

## PRELIMINARY DRAFT

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 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 contain errors 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). **The following matters are currently under consideration and development by the staff:**

- The staff is developing a more robust technical basis and several sensitivity studies to address the issue of LOCA frequency allocation discussed in Section C.2 and draft Appendix C.
- The staff is developing additional guidance on how to treat partial breaks (e.g., five inch equivalent opening on a 31 inch pipe)
- The staff is developing additional guidance on the applicability of the generic NUREG-1829 data for specific sites. This guidance also addresses site-specific LOCA frequency contributors such as water hammer and seismically-induced LOCA. The level of detail required for this guidance is still being finalized.
- The staff is updating the language on screening to clarify that break locations that produce and transport debris may not be screened from the analysis based strictly on assumed low frequency.
- The staff is updating the section on periodic updates (C.7) to highlight that the NUREG-1829 LOCA frequencies were originally published with an "expiration date" of 15 years.

NRC Staff Responses to Public Comments on DG-1322:  
*"RISK-INFORMED APPROACH FOR ADDRESSING THE EFFECTS OF DEBRIS ON  
POST-ACCIDENT LONG-TERM CORE COOLING"*  
*Federal Register 80 FR 21658 (April 20, 2015)*

### I. INTRODUCTION

This document presents the NRC's responses to written public comments received on Draft Guide (DG)-1322, "Risk-Informed Approach for Addressing the Effects of Debris on Post Accident Long-Term Core Cooling" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15023A025), in response to a separate *Federal Register* (FR) entry (80 FR 21658, April 20, 2015).

### II. OVERVIEW OF COMMENTERS AND COMMENTS

The staff received 7 comment submissions and a total of 217 individual comments. Table 1 presents information on the commenters who submitted comments on DG-1322.

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Table 1.

Name	Affiliation	ADAMS Accession No.		Identifier
		Incoming	Annotated	
-	-	ML15189A068	ML15232A220	ANON1
Scott Bauer	STARS Alliance	ML15189A067	ML15232A218	STARS2
Wayne Harrison	STP Nuclear Operating Co.	ML15187A119	ML15232A199	STP2
Robert Meyer	-	ML15189A071	ML15232A206	RtM1
Charles Pierce	Southern Nuclear Operating Company	ML15189A072	ML15232A210	SNC2
Timothy D. Sande	Enercon Services, Inc.	ML15191A324	ML15232A227	ECON1
Jack Stringfellow	PWR Owners Group	ML15188A027	ML15232A202	PWROG2

The first comment by the STARS Alliance was a general endorsement of the comments provided STP Nuclear Operating Company. The NRC response to STP2 comments should be taken as responding to comment STARS2-1 as well, but the STARS2-1 designator is not explicitly referenced in the NRC responses for ease of reading. Similar comments were grouped as appropriate to facilitate providing NRC responses.

Comments were binned into the following categories for convenience:

- a. Comments on the Scope of 10 CFR 50.46c and RG Applicability
- b. Comments on the Risk Assessment
- c. Comments Related to use of NUREG-1829
- d. Comments Related to Acceptance Criteria
- e. Comments Related to Uncertainty
- f. Comments Related to Screening
- g. Comments Related to the Simplified Approach
- h. Comments Related to Containment
- i. Comments Related to In-Vessel Effects
- j. Comments Related to DID and SM
- k. Comments Related to Monitoring and QA
- l. Comments Related to RG Organization
- m. Editorial Comments
- n. Other Comments

a. Comments on the Scope of 10 CFR 50.46c and RG Applicability

**Comment:** DG-1322 relies on a number of specific approaches and acceptance criteria that were developed for the current fleet of pressurized water reactors (PWRs). The draft regulatory guide does not provide guidance when one or more of these approaches are not applicable, as might be the case for a new generation plant. The staff should consider delineating applicability requirements for the identified approaches provided in DG-1322. [PWROG2-10]

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**NRC Response:** The NRC agrees that the detailed guidance is applicable to PWRs, as stated in the second paragraph in the *Purpose* section. Section C of the RG has been changed to provide general guidance on a risk-informed approach that complies with 10 CFR 50.46c, with the PWR-specific details moved into appendices. This approach will allow the NRC to update the guidance for other reactor types as needed by adding additional appendices.

**Comment:** Is the purpose of the rule to also allow for use of the risk-informed approach in other GDCs and rules? If so, should that purpose also be stated in the RG? [STP2-2]

**NRC Response:** The NRC notes that this RG is to provide guidance on the alternate risk-informed approach of 10 CFR 50.46c and does not intend to extend the RG scope beyond that rule. Therefore, the *Purpose* section was not changed as a result of this comment.

**Comment:** The staff should consider moving as much language as possible from the rule language to the regulatory guide. [PWROG2-8]

**NRC Response:** The NRC agrees with this comment and notes that 10 CFR 50.46c is written in a very general manner and the detailed guidance is provided in this RG and other guidance referenced in this RG.

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### b. Comments on the Risk Assessment

Scope – Hazards, Modes and Initiating Events

**Comment:** It would be beneficial to more clearly describe the NRC's expectations regarding the evaluation of initiating events, plant operating modes, and hazard groups that could affect the risk associated with GSI-191. The bulk of the NRC's and industry's resolution efforts (for both deterministic and risk-informed GSI-191 evaluations) has focused on unisolable LOCAs using internal events PRA with the plant in Mode 1 or 2. Essentially all of the guidance in the draft guide focuses on LOCAs. As currently worded, a licensee would have to show, on a plant-specific basis, that initiating events resulting from other hazards (e.g. Seismic) and operating modes would not result in LOCAs requiring recirculation which could be adversely affected by debris. Clarify if this is the intent. It would be beneficial to provide additional discussion regarding how licensees should address the risk associated with debris effects for non-LOCA events that require recirculation. [ECON1-1, ECON1-4, STP2-9]

**NRC Response:** The NRC agrees in part and disagrees in part with the comment. The NRC agrees that the RG should clearly describe which initiating events, plant operating modes, and hazard groups should be included in the risk assessment and has clarified this in the RG. The NRC disagrees that these should be limited to the design basis or licensing basis events or that hazards, plant operating modes, or initiating events should be excluded *a priori*. The RG does not preclude screening of hazards, plant operating modes, or initiating events consistent with the consensus standards, as endorsed by NRC. This has also been clarified in the RG.

**Comment:** Paragraph C.1 states that the PRA required by 10 CFR 50.46c(e) must include all relevant initiators and operating modes for all hazard groups "for which debris could adversely affect core damage frequency (CDF) or large, early release frequency (LERF)." This is somewhat contrary to the draft rulemaking language, which states in Section 10 CFR 50.46c(e)(1)(iv) to use "a PRA that, as a minimum, models severe accident scenarios resulting from internal events occurring at full power operation ... " The expectation for the PRA scope and level of detail is not consistent. [PWROG2-15]

**NRC Response:** The NRC disagrees that the RG is not consistent with the rule. However, as a result of comments received on the proposed rule, the NRC re-wrote 10 CFR 50.46c(e)(1) to more clearly discuss the risk-informed approach. This RG was also clarified to be more explicitly consistent with the improved rule language.

**Comment:** In C.1, "all relevant initiating events" is not limited to LOCAs. For plants with High Head injection capable of lifting relief valves, transients may have to be considered. Some plants place reliance on the containment recirculation sump strainers as an alternative source for supplying core cooling during conditions where there is a loss of refueling canal water level in Mode 6 or loss of secondary to heat sink event. [STP2-10, STP2-12]

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**NRC Response:** The NRC agrees that the initiating events for the risk-informed approach should not be limited to LOCAs; see the response to comments [ECON1-1, ECON1-4, STP2-9].

**Comment:** In C.1, it should be modified to clarify that the only initiating events that need to be considered are those that could generate debris from the effects of a jet from a RCS pipe break. An initiating event should be a design basis event described in the FSAR that will result in generation of debris that can adversely affect long-term cooling [STP2-10, STP2-11, STP2-15] C.1 should state the scope of PRA models required for this analysis in terms of operating modes and hazards required for the risk analysis, such as: "Relevant events are limited to those which result in LOCAs requiring recirculation which could be adversely affected by debris." [SNC2-5]

The guidance in C.1 and C.5 should limit the operating mode of concern to at-power events, consistent with the full power (plus 2%) Appendix K models used to run LBLOCA and SBLOCA analyses. In general, the at-power modes should be bounding as a break at higher pressure is likely to result in a larger zone of influence that generates more debris. Other plant operational modes could be generically excluded. There should be no need to require a low-power or shutdown PRA model. [STARS2-2, STARS2-4, PWROG2-16]

**NRC Response:** (Note that similar comments were received on the proposed 50.46c rule, including comments PL1-15, -33, -36, -46, -58, -86, -89; WC1-12, -40, -43, GEH1-16; and PWROG1-7.)

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. This may be done qualitatively, provided that the licensee can demonstrate that risk contributions from a specific mode or hazard would not alter the results of comparison with the risk acceptance guidelines. The NRC's position is that it is the responsibility of each licensee – not the NRC - to make this argument on a site-specific basis.

**Comment:** Consider rewording paragraph C.14.d.1 as the term HELB has a very specific definition as a Hazard Event which is beyond the scope of DBA mitigation requirements. [STARS2-10, STP2-86]

**NRC Response:** The NRC agrees with the comment and has removed reference to HELB in Section C of the RG. However, as noted in previous responses, the risk assessment is not limited to DBA mitigation requirements. Note that HELB is still mentioned in the Background in Section B of the RG.

Initiating Event Frequency

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**Comment:** In C.14.d.(1): It is not clear what is meant by “HELB locations” as this term is not defined or used in C.6. If HELB is interpreted to apply to feed-line and steam-line breaks, such initiating events are not included in NUREG-1829. Current definitions of HELB would seem to be apply to both LOCA sensitive components as well as feed-water and main steam line components. If feed line and steam line breaks are intended to be included, no criteria are given for initiating event frequency bases. [STP2-81]

**NRC Response:** The NRC agrees with the comment and has removed the reference to “HELB locations.” If non-LOCA initiators screen into the analysis (e.g., they meet the screening criteria in the RG), their frequency should be determined in a manner consistent with the ASME PRA Standard.

