which the minimum time…" is used and it is not clear which temperature should be used for periodic testing in scenarios where breakaway oxidation wasn't demonstrated before 5000 seconds at any temperature. DG-1261 should be modified to resolve this discrepancy. [A1-23]

NRC Response: The NRC agrees with this comment. The NRC agrees that the regulatory guide did not provide sufficient guidance on how to proceed with periodic testing in the case where initial scoping tests results showed that there are no temperatures for which the cladding demonstrated breakaway oxidation before 5000 seconds. The NRC modified RG 1.222 to state that "the temperature at which the minimum time to breakaway oxidation was measured, or at 1000 °C, if all temperatures show no breakaway oxidation by 5000 seconds."

Comment: The vendor quality control and assurance program is capable of achieving the goal of assuring only loading fuel unaffected by breakaway oxidation into reactors. The NRC should reconsider the technical basis and hence the need to conduct periodic testing and associated reporting. [GEH1-49, EPRI1-1] The requirement for periodic testing in the rule could be eliminated and DG-1261 could be used for screening tests for breakaway oxidation. [RM1-8]

NRC Response: The NRC agrees with this comment in part. The NRC does not agree that vendor quality control and assurance programs are adequate to achieve the goal of assuring only loading fuel unaffected by breakaway oxidation into reactors because this approach is not legally binding. However, the NRC agrees that it is possible to revise the periodic testing and reporting requirements in a way that adds flexibility, decreases cost and burden of breakaway oxidation testing and still achieves the safety objective. The rule language, RG 1.222 and RG 1.224 have been modified to remove requirements for reporting periodic testing in annual reports. The final Regulatory Guide will require that a periodic confirmatory test program plan be established. A new section is included in RG 1.222, which provides guidance on how to establish an acceptable frequency for confirmatory measurements.

Comment: The requirement to test for breakaway oxidation performance every reload batch is not consistent with cladding manufacturing process and the NRC position to "confirm that slight composition changes for manufacturing changes have not inadvertently altered the cladding's susceptibility to breakaway oxidation." The requirement should be modified to require that a periodic test program should be devised to demonstrate that the manufacturing process continues to produce cladding that supports the established analytical time limit and this test program should be subject to review and acceptance by the NRC. [A1-19]

NRC Response: The NRC agrees with this comment. The NRC included a question in the proposed rule package to elicit information related to the constraints and considerations important to the frequency of periodic testing. The NRC determined that the proposal for each fuel vendor to develop a test program for review and approval for use by the NRC would be consistent with the intent of the periodic testing requirement. The final Regulatory Guide will require that a periodic confirmatory test program plan be established. A new section is included in RG 1.222 that provides guidance on how to establish an acceptable frequency for confirmatory measurements.

b. Extent of Repeat Testing

Comment: DG-1261 does not provide consistent guidelines for repeat testing. Section A-10, paragraph 3 and Appendix E specify a different number of repeat tests for samples with a bounding or design-basis scratch. The guidance should be consistent. [WEC1-39] Appendix E also does not clearly state the testing required for repeatability and scratch testing in scenarios in which no minimum time-temperature is determined. This scenario should be identified with its own matrix of tests with the temperature for each test in the matrix identified. [A1-34]

NRC Response: The NRC agrees with this comment. The NRC agrees that the guidance must be consistent throughout the document to avoid misunderstanding or misuse. Appendix E and Section A-10 have been modified to be consistent and an additional matrix of tests has been presented to clarify the testing required for repeatability and scratch testing in scenarios in which no minimum time-temperature is determined.

Comment: DG-1261 requires 5 repeat tests for test conditions under which breakaway oxidation does not occur. This introduces undue burden and is not consistent with the extent of testing presented in NUREG/CR-6967 which showed that no more than 2 repeats were conducted at any given test condition. Only 2 repeat tests should be required. [GEH1-50]

NRC Response: The NRC agrees with this comment. The NRC agrees that 2 additional tests, after the minimum breakaway oxidation temperature is determined, will be sufficient to ensure that any stochastic variability in breakaway performance will be identified. The NRC revised RG 1.222 to indicate that if 2 additional tests (3 totals) are conducted at the same test conditions and both show breakaway oxidation does not occur, no further testing is necessary at that temperature.

c. Temperature Measurement, Calibration and Control

Comment: The requirements in DG-1261 to attach calibration certificates to data reports is redundant to routine activities undertaken under fuel vendor's quality assurance programs and should be removed. [GEH1-48]

NRC Response: The NRC disagrees with the comment. The vendor quality assurance programs vary and temperature measurement, and thus thermocouple calibration, is essential to the data quality of breakaway oxidation testing. Providing the calibration certificates to data reports enables the NRC to ensure that the temperature measurements are appropriately reliable. No change was made to RG 1.222 in response to this comment.

Comment: The discussion of heating methods is not focused on the proper concern and the description of some heating methods as "not recommended" can easily be interpreted to mean a method is "not allowed." The proper concern is with temperature control. Recommendations for specific heating methods should be removed and section A-5.2 through A-5.5 can be replaced with a single section focusing on adequate temperature control or the ability of a certain heating method to demonstrate breakaway oxidation results similar to published in NUREG/CR-6967. [A1-25]

NRC Response: The NRC agrees with the comment that temperature control is very important, but disagrees with the comment that specific heating methods should be removed and that section A-5.2 through A-5.5 can be replaced with a single section focusing on adequate temperature control. No change was made to RG 1.222 in response to these comments.

Comment: DG-1261, section A-6.2, refers to procedures for relating sample temperatures to holder temperature. Alternate means for establishing sample temperature without measurement of the holder temperature should be permitted. Specifically, if using resistance furnace, the large uniform hot zone permits the inclusion of cladding specimens that are instrumented with a thermocouple next to the test specimen. In this case, each test can be run with an instrumented, non-oxidized cladding specimen to establish specimen temperature and this method of establishing specimen temperature should be permitted [WEC1-34]

NRC Response: The NRC agrees with this comment. The NRC acknowledges that a resistance furnace has a large uniform heating zone and alternate means for establishing sample temperature may be adequate provided a benchmark testing has established the relationship between the sample TC and the monitor TC. The NRC revised RG 1.222 to provide additional discussion of temperature control and monitoring for resistance furnaces.

d. Effect of Heating/Cooling Rate Control

Comment: Section A-8.3 of DG-1261 specifies that the heating time to reach 650°C should be < 100 seconds and Section A-5.1 specifies that the total ramp from 650°C to the target temperature and from the target temperature to 650°C should be <10% of the isothermal time. These specifications should be modified to permit heating rates that are representative of those for a SBLOCA because experience shows that slower heating rates result in longer times to the onset of breakaway oxidation. [WEC1-38]

NRC Response: The NRC agrees in part with the comment. The NRC agrees that it is reasonable to run the breakaway oxidation tests at heating rates that are representative of those for a SBLOCA. However, ANL's tests on E110 alloys showed early breakaway oxidation when slower heating rates were used. The purpose of establishing test procedures for breakaway oxidation testing is to provide a means of performing repeatable and consistent measurements for the onset of breakaway oxidation. The NRC has revised RG 1.222 to recommend heating rates ≥5°C/s for breakaway oxidation tests and include discussion on the effect of slow heating rates on breakaway oxidation times.

Comment: It is not clear that the rate of cool down and the requirement to maintain steam flow until the sample temperature reaches 800 °C in DG-1261 are technically justified. The cool down prescription should be removed and methods such as direct quench should not be precluded. [A1-30]

NRC Response: The NRC agrees with the comment that the cool down prescription can be removed and methods such as direct quench can be allowed. The final Regulatory Guide was modified to reflect this change. However, it has been shown that cooling rate and quench temperature are associated directly with the PQD. Recent tests at ORNL confirmed that the ductility of directly quenched specimen at target temperature is lower than a slow cooled (to RT) specimen or a specimen quenched from 800 °C. The final version of RG 1.222 includes this discussion.

e. Weight Gain Benchmark

Comment: DG-1261, section A-6.3, states that Zircaloy-2, Zircaloy-4 and ZIRLO cladding oxidized at 1000 °C for ≤2000 seconds should be in good agreement with the Cathcart-Pawel (CP) correlation predictions. Multiple studies have shown that weight gain measurements of these claddings exceed CP predictions by more than 10% at 1000 °C. The regulatory guide should be changed to allow for sample weight gains to be compared to well-established vendor generated data for all alloys. [WEC1-35, GEH1-51, EPRI1-2]

NRC Response: The NRC agrees with this comment. The NRC agrees that demonstrating that weight-gain is in good agreement with well-established vendor generated data for all alloys is adequate for a weight-gain benchmark. The referenced vendor generated data should be from licensing topical reports. The final version of RG 1.222 has been revised to reflect this position.

Comment: The thermocouple calibration and temperature benchmark should be sufficient and the weight gain benchmark could be removed. If, however, a weight-gain benchmark is necessary, the guide should be more flexible in the prescriptions. Only one test temperature should be required. DG-1261 requires benchmarking at two temperatures, 800 °C and 1000 °C, for 2000 seconds. The test temperature and time should also be more flexible to allow for closer benchmark results. The CP correlation will benchmark better at higher temperature and shorter times. [A1-26]

NRC Response: The NRC agrees with this comment in part. The NRC does not agree that the weight gain benchmark can be removed. The NRC does agree that demonstrating that weight-gain is in good agreement with well-established vendor generated data, rather than the CP correlation, for all alloys is adequate for a weight-gain benchmark. Further, the NRC agrees that greater flexibility for benchmark hold time is reasonable; a test time greater than 1000 seconds can be proposed by the vendor. Finally, at this time the NRC will keep the requirement to conduct benchmarking testing at 800 and 1000 °C, with the expectation that the concern for accuracy at these temperatures was addressed by adding flexibility to compare to vendor generated data and reduce the test time. The final version of RG 1.222 has been revised to reflect this position.

f. Effects and Definition of Cladding Surface Scratch

Comment: The definition of a "design-basis" scratch should not include a specific tolerance on the scratch width. Rather, a scratch ≥ 45 µm wide should be sufficient. [WEC1-32]

NRC Response: The NRC agrees with the comment. The NRC agrees that the tolerance of +/- 5 µm specified in the DG was not practical nor was it technically justified. The default definition of a "design-basis" scratch has been removed from the final Regulatory Guide. The approval of a new fuel design will include approval of the dimensions of a "design-basis" scratch and RG 1.222 explains that the "design-basis" scratch can be supported by manufacturing observations etc.

Comment: DG-1261 states that "if it has been shown that scratches and post polishing cleaning have an insignificant effect (i.e., results within data scatter) on the minimum breakaway oxidation time, then as-manufactured cladding may be used for periodic testing." Testing of a bounding scratch on a periodic basis is not reasonable given the low-level effect identified in NUREG/CR-6967 and testing with scratched samples on a periodic basis is overly burdensome. It should be acceptable to use the time impact as determined in the initial scoping tests in conjunction with the results from the periodic testing phase in order to use as-manufactured cladding in the periodic tests. [A1-24]

NRC Response: The NRC agrees with the comment. The NRC agrees that testing as-manufactured cladding is adequate for periodic confirmation that a cladding material has not been inadvertently altered to reduce the time to breakaway oxidation. The final version of RG 1.222 clarifies that periodic testing can be performed at the worst temperature, for only the time of the analytical limit and does not have to be performed on a sample with a "design basis scratch," unless initial testing indicated that a scratch resulted in significant variability in breakaway oxidation behavior.

Comment: DG-1261 does not provide consistent guidelines regarding testing with scratched cladding samples. Section A-10 states that all breakaway oxidation samples should be

conducted with scratched samples while Appendix E implies that testing of scratched samples only occur after defining the temperature and minimum time to breakaway oxidation using non-scratched samples. The guidance should be consistent. [WEC1-41]

NRC Response: NRC agrees with this comment. The NRC agrees that the guidance must be consistent throughout the document to avoid misunderstanding or misuse. Revisions have been made to RG 1.222 to clarify requirements related to tests with scratched cladding samples.

g. Identifying ad Reporting the Onset of Breakaway Oxidation

Comment: The use of a Thermogravimetric Analyzer (TVA) to measure on-line weight gain should be allowed, along with sample sized suited to TVA use, for the purposes of detecting the onset of breakaway oxidation and determining the temperature with the minimum time to reach breakaway oxidation. [WEC1-30, GEH1-53]

NRC Response: The NRC agrees in principle with the comment that the use of a TVA to measure on-line weight gain should be acceptable. However, there is not enough data available to include steam flow, sample size effects, and temperature ramp conditions appropriate to breakaway oxidation study with the TVA. More TVA data for detecting the onset of breakaway oxidation and determining the temperature with the minimum time to reach breakaway oxidation, which is comparable to the breakaway oxidation tests with equipment described in this DG, are required. No change was made to RG 1.222 in response to these comments.

Comment: The maximum test time of 5000 seconds should be modified to be “5000 seconds or the time to exceed the limiting equivalent cladding reacted (ECR) for the ductile-to-brittle transition.” [WEC1-40]

NRC Response: NRC agrees with this comment. The NRC agrees that it is not necessary to demonstrate breakaway oxidation is precluded at conditions that exceed simultaneous requirements limiting ECR. The final version of RG 1.222 provides guidance for establishing a maximum test time that corresponds to the time required to reach the PQD ductile-to-brittle transition ECR at the temperature of a given breakaway oxidation test.

Comment: DG-1261 does not provide consistent guidance regarding the criterion to be used to assess the onset of breakaway oxidation. Section A-10 states that all five tests run at 1000 °C for 5000 seconds must exhibit lustrous black oxide or < 200 weight parts per million (wppm) hydrogen to conclude that the breakaway oxidation time is > 5000 seconds. Section A-9.4 states that the average minus one standard deviation should be compared to the 200 wppm hydrogen pickup to determine if the breakaway oxidation time is > 5000 seconds. The criterion provided in A-9.4 should be used to assess the onset of breakaway oxidation. [WEC1-42]

NRC Response: The NRC agrees with this comment. The NRC agrees that the guidance must be consistent throughout the document to avoid misunderstanding or misuse. The text in section A-10 and A-9.4 have been revised to be consistent and clarify conditions where surface conditions could be used in place of hydrogen content measurements. In addition, the final Regulatory Guide has been updated to remove the requirement to consider standard deviation. The final version of RG 1.222 provides guidance that a total of 3 tests at the same conditions are required and that the hydrogen pickup measurements from each test must show hydrogen pickup less than 200 wppm to preclude further testing. The 200 wppm criterion should be

applied to each sample uniquely; repeat samples cannot be averaged and compared to the 200 wppm criterion.

Comment: Paragraph 8 of Section A-10 describes another approach for establishing the minimum breakaway time where testing at seven temperatures may not be required. It is recommended that additional details of this approach be provided. [WEC1-43]

NRC Response: The NRC agrees with this comment. The NRC agrees that the guidance must be clear and easy to follow to avoid misunderstanding or misuse. Section A-10, as well as the logic diagrams in Appendix E, have been revised to provide additional clarity.

Comment: Paragraph 9 of Section A-10 is unclear. The paragraph indicates that there is larger data scatter within the critical temperature range for breakaway. However, the larger scatter in Figure A-3 than in Figure A-2 may also be due to the larger temperature range of the breakaway tests, the larger number of tests, and a larger variety of samples types. It is recommended that Figures A-2 and A-3 be eliminated along with paragraph 9 as the conclusion regarding temperature sensitivity of breakaway oxidation is not clearly supported by the data. [WEC1-44]

NRC Response: The NRC agrees with the comment. The NRC agrees that the guidance must be clear and easy to follow to avoid misunderstanding or misuse. Figures A-2 and A-3 and the associated discussion have been removed.

h. Definitions and Specifications Related to Hydrogen Content

Comment: Consistency should be maintained throughout the guide regarding the hydrogen criterion to be clear about the distinction between hydrogen pickup and hydrogen content measured following a breakaway oxidation test. [WEC1-33]

NRC Response: The NRC agrees with the comment. Many zirconium-based claddings contain a small amount of hydrogen in the as-fabricated condition and the guidance did not specify how to account for this hydrogen content in the measurement of hydrogen content measured following a breakaway oxidation test in the determination of the hydrogen pickup that occurred during the test. The final version of RG 1.222 clarifies that the hydrogen criterion for breakaway oxidation is 200 wppm hydrogen pickup, where the as-fabricated hydrogen content should be subtracted from the hydrogen content measured following a breakaway oxidation test.

Comment: The DG does not specify if the 200 wppm H pick up is relative to one-sided or two-sided oxidation tests. This should be clarified throughout the guide. [A1-31]

NRC Response: The NRC agrees with this comment. The NRC agrees that the guidance must be specific to avoid misunderstanding or misuse. The final version of RG 1.222 clarifies that the 200 wppm H pickup is an empirical limit based on observations from two-sided oxidation tests and that the 200 wppm H pickup criteria is applicable to both one- and two-sided oxidation tests.

Comment: The application of the standard deviation to the hydrogen pickup results from repeat testing for breakaway oxidation is overly conservative considering there are only five samples. Either the requirement to consider the standard deviation in the comparison should be removed, or the standard deviation should be added to the average hydrogen pick up value and compared to the 200 wppm criterion. [A1-32]

NRC Comment: The NRC agrees with this comment. The NRC agrees that the small sample size and expected variability will result in a large standard deviation and will be overly conservative if subtracted from the average. The final Regulatory Guide has been updated to remove the requirement to consider standard deviation. The final version of RG 1.222 provides guidance that a total of 3 tests at the same conditions are required and that the hydrogen pickup measurements from each test must show hydrogen pickup less than 200 wppm to preclude further testing. The 200 wppm criterion should be applied to each sample uniquely; repeat samples cannot be averaged and compared to the 200 wppm criterion.

Comment: The intention and recommendations contained in section A-9.6 are not clear. It is not clear if the additional testing is required to use either method or what the staff is recommending. This section should be removed or clarified. [A1-33]

NRC Response: The NRC agrees with this comment. This section has been revised to provide two specific recommendations. First, for one-sided oxidation tests, a recommendation has been added to perform hydrogen analysis on a sample sectioned 1 inch from both weld joints to avoid possible end cap weld effects. Second, for two-sided oxidation tests, a recommendation has been added to caution that inner surface oxidation could produce early breakaway oxidation, which would not be expected in reactor, although results based on such tests would be conservative and therefore acceptable.

i. Water Quality

Comment: DG-1261 states "ASTM G2/GM2-06 specifies that Grade A water with ≤45 parts per billion should be used for corrosion tests in pressurized water and steam." The 45 ppb oxygen content is difficult to achieve and not reasonable for this application. The oxygen content requirement should be removed. [A1-28, GEH1-52] Grade A water does not imply low oxygen levels, the low oxygen level is achieved by steaming or venting procedures. It is recommended that water quality be specified as Grade A or Type II with no requirements for steaming to achieve low oxygen levels. [WEC1-36]

NRC Response: The NRC agrees with this comment. The NRC did not intend to require the use of water with ≤45 parts per billion oxygen content, but only to state that was the oxygen content requirement associated with the ASTM G2/GM2-06 guidelines. The NRC also intended to make it clear that water quality can influence the time to the onset of breakaway oxidation and therefore that purified water was strongly recommended. Nevertheless, the NRC agrees that the DG can be clearer in the language of requirements and recommendations and in referring to specific industry standards. The NRC revised RG 1.222 to make the discussion of water quality more clear, in particular to specify that Type II and Type I water are both acceptable options for breakaway oxidation testing.

Comment: The fluid quality varies during any LOCA and is most certainly not the quality of pure steam. This measurement of the time to the onset of breakaway oxidation with purified water is rigged to eliminate temperature overshoot and runaway oxidation and is not relevant to the realities of runaway oxidation during a LOCA. [RL10-2]

NRC Response: NRC agrees with the comment that fluid quality varies during a LOCA and is not the quality of pure steam, but disagrees with the comment that controlling steam quality to with the specified range is not relevant. The NRC believes that the testing protocol outlined in

RG 1.222 will provide meaningful insight into the performance of cladding material under long-term exposure to steam conditions and will identify poor performing cladding alloys. No change has been made to the final Regulatory Guide in response to this comment.

j. Steam Flow Requirements

Comment: DG-1261 states "The average steam flow rate should be in the range of 0.5 to 30 mg/square centimeter per second" and states that "it is not clear why higher steam flow rates would have an effect on weight gain and oxidation kinetics." There should not be a restriction without a technical justification. The upper limit on steam flow rate should be removed. [A1-29]

NRC Response: The NRC agrees with this comment. The NRC believes that the upper limit on steam flow rate should not be removed, because of the uncertainties when the steam flow rate is higher than 30 mg/square centimeter per second. This was clarified in the final Regulatory Guide.