**Comment:** The discussion in paragraph C.14 suggests the need to justify the use of "plant-wide" LOCA frequencies to individual locations. The staff indicates it is acceptable to use information from the In-Service Inspection (ISI) program, but provides no specific guidance on how this can be performed. It is expected that any LOCA frequencies developed for specific locations will be conservatively high. [PWROG2-34]

**NRC Response:** The NRC disagrees with the comment, which it interprets to mean that the NRC should provide specific guidance on how information from the ISI program might be used. Risk-Informed ISI programs contain insights about degradation mechanisms that exist at various locations. This information may be useful in apportioning plant-wide LOCA frequencies to specific locations, although the specifics of such an analysis are left up to the licensee. The NRC does not agree that LOCA frequencies for specific locations will necessarily be conservatively high, because an analyst can assign frequencies to individual locations in a manner that preserves the plant-wide frequencies.

**Comment:** Paragraph C.14.e.(2) appears to endorse the STP pilot project hybrid LOCA frequency methodology for allocating frequencies to individual welds. However, for the RoverD approach, the pilot project is using the simplified top-down LOCA frequency methodology. Does the NRC staff consider the top-down methodology to be a reasonable approximation for the simplified approach? If so, the RG should include this option. [ECON1-32]

**NRC Response:** The NRC agrees with the comment, which it interprets as saying that the RG should provide guidance on allocating frequencies to individual welds. The RG was updated to include guidance on both the “top down” and “hybrid” approaches.

**Comment:** Paragraph C.14.d.(2) states that licensees should select frequencies that would not underestimate the mean CDF, LERF,  $\Delta$ CDF, and  $\Delta$ LERF as compared to alternative methods. Is the requirement that licensees must always use the worst case model anytime there is an

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alternative set of models? This does not appear to be consistent with the guidance in RG 1.174, which specifies that conservatisms should generally be avoided. [ECON1-29]

**NRC Response:** The NRC agrees with the comment and supports realistic risk analyses as set forth in RG 1.174. The intent of paragraph C.14.d(2) was that, if an analyst desires to fit a distribution to the quantiles or other statistics provided in NUREG-1829, he or she should choose a distribution that maintains the mean value reported in that NUREG report. The choice of which statistics the analyst should use, e.g., those derived from arithmetic aggregation or geometric aggregation, should be addressed under the uncertainty evaluation. The RG was clarified in both of these areas as a result of this comment.

### Comments on PRA Modeling

**Comment:** C.14 suggests that some new, novel PRA modeling approach would be needed that would account for a series of individual LOCAs, i.e., by modeling specific locations (this is not addressed in paragraph C.15). This is contrary to the typical time-averaged approach in a PRA, and invites concern and comments about completeness and comprehensiveness of a model that considers specific LOCA locations. [PWROG2-36]

**NRC Response:** The NRC agrees in part and disagrees in part with this comment. The NRC agrees that considering LOCA frequencies for individual welds is new, but does not agree that it conflicts with the PRA. The RG was updated to explicitly discuss allocating initiating event frequencies to individual locations.

**Comment:** Paragraphs C.14 and C15 presume that licensees modify existing PRA models to incorporate the results of the risk informed modelling. If  $\Delta$ CDF and  $\Delta$ LERF can be calculated independent of the existing PRA model (e.g., in the simplified approach), then it should not be required to modify the existing model. [STARS2-9, ECON1-34] Changes to the PRA should only be required to the extent that such changes are necessary to achieve a high quality analysis of the delta CDF and LERF. [STP2-91]

**NRC Response:** The NRC agrees with this comment and has clarified the RG.

**Comment:** In C.3, "changes to the PRA " are mentioned. Are these changes to the "baseline" PRA, or changes that are used to determine a delta-CDF (or delta-LERF)? [PWROG2-20]

**NRC Response:** The NRC notes that C.3 was intended to identify changes to the PRA model that may be necessary in order to determine the risk of debris. This is actually a delta risk, as the "base case" analysis is assumed to be a plant that does not have debris. Clarifications were made to the RG to address this and related comments.

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**Comment:** In C.3: The integration of SSC failure modes into the PRA fault model needs to consider whether the SSC is modeled in the PRA. If the SSC is modeled, is the new failure mode comparable to the failure modes already modeled, e.g., would a debris-related failure mode result in a partial versus full SSC failure? Would the effects of a debris-related failure mode be different from the effect currently modeled for the SSC? [PWROG2-21]

**NRC Response:** The NRC disagrees with the comment. The debris risk referred to in 10 CFR 50.46c is compared to a plant without debris. The analyst may have to remove any existing debris-related failure modes from a “baseline” PRA model to allow calculation of this delta risk. Comparison of debris-related failure modes to other failure modes should not be necessary. The guidance on delta risk was clarified in the RG.

**Comment:** In C.3: Most currently modeled SSC failure modes are not (LOCA break) size or location dependent. The effect (impact) of a debris-related failure mode is likely to be both (LOCA break) size and location dependent. How should they be modeled in the fault tree? Does this impact the event tree analysis? [PWROG2-22]

**NRC Response:** The NRC does not agree with this comment, which it interprets as saying the RG should provide guidance on how to model the debris in fault trees or event trees. The RG does not go down to that level of detail. The analyst should refer to the ASME/ANS PRA Standard, as endorsed in RG 1.200, and other extant guidance, when considering how the debris phenomenon should be represented in the PRA.

**Comment:** C.3 states that the failure modes will be “incorporated” into the PRA which is not necessary for a thorough and RG 1.200 compliant analysis to be completed. An alternative is to use the PRA of Record which meets RG 1.200 and related Peer Review and ASME requirements to generate information illuminating the likelihood and frequency of Recirculation following a postulated event with full fidelity as to the scenario circumstances such as number and type of pumps functioning and flow rates and related phenomena. This can be analyzed to determine the impact of all identified phenomena and potential failure modes with failure representing a delta CDF or LERF with and without consideration of mitigative actions. Such effects are consistent with application of the RG 1.174 criteria. [STP2-22]

**NRC Response:** The NRC agrees with the comment, which it understands to say that failure modes may not need to be incorporated into the PRA if some other approach, such as the simplified approach presented in Appendix B of this RG, is used. However, 10 CFR 50.46c requires use of an internal events, at-power PRA as part of the risk assessment. The RG was revised to provide guidance on the use of this PRA in the assessment of the risk of debris, but does not require incorporation of failure modes into that PRA.

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**Comment:** Paragraph C.15 describes an acceptable approach for the licensee to estimate the change in risk that is attributable to the explicit consideration of debris in the PRA model. DG-1322 recommends that licensees follow their existing processes that comport with RG 1.200 and their PRA peer reviews. To ascertain that the change in risk (i.e.,  $\Delta$ CDF,  $\Delta$ LERF) is small, the criteria established in RG 1.174 should be used. These are all common-sense, high-level, generic statements related to making a change to the PRA. The draft regulatory guide is silent on how these changes can be effectively made, and how to treat changes that are new or novel (see comments on paragraph C.14). [PWROG2-37]

**NRC Response:** The NRC does not agree with this comment, which it interprets as saying the RG should provide guidance on how to model the debris in fault trees or event trees. The RG does not go down to that level of detail. The analyst should refer to the ASME/ANS PRA Standard, as endorsed in RG 1.200, and other extant guidance, when considering how the debris phenomenon should be represented in the PRA.

### Integrated Model

**Comment:** Section C.5.b states that the PRA 24 hour mission time may not be applicable if long term effects are expected to occur outside that time frame. It seems that 30 days, which is typically used for deterministic GSI-191 evaluations, would be a reasonable mission time for the risk-informed evaluations also. [ECON1-11]

**NRC Response:** The NRC understands the comment, but notes that justification of the mission time for a risk assessment is covered in the ASME/ANS PRA Standard, as endorsed by RG 1.200. The final RG references RG 1.200 for guidance on an appropriate mission time for the risk assessment. While 30 days may be reasonable to conclude that a safe, stable end state has been achieved for the risk assessment, this or some other value should be justified by the analyst.

**Comment:** In C.3: The integration of SSC failure modes into the PRA fault model needs to consider whether mission success definitions need to be recalculated? What new deterministic calculations might be needed? [PWROG2-23]

**NRC Response:** The NRC does not agree with the comment, which it interprets to mean that the RG should provide a listing or description of any new deterministic calculations that might be necessary to perform the risk assessment. Possible new engineering calculations, whether realistic or conservative, would be identified by the analyst depending upon the overall approach used in the risk assessment. The RG was not changed as a result of this comment.

**Comment:** Section C.20 includes this footnote defining PRA, "In this context, "PRA" also includes any complementary analyses (e.g., debris evaluation model, human reliability analysis) that are used to calculate the increase in risk attributable to debris." This appears to indicate

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agreement with the ability to perform the risk analysis without modifying the PRA model. However this guidance is hidden in the very back, vague in completeness as a lost footnote. This guidance should be front and center in the final regulatory guide and comprehensive allowing the full range of analyses provided that the applicable statement of the ASME Standard and RG 1.200 are not violated. [STP2-8]

**NRC Response:** The NRC agrees with the comment and has revised the RG and the final 10 CFR 50.46c to more clearly describe the risk-informed approach, including the risk assessment. The footnote referred to in the comment has been removed and the sentence made more general; that is, to reference the risk assessment rather than the PRA, which may form only one portion of the risk assessment. Also, the RG now makes it clear that modifications to the PRA may not be required for some approaches to the risk assessment; e.g., the simplified approach.

**Comment:** In C.5, specify the criteria to be used to identify components important to the risk-informed analysis of debris effects. Component contribution to CDF/LERF is specific to the ECCS equipment operational configurations/alignments of the high likelihood configurations used in the risk evaluations. Clarify which integrated model (or models). The integrated submodels in C.4 or the modified PRA model? [SNC2-9, STP2-29]

**NRC Response:** The NRC agrees that paragraph C.5 should be clarified. The intent of C.5.a was for the analyst to determine the operating modes and SSCs to be included in the risk assessment. The phrase “important to the risk-informed analysis” was not intended to mean “important to risk.” This guidance was clarified in the RG, including the concept of “integrated models.”