Comment: The provisions in the regulatory guide should be made to include steam flow and temperature ramp conditions appropriate to oxidation equipment using TVA instruments. [GEH1-54]

NRC Response: The NRC agrees with the comment that TVA could be used for oxidation study. However, the NRC is not aware of the appropriate data to include steam flow and temperature ramp conditions appropriate to breakaway oxidation study with the TVA. At this time, no change was made to RG 1.222 to address the use of TVA instruments.

Comment: Requiring the samples to be heated to 300 °C in a stable steam flow is incompatible with use of a resistance furnace. The protocol for purging the steam chamber and stabilizing steam flow should permit heating samples from room temperature or an intermediate temperature (e.g., <400°C) to the target oxidation temperature following stabilization of the steam flow. [WEC1-37]

NRC Response: The NRC agrees with this comment in principle. The NRC agrees that it is reasonable not to restrict the test temperature to exactly 300 °C. However, the NRC is also aware that new alloys could have phase transition temperatures that are relatively low and the phase transition temperature should be avoided during this experimental step. The final version of RG 1.222 allows for samples to be heated in a stable steam flow with 100 °C<T<300 °C, but also points out that phase transition temperatures should be avoided.

Comment: DG-1261 states that the average steamflow rate should be in the range of 0.5 to 30 mg/square centimeter per second. This specification is an absurdity. The average steamflow rate of 0.03 to 1.7 feet per second most certainly does not include the range of steam and steam-water fluid conditions during the wide range of LOCAs**.** [RL10-3]

NRC Response: NRC agrees with the comment that the average steam flow rate specified in RG 1.222 does not include the entire range of steam and steam-water fluid conditions during a wide range of LOCAs, but disagrees with the comment that this specification is an absurdity. The NRC believes that the testing protocol outlined in RG 1.222 will provide meaningful insight into the performance of cladding material under long-term exposure to steam conditions and will identify poor performing cladding alloys. No change has been made to RG 1.222 in response to this comment.

Comment: DG-1261 states that breakaway oxidation tests should be conducted at a steam pressure at or slightly above atmospheric pressure. LOCAs would not occur at only slightly above atmospheric pressure**.** [RL10-4]

NRC Response: NRC agrees with the comment that LOCAs would not occur only slightly above atmospheric pressure,. However, the NRC also believes that the testing protocol outlined in RG 1.222 will provide meaningful insight into the performance of cladding material under long-term exposure to steam conditions and will identify poor performing cladding alloys. No change has been made to RG 1.222 in response to this comment.

k. Table 1 of DG-1261

Comment: The temperatures identified in Table 1 of DG-1261 are not the same as those measured by various laboratories and it is recommended that Table 1 not be included in the Regulatory Guide. [WEC1-31]

NRC Response: The NRC agrees with the comment. Table 1 was developed with the intention of making default critical temperatures for breakaway oxidation available for use for materials already tested in the NRC's LOCA research program and thus eliminate the need for additional vendor testing on these particular alloys. Based on comments from multiple vendors, there is a clear preference for each vendor to provide the critical temperature for breakaway oxidation for their alloys based on their own testing and therefore there is no need to identify default values. Table 1 has been removed from RG 1.222.

Comment: DG-1261 A-4.2 states that the minimum sample length should be 25 mm but justification for the numeric value is not given. The minimum sample length should be set at 8mm since the majority of researchers since 1999 investigating high temperature steam oxidation of Zr-alloys use cladding samples 8-20 mm in length. [GEH1-55]

NRC Response: The NRC agrees with the comment that justification for the numeric value of the minimum sample length is not given. However, the NRC believes that the minimum sample length should be longer than 8mm. End effects were observed by ANL, which show early breakaway near the cladding end for two-sided oxidation tests. Therefore, without data to demonstrate the shorter samples would not experience confounding end effects, it is recommended to keep the minimum sample length to be at least 25 mm at this time. No change was made to RG 1.222 in response to this comment.

l. General Comments

Comment: M5® is a registered trademark of AREVA and should always be represented as M5®. [A1-35]

NRC Response: NRC agrees with this comment. The final guide has been revised to use M5® and include a footnote at the end of the main document as "M5® is a registered trademark of AREVA NP."

Comment: A demonstration of the testing technique to produce breakaway oxidation is perhaps more important than benchmarks and would allow for some requirements and restrictions to be removed. The vendor's testing device could be qualified by demonstrating that

a single test, using the vendor's testing protocol, on a material tested previously showed results comparable to the published time. [A1-27]

NRC Response: The NRC agrees with the comment in principle that a demonstration of the testing technique to produce breakaway oxidation is important. However, the NRC believes that a thermal benchmark test is also necessary. The NRC needs to ensure that the test temperature is properly controlled, measured, and recorded; which is usually demonstrated by a thermal benchmark test. At this time, it is not clear that a single test using the vendor's testing protocol, on a material tested previously, showing results comparable to the published time could be sufficient. If more details were provided on how such a demonstration of testing technique would be conducted and reported, this approach could be reasonable. However, at this time, no change was made to RG 1.222 in response to this comment.

Comment: Acceptable test programs for breakaway oxidation at vendor facilities still need to be created and reviewed by the NRC. It is requested that updated drafts of DG-1261 be made available as soon as reasonably possible in order to develop an acceptable test programs. [A1-16]

NRC Response: The NRC interprets this comment to imply that the commenter differentiates between acceptable vendor test programs and the test program described in DG-1261. If this is the case, the NRC disagrees with the comment that additional test programs need to be developed by vendors to be reviewed and accepted by the NRC. The intention of DG-1261 was to outline an acceptable test program that, if followed, required no additional development effort on the part of the vendors or licensee.

Comment: Draft Regulatory Guide is an absurdity [RL10-1]

NRC Response: No response necessary. No change was made to RG 1.222 in response to this comment.

B. DG-1262, "Testing for Post Quench Ductility"

a. Thermocouples, Temperature Control and Heating Method

Comment: DG-1262 states "type S thermocouples (TCs) should be used to record temperature and control furnace power." This recommendation is overly restrictive. Other types of temperature measurements, such as Type R TCs and pyrometers, are adequate but are ignored. Experience with EDGAR (thermal-mechanical tests) and CINOG tests (high temperature oxidation tests) have shown acceptable results with pyrometers for temperature control. The Regulatory Guide should state that Type S TCs are an example of an acceptable means to record temperature and control furnace power, but others can be demonstrated as adequate with the procession of the thermal benchmarking section. [A1-51]

NRC Response: The NRC agrees with the comment that Type R thermocouples should be acceptable to record temperature and control furnace power, but disagrees with the comment that pyrometers are adequate. The final Regulatory Guide has been modified to identify that Type R thermocouples are acceptable to record temperatures and control furnace power. The NRC believes that specimen temperature measurement and recording are critical to a valid experiment. The temperature reading from optical pyrometry for induction heating needs careful calibrations with reliable standards at high temperature, and it is also not clear whether the use of optical pyrometry to measure temperature requires etching of the cladding surface. At this time, the NRC does not have sufficient information to evaluate the uncertainties concerning the temperature measurements and recording of optical pyrometry without surface preparation. Therefore, no change is being made to address the optical pyrometry at this time.

Comment: It is recommended that the use of Type K thermocouples be allowed provided their accuracy in measuring temperature can be demonstrated and local quality assurance procedures are followed. [WEC1-47]

NRC Response: The NRC disagrees with the comment that Type K thermocouples should be allowed. It is well known that Type K thermocouples have much less accuracy than Type S thermocouples at high temperatures. At 1200C, a typical Tolerance Value for Type K TC is ±0.75% (±9C) and the Tolerance Value for Type S TC is ±0.25% (±3C). The final version of RG 1.223 includes this discussion of Type K thermocouples.

Comment: It is requested that attachment of thermocouples to the sample during thermal benchmarking include welding thermocouples or strapping sheathed thermocouples to the outer surface. For resistance furnaces, strapped thermocouples adequately reflect the sample temperature due to the much more uniform temperature than achieved in radiant furnaces [WEC1-48].

NRC Response: The NRC disagrees with this comment, tentatively, due to lack of available data to directly compare welded and strapped thermocouples in thermal benchmarking applications. With additional data, it is possible that these approaches could be acceptable. However, one aspect that will be important to demonstrate is the ability of different thermocouple attachment methods to capture the Zr-water reaction heat, which will be more significant in low steam flow environments such as resistance furnace set ups. At this time, no change has been made to RG 1.223 to allow strapped thermocouples in thermal benchmarking applications without additional data; however, the points above were added to the RG.

Comment: The requirements in DG-1262 to attach calibration certificates to data reports is redundant to routine activities undertaken under fuel vendor's quality assurance programs and should be removed. [GEH1-48]

NRC Response: The NRC disagrees with the comment. The NRC understands that vendor quality assurance programs vary. Regardless, temperature measurement, and thus thermocouple calibration, is essential to the data quality of breakaway oxidation testing. Providing the calibration certificates to data reports enables the NRC to ensure that the temperature measurements are appropriately reliable. No change was made to RG 1.223 in response to this document.

Comment: The discussion of heating methods is not focused on the proper concern and the description of some heating methods as "not recommended" can easily be interpreted to mean a method is "not allowed." The proper concern is with temperature control. Recommendations for specific heating methods should be removed and section 5.2 through 5.5 can be replaced with a single section focusing on adequate temperature control or the ability of a certain heating method to demonstrate results similar to those that are generally accepted. [A1-36]

NRC Response: The NRC agrees with the comment that temperature control is very important, but disagrees with the comment that specific heating methods should be removed and section 5.2 through 5.5 can be replaced with a single section focusing on adequate temperature control. Considering the importance of temperature control in relation to each heating method, the NRC believes that each heating method should be addressed individually. However, the NRC also agrees that "not recommended" can easily be interpreted to mean "not allowed" and therefore RG 1.223 has been revised to clarify that induction heating may be allowed, provided there has been a demonstration of temperature control through benchmarking.

Comment: The regulatory guide should provide criteria for thermal benchmarking that are independent of heating method and address heating methods besides radiant and resistance heating device, such as direct electrical and induction heating. [A1-37]

NRC Response: The NRC agrees with the comment in principle, that providing criteria for thermal benchmarking that are independent of heating method is ideal. However, at this time, the NRC does not have significant experience with direct electrical or induction heating and therefore does not have adequate information to develop technology-independent criteria. Therefore, at this time no change was made to RG 1.223 in response to this comment.

Comment: Section 12.1 specifies the test time from 300 °C to the quench to be reported. The test time should be defined as the time from the initial rapid temperature ramp to the quench, as the initial sample temperature may not be 300 °C. [WEC1-54]

NRC Response: The NRC agrees with this comment in principle. The NRC agrees that it is reasonable not to restrict the test temperature to exactly 300 °C. However, the NRC is also aware that new alloys could have phase transition temperatures that are relatively low and the phase transition temperature should be avoided during this experimental step. The final version of RG 1.223 allows for samples to be heated in a stable steam flow with 100 °C<T<300 °C and defines the test time as the "time from *the initial rapid temperature ramp* to the quench."

b. Weight Gain Benchmark

Comment: Multiple studies have shown that weight gain measurements of Zircaloy-2,Zircaloy-4 and ZIRLO claddings exceed CP predictions by more than 10% at 1000 °C. It is recommended that the weight gain benchmark to CP be eliminated for testing at 1000 °C, although CP is a suitable benchmark at the higher oxidation temperatures of 1100 °C and 1200 °C. [WEC1-49, GEH1-56]

NRC Response: The NRC agrees with this comment. The NRC agrees that the weight gain benchmark at 1000 °C can be eliminated because of the expected variability from CP predictions. The guidance will still require weight gain benchmarks at 1100 °C and 1200 °C. The final version of RG 1.223 has been revised to reflect this position.

Comment: The thermocouple calibration and temperature benchmark should be sufficient and the weight gain benchmark could be removed. If, however, a weight-gain benchmark is necessary, the guide should be more flexible in the prescriptions. Only one test temperature should be required. [A1-38]

NRC Response: The NRC agrees that the weight-gain benchmark could be made more flexible in the prescriptions. The NRC agrees that the weight gain benchmark at 1000 °C can be eliminated because of the expected variability from CP predictions. The NRC removed this requirement from the final version of RG 1.223. The guidance already allowed for demonstrating that weight-gain is in good agreement with well-established vendor generated data, rather than the CP correlation.

Comment: DG-1262 does not describe how to handle samples with oxide spallation when completing the weight gain benchmark. The DG should allow the investigator to disregard weight gain measurements if oxide spalls. [A1-42]

NRC Response: The NRC agrees that RG 1.223 should specify how to handle samples with oxide spallation when completing the weight gain benchmark. However, the NRC does not agree that the guidance should be to disregard the occurrence of oxide spallation as this phenomenon is not expected for a sample subjected to test conditions corresponding to 10% CP-ECR. The occurrence of oxide spallation should prompt additional testing to identify the root cause of the issue. The final Regulatory Guide has been revised to reflect this position.

Comment: Section 9.3 states that “post test hydrogen values should be corrected for weight gain so that the reference weight for hydrogen content is the pre-test weight.” It is recommended that details for performing the correction be clearly stated. [WEC1-53]

NRC Response: The NRC agrees with the comment that details for performing the correction for weight gain for calculating post test hydrogen values should be provided in the guidance. The final version of RG 1.223 includes this procedure in Section A-9.3.

c. Water Quality

Comment: DG-1262 states “ASTM G2/GM2-06 specifies that Grade A water with ≤45 parts per billion should be used for corrosion tests in pressurized water and steam.” The 45 ppb oxygen content is difficult to achieve and not reasonable for this application. The oxygen content requirement should be removed. [A1-39] Grade A water does not imply low oxygen levels, the low oxygen level is achieved by steaming or venting procedures. It is recommended that water

quality be specified as Grade A or Type II with no requirements for steaming to achieve low oxygen levels. [WEC1-50]

NRC Response: The NRC agrees with this comment. The NRC did not intend to require the use of water with ≤45 parts per billion oxygen content, but only state that was the oxygen content requirement associated with the ASTM G2/GM2-06 guidelines. The NRC also intended to make it clear that water quality can influence corrosion and therefore that purified water was strongly recommended. Nevertheless, the NRC agrees that the language of "requirements" and recommendations in the Regulatory Guide should be clarified. The The NRC revised RG 1.223to make the discussion of water quality more clear, in particular to specify that Type II and Type I water are both acceptable options for testing.

d. Steam Flow Requirements

Comment: DG-1262 states "The average steam flow rate should be in the range of 0.5 to 30 mg/square centimeter per second" and states that "it is not clear why higher steam flow rates would have an effect on weight gain and oxidation kinetics." There should not be a restriction without a technical justification. The upper limit on steam flow rate should be removed. [A1-40]

NRC Response: The NRC agrees with the comment that technical justification should be provided. The conclusions of the studies of Aomi, et al., and Kawasaki regarding steam flow rate effects had already been included in DG-1262, but RG 1.223 now clarifies the basis for the resulting steam flow restrictions.

Comment: Requiring the samples to be heated to 300 °C in a stable steam flow is incompatible with use of a resistance furnace. The protocol for purging the steam chamber and stabilizing steam flow should permit heating samples from room temperature or an intermediate temperature (e.g., <400 °C) to the target oxidation temperature following stabilization of the steam flow. [WEC1-51] DG-1261 also specifies that stabilization of steam flow and 300 °C sample temperature should occur within 500 seconds. DG-1262 should be revised to allow flexibility on pretest hold temperature or should provide a basis for the stabilization temperature and time specified in the DG. [A1-41]

NRC Response: The NRC agrees with these comments in principle. The NRC agrees that it is reasonable not to restrict the test temperature to exactly 300 °C. However, the NRC also believes that new alloys could have phase transition temperatures that are relatively low and the phase transition temperature should be avoided during this experimental step. The final version of RG 1.223 allows for samples to be heated in a stable steam flow with 100 °C<T<300 °C, but also points out that phase transition temperatures should be avoided.

e. Quench Procedures

Comment: Section 8.4 specifies that steam flow is maintained until the sample temperature reaches 800 °C. This is followed by a flow of water to quench the sample. The protocol needs to include an acceptable temperature range of the sample (e.g., 700 °C-800 °C) prior to immersing the sample in water. [WEC1-52]

NRC Response: The NRC agrees with the comment that the protocol needs to include an acceptable temperature range of the sample prior to immersing the sample in water. However, ductility results will vary with quench temperature and NRC does not have data to justify

significant deviation from 800 °C and still ensure consistency. A temperature range of the sample of 800 °C ± 20 °C is reasonable with the available data. This position is reflected in the final version of RG 1.223

Comment: Direct quench is a method used in the industry for PQD testing and has been shown to be an acceptable approach by investigators in a referenced paper by J.C. Brachet et al. The text in Section 5.1 of DG-1262 prevents the use of direct quench from the oxidation temperature and should be modified to allow for direct quench from the oxidation temperature or partial cooling before quench. [A1-50] The text in Section 8.4 of DG-1262 prevents the use of direct quench from the oxidation temperature and should be modified to allow for direct quench from the oxidation temperature or partial cooling before quench. [A1-53]

NRC Response: The NRC agrees with the comment that the cool down prescription can be modified to allow for direct quench from the oxidation temperature. The final Regulatory Guide was modified to reflect this change. However, it has been shown that cooling rate and quench temperature are associated directly with the PQD. Recent tests at ORNL confirmed that the ductility of directly quenched specimen at target temperature is lower than a slow cooled (to Room Temperature) specimen or a specimen quenched from 800 °C. The final version of RG 1.223 includes this discussion.

f. Requirements Related to Ring Compression Testing

Comment: The recommendations regarding use of thermocouples to control furnace or oven power at 135°C for ring compression tests are overly restrictive. Many types of temperature sensors (such as resistance thermometers) are appropriate, but ignored in the DG. The DG should be modified to require that devices used to control and measure temperature should be calibrated to recognized standards and all instances of “TC” should be changed to “temperature sensor.” [A1-54]

NRC Response: The NRC agrees with the comment that use of resistance thermometers to control furnace or oven power at 135 °C for ring compression tests should be acceptable, if they are calibrated to recognized standards, such as a NIST traceable standard. Instances of “TC” have been changed to “temperature sensor” in the sections related to temperature measurement of the ring-compression test furnace or oven. However, the NRC still believes the vendor needs to specify the devices used to control and measure the test temperature to provide assurance that the temperature is recorded correctly. The final version of RG 1.223 reflects this position.

Comment: The text in Section 11.4 of DG-1262 implies that a diameter measurement is suspect if it is for a sample with a loose crack, but that is not clearly stated. There is also no discussion on how to determine whether a crack is tight or loose. The guidance should provide clarification on what constitutes a tight or loose crack and on the validity of data from samples containing them. [A1-56]

NRC Response: The NRC agrees with this comment. The NRC agrees that the guidance must be clear and easy to follow to avoid misunderstanding or misuse. Guidance to discern whether a crack is tight or loose has been added to section A12.2 of the final regulatory guide.

g. Determining the Ductile-to-Brittle-Threshold

Comment: DG-1262 states "…three tests should be conducted at the intermediate CP-ECR to confirm the embrittlement threshold" and it is not clear how to interpret the outcome if the three tests give different results. Additional guidance should be provided on how to interpret the data if different samples give different results. For clarity, mention interpolation and provide a cross reference to Section 12.2. [A1-45] In section 12.2, the guidance states that the CP-ECR for the ductile-brittle transition may be determined from interpolation between ductile and brittle results, and an example is presented. The example does not include interpolation. Delete the example or replace it with a more detailed example that reports strains and then interpolates. [A1-46] In section 12.2, the guidance discusses extrapolation to define the transition CP-ECR, however the method for the extrapolation is not entirely clear. The method may be interpreted as an extrapolation on mean values; or alternatively, as an extrapolation on minimum values. Specify that the mean value be used. For clarity, add the trend line used for extrapolation in Figure 2. [A1-47]

NRC Response: The NRC agrees with the comment that it is not clear how to interpret the outcome of the three tests if they produce a combination of ductile and brittle results and that the expectations of interpolation and extrapolation should be clearer. The NRC agrees that the approach should be clarified to avoid misunderstanding or misuse. The NRC revised RG 1.223 to include discussion of averaging offset and permanent strain values when there are results in the ductile and brittle range. In addition, the discussion of interpolation has been revised for added clarity. A number of revisions have been made to the discussion of determining the ductile-to-brittle transition from ring compression data as a result of written comments as well as discussion at a public workshop on the regulatory guides (ML15132A743).