**Comment:** It is unclear how the examples in C.4.f (e.g., strainer blockage, in-vessel effects, and ex-vessel downstream effects) relate to the requirement that licensees utilize integrated models to evaluate strainer and downstream system performance including effects of safety-related and non-safety related system activation. It would be clearer to provide examples of system actuations (e.g., automatic suction swapover, initiation of containment spray, etc.). [STARS2-3]

**NRC Response:** The NRC disagrees with the comment. The examples provided are for each of the specific areas listed. The integrated model determines success/failure of the strainer and downstream components.

**Comment:** Paragraph C.14 describes the need to integrate the models developed in paragraphs C.5 through C.9 (simple method) or in paragraphs C.5 through C. 13 (excluding paragraph C.9). DG-1322 provides no explicit guidance on how these models should be integrated, or what characteristics are expected in an integrated model. [PWROG2-31]

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**NRC Response:** The NRC agrees with the comment, which it interprets to mean that additional guidance is needed regarding what is meant by an “integrated model.” The RG was enhanced to provide additional clarity.

Quantification

**Comment:** One specific concern with the paragraph C.15f is the requirement for power plant states and configurations that are not explicitly modeled and not screened (as per paragraph C.1), they should be assumed to lead to core damage. This may be a conservative assumption. Further, the CDF and LERF for these unaccounted states and configurations should be quantified. This may ameliorate the conservative concerns, but then necessitates the development a whole new portion of the PRA, whose risk contribution may not justify the development effort. [PWROG2-38]

**NRC Response:** The NRC does not agree with the comment. The guidance in C.15f is consistent with the ASME/ANS PRA Standard, as endorsed by RG 1.200. The analyst always has the option to explicitly model any unaccounted states or configurations that prove problematic to the results.

**Comment:** Current PRA analyses already include in many cases a probability of recirculation failure and the current analyses is actually a refined calculation with all known information of a possibility previously simply estimated. Certainly structural failure and collapse were envisioned as low probability events in the original analysis of some plants. It is an important distinction that the actual risk relative to the prior PRA values may even go down for some plants. [STP2-24]

**NRC Response:** The NRC does not agree that the actual risk may go down. Debris would result in additional or more likely failure modes than those considered in the risk assessment. In any event, for the purpose of meeting 10 CFR 50.46c, the debris risk is compared to a debris-free condition. This point has been clarified in the RG.

**Comment:** Paragraph C.15.g is not clear. The modified PRA model is to be used to estimate mean values of CDF and LERF. On what basis is delta-CDF and delta-LERF to be estimated and used in Figures 4 and 5 of RG 1.174? How can and why should delta-CDF and delta-LERF be estimated if there is an a priori assumption that the debris effects are negligible? [PWROG2-39]

**NRC Response:** The NRC disagrees, as C.15g(1) described how to calculate the delta CDF and delta LERF for this application. This information is retained in the final RG in paragraph C.1. RG 1.174, referenced in this RG, provides adequate guidance on how to use the risk acceptance guidelines.

c. Comments Related to use of NUREG-1829

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**Comment:** Clarify all the requirements in 14.d starting with what is required to confirm NUREG-1829 values are applicable. Clarify whether the listed requirements apply if the NUREG-1829 values are used in the analysis. [SNC2-14, SNC2-15, STP2-70]

**NRC Response:** The NRC agrees with this comment and modified the RG to clarify which actions are applicable to licensees that chose to use the LOCA frequencies from NUREG-1829.

**Comment:** C.14.e.(2) – As far as I know, there is no technical basis for assuming a smaller break in a larger pipe and then determining the appropriate break frequency. This is outside the basis for the frequencies identified in NUREG-1829. The overall effort would be better justified, and less complicated, if only DEGBs were considered. [STP2-75] The RG should specify whether the partial break approach or DEGB only should be used. [ECON1-33]

**NRC Response:** The NRC agrees in part with this comment. The LOCA categories in NUREG-1829 are defined according to the flow rate of makeup water supply, as discussed in Section 3.7. Thermal-hydraulic correlations were used to assign effective break sizes to flow rates. For example, LOCA category 3 corresponds to a 5000 gpm flowrate and (for a PWR) an effective break size of 3 inches. As stated in this section, “the break size corresponds to a partial fracture for pipes with larger diameters than the break size, a complete single-ended rupture in pipes with the same inside diameter, or a DEGB in pipes having inside diameters  $1/\sqrt{2}$  times the break size.”

NUREG-1829 does not define the relative likelihood of these contributors, although it does state that “most panelists expect that the smallest diameter piping system or subcomponent that could support a particular LOCA size or category is the dominant LOCA frequency contributor.” (Section 6.3.1).

A similar statement is provided for non-piping components. The NRC considers any model that is consistent with this guidance to be acceptable for the purposes of implementing the risk-informed alternative of 10 CFR 50.46c. The RG has been updated to more explicitly state this expectation.

**Comment:** In C.14.d.(1): This item presumes that the PRA model initiating events used in the GSI-191 application are aggregated LOCA frequencies as normally assumed in base-line PRAs and given in NUREG-1829. If the PRA model initiating events are defined as LOCAs at specific locations, there is no guidance given in NUREG-1829 how to allocate the LOCA frequencies and their uncertainties to specific components and specific locations. Hence there is interplay between item 6d and 6e in this draft RG. NUREG-1829 acceptability is tied to this modeling approach. [STP2-80]

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**NRC Response:** The NRC agrees with this comment. NUREG-1829 provides plant-wide LOCA frequencies but location-specific frequencies may be appropriate if the impact of a LOCA (in terms of debris generation and transport) varies significantly according to location. Additional guidance was added to the RG to clarify NRC expectations with respect to location-specific LOCA frequency.

**Comment:** In C.14.d.(1): It is not clear how one can confirm that NUREG-1829 values are applicable to a specific plant based on the information available in NUREG-1829. First it is not clear how or whether plant-to-plant variability in LOCA frequencies was considered or accounted for in NUREG-1829. Does the uncertainty presented in the NUREG-1829 LOCA frequencies include both plant-to-plant variability and within plant uncertainty? For example the Base Case analyses that were performed to inform the expert elicitation for PWRs were based on a 3-loop Westinghouse PWR design with a specific configuration. How different designs such as 2-loop and 4-loop Westinghouse PWRs, CE and B&W designs that employ different loop configurations and piping materials, and differences in pipe sizes, damage mechanisms, etc. from plant to plant were accounted for in the reference which would be important to prepare a justification for a specific plant. Given that situation, how one can in principle justify that the NUREG-1829 values are applicable to any specific plant is difficult to envision. The problem is that NUREG-1829 provides no justification that the results are applicable to any specific plant. [STP2-68, STP2-82]

**NRC Response:** The NRC agrees in part with this comment. The NUREG-1829 LOCA frequencies represent generic, or average, estimates for the commercial fleet and are not meant to represent a specific site or design. Furthermore, the uncertainty bounds listed in the NUREG represent the uncertainty of the experts with respect to these *generic* estimates, rather than bounding values associated with one or two plants.

The experts developed these generic estimates using representative assumptions about important variables such as material conditions, plant geometry, degradation mechanisms, loading, and maintenance practices. The experts also assumed normal plant operational cycles and loading histories (e.g., pressure, thermal, residual). Finally, the experts assumed that plant construction and operation comply with all applicable codes and standards required by regulation and technical specifications. A good summary of these assumptions is contained in the executive summary to NUREG-1829, beginning on page xv.

The NRC considers the LOCA frequencies in NUREG-1829 to be acceptable for licensees implementing this RG, provided that the licensee demonstrates that the plant in question is not an outlier for which the results of NUREG-1829 would not apply. To do this, the licensee should provide a qualitative discussion of the previously mentioned variables (i.e., material conditions, plant geometry, etc.) that provides reasonable confidence that no unusual site-specific

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conditions exist (e.g., one-of-a-kind material, unusual plant geometry, etc.). This has been clarified in the RG.

**Comment:** C.14.d.(2): Although NUREG-1829 includes aggregated LOCA frequency results using both the geometric mean and mixture distribution method, in the discussion of these results, NUREG-1829 appears to give more weight to the geometric mean method. As noted in this discussion, a major problem with the mixture distribution method is that the results are too highly skewed to the input from the expert with the most pessimistic results. In addition, the results of using the geometric mean method are more prominently displayed in the executive summary and in the results section of the report. Hence the statement that NUREG-1829 does not advocate any specific aggregation method appears to be somewhat at odds with how this issue is presented in the report. Given this, the statement that the NRC finds the mixture distribution method acceptable and then asks the user of the RG to justify use of geometric mean is questioned. By what basis has the staff shifted its position from NUREG-1829 which at best was neutral on the issue? Is it just because the NUREG-1829 results for the mixture distribution have larger values? [STP2-83]

**NRC Response:** The NRC disagrees with this comment. NUREG-1829 states that, "because alternative aggregation methods can lead to significantly different results, a particular set of LOCA frequency estimates is not generically recommended for all risk-informed applications." This RG notes that the aggregation approach is a key assumption and should be addressed as part of the uncertainty analysis.

**Comment:** C.14.d.(2): The uncertainty quantiles referred to in NUREG-1829 are applicable to the uncertainties in the aggregated LOCA frequencies. What is more important for this application is the uncertainty in the LOCA frequencies at specific locations that may be the most important for debris induced core damage frequency. Uncertainties in location specific LOCA frequencies would be expected to be much greater but these are not available in NUREG-1829. [STP2-84]

**NRC Response:** The NRC agrees with this comment and has revised the section of the RG pertaining to uncertainty. Consideration of uncertainty with respect to location-specific LOCA frequencies should be treated in accordance with the revised guidance in this section. The discussion on location-specific LOCA frequency was also enhanced in response to multiple comments.