Comment: The text in section 12.2 provides a ductility limit of 3.1%, but figure 3 shows a ductility limit of 2%. Delete the "ductility limit" line in Figure 3 or provide other clarification. [A1-48]

NRC Response: The NRC agrees with this comment. The ductility limit in Figure 3 is not consistent with the text in section 12.2. Figure 3 has been updated to reflect the CP-ECR-dependent ductility limit for permanent strain values that is provided in Appendix C.

Comment: There should be a provision for testing cladding in target hydrogen bins where the maximum difference in hydrogen content within a single bin is as large as 60 wppm. The average hydrogen content of the samples analyzed in the same bin should be used to evaluate the ductile-to-brittle transition against the limit. [WEC1-45]. Since the bins may vary from the target, the resulting ductile-to-brittle transition should not be required to be a whole number ECR. [WEC1-46]

NRC Response: The NRC agrees with this comment. The NRC agrees that a provision for testing cladding in target hydrogen bins will produce technically valid results and that this approach provides practical flexibility for creating pre-hydride samples for testing. The final version of RG 1.223 states that samples can be "binned" together for evaluation if the average hydrogen content of the samples is within ±10% or ±30 wppm, whichever is less, of the bin level. Additional discussion on the technical basis for this revision is available in Yong et al., "*Post-Quench Ductility Study of Zircaloy-4 Cladding under LOCA Conditions*", A Letter Report to the NRC (ML15107A376). In addition, the final RG has been updated to state that the resulting ductile-to-brittle transition is not required to be a whole number ECR.

h. General Comments

Comment: The phrases “range relevant” and “anticipated range” regarding hydrogen content in the metal of irradiated cladding are not clearly defined. The relevant or anticipated range may be defined differently for different materials. The phrases, “be in a range relevant to the cladding material” and “cover the anticipated range of hydrogen content in the metal of irradiated cladding material” should be replaced with “extend to the best-estimate hydrogen concentration at maximum burnup.” [A1-43]

NRC Response: NRC agrees with the comment that the phrases “range relevant” and “anticipated range” regarding hydrogen content in the metal of irradiated cladding are not clear. In the final version of RG 1.223, the NRC replaced these terms with the suggested text.

Comment: In several places throughout the guide, phrases such as “standards that are traceable to NIST” and “NIST-traceable standards” are used. Laboratories outside the U.S. may rely on other measurement standards. 10 CFR 50, Appendix B, item XII does not require the use of a particular measurement standards laboratory. The quoted text should be changed to “recognized standards.” [A1-57]

NRC Response: NRC agrees with this comment. The NRC agrees that this flexibility is reasonable considering that many fuel vendors supplying the U.S. market have affiliates internationally that collaborate to test their materials. The final version of RG 1.223 indicates that recognized standards are acceptable.

Comment: M5® is a registered trademark of AREVA and should always be represented as M5®. [A1-58]

NRC Response: NRC agrees with this comment. The final guide has been revised to use M5® and include a footnote at the end of the main document stating “M5® is a registered trademark of AREVA NP.”

Comment: The testing to confirm a post-quench ductility limit curve is presented in Section 10.2 of DG-1262, and the discussion in this section is somewhat contradictory to that presented in DG-1263. DG-1262 and DG-1263 should not present the same material, or if they do, they should not contradict each other. [A1-44]

NRC Response: The NRC agrees with this comment. The NRC agrees that the guidance must be consistent throughout the document to avoid misunderstanding or misuse. Various changes have been made to both RGs to better separate the functions of these two DGs and ensure consistency where topics overlap.

Comment: On page 7, Section 2 of DG-1262 there appears to be a typographical error. The text reads “the beta layer will retain ductility as long as its oxygen content is low (e.g., <0.6 weight parts per million (wppm)),” however page 37 of NUREG/CR-6967 states that “an average oxygen content of ≈ 0.6 wt.% is enough to embrittle the Zry-4 prior beta layer following quench.” Correct the text to read 0.6 wt%, rather than 0.6 wppm, if that is what was meant. [A1-49]

NRC Response: The NRC agrees with this comment, and has revised RG 1.223 to correct this error.

Comment: On page 14, Section 6.3 of DG-1262 there appears to be a typographical error. The text reads "for Zr-lined Zry-2 and alloys of Zr-1 and niobium, the measured weight gain at 1000 °C is considerably lower than the CP-predicted weight gain." Correct the text to read "for Zr-lined Zry-2 and alloys of zirconium with 1% niobium, the measured weight gain at 1000 °C is considerably lower than the CP-predicted weight gain" if that is what was meant. [A1-52]

NRC Response: The NRC agrees with this comment, and has revised RG 1.223 to correct this error.

Comment: On page 20, Section 11.2 of DG-1262 there appears to be a typographical error. The text reads "The crosshead displacement rate for ring-compression samples should be in the range of 0.083 to 0.33 mm/s (0.5 to 2 mm/minute)." The values are not equivalent. The text should be corrected. [A1-55]

NRC Response: The NRC agrees with this comment, and has revised the statement in RG 1.223 to read "The crosshead displacement rate for ring-compression samples should be in the range of 0.0083 to 0.033 mm/s (0.5 to 2 mm/minute)."

Comment: The test procedures should be applicable above 2200 °F if there is sufficient steam flow. [EPRI1-3]

NRC Response: The NRC disagrees with this comment. At this time, there is not adequate information to develop test procedures applicable above 2200 °F. In addition, the proposed rule limits peak cladding temperatures to 2200 °F and therefore testing above 2200 °F is outside the scope of this regulatory guide. No revisions to the RG 1.223 have been made in response to this comment.

C. DG-1263, "Establishing Analytical Limits for Zirconium-Based Alloy Cladding"

a. Determination of Ductile-to-Brittle Transition

Comment: The regulatory guide should be modified to make provisions to determine the ductile-to-brittle transition by (1) the use of curve fitting of the test data to determine ductile-to-brittle transition within each hydrogen bin, (2) determination of the final curve by fitting the ductile-to-brittle transition points from the individual hydrogen bins, or alternatively, (3) performing a fit of the ductile-to-brittle transition as a function of both the hydrogen and ECR using (1) or (2). [WEC1-55, EPRI1-9] Alternatively, provisions for using a scatter plot of pre-test ECR verses post-test hydrogen, in which the transition ECR is determined by defining a line that separates tests showing brittle and ductile behaviors could be provided. [GEH-57, EPRI1-10]

NRC Response: The NRC agrees with these comments to the extent that they argue for including additional provisions to determine the ductile-to-brittle transition from data. The NRC agrees that a provision for testing cladding in target hydrogen bins will produce technically valid results and that this approach provides practical flexibility for creating pre-hydride samples for testing. The final version of RG 1.223, "Testing for Post-Quench Ductility" has been revised to state that it is acceptable to "bin" samples together for evaluation if the average hydrogen content of the samples is within ±10% or ±30 wppm, whichever is less, of the bin level. Additional discussion on the technical basis for this revision is available in Y. Yan et al., "Post-Quench Ductility Study of Zircaloy-4 Cladding under LOCA Conditions" (ML15107A376). The testing reported in this report supports the determination of the final curve by fitting the ductile-

to-brittle transition points from the individual hydrogen bins. However, the limiting testing completed by ORNL does not make it clear that a scatter plot approach or performing a fit of the ductile-to-brittle transition as a function of both the hydrogen and ECR and therefore guidance consistent with these approaches has not been added to the regulatory guide. If more details were provided on how such a demonstration of testing technique would be conducted and reported, this approach could be reasonable.

Comment: A provision should be added that allows for the adoption of the proposed 50.46c ductile-to-brittle transition limits for new alloys by showing similar PQD performance through testing both a new alloy and an existing approved alloy. This will account for the potential impacts of test setups. [WEC1-57] Data demonstrates that the PQD performance of the Optimized ZIRLO™[9] cladding material is comparable to that of the ZIRLO cladding material and therefore requests that the Optimized ZIRLO™ material be included in DG-1263 as one of the materials for which Figure 2 is applicable. [WEC2-1]

NRC Response: The NRC agrees with this comment in part. The NRC does not believe an adequate technical basis exists to write guidance for a provision that allows for the adoption of the proposed 50.46c ductile-to-brittle transition limits for new alloys by showing similar PQD performance through testing both a new alloy and an existing, approved alloy. However, if additional information to support a technical basis for this provision is developed, this approach could be considered for approval as an experimental technique. Such an approach would not require rule making since the proposed rule language states, "Analytical limits on peak cladding temperature and integral time at temperature shall be established that correspond to the measured ductile-to-brittle transition for the zirconium-alloy cladding material based on an NRC-approved experimental technique." The NRC agrees that the approach defined in this comment may be accepted on a case-by-case basis. The NRC has reviewed the information provided in WEC2 and agrees this approach would be acceptable for Optimized ZIRLO™ (see ML15209A314). No change was made to RG 1.224 in response to this comment.