**Comment:** Paragraph C.14.d.(2) appears to require the use of an arithmetic mean aggregation. However, the arithmetic mean is grossly skewed by the pessimistic opinion of one of the NUREG-1829 experts. The geometric mean would appear to be a better aggregation method since it more accurately represents the range of expert opinions. [ECON1-30]

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**NRC Response:** The NRC disagrees with this comment for two reasons. First, the RG does not require the use of the arithmetic mean. Rather, the RG notes that the aggregation approach is a key assumption and should be addressed as part of the uncertainty analysis.

Second, the NRC's position is that the results of any expert elicitation process should reflect the state-of-the art uncertainty as expressed by the diversity of expert judgments. Therefore, the NRC disagrees with the notion that a difference in expert opinions – even if significant – is a rationale for rejecting a particular aggregation scheme. On the contrary, this difference of opinion is an important piece of information that should be reflected in the aggregated results. For these reasons, aggregating the opinions of experts via arithmetic mean is an accepted technique that has been used in a variety of regulatory applications, including NUREG-1150.

**Comment:** Paragraph C.14.d.(4) states that statistical distributions should preserve the mean values of the initiating event frequencies from original source documents, such as NUREG-1829. NUREG-1829 presents mean values derived using a geometric mean aggregation in the summary tables, so this requirement appears to conflict with the previous recommend in Paragraph C.14.d.(2). [ECON1-31]

**NRC Response:** See the response to ECON1-30.

### d. Comments Related to Acceptance Criteria

**Comment:** Scenario results and subsequent analysis may have more usefulness for decision-making regarding design alternatives than core damage and large early release. For example, “risk curves” might be more useful for industry and USNRC investigators when evaluating design alternatives and risk of vulnerabilities in adopted designs. That is, it seems we are concerned with the significance of the various problems that may arise in design alternatives rather than these frequencies. [ANON1-2]

**NRC Response:** The NRC agrees with the comment, which it interprets to mean that the risk metrics could be expanded beyond CDF and LERF currently used. This RG is intended to provide means acceptable to the NRC for meeting 10 CFR 50.46c(e) and (m) and uses the current NRC framework for risk-informed regulation of power reactors as set forth in RG 1.174. No change was made to this RG as a result of this comment.

**Comment:** In C.9: for a simplified approach, acceptance criteria for the “tests” should be addressed. That is, direction above what important test constituents should be included would add clarity. [STP2-46]

**NRC Response:** The NRC partially agrees with this comment. The guidance clearly references RG 1.82 for strainer assessment, WCAP-16530 for chemical effects, WCAP-16406 for downstream ex-vessel effects, and WCAP-16793 for in-vessel effects. These documents

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provide guidance for assessment of the major areas associated with debris effects on long-term cooling. These documents and their associated safety evaluations provide references to additional guidance for assessments of debris effects. The intent of the simplified approach is to use existing guidance to evaluate limits beyond which long-term cooling may fail. Generally these limits are expected to be defined in amounts of debris. Because the RG references guidance that is appropriate for evaluating these various phenomena, no changes were made.

**Comment:** In the consideration of in-vessel effects within the context of C.9, guidance should be expanded on what processes are acceptable for inferring applicability of the tests to unanalyzed (or untested) plant states. For example, a test that involves n-1 ECCS trains may be interpreted to address the more likely nominal case of n ECCS trains. Acceptance criteria for both strainer failure criteria and in-vessel criteria would be helpful. Again, this is a case where the guidance in C.9 may differ than other guidance (e.g., C.15 f). Is the guidance in C.12 c applicable if C.9 is followed? [STP2-56]

**NRC Response:** The NRC disagrees with this comment. For the simplified approach the licensee should address all cases by ensuring that the tests performed are applicable to the conditions to which the results are applied. If a case is not covered by testing and cannot be evaluated to be bounded by the test conditions it should be treated as a failure. The licensee should not attempt to use a combination of a simplified and risk-informed methods to evaluate a single break case. If breaks can be shown to result in successful long-term cooling using a simplified approach they are not further evaluated using a risk-informed approach. It is not clear why the comment compares the guidance in section 9 of the draft guide with guidance in other sections. Section 9 is for the simplified approach while the other sections referred to in the comment are for a full risk-informed approach. The RG was revised to separate the detailed and simplified approaches to the systematic risk assessment, but no change was made regarding additional guidance on acceptable testing.

**Comment:** The staff should be more specific on their acceptance criteria for correlations that support the model, or specify limitations on assumptions for phenomena such as failure of coatings and transport time. Additional specificity is needed with respect to testing requirements to support models and correlations. (Applies to C.10 – 13) [STP2-57]

**NRC Response:** The NRC disagrees with this comment. For a full risk-informed approach, the NRC will consider information provided by the licensee to justify correlations that are used in the models. It is the responsibility of the licensee to demonstrate that the acceptance criteria and models are valid. The licensee should provide assurance that their correlations are valid for the conditions to which they are applied and any uncertainty associated with the correlations should be propagated through the models. If the uncertainties are very large and result in cases with unrealistic outputs it is likely that the staff will request that the correlations and assumptions be

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refined. The NRC staff will review the application using existing guidance as the starting point. Deviations from accepted guidance should be justified in the application.

**Comment:** Long-Term Cooling Risk-Informed approach needs to consider the effects of back-flushing sump strainers to reconfigure debris. Installing a back-flush line in sumps would greatly reduce risk. A Back-flush line-up may already be available if the analysis would support the operation. [RtM1-1]

**NRC Response:** The NRC agrees with this comment. However, the guidance does not attempt to define the compensatory or mitigative measures that may be implemented by individual licensees. Licensees are encouraged to evaluate the measures available to mitigate phenomena that can have adverse effects on long-term cooling. These measures can be included in the models used to evaluate the risk of debris on long-term cooling. The models should consider all necessary aspects of the mitigative measures when assigning success/failure ratios to the actions. One note specifically on strainer back flushing is that it may increase debris penetration through the strainer. This type of unintended effect should also be evaluated by the models.

### e. Comments Related to Uncertainty

**Comment:** Section C.14.d.4 states: “Statistical distributions chosen to represent the uncertainty about parameters in the integrated model and in the modified PRA should preserve the mean values of the initiating event frequencies from original source documents, such as NUREG-1829.” The words “if used” should follow “statistical distributions”. Also, this requirement is framed in a manner that presumes the PRA model initiating events are aggregated LOCA frequencies and not location dependent LOCA frequencies. [STP2-69, STP2-85]

**NRC Response:** The NRC agrees with the editorial portion of this comment but believes that the use of the word “chosen” already provides the desired flexibility. The RG was not changed as a result of this editorial comment. For the portion of the comment relating to location-dependent LOCA frequencies, refer to the response to [STP2-84].

**Comment:** Further, paragraph C.14.e (2) states that the impact on CDF and LERF of assumptions (related to using plant-wide LOCA frequencies at specific locations) should be quantified - it is not clear how this quantification is to be accomplished. [PWROG2-35]

**NRC Response:** The NRC agrees with this comment and has revised the discussion on uncertainty and added guidance on location-specific initiating event frequency allocation. Consistent with NUREG-1855, various options including screening and sensitivity studies are available.

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**Comment:** In C.4, the draft guide does not provide sufficient details or explanation of expectations for uncertainty analyses. Address whether distributions of parametric uncertainty are required for each submodel that generates an input into the analyses, and whether sensitivity analyses which determine the parameters that the analyses are most sensitive to are required to be used. [SNC2-8]

**NRC Response:** The NRC agrees with this comment and has revised the discussion on uncertainty to provide additional detail.

**Comment:** Section C.6.e does not provide sufficient details or explanation of expectations for uncertainty analyses. Conditional failure probabilities for sump strainer and core blockage determined based on the analyses in C.6.a through C.6.d will be incorporated into the PRA model used to calculate CDF/LERF impacts. State whether the uncertainty analysis (based on the state of knowledge) run as part of PRA model quantification is sufficient to satisfy this requirement. [SNC2-11, SNC2-12]

**NRC Response:** The NRC agrees with this comment and has revised the discussion on uncertainty.

**Comment:** In C.4, we need more explanation and details of expectations for uncertainty analyses. Are distributions of parametric uncertainty required for each submodel that generates an input into the analyses? Can sensitivity analyses which determine the parameters that the analyses are more sensitive to be used? [STP2-27] Some consideration could be given to adding clarity to guidance on uncertainty as it applies to risk assessment versus design uncertainties. [ANON1-5]

**NRC Response:** The NRC agrees with this comment and has revised the discussion on uncertainty.

**Comment:** C.6.e - "The licensee should identify relevant data and model uncertainties, ... . RG 1.174 contains additional guidance on uncertainty quantification and propagation." This statement is awkward as it states what is required only to then add exceptions. It would be clearer to state the requirement explicitly as in "For cases in which conservative deterministic values that overestimate the CDF and LERF ..." Further the requirement should be to illuminate the uncertainty which may be done by propagation of uncertainties or by sensitivity studies. [STP2-32]

**NRC Response:** The NRC agrees with this comment and has revised the discussion on uncertainty.

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**Comment:** C.6: We need more explanation and details of expectations for uncertainty analyses. Conditional failure probabilities for sump strainer and core blockage determined based on the analyses in C.6.a through C.6.d will be incorporated into the PRA model used to calculate CDF/LERF impacts. We need to know if the uncertainty analysis program UNCERT (based on the state of knowledge) run as part of PRA model quantification is sufficient to satisfy this requirement. [STP2-33]

**NRC Response:** The NRC agrees with this comment and has revised the discussion on uncertainty.

**Comment:** C.6.e. should allow for sensitivity studies to be used in lieu of propagating uncertainties into the integrated model. This is consistent with Regulatory Guide 1.174. This statement is also awkward as it states what is required only to then add exceptions. It would be clearer to state the requirement explicitly as in “For cases in which conservative deterministic values that overestimate the CDF and LERF ...” Further the requirement should be to illuminate the uncertainty which may be done by propagation of uncertainties or by sensitivity studies [STP2-35]

**NRC Response:** The NRC agrees with this comment and has revised the discussion on uncertainty.

**Comment:** Would the requirement in C.6 e [relevant data and model uncertainties] be applicable for a plant following the guidance in C.9? [STP2-36]

**NRC Response:** In general, yes. Licensees following the guidance in C.9 do not need to quantify uncertainty with respect to the test (provided the conditions in this section of the RG are met) but would still need to consider uncertainty related to other aspects of the analysis, such as LOCA frequency. This has been clarified in the RG.

**Comment:** Section C.9 states four requirements: each should allow exploration of the conservatisms to illuminate sensitivity and uncertainty. [STP2-47]

**NRC Response:** The NRC agrees with this comment and has revised the discussion on uncertainty. Consensus methods exist for this section (e.g., RG 1.82); therefore, quantification of uncertainty with respect to the test is not required, provided these consensus methods are followed.

**Comment:** C.9.e, C.10.d, C.11.d, C.12.d and C.13.g should allow for sensitivity studies to be used in lieu of propagating uncertainties into the integrated model. This is consistent with Regulatory Guide 1.174. This statement is also awkward as it states what is required only to then add exceptions. It would be clearer to state the requirement explicitly as in “For cases in

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which conservative deterministic values that overestimate the CDF and LERF ...” Further the requirement should be to illuminate the uncertainty which may be done by propagation of uncertainties or by sensitivity studies. [STP2-34, STP2-38, STP2-54, STP2-58, STP2-60, STP2-61, STP2-63]

**NRC Response:** The NRC agrees with this comment. The RG has been modified to clarify that sensitivity studies may be used, consistent with RG 1.174 and NUREG-1855.

**Comment:** Section C.14 includes five areas for treatment by “propagation of relevant parameter and model uncertainties” and by “treatment of distributions” which ignores the ability to demonstrate through the simplified approach conformance to RG 1.174 and through sensitivities robustness of that conformance without statistical analysis. This should be corrected to support the simplified approach. [STP2-65]

**NRC Response:** The NRC agrees with this comment and has revised the guidance on uncertainty.

**Comment:** C.14.a – Uncertainty determination and propagation is not necessary for those parameters that are established under conservative and bounding deterministic methodologies. [STP2-72, STP2-73]

**NRC Response:** The NRC agrees with this comment. Conservative and bounding methodologies, when used according to NUREG-1855, are an acceptable alternative to uncertainty quantification and propagation. The RG has been revised to refer to NUREG-1855.

**Comment:** The remainder of section C.14 includes five areas for treatment by “propagation of relevant parameter and model uncertainties” and by “treatment of distributions” which ignores the ability to demonstrate through the simplified approach conformance to RG 1.174 and through sensitivities robustness of that conformance without statistical analysis. This should be corrected to support the simplified approach. [STP2-79]

**NRC Response:** The NRC agrees with this comment and has revised the guidance on uncertainty.

**Comment:** Section C.15.g.2 suggests that mean frequencies should be generated from propagation of parametric uncertainties using the PRA and integrated model for comparison to RG 1.174 risk acceptance guidance. A statement should be added that sensitivity studies are acceptable in lieu of uncertainty propagation where it can be demonstrated that there would be no change in the conclusion that the acceptance guidance still would be met. [STP2-92]

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**NRC Response:** The NRC agrees with this comment and has revised the guidance on uncertainty.

**Comment:** Paragraph C.6.e implies that use of conservative deterministic approaches (that may lead to overestimating CDF and LERF) obviates the need to propagate uncertainty. The PWROG requests that the staff clarify that this is their intent. [PWROG2-25]

**NRC Response:** The NRC agrees with this comment. Treatment of a particular source of uncertainty through a conservative approach obviates the need to quantify and propagate the uncertainty from that particular source. The RG has been clarified.

**Comment:** These sub-paragraphs [C.5 through C.9 (simple method) or in paragraphs C.5 through C. 13 (excluding paragraph C.9)] are all related to the development of a complex uncertainty model to permit the propagation of parameter and model uncertainty through the integrated model via a Monte Carlo simulation. Does the staff recognize a Monte Carlo simulation based on the integrated deterministic models may be difficult and time-consuming to execute (and may limit the number of trials that are practical to run)? [PWROG2-32]

**NRC Response:** The NRC understands the challenges associated with complex Monte Carlo analyses. The RG has been revised to clarify that simplified approaches to considering uncertainty (e.g., screening, bounding analyses) are acceptable, consistent with the guidance contained in NUREG-1855.

**Comment:** The uncertainty analysis suggested in paragraph C. 14 may not be very realistic, considering the important parameters in the deterministic models, and the need to estimate failure distributions of passive components. [PWROG2-33]

**NRC Response:** The NRC agrees in part with this comment. The goal of the uncertainty analysis is not necessarily to be realistic, but to provide confidence that the risk acceptance guidelines in RG 1.174 are met. The RG was updated to refer to NUREG-1855.

**Comment:** In paragraph C. 16. b, it is not clear how "completeness" can be ensured. [PWROG2-40]

**NRC Response:** The NRC understands this comment but notes that it is the responsibility of the licensee to provide information that is complete and accurate. No change was made to the RG as a result of this comment.

**Comment:** In addition to the detailed uncertainty method described in C.14.a, it would be beneficial to provide an option for quantifying uncertainty using sensitivity analysis. [ECON1-28]

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**NRC Response:** The NRC agrees with this comment and has revised the guidance on uncertainty to clarify that such an approach is permitted.

**Comment:** The staff should consider adding text to better explain acceptable methods related to the use of Monte Carlo simulation used to generate the necessary inputs to the PRA model. [PWROG2-9]

**NRC Response:** The NRC disagrees with the comment, but has improved the uncertainty section by referring to NUREG-1855 as an acceptable approach. Specific details on acceptable Monte Carlo approaches are beyond the scope of this RG but the NRC's position is that NUREG-1855 contains sufficient information to implement the technique for the purposes of this RG.

### f. Comments Related to Screening

**Comment:** In C.9, "the licensee may select a simplified "go/no-go" approach by assuming a justifiable range of debris loads ..." This is conservative as noted but also ignores the ASME Standard that allows and encourages screening. While CCDP can and should be set to zero for cases that do not create enough debris the cases that do potentially create such debris may still be evaluated to determine potential for mitigation or core damage. [STP2-40]

**NRC Response:** The NRC agrees in part and disagrees in part with the comment. The NRC agrees that the simplified approach is conservative in assuming that non-screened weld locations result in core damage but disagrees that the RG ignores the ASME/ANS PRA Standard. The NRC has endorsed in RG 1.200, with clarifications and exceptions, the PRA Standard. The guidance in this RG on the risk-informed approach to debris is not intended to discourage screening approaches and leaves it up to the analyst as to whether a bounding, simplified approach, a detailed, more realistic approach, or something between these is employed. No change was made to the RG as a result of this comment.

**Comment:** The screening approach can be used to define the scenarios and frequencies within which the plant might be Vulnerable to Core Damage (VTCD) in that they do not screen with conservative values but that does not equate to plant damage. Such scenarios are cases for which the plant may be VTCD or Vulnerable to Large Early Release (VTLER). Other available features or actions would still need to fail and the conservative assumptions would have to actually occur – conditions that can be analyzed. [STP2-41]

**NRC Response:** The NRC does not agree with the comment, which it interprets as re-defining screening criteria that is set forth in the ASME/ANS PRA Standard as endorsed in RG 1.200. The NRC does not discourage the use of appropriate screening or the use of bounding analyses. It is not clear what the commenter means by the acronyms VTCD and VTLER or what benefit there is to using these new terms. This RG relies to a great extent on already-

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published guidance and past experience with risk-informed changes to the licensing basis, including RG 1.174 and RG 1.200, none of which used the VTCD or VTLER concepts.

**Comment:** Thus the simplified approach may allow screening of insignificant scenarios thereby allowing the analyst to focus more clearly on the non-screened cases. These can then be analyzed in great detail to generate best estimate CDF and LERF or to by sensitivity studies illuminate the sensitivity. [STP2-42]

**NRC Response:** The NRC agrees with this comment, which is consistent with the guidance provided or referenced in the final RG.

**Comment:** In C.14: "The licensee should combine the submodels ... with the goal of computing failure probabilities in the modified PRA model to evaluate debris effects." For the simplified approach this section and the remainder still apply. This should allow for deletion of scenarios screened as described in comment Item 24 above [STP2-40] and should also define the term "model" to include bounding assumptions where appropriate or desired when properly defined and characterized. [STP2-64, STP2-78]

**NRC Response:** The NRC agrees with the comment with the understanding that "deletion of scenarios" means that scenarios meeting valid screening criteria may be removed from further consideration in the estimate of debris risk. The NRC has improved the discussion regarding models, submodels, and integrating the models to provide clearer guidance.

### *g. Comments Related to the Simplified Approach*

**Comment:** In C.3: "the licensee should evaluate failure modes identified from Paragraph C.2 of this RG and identify how to incorporate these failure modes into the probabilistic risk assessment (PRA) model to be used for the risk assessment, which is used to calculate CDF and LERF" – incorporate into the PRA model, if applicable. The simplified approach/RoverD assumes a CCDP of 0.0 or 1.0 which precludes the need for use of the PRA model (i.e. plant mitigating systems) for calculating CDF. Need a defined method for calculating LERF for the simplified approach (i.e. correlating CDF to LERF). [STP2-21]

**NRC Response:** The NRC does not agree with the comment, which is that a defined method for calculating LERF should be included in this RG. However, the RG does say that, for the simplified approach, the analyst may estimate LERF by comparison of the types of scenarios that lead to LERF in the base PRA model and the types of scenarios in the risk assessment of debris, provided the chosen approach is justified.

**Comment:** there is a need for additional clarity in differences in the requirements for the integrated approach as opposed to the simplified approach. [STP2-1]

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**NRC Response:** The NRC agrees with this comment. The Regulatory Guide was revised to clarify the ways in which deterministic and risk evaluations may be used, either alone or in conjunction, to determine the overall plant risk.