Comment: DG-1263 specifies 3 repeat tests at the ductile-to-brittle transition. It is not clear what the intent of these tests is, given that significant scatter in ductility is expected at the transition point. The use of repeat tests above or below the detected limit to confirm ductile or brittle behavior should be permitted, as opposed to average tests with inherent and expected variability. [WEC1-56] There is no need to specify three tests near each ECR level being tested. If a test is conducted at or above the desired ECR limit level and the sample is ductile by the criteria of DG-1262, there is no need for testing at lower ECRs at that hydrogen level. If repeatability must be demonstrated, it would be better to test at nearby hydrogen concentrations as opposed to differing ECR levels. If the test results are not ductile, by the criteria of DG-1262, then a second sample should be tested at a lower ECR level. The target ECR could be selected as one that is expected to result in a ductile sample. If interpolation or averaging is to be part of the evaluation, it is important to ensure that each test included results in a measurable amount of plastic deformation. Results with no ductility and those with ductility cannot be meaningfully interpolated or averaged. [A1-64] If this proposal is accepted, the Regulatory Positions [A1-78] and Appendix B [A1-79] should be updated accordingly.

NRC Response: The NRC agrees with this comment in part. The NRC agrees that repeat testing at a specific ECR level is not needed when conducting testing to show agreement with the NRC-developed analytical limit provided in the RG 1.224. The guide already reflects this

[9]Optimized ZIRLO is a trademark of Westinghouse Electric Company LLC.

position. The NRC disagrees that repeat testing should be removed when conducting testing to support an analytical limit other than the NRC-developed limit provided in the RG 1.224. Detailed discussion on the data needed to support an analytical limit other than the NRC-developed limit is now contained in RG 1.223. RG 1.223 now includes detailed discussion of of repeat testing, interpolation and averaging has been added to RG 1.223 to reduce the potential for confusion.

Comment: DG-1263 discusses the concept of averaging the result of ring compression tests in order to establish an experimental result. The parameter to averaged be should be specifically identified and how to average ductile and brittle results should be made clear. If the parameter is the permanent strain, then all tests to be averaged need to have resulted in some measurable amount of permanent strain and this needs to be made clear and the examples in Appendix B need to be recast. [A1-73]

NRC Response: The NRC agrees with this comment. The NRC agrees that additional information on the concept of averaging results is needed in the regulatory guide to prevent confusion and misinterpretation. Additional discussion of repeat testing, interpolation and averaging has been added to RG 1.224 to reduce the potential for confusion.

Comment: The term "best-estimate," in reference to the ductile-to-brittle transition for zirconium alloys presented in DG-1263 is not clearly defined. It is implied in the DG that part of the meaning is that there is not retained margin in the curve. [A1-74]

NRC Response: The NRC agrees with this comment. The following definition of "best-estimate," in reference to the ductile-to-brittle transition for zirconium alloys, has been included in RG 1.224: "The curve is a best estimate in that the NRC has confidence that the transition from ductile to brittle lies near, but not below the line."

b. Applicability of Figure 2

Comment: The applicability of Figure 2 should be expanded to include those alloys within the same family of alloys tested at Argonne, where the definition of "family of alloys" is alloys created with the alloying elements included in the ANL test program with reasonable extensions of their concentrations. As such, the family would consist of zirconium alloys make up for Nb<1.5%, Fe<0.3%, Sn<2%, Cr<0.2%, Ni<0.2%, O >900ppm. [A1-60] The boundary of applicability could be defined by the solubility of alloying elements in the beta phase. [EPRI1-6]

NRC Response: The NRC assumes that the comment implies that the applicability of Figure 2 should be expanded without additional testing of the new cladding alloys characterized as in the same "family of alloys" as the alloys tested at ANL. The NRC does not agree with this comment, because the Commission does not agree that an adequate technical basis exists to support this proposal at this time. The ANL program included testing of two batches of Zircaloy-4 material in the same "family" of alloys as defined above that showed embrittlement in the as-received condition at significantly different values. Treatment of these two batches of material as one family would not be appropriate. However, the NRC does agree that new cladding alloys that are very similar to those tested at ANL can be approved using a reduced testing matrix. Regulatory Guide 1.224 has been revised to reflect this position.

Comment: A discussion of what constitutes a "new alloy," for the purposes of applicability of Figure 2, should be added to the RG. A provision should be added to allow a vendor wishing to

qualify an extension to an alloy family to present material and rationale supporting the extension for NRC review and approval. [A1-61]

NRC Response: The NRC disagrees with this comment. This RG is not the appropriate place to define what constitutes a "new alloy." This is something that should be addressed more broadly. However, RG 1.224 has been revised to reflect a significant range of applicability for which Figure 2 can be readily adopted and this may address the underlying concern of this comment.

c. Weight Gain Correlations (Baker-Just, Cathcart-Pawel)

Comment: It is not clear if the entire temperature range was considered when deriving the CP-ECR used for the analytical limits presented in DG-1263. NUREG/CR-6967 states that "for the ANL work, the integral in Equation 7 is converted to an integral with respect to temperature and the integration for the high-temperature oxidation tests (e.g., Figure 10) is usually performed for T ≥ 1000 °C." Please identify if a lower temperature threshold was considered for the derivation of the analytical limits presented in DG-1263, and if so, list it in the draft guidance. [WEC1-63]

NRC Response: The NRC agrees with this comment. As the CP set of correlations was only validated for T ≥ 1000ºC (1273 K), the lower temp threshold should be 1000 °C for this calculation. The final version of RG 1.224 reflects this position.

Comment: It is strange that only Cathcart-Pawel is used in Figure 1; there is no comparison to Baker-Just**.** [RL1-2]

NRC Response: The NRC disagrees with this comment. Figure 1 and Figure 2 in this guide are empirical correlations where the data was evaluated using the CP weight gain equation to determine the ECR. Therefore these figures are only acceptable for evaluation against calculations where CP was used. No change to RG 1.224 was made in response to this comment.

d. Testing of Irradiated Material

Comment: GEH/GNF recommends that testing or pre-hydrided cladding be an acceptable surrogate for irradiated cladding, for Zr-alloys similar in composition to ones tested at ANL, and that testing of irradiated cladding is optional. [GEH1-59] It is recommended that the requirements for testing irradiated material be eliminated for alloys that meet the following conditions: (a) the alloy uses the same zirconium reduction method as the alloys tested at ANL, (b) the alloy uses alloying elements at concentrations that do not exceed the concentrations of the alloys tested at ANL, and (c) the planned irradiation does not exceed the fluence of the tested alloys. Alloys meeting these conditions would have the same levels of original and transmuted elements both from alloying additives and from impurities and therefore any impact on oxygen solubility would be the same as the alloys tested at ANL. [WEC1-58] For alloys where condition (b) cannot be met, the guidance should be to perform testing of irradiated cladding to show similarity in terms of PQD behavior to the pre-hydrided cladding only at one hydrogen level which is at or above two-thirds of the maximum best estimate hydrogen level. This is a level of hydrogen content that is practical to achieve in lead test assembly irradiations. [WEC1-59]

NRC Response: The NRC agrees with GEH1-50 in part and agrees with WEC1-58. The NRC agrees that this approach is reasonable, provides appropriate, technically-justified boundaries

and creates desirable flexibility and ease for introducing improved alloys in the future. Final RG 1.224 reflects that new alloys that (1) use the same reduction method, (2) operate less than or equal to the maximum fluence, (3) include only the alloying elements present in the materials tested and (4) have similar alloying content of each element to the materials tested, may adopt Figure 2 with a reduced level of testing. The NRC does not agree with WEC1-59. The NRC continues to believe for alloys that differ from the existing database by the 4 characteristics identified above, testing of irradiated material is required.

Comment: For irradiated cladding, the requirement to be within 50 wppm of the hydrogen target is too stringent. Further, an examination of expected decrease in fuel rod power capabilities with burnup and the characteristic exponential decrease in allowable ECR limit with burnup reveals that there exists a burnup at which the margin to embrittlement will be minimized, at approximately 75 to 80 percent of the maximum hydrogen concentration. Irradiated testing should occur within 100 ppm of (1) the maximum expected hydrogen content during operation and (2) at 75% of the maximum expected hydrogen content during operation. [A1-65, EPRI1-5] If this proposal is accepted, the Regulatory Positions [A1-78] and Appendix B [A1-79] should be updated accordingly.

NRC Response: The NRC agrees with this comment. The NRC agrees that this approach is reasonable, provides appropriate, technically-justified boundaries and creates desirable flexibility and ease for introducing improved alloys in the future. The final version of RG 1.224 reflects this position.

Comment: The irradiated testing must confirm the desired ECR limit curve. If the curve is not confirmed, the testing should be expanded such that the burnup-embrittlement dependency of the alloy can be determined. [A1-66]

NRC Response: The NRC agrees with this comment. The NRC agrees that additional testing should be completed if the results of irradiated testing are not consistent with the desired ECR limit curve. The NRC updated RG 1.224 to reflect the need for additional testing in this scenario.

Comment: Use of test specimens with hydrogen pre-charge can provide a suitable surrogate for irradiated materials, obviating the need for the hydrogen concentration to be within 50 ppm of irradiated data. [EPRI1-4}

NRC Response: The NRC disagrees with the comment that testing of hydrogen pre-charged samples can provide a suitable surrogate for irradiated material in all cases. However, the NRC has revised RG 1.224 to reflect a significant range of conditions in which new alloys can adopt Figure 2 without testing irradiated material. The final RG has been revised to reflect this position.

e. Readability and Clarity

Comment: The guidance provided on developing a suitable PQD ECR criteria curve for an alloy that differs from those for which Figure 2 has been deemed applicable or for a different peak oxidation temperature is repetitive, a more concise description would contribute to ease of understanding and facilitate both submittals for review and the review itself. [A1-62] In Particular, as-received and prehydrided cladding could be combined under the heading “unirradiated cladding.” [A1-63]

NRC Response: The NRC agrees with this comment. Accordant improvements have been incorporated into RG 1.224.

Comment: The term "integral time at temperature" is a key concept used throughout the guide and a definition should be provided. [A1-67]

NRC Response: The NRC agrees with this comment. The following definition of "integral time at temperature" has been included in RG 1.224: "The process of embrittlement at high temperature is dependent on the diffusion of oxygen into the cladding and as such depends on the cladding temperature and the span of time for which the cladding is exposed to that temperature. A convenient way to establish this influence is through the application of a prediction of the oxide layer increase during the transient. ECR during the transient is calculated with the Cathcart-Pawel correlation a, is used to integrate time-at-temperate in this Regulatory Guide."