**Comment:** In C.3: For the simplified approach, discussed later in the RG, the base PRA model may not have to be modified since success is established by bounding deterministic evaluations and all other cases are assumed to go to failure. [STP2-20]

**NRC Response:** The NRC agrees with this comment. The RG has been revised to allow the use of a simplified approach without revision to the PRA model. The effect on risk may be calculated without using the PRA.

**Comment:** C.3 goes on to state, “Changes to the PRA should be clearly described in the application to the NRC.” As stated above these may not be “changes” but fully developed analysis of continued mitigation of an alternative end state, namely Recirculation to evaluate the delta CDF and LERF. [STP2-23]

**NRC Response:** The NRC agrees with this comment. The regulatory guide has been revised to clarify that changes to the PRA should be described. If changes to the PRA are not required no description is necessary.

**Comment:** In C.4: For the simplified approach, an integrated model will most likely not be required. Therefore, uncertainty modeling will also not be required. This is supported by the statements in C.6.e and C.7.d. [STP2-28]

**NRC Response:** The NRC agrees with this comment. If a simplified approach using staff accepted methods is implemented uncertainty need not be addressed. The guidance has been revised to indicate that the NRC staff considers staff accepted methods to be conservative such that uncertainty need not be addressed. For portions of the model that do not use staff accepted methods uncertainty must be included in the evaluation.

**Comment:** The wording should be changed for C.5 to require a description of those items described in C.5.a and C.5.b for both the simplified risk-informed approach and a risk-informed approach that relies upon an integrated model. C.5.c and C.5.d are only required for the latter approach. [STP2-30]

**NRC Response:** The NRC agrees with this comment. The regulatory guidance has been clarified to allow more flexibility in the implementation of simplified approaches.

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**Comment:** In C.5, C.14 and C.15: Simplified approach precludes the need for use of the PRA model (i.e. plant mitigating systems) for calculating CDF. Need a defined method for calculating LERF for the simplified approach (i.e. correlating CDF to LERF). [STP2-31, STP2-77]

**NRC Response:** The NRC disagrees with this comment. Although the simplified approach may not require the use of PRA to calculate delta risk (CDF and LERF), the baseline risk must still be calculated for comparison to the risk acceptance guidelines. Furthermore, the NRC does not agree that a simplified approach for estimating or bounding LERF is necessary in this RG, because methods to estimate LERF are provided in other guidance documents, including the ASME/ANS PRA Standard as endorsed in RG 1.200.

**Comment:** In C.9: Simplified does not “calculate time-dependent flow conditions at the strainer or in the vessel but would instead compare each scenario to a threshold value determined by testing.” This may be used to say what the owners group is doing on saying chemical production is not for X hours cannot be used or it can be read as only time dependent debris and flows based on T/H should not be used. [STP2-48]

**NRC Response:** The NRC agrees with this comment. The guidance does not prohibit time dependent evaluations and evaluations that depend on other factors such as flow to be used. The RG was revised to make it clear that the analyst may account for changes in thermal-hydraulic conditions over time, such as flow and temperature.

**Comment:** C.11.a – Shouldn't this statement also be provided in Section 9 since it applies to both the simplified approach and a more extensive risk-informed approach? [STP2-59]

**NRC Response:** The NRC agrees with this comment. The format of the draft guide was confusing. The information in section 11 is relevant to simplified approaches, but section 11 was within the fully risk-informed section of the guidance. The guidance has been revised to clarify how the simplified solution can be implemented.

**Comment:** C.14 would read we have to modify PRA model, Is this true in the simplified approach? [STP2-66]

**NRC Response:** The NRC agrees with this comment. The PRA may not have to be revised if a simplified approach is used. The guidance has been revised to clarify what is required when using simplified or fully risk-informed approaches.

**Comment:** Several comments noted that the baseline PRA may not need to be revised if a simplified approach is used. [STP2-67] [STP2-74] [STP2-88] [ECON1-7] In C.15 should relate to the use of baseline PRA information and models in a manner consistent with RG 1.200. [STP2-90]

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**NRC Response:** The NRC agrees with this comment. The PRA may not need to be modified if a simplified approach is used. The guidance has been revised to clarify that the PRA may not need to be revised if a simplified approach is used.

**Comment:** The guidance provided in section C.14 and C.16 does not apply to a simplified approach. An integrated model may not be necessary to calculate  $\Delta$ CDF since this value will be principally derived from the NUREG-1829 break frequencies. There will be a submodel evaluation tool (CASA or CASA type software, or spreadsheet) that will manipulate the inputs and compare them against the failure criteria to establish the bounding quantities of debris that results in success/failure for both the strainer and in-vessel. Once this debris quantity is known, the tool will then determine the break size that results in the success/failure transition point. As stated, this model does not require an integrated model. [STP2-71, STP2-93]

**NRC Response:** The NRC agrees partially with this comment. Some aspects of sections C.14 apply to a simplified model. For example, even the simplest model has to determine how much debris is generated from each break and how much of this debris transports to the strainer and into the vessel. The guidance in C.16 may also be applicable to a simplified approach although the description of the plant response could be much simpler than that for a fully risk informed model. Although the simplified models are less complex than a fully risk-informed model they are necessary to evaluate the response of the system to a LOCA and they must be described to the extent that it is shown that they represent the phenomena being evaluated. The guidance has been revised to clarify the requirements for simplified and fully risk-informed methods.

**Comment:** Skipping to C.14 from C.9 for the simplified approach: C.14 needs to more clearly distinguish between the integrated model and the simplified approach. For instance, the STP RoverD approach does not involve inputs into the plant PRA. Suggest splitting C.14 into separate sections for the integrated approach and the simplified approach. Having separate sections for simplified and integrated approach should also be considered. [STP2-76]

**NRC Response:** The NRC agrees with this comment. The guidance has been revised to more clearly state what analyses are required for each approach. The simplified and full risk-informed approaches are each described in a separate section.

**Comment:** In C.15: Because the simplified approach approximates CDF with LOCA initiating event frequency, it would not be appropriate to use that value to modify the baseline PRA. The simplified calculation serves only to show that the CDF is within RG 1.174 acceptance criteria, but does not establish an actual LOCA CDF. [STP2-89]

**NRC Response:** The NRC agrees with this comment. The guidance has been revised to clarify that the baseline PRA may not need to be modified if a simplified approach is used.

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**Comment:** In the "simple method" of C.9, two conditions are to be evaluated: (a) debris loads that are sufficient to fail the strainer, and (b) in-vessel debris loads that are sufficient to prevent adequate flow to the core. DG- 1322 states multiple times that the determination of the threshold value is to be done by testing. (Note that in paragraphs C.6 and C.7, model validation can be done via testing, empirical data, analogy to other systems, or comparison with other calculations (or detailed computational fluid dynamic models); for the "simple" method, the only acceptable method in the draft regulatory guide is testing.) The PWROG requests that the staff clarify that this is their intent. [PWROG2-28]

**NRC Response:** The NRC agrees that the RG should be clarified; this was done by separating the detailed and simplified approaches into two appendices. The NRC notes that the simplified approach is strictly based on testing, as stated in the RG. However, the RG says that a "hybrid approach" may be used, and analysts are free to propose and justify other approaches not presented in the RG.

**Comment:** In general, the simplified approach should be treated as a continuum approach that can be refined as necessary to meet plant-specific needs. For example, a licensee may use a simplified strainer model, but implement a refined core blockage model based on realistic, time-dependent penetration. Another licensee may calculate chemical effects as a function of break-specific conditions and compare this debris load to the chemical quantity from an acceptable head loss test. In the second example, it would be necessary for the licensee to address the guidance in Paragraph C.11. [ECON1-15]

**NRC Response:** The NRC agrees with this comment. The guidance has been revised to allow simplified, fully risk-informed, or hybrid approaches to be used.

### h. Comments Related to Containment

**Comment:** Paragraph C.8 is worded in a way that implies the need for conservatism in evaluating containment pressure. Consider rewording this paragraph to emphasize realistic modeling. The last sentence should be revised to state that licensees should use realistic, sequence-specific containment pressures in NPSH computations. The basis for the containment pressure used in NPSH calculations should be clearly documented. [STARS2-6]

**NRC Response:** The NRC disagrees with this comment. This is a case where safety margin is gained by following guidance in RG 1.82 and other guidance documents. The paragraph also implies that the licensee may use other methods as long as they are justified. In general, if the licensee does not have the use of accident pressure approved in their CLB, the staff will carefully evaluate its use in the evaluation. The NRC has evaluated the use of containment accident pressure in the calculation of NPSH and has published draft guidance on its use at

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ML13015A437. Although this guidance is not final at this time the NRC is working to incorporate it into RG 1.82 via reference.

**Comment:** This RG is focused on debris effects on ECCS and containment spray in their long-term cooling role. There needs to be regulatory guidance for containment heat removal that typically relies on CSS operating in conjunction with ECCS and for containment atmosphere cleanup, which relies on CSS to manage dose, including dose to the control room. [STP2-3]

**NRC Response:** The scope of this RG is the alternative risk-informed approach set forth in 10 CFR 50.46c and does not apply to other regulations or GDCs. No changes were made to the RG as a result of this comment.

**Comment:** In C.8: Recommend providing a reference for acceptable use of containment pressure beyond saturation. [STP2-39]

**NRC Response:** The NRC disagrees with this comment. This is a case where safety margin is gained by following guidance in RG 1.82 and other guidance documents. Reduction in the margin should be justified. It is anticipated that any use of accident pressure will be considered on a plant specific basis. The staff is not aware of a good example for the use of pressure beyond saturation. The NRC has evaluated the use of containment accident pressure in the calculation of NPSH and has published draft guidance on its use at ML13015A437. Although this guidance is not final at this time the NRC is working to incorporate it into RG 1.82 via reference.

### i. Comments Related to In-Vessel Effects

**Comment:** In the paragraph that immediately follows C.2 g, "The licensee may exclude debris-related failure modes from further consideration if a bounding analysis" it seems that the example given for screening does not have to consider chemical effects. Whether or not this is the case in NRC's view should be explicit. [STP2-18]

**NRC Response:** The NRC agrees that the referenced paragraph is not clear. The intent is that chemical effects be considered in all analyses. The example cited in the comment is only a single case and is not intended to cover all scenarios or phenomena. The example has been generalized to simply refer to debris, not specific types of debris.

**Comment:** Delete paragraph C.2.g and C.13.c. Boric acid precipitation is independent of GSI-191. [STP2-62] Delete paragraph C.2.g. Boric acid precipitation is independent of GSI-191. Paragraph C.2.e. adequately addresses long-term core cooling considerations applicable to GSI-191. [STP2-17]

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**NRC Response:** The NRC disagrees with this comment. The NRC and industry are currently evaluating an appropriate resolution path for this issue and may update the guidance in a future revision of this RG or the safety evaluation approving an industry topical report. No change was made to this RG as a result of this comment.

**Comment:** Paragraph C.13.c indicates that the licensee should address the potential for boric acid precipitation. Recent work to be published in WCAP-17788-NP will specifically address boric acid precipitation concerns relative to debris. Should this document (or its safety evaluation report) or other documents be referenced in DG-1322? Should there be a more explicit discussion related to boric acid precipitation in DG-1322? [PWROG2-29]

**NRC Response:** The NRC disagrees with this comment. The NRC has not reviewed and accepted the evaluation of boric acid precipitation in WCAP-17788. If the NRC finds the methodology in the topical report acceptable, licensees may reference it to address boric acid precipitation. The guidance has been revised to allow boric acid precipitation to be addressed using NRC approved methods.

**Comment:** In-vessel debris limits are discussed in Section C.9, but boron precipitation is not introduced until Section C.13 c. Does a utility following C.9 guidance need to consider boron? (see comment 4 to item 24) [STP2-45]. [STP2-55]

**NRC Response:** The NRC agrees with this comment. The need to address boric acid precipitation has been added to the guidance for simplified evaluations.

### j. Comments Related to DID and SM

**Comment:** Consideration should be given to removing defense in depth and safety margin from regulatory risk guidance [ANON1-8]

**NRC Response:** The NRC does not agree with this comment. RG 1.174 sets forth key principles of risk-informed regulation, which include both defense-in-depth and safety margins. These principles distinguish a *risk-based* approach from the *risk-informed* approach adopted by the NRC. While RG 1.174 provides some elements or attributes for assessing whether adequate defense-in-depth and safety margins have been maintained, this RG provides specific and more detailed guidance on assessing those elements or attributes for the risk-informed consideration of debris.

**Comment:** Paragraph C.18 indicates that parameter values should be consistent with licensing basis calculations, which are inherently conservative. This should be revised to state that realistic parameters should be used and clearly documented. [STARS2-11] The author has the impression that there is an expectation that risk assessment should include similar bias

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uncertainty as well. If followed, such practice could cause unrealistic assessments of risk and possibly lead to wrong conclusions regarding design alternatives. [ANON1-6]

**NRC Response:** The NRC agrees in part and disagrees in part with the comment. The NRC agrees that realistic parameters may be used in a risk assessment provided such use is justified and clearly documented. The NRC disagrees that use of licensing-basis parameters is not appropriate for some parameters. Codes and standards often specify parameters that include margin. The failure data included in PRA models is based on equipment that was designed to applicable codes and standards and therefore includes margin. Parameters such as NPSH required should remain at the licensing basis values to preserve adequate safety margins. Paragraph C.18 allows the use of realistic values for parameters if justified. This might be appropriate for pump flow rates, for example, where the as-built system may greatly exceed the flow rates realistically necessary to mitigate the scenarios of interest. No change was made to the RG.

**Comment:** The risk assessment should evaluate the integrated design realistically “as designed” with unbiased uncertainties and thereby avoid double-counting of safety margins. This approach may provide the best chance of revealing vulnerabilities in the integrated design otherwise missed in individual component designs. [ANON1-7]

**NRC Response:** The NRC agrees that the risk assessment should be based on the as-designed plant. While the NRC supports realistic risk assessments, it also recognizes that conservative or bounding analyses may be used; for example, in screening out hazards, initiating events, or plant operating modes from further consideration. As stated in the response above, the safety margins afforded by compliance with codes and standards should not be reduced without justification.

**Comment:** In paragraph C.9, DG-1322 provides a "simple" method to determine if the debris load is sufficient to defeat long-term cooling by comparison to a threshold value. This simple method may be too conservative if the number of sequences (as evaluated on the basis of debris-related failure modes) yields a high CDF value. The use of a bounding threshold value may also introduce conservative results. This is the usual balance between conservatism and model complexity (more complex, generally less conservative). What criteria should the analyst use to determine if the level of conservatism (for the simple model) is too great to produce usable results? [PWROG2-27]

**NRC Response:** The NRC disagrees with the comment, which it interprets as saying that the NRC should provide criteria to allow an analyst to determine if the conservatism in a simple model is too great to produce usable results. The RG provides guidance regarding a detailed risk assessment and a simplified approach. It is up to the analyst to determine which of these, or some other approach, will serve his or her purpose. For example, if the simple model is not

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useable, the analyst will have to go to a more complex model. However, there may be some cases where the risk acceptance criteria cannot be met or where adequate defense-in-depth or safety margins cannot be maintained, and the risk-informed approach would not be viable.

**Comment:** The abscissas in the CDF,  $\Delta$ CDF and LERF,  $\Delta$ LERF figures in Regulatory Guide 1.174 probably (for many reasons) do not meaningfully represent absolute risk values. For example, organizational risk contribution (not human reliability), known to be at the root cause of core damage events and in fact most major industrial accidents, is not explicitly included in regulatory risk guidance. [ANON1-3] The requirement in Regulatory Guide 1.174 “Over-reliance on programmatic activities ...” seems to be aimed at the issue but is part of guidance on defense in depth, as opposed to an explicit requirement of the risk assessment. [ANON1-4]

**NRC Response:** The NRC agrees that nuclear power plant risk assessments do not estimate “absolute risk values.” There are known limitations of PRA models (e.g., modeling of errors of commission) as well as modeling uncertainty. This uncertainty is one reason the NRC has adopted a *risk-informed* rather than *risk-based* approach to regulation. The defense-in-depth philosophy and use of safety margins help compensate for uncertainty, including the “unknown-unknowns” and other PRA limitations. The NRC agrees that the information for evaluating defense-in-depth is intended to compensate for the limitations and uncertainty inherent in the risk assessment. No change was made to the RG as a result of this comment.

### k. Comments Related to Monitoring and QA

**Comment:** Paragraph C.19 needs to be re-worded to be consistent with the guidance in RG 1.174 regarding quality program requirements associated with aspects of the risk assessment. [STARS2-12]

**NRC Response:** The NRC agrees that the guidance in paragraph C.5 of RG 1.174 contains the appropriate QA requirements for the risk-informed approach to addressing debris. In fact, that is what paragraph C.19 says. C.19 also points out that this risk-informed approach relates to safety-related SSCs, to make it very clear that the portion of C.5 of RG 1.174 related to safety-related applications is applicable in this case. The QA guidance in the RG was clarified.

**Comment:** Paragraph C.19 appears to require licensees to complete the risk-informed GSI-191 evaluations in accordance with an Appendix B QA program. During the development of the risk-informed approach by the STP pilot project, the NRC staff had generally agreed with STP that although quality is important, it is not necessary to follow the Appendix B requirements. Please clarify whether the NRC staff expects licensees to complete all aspects of the risk-informed GSI-191 evaluations under an Appendix B QA program or if this requirement is only applicable to certain portions of the evaluation. [ECON1-37]

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**NRC Response:** The NRC does not agree that paragraph C.19 requires an Appendix B QA program. To the contrary, C.19 clearly references paragraph C.5 of RG 1.174 as the appropriate level of QA and notes that the risk-informed approach for debris is needed to demonstrate that the design of safety-related SSCs meets NRC requirements. Paragraph C.5 in RG 1.174 states that, for such applications, four “pertinent” quality assurance requirements of Appendix B to 10 CFR Part 50 should be met (summarized here from RG 1.174):

- Use personnel qualified for the analysis.
- Use procedures that ensure control of documentation, including revisions, and provide for independent review, verification, or checking of calculations and information used in the analyses.
- Provide documentation and maintain records in accordance with the guidelines in Section 6 RG 1.174.
- Use procedures that ensure that appropriate attention and corrective actions are taken if assumptions, analyses, or information used in previous decision-making are changed (e.g., licensee voluntary action) or determined to be in error.

Note the 10 CFR 50.46c(e)(1)(iv) requires that the risk-informed analysis be performed under a QA program. The NRC does not expect the risk-informed analysis to be performed under Appendix B, but rather under a QA program that includes at least the four requirements above. As a result of apparent confusion generated by paragraph C.19, the QA portion of this RG has been re-written.

**Comment:** Paragraph C.20 refers to an implementation and monitoring program. If the NRC intent is that the design change process be followed for NRC approved inputs to the PRA model, this paragraph should state that requirement. There is no need for an implementation and monitoring program to ensure configuration control in containment. [STARS2-13]

**NRC Response:** The NRC agrees with the comment. The NRC’s intent is not to prescribe a process for requiring NRC approval for inputs into the PRA. In fact, the RG clearly states that licensees are able to credit existing programs but are not required to do so. Furthermore, the objective of paragraph C.20 is not to ensure “configuration control in containment.” Changes to the plant outside of containment (e.g., modification to ECCS equipment) could impact the plant’s response to an event involving debris. Therefore, the guidance in this section – consistent with RG 1.174 – calls for a comprehensive implementation and monitoring strategy to ensure that the risk associated with debris remains low. The RG was not revised as a result of this comment.

**Comment:** In Section A, Related Guidance, provide specific guidance on expectations for how often and under what circumstances the analysis inputs/assumptions Guidance, and PRA results should be reconfirmed to still be valid. [SNC2-4]

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**NRC Response:** The NRC agrees with the comment and has provided additional guidance in Section C of the RG, including the regulatory requirement to update the risk-informed analysis no less frequently than every 48 months.

**Comment:** In C.20, the expectations for performance monitoring requirements as referenced in this section are unclear. Provide specific guidance on expectations for how often and under what circumstances the analysis inputs/assumptions and PRA results should be reconfirmed to still be valid. [SNC2-16]

**NRC Response:** The NRC agrees with the comment and has made changes to the RG to clarify that reconfirmation of the analysis results should take place at least once every four years.

**Comment:** Does the discussion under "Related Guidance" imply that we will need a process to periodically monitor performance and confirm that analysis inputs/assumptions and PRA results are still valid? [STP2-5]

**NRC Response:** Yes. The final rule, 10 CFR 50.46c, requires a monitoring program. This is consistent with the principles of risk-informed decision-making outlined in RG 1.174, one of which is performance monitoring. Revised paragraph C.5 contains specific guidance.

**Comment:** In C.20: Does this imply that we will need a process to periodically monitor performance and confirm that analysis inputs/assumptions and PRA results are still valid? [STP2-94]

**NRC Response:** Yes, that is the intent of paragraph C.20.

**Comment:** This regulatory guide describes the methods for evaluating GSI-1 91 phenomena and the associated risk for an as-built and as-operated plant. However, there is no discussion on how a licensee that implements a risk-informed approach would address plant operability following the discovery of an unexpected condition (e.g., new types or additional quantities of debris in containment). Ideally, a licensee that has an integrated model (i.e., the model that was developed for the licensing submittal) could use the model to evaluate an operability issue in a consistent manner. In other words, if a plant has a risk-informed licensing basis (e.g., GSI-191 ACDF is less than  $1 \times 10^{-6}$ ), the licensee should be able to show that the plant is operable by evaluating the unexpected condition and showing that it does not increase risk above the licensing basis threshold. Regardless of the methodology, it would be valuable to add a section providing guidance for operability evaluations. [ECON1-3]

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**NRC Response:** Licensees implementing this RG should refer to the guidance on operability in Inspection Manual Chapter 0326. This guidance does not allow operability determinations to be risk-informed but does allow the use of PRA to inform the timing and scope of corrective actions. 10 CFR 50.46c(m) contains requirements for reporting and corrective action, and related guidance has been added to the RG.

**Comment:** In C.20, it appears that the licensing basis for a plant implementing the risk-informed approach would be a) risk associated with debris effects is small, and b) defense-in-depth and safety margins are maintained. If this is correct, if (when) an unexpected condition is discovered, would it be necessary to consider the risk impact as part of the operability evaluation? [ECON1-38]

**NRC Response:** See response to [ECON1-3].

### I. Comments Related to RG Organization

**Comment:** It is not clear which regulatory positions apply to the simplified approach and which apply to the detailed approach, and the guidance appears conflicting in some cases. [STARS2-7, STP2-45, STP2-52] The approach presented in the form of a flowchart may be warranted. [PWROG2-11]

**NRC Response:** The NRC agrees with the comment and re-organized the RG to clearly set forth guidance on the detailed and simplified approaches.

**Comment:** For the simplified approach, instead of referencing C.11 and C.13, provide guidance that the simplified approach uses values that bound all scenarios (demonstrated through testing) for chemical effects and debris strainer penetration downstream effects. [STARS2-7]

**NRC Response:** The NRC agrees with the comment and re-organized the RG to clearly set forth guidance on the detailed and simplified approaches.

**Comment:** As the requirement regarding uncertainty is repeated throughout C.5 through C.13 and elsewhere in this RG, it would be beneficial to have one section on uncertainty which addresses all requirements for uncertainty and sensitivity analyses. This would include what is required for the integrated submodels, propagation of inputs into the PRA models (including identification of areas where propagation of uncertainty is not required), and PRA model quantification. Discussion of suitable methods such as those described in C.14 should be provided. [STP2-34, 37, 38; SNC2-3, SNC2-13, ECON1-13]

**NRC Response:** The NRC agrees with the comment and re-organized the RG to put the comprehensive uncertainty guidance in one location.

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### *m. Editorial Comments*

**Comment:** In C.5.d, clarify which integrated model (or models). It's unclear whether the statement applies to the integrated submodels in C.4 or the modified PRA model. [SNC2-10]

**NRC Response:** The NRC agrees with this comment and has clarified the RG as appropriate.

**Comment:** Should GDC 38 and 41 also be included under "Applicable Rules and Regulations?" [STP2-4]

**NRC Response:** The NRC agrees with this comment and added these to the RG.

**Comment:** There are a number of areas that would benefit from clarification, additional guidance, or examples to reduce ambiguity and eliminate possible differing interpretations. For example, a better definition of the relevant initiating events is needed, as well as more specificity on which PRA models are included in the scope of certain requirements. [SNC2-2]

**NRC Response:** The NRC agrees with this comment and has clarified the RG as appropriate.

**Comment:** In C.3 and C.15, clarify if the intent is to permanently incorporate into the plant's baseline model of record or just in the PRA model used in the analysis to calculate delta CDF and LERF for GSI-191 impacts. [SNC2-6, STP2-19, STP2-87]

**NRC Response:** As stated by RG 1.174 and RG 1.200, the necessary scope, level of detail, and technical adequacy of a PRA depend on the application for which it is being used. The guidance in this RG is limited to analyses used to demonstrate compliance with 50.46c(e). Integrating the results of these analyses (e.g., a new basic event representing sump clogging) into PRA models that are used for other applications may provide useful insights but is beyond the scope of this RG. A decision about if and how to update PRA models used for other applications should be made in a manner consistent with the appropriate guidance documents for those applications. The RG has added a section on periodic update of the risk-informed analysis that provides additional clarity.

**Comment:** Consideration might be given to how much emphasis is placed on frequency of core damage and frequency of large radiation release in guidance. [ANON1-1]

**NRC Response:** The NRC agrees with the comment. RG 1.174 states that, "the more emphasis that is put on the risk insights and on PRA results in the decision-making process, the more requirements that have to be placed on the PRA in terms of both scope and how well the risk and the change in risk is assessed." Because the RG invokes RG 1.174 (including the risk acceptance guidelines), it already incorporates this concept.

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**Comment:** In C.1: Provide examples of other scenarios not meeting all four criteria that should be considered for inclusion in the risk analyses. [STP2-14]

**NRC Response:** The NRC believes that the commenter may have misinterpreted the screening criteria in C.1, which are provided as an example only. A scenario is screened *into* the analysis if all four criteria are met and screened *out* of the analysis if any one of the criteria are not met. Therefore, the sample scenario described by the commenter (where one or more criteria were not met) would be screened out and would not normally be included in the risk analysis. A minor change was made to the wording of the fourth criterion to improve clarity.

**Comment:** In C.2: “The license should identify the debris related failure modes for each SSC whose successful operation helps to mitigate the -----“Does this mean SSC as a component or as a system as the example states e.g. pump of the system, or the RHR system or the entire ECCS as a component? Also does this mean listing each valve in the system also for downstream wear? [STP2-16]

**NRC Response:** The NRC agrees that the analyst must consider any failure modes that could adversely affect long-term core cooling, whether the failure mode applies to a structure, system, or component. The NRC would expect that the wear evaluation would be performed in accordance with WCAP-16406 and would likely result in screening out wear as a failure mode. This WCAP was referenced in DG-1322, and the RG was not changed in this respect.

**Comment:** Section C.3: perhaps adding 'e.g. HHI in large LOCA response models' after the reference to safety injection flow rates would add clarity. [STP2-25]

**NRC Response:** The NRC does not agree with this comment, because the description should be kept general and LHI flow rates are just as important.

**Comment:** 9.b says we determine the initiating event could results in debris loads that are predicated to cause head loss greater than shown under C.9.a. Does this say we don't have to do this in detail as defined in C.1, C.2, C.3, etc.? If not PWROG analysis, what would it be? How would “not blocked” be determined by analysis? [STP2-49]

**NRC Response:** The NRC agrees that the simplified approach was neither clear nor complete. The RG was changed to separate these approaches into individual appendices. The simplified approach now clearly points to the appropriate portions of the detailed approach, as suggested by this comment.

**Comment:** C.9 – Apparently absent from this section is discussion of debris penetration. Recommend modifying the statement in C.12.a and adding language to this section since this is

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a consideration for the simplified approach. [STP2-50] Apparently absent from this section is discussion of ex-vessel effects. Recommend adding the statement from C.13.a to this section. [STP2-51]

**NRC Response:** The NRC does not agree with the comment. C.9 is simply defining the initiating events and debris loads that could result in a loss of cooling. C.12 discusses how to determine how much debris could reach the core.

**Comment:** C.9b. "... assume system failure whenever those conditions are predicted to occur." What is the definition of "system" used here? Using the simplified approach just assumes a CDP of 0.0 or 1.0. [STP2-53]

**NRC Response:** The NRC notes that the simplified approach uses testing to establish threshold values for debris, below which systems necessary to provide long-term core cooling will function. Failure is assumed to occur if any threshold is exceeded. No change was made to the RG to address this comment.

**Comment:** In paragraph C.3, the terms "baseline PRA," "negligible," and "clearly" (twice) are used. Does "baseline" PRA refer to a base case PRA, i.e., PRA of record? What does "negligible" mean in this context, as referring to risk increase? What does "clearly" mean in this context? [PWROG2-19]

**NRC Response:** The NRC agrees with the comment, which it interprets as saying that clarification of C.3 is needed. That paragraph does define the "baseline" PRA as the PRA model that is used to calculate the CDF and LERF, assuming negligible (zero) contribution from debris. The two instances of "clearly" were removed from the RG.

**Comment:** In paragraph C.4, the staff should clarify that some of the stated items in the integrated model could be handled via test results (i.e., chemical effects). The staff should also define what is meant by "integrated models." [PWROG2-24]

**NRC Response:** The NRC agrees that the term "integrated model" was unclear. The RG was revised to be more clear - that submodels may be developed for various phenomena related to debris generation, transport, and effect; that these submodels get integrated to produce inputs to a modified PRA model; that