Comment: Regulatory Position 3 is not clear and should be clarified. The statement implies that perhaps seven oxidation levels have been studied in (a) for pre-hydrided material not just four. The discussion in (b) appears to be about how the conduct of the irradiated testing is done. However that testing is done in (a) and the expansion or continued development in (b) is not straight forward and confusing. [A1-72]

NRC Response: The NRC agrees with this comment. The Regulatory Position section has been revised to provide a more clear description of the testing protocol, as well as to reflect the revisions made to RG 1.223 that impact RG 1.224.

Comment: In footnote 3 in Section C, there appears to be a few words missing. The commenter believes this sentence should read "For a zirconium alloy with an anticipated, end of life hydrogen content *of 400 ppm*, the range of material conditions…" If this is the intention, add the words "of 400 ppm" after "hydrogen content." [A1-71]

NRC Response: The NRC agrees with this comment. The footnote has been revised accordingly.

Comment: The wording of the ring compression test equation is not clear. The units for Cathcart-Pawel are not specified and it is not clear that it is the correlation developed in Appendix A. [A1-75]

NRC Response: The NRC agrees with this comment. The units for strain and CP-ECR have been added to the RG 1.224 and reference is made to Appendix A.

Comment: The commenter believes that the statement on page 7 that reads "in some instances, a zirconium-alloy cladding material may experience the transition from ductile-to-brittle behavior at a <u>higher level</u> of oxidation than the established database" is incomplete and that the underlined phrase should be "<u>higher or lower level</u>." [A1-76]

NRC Response: The NRC agrees with this comment, and has revised RG 1.224 accordingly.

f. Cladding Inner Surface Oxidation

Comment: The title and text of the section "Accounting for Double-sided Oxidation due to Fuel Cladding Bond Layer" could lead to a misinterpretation between the phenomenon (oxygen

ingress vs. interior oxidation) and the acceptable approaches. There is no inside oxidation during the transient except at a cladding rupture location. The title of this section should be changed to "Accounting for Oxygen Ingress from the Inside of the Cladding" and the text should read "one acceptable approach would be to use twice the oxidation on the exterior of the cladding for un-ruptured locations on the fuel rods with…" [A1-77] It is not clear if applying CP-ECR without the oxidation reaction heat would be an acceptable approach. An acceptable approach for accounting for inner surface oxidation before burst should be described. [WEC1-62]

NRC Response: The NRC agrees with this comment. Regulatory Guide 1.224 has been revised to distinguish between oxygen ingress and interior oxidation. The title of this section has be changed and the text reads "one acceptable approach would be to use twice the oxidation on the exterior of the cladding for un-ruptured locations on the fuel rods with a local exposure beyond 30 GWd/MTU." The RG now states that it's acceptable to apply the CP-ECR oxidation equation, without the reaction heat.

g. Hydrogen Pickup Models and Their Use

Comment: The guidance should be clarified to indicate that it is acceptable to use the best-estimate predicted circumferential average hydrogen content for the individual fuel rod to establish the allowable ECR for the rod. Accounting for uncertainty in the prediction of cladding hydrogen content would be excessively conservative, given the considerable conservatism in the derivation of the "embrittlement Oxidation Limit vs. Pre-transient hydrogen content" curve associated with the assumptions inherent in the testing method. [WEC1-60]
Comment: DG-1263 does not present consistent requirements regarding the hydrogen model. The DG states that the database for building a model should account for radial, circumferential and axial variables, however elsewhere in the DG it is stated that comparison with the analytical CP ECR limit should be performed on the basis of the circumferential average peak axial hydrogen content evaluated from such a model. The typical method for measuring hydrogen uptake is the hot-gas extraction technique, which yields the circumferential average for a given axial height of the fuel rod segment. DG-1263 should provide consistent wording to the effect that models should address circumferentially averaged hydrogen content. [WEC1-61, GEH1-61]
Comment: The requirement that radial and circumferential variability be quantified in the hydrogen pickup model should be removed. It is sufficient to use the axial hydrogen variability for determining the analytical limit for cladding embrittlement based on local hydrogen concentration. [EPRI1-8] The method to determine the circumferential average should be determined by the vendors and would need to be approved by the NRC in the vendor methods report. [A1-68]

Comment: The requirement that the hydrogen pickup model encompass all applicable operating conditions and reactor coolant chemistry should be removed. The suggestion to bound all operating conditions and coolant chemistries is potentially burdensome and perhaps detrimental to efforts to improve coolant chemistry (e.g., crud control). The requirement should be changed to state that the conditions over which the data is obtained should justify the applications of the hydrogen model to the operating conditions and coolant chemistry to which the model is applied. This would allow some provision for small alterations of conditions of application and for reasonable extrapolations. [A1-69]

NRC Response: The NRC agrees with these comments. The final version of RG 1.224 indicates that it is acceptable to:

- Develop a hydrogen pickup model from circumferentially averaged hydrogen content measurements (such as hot-vacuum extraction).
- Use the axial hydrogen variability for determining the analytical limit for cladding embrittlement based on local hydrogen concentration.
- Allow vendors to justify the applications of the hydrogen model to the operating conditions and coolant chemistry to which the model is applied.

Comment: Collecting data and developing models can take a substantial effort. Further, the required approval process can be extensive. In combination, these may impact the timely achievement of compliance, particularly for Category 1 plants. The NRC could provide an additional figure of a bounding PQD limit curve, with CP-ECR verses burnup. The development of an alternative ECR limit curve dependent on burnup would provide a conservative approach that would ease plant compliance to the rule and support the deployment of safer more embrittlement resistance claddings. [A1-70] Alternatively, an ECR verses burnup plot could be provided for each approved cladding alloy**.** [GEH1-58]

NRC Response: The NRC agrees with this comment in part. The NRC agrees that it is possible to support timely implementation of this rule through conservative default models, however the NRC believes this would be best accomplished though default hydrogen pickup models, rather than a bounding PQD limit curve, with CP-ECR verses burnup, or an ECR versus burnup plot could be provided for each approved cladding alloy. However, it is important to point out that the proposal of such figures for use in a methodology to develop an analytical limit is not precluded by the rule language. The NRC revised RG 1.224 to include acceptable fuel rod cladding hydrogen uptake models for the current commercial zirconium alloys.

h. Temperature Range of Interest for Breakaway Oxidation Analytical Limit

Comment: The rule and some instances in DG-1263 include the phrase “temperature at which the zirconium alloy has shown to be susceptible,” however in other instances a temperature of 650°C is given. Modern Zircaloy-4 cladding showed low hydrogen content, i.e. not developing breakaway oxidation, after 7000 seconds of testing at 800°C (ML14175A116). The risk of developing cladding embrittlement due to breakaway oxidation is therefore low at 800°C, and even lower for temperatures below 800°C. The term “temperature at which the zirconium alloy has been shown to be susceptible” should be used consistently throughout DG-1263 and both the time and temperature obtained using DG-1261 should be used to define the analytical limit in DG-1263. For example, the analytical temperature limit could be based on testing for 5000 seconds at different temperatures. [GEH1-60, EPRI1-7]

NRC Response: The NRC agrees with this comment. The NRC indicated in the DG that alternate temperatures could be proposed if adequate supporting data were provided. The NRC agrees that the data presented in the referenced material and two TOPFUEL conference papers (add references) justify establishing the lower temperature value at 800°C rather than 650°C. This position is reflected in RG 1.224.

i. Other

Comment: While the proposed rule seeks to maintain the level of protection contained in the current regulation by requiring that new technical matters be addressed, the level and complexity of testing associated with licensing a new cladding alloy under the proposed rule will have a detrimental effect on the introduction of improved cladding materials that would benefit

public health and safety. Specific recommendations are provided pertaining to draft regulatory guide DG-1263**.** [WEC1-2]

NRC Response: The NRC disagrees with this comment. The NRC has reviewed the specific recommendations provided by the commenter, along with all other comments provided during the public comment period. The NRC has revised the regulatory guides and rule language to address the level and complexity of the testing associated with licensing a new cladding alloy under the proposed rule. With these revisions, the NRC does not believe the rule and regulatory guidance will have a detrimental effect on the introduction of improved cladding materials. No changes have been made to the regulatory guides in response to this comment.

Comment: M5® is a registered trademark of AREVA and should always be represented as M5®. [A1-59]

NRC Response: The NRC agrees with this comment. The final guide has been revised to use M5® and include a footnote at the end of the main document as "M5® is a registered trademark of AREVA NP."

Comment: The definition of the two hydrogen regimes (above and below 400 wppm) as in DG-1263 is unnecessary because test temperatures were reasonable prototypical and higher temperatures could not be reached before hitting the limiting curve. [WEC1-6, RM1-5]

NRC Response: The NRC disagrees with this comment. The analytical limit presented in the RG is based on the data obtained in the NRC's LOCA research program. Since PQD tests above 400 wppm hydrogen were conducted at a peak oxidation temperature below 1204 °C (2200 °F), a separate PCT analytical limit must be defined that is consistent with test temperature. No changes have been made to the regulatory guides in response to this comment.

D. <u>DG-1322, "Risk-Informed Approach for Addressing the Effects of Debris on Post Accident Long-Term Core Cooling"</u>

Comment: The proposed RG will need to define "extended period of time". The currently accepted value for GSI-191 is 30 days. [PL1-70, WC1-24]

NRC Response: The NRC agrees with the comment, which it interprets to mean that a discussion of the mission time for the risk-assessment under 10 CFR 50.46c(e) should be included in the associated Regulatory Guide. DG-1322 included guidance on mission time and this was retained in RG 1.229.

V. NRC RESPONSES TO COMMENTS ON THE DRAFT REGULATORY ANALYSIS

Comment: The U.S. court of appeals for the D.C. Circuit ruled in 1987 that in setting or enforcing the standard of "adequate protection" to the public health and safety set forth in Atomic Energy Act Section 182.a., the NRC "may not consider the economic costs of safety measures." Here the NRC requires licensees to provide "'extra-adequate' protection" such as by ordering plants already satisfying the adequate protection standard to take additional safety measures, under the authority of AEA Section 161, "the Commission may take into account economic costs." Union of Concerned Scientists v. NRC, 824 F.2d 108, 114, 118. Further, the NRC Regulatory Analysis Guidelines, NUREG/BR-0058, Rev. 4 (2004), states (p.7) that "if there is more than one way to achieve compliance or reach a level of adequate protection, and the Commission finds it necessary or appropriate to specify the way, costs may be a factor in that decision." In our view, the proposed rule allows more than one way to achieve compliance and/or reach an appropriate level of adequate protection; therefore, consideration of the cost to the industry to comply with this rule can and should be considered**.** [NEI 1-52]

Response: The NRC does not agree with this comment. The NRC's position is that there is only one way to achieve compliance, and the regulatory analysis is provided for information only. Furthermore, the NUREG/BR-0058 guidance describes a method for exploring the cost effectiveness of various alternatives under consideration if there is more than one way to achieve compliance or reach a level of adequate protection and the Commission finds it necessary or appropriate to specify which method is used. This is not the case in this circumstance. Therefore no changes to the regulatory bases or to the rule language were made.

Comment: As indicated in the reference to the proposed rule, the NRC conducted an audit of the Owners Group reports and supporting General Electric-Hitachi (GEH), AREVA, and Westinghouse engineering calculations. Based on the OG reports and supplemental information collected during the audits, the NRC was able to confirm, for every operating reactor, current safe operation of the units….Continue to monitor, on an annual basis, the continued safe operation of each plant. There is no pressing need to change the process. [NEI1-53] [NEI1-1]

Response: The NRC does not agree with this comment. As approved by the Commission and discussed in the Statements of Consideration for the proposed rule, this is an adequate protection rulemaking. The rule, by requiring applicants and licensees to address new technical matters not currently required to be addressed by the NRC's existing ECCS requirements, provides adequate protection to the health and safety of the public by maintaining that level of protection that the NRC previously thought would be achieved by the former requirements. Nonetheless, the NRC has worked to establish the most cost-efficient means by which to impose the new requirements. Furthermore, no valid argument was provided in the comment explaining why the rulemaking as a whole either: falls within the definition of backfitting in 10 CFR 50.109(a)(1); or constitutes a violation of any applicable issue finality provision in 10 CFR Part 52. No change was made to the regulatory analysis, backfitting and issue finality discussion or the language of the regulation as a result of this comment.

Comment: Several comments asserted that the NRC's cost estimates were substantially low.

- "The no-action alternative requires that the embrittlement issue and the risk-informed approach to evaluating the effects of debris on long-term cooling be resolved on a case-by-case basis (e.g., license amendments, orders). This would require exemption requests and other administrative costs that are shown in the attributes as negative costs." This statement does not take into consideration the increased costs placed on

the license holders to perform the required analysis. As it is the NRC's intent to proceed with the rule without a backfitting analysis per 10 CFR 50.109(a)(4)(ii), industry feels it is important, moving forward, that the NRC have a better concept of the inaccuracies contained within the regulatory analysis. The overall perception by the industry is that the NRC's cost estimates for industry activities was substantially below what we expect. Comments received from one fleet (22 plants) have estimated costs in excess of $1 million/unit… Work with the industry to understand the true cost of implementing new regulations and re-perform the regulatory analysis using improved cost estimating. [NEI 1-54]

- Costs are under-predicted [D1-8] [NEI1-2]
- Although Table 2 of the RA estimates that LOCA evaluation models can be developed and licensed for $300K, the NRC review costs alone are approaching an order of magnitude greater than this. [WEC 1-28]
- Costs of setting up, qualifying and then performing the PQD testing…exceed $1,000,000. [WEC 1-29]
- The manpower estimates provided in the regulatory analysis seem low. [GEH1-33]

Response: The NRC agrees with the general principle which apparently underlies the comment, *viz*., that the NRC must perform regulatory analyses and backfitting analyses which do not deliberately or systematically underestimate the costs of compliance by regulated entities, and which are based upon best available cost data or realistic estimates of costs. The NRC met with industry representatives in public meetings to understand the cost drivers and to collect actual costs and industry estimates associated with implementing rule provisions. Additionally, the NRC reiterated the opportunity to provide input on the cost estimates associated with complying with 10 CFR 50.46c via letters to GEH, WEC, and AREVA. These are found under the following ADAMS accession numbers, respectively: ML15244B351, ML15244B400, and ML15245A008.

Changes were made to the regulatory analysis consistent with the discussion above and the industry cost information provided during these meetings.

Comment: While plants in Track 1 do meet some of the new requirements in the proposed rule, new codes and methods and analyses will be required for compliance. Since the required new vendor methods have not been developed or submitted for approval by the NRC, indicating that the efforts required to meet the new requirements will only require a low level of effort is premature. The cost/benefit of the proposed rule has not been adequately established. For a plant to be in compliance, its Technical Specifications will need to be revised to include the new vendor methods. The number of additions to the proposed rule have made Track 1 compliance rise to a level requiring a medium to high level of effort….Recommend removing the new additions and bring the proposed rule back to its original response to the two petitions. Allow orders, ongoing reviews, and other methods to ensure compliance with the other requirements proposed in this rule. [NEI 1-55]

Response: The NRC agrees with this comment in part. The NRC agrees with the general principle which apparently underlies the comment, *viz*., that the NRC must perform regulatory analyses and backfitting analyses which do not deliberately or systematically underestimate the costs of compliance by regulated entities, and which are based upon best available cost data or realistic estimates of costs. The NRC met with industry representatives in public meetings to understand the cost drivers associated with these industry estimates. Changes were made to

the regulatory analysis consistent with the discussion above and the industry cost information provided during these meetings.

The NRC does not agree with this comment that the new additions should be removed and the proposed rule should revert back to its original response to the two petitions. No changes to the rule language was made in response to this comment.

Comment: The regulatory analysis assumes the indirect industry cost of revised ECCS analysis of record (AOR) is $300,000. This is based on a three year period, 1.5 FTE/year, and a labor rate of $200,000/year. The NRC assumes that 12 AORs will be required for Track 2 plants, which results in a total cost of $3.6 million, as reflected in Table 8, page B-10.
It is not clear if the NRC's estimated cost for new AORs includes both, (1) new AOR for short-term cooling for peak cladding temperature and cladding embrittlement, and (2) new AOR for long-term cooling.

One of the PWR fuel vendors has informed the industry that all of their currently licensed ECCS evaluation models will be replaced by one new ECCS evaluation model, currently being reviewed by the NRC. This new ECCS evaluation model wasn't developed to address the new criteria per 10 CFR 50.46c; for example it does not explicitly address long-term core cooling. None of the currently licensed ECCS evaluation models used by this vendor will be revised to address the criteria proposed in 10 CFR 50.46c. This vendor has cited an NRC desire to reduce the number of licensed ECCS models as partial justification for retirement of the currently licensed ECCS evaluation models once 10 CFR 50.46c becomes effective. For a plant in Track 2, recent cost estimates to obtain a new ECCS analysis of record using this new ECCS evaluation model when approved (short-term cooling only) could be an order of magnitude higher than that assumed by the NRC. One large fleet estimates a cost of $1 million / unit. This discrepancy greatly undermines any usefulness of the total cost estimate for the industry as provided in the Regulatory Analysis….recommend working with fuel vendors and licensees to obtain actual cost data when estimating industry costs to perform new ECCS analyses of record. [NEI1-56]

Response: The NRC agrees with the general principle which apparently underlies the comment, *viz*., that the NRC must perform regulatory analyses and backfitting analyses which do not deliberately or systematically underestimate the costs of compliance by regulated entities, and which are based upon best available cost data or realistic estimates of costs. The NRC collected actual cost data from fuel vendors and licensees and has revised the regulatory analyses to reflect these new inputs.

Comment: The regulatory analysis assumes the indirect industry cost of revised ECCS evaluation models for PQD and oxidation is $300,000/alloy. This is based on a two year period, 0.75 FTE/year/alloy, and a labor rate of $200,000/year. The number of alloys considered for the cost estimation to develop new ECCS models is unclear. The data shown in Table 8 implies 6 alloys, since a yearly cost of $900,000 is presented for new LOCA models (PDQ and breakaway). However, the text related to breakaway oxidation testing states that 9 cladding alloys are considered. Also, it is not clear how many of the estimated 12 new ECCS models (PDQ and breakaway) are anticipated to share a common alloy. …Recommend revising the regulatory analysis so that consistent assumptions are used for cost estimations, and that all assumptions are explicitly stated. [NEI 1-57]

Response: The NRC agrees with the general principle which apparently underlies the comment, *viz*., that the NRC must perform regulatory analyses and backfitting analyses which

do not deliberately or systematically underestimate the costs of compliance by regulated entities, and which are based upon best available cost data or realistic estimates of costs. The NRC sought to understand the cost drivers associated with these industry estimates and has incorporated this information into the regulatory analysis for the final rule.

Comment: The regulatory analysis does not consider other ongoing interactions between the industry and the NRC staff with regards to LOCA accidents. This results in uncertainty in the licensee's exception of requirements to be met for compliance. Recommend additional schedule flexibility for rule compliance should be considered for separate analysis. [D1-9]

Response: The NRC agrees with this comment in part. The implementation rule language has been revised with a requirement for licensees to submit an implementation plan within 180 days. Schedule requirements have been established within the rule for (1) submitting a license amendment request documenting compliance and (2) complying with the rule. See responses to comments NEI1-106, NEI1-32, WEC1-23, D1-2, D1-4, SNC1-2, and NEI1-35.

Comment: Appendix B Tables Industry and NRC Cost Estimates. Since development of these tables used inaccurate information associated with required activities and costs, these tables are incorrect. [NEI 1-58]

Response: The NRC agrees with this comment in part. The NRC agrees with the general principle which apparently underlies the comment, *viz*., that the NRC must perform regulatory analyses and backfitting analyses which do not deliberately or systematically underestimate the costs of compliance by regulated entities, and which are based upon best available cost data or realistic estimates of costs. The NRC disagrees that these table used inaccurate information as these inputs were based on the best available cost data and realistic estimates available at that time. The NRC collected actual cost data from fuel vendors and licensees and has revised the Appendix B Tables containing industry and NRC cost estimates to reflect these new inputs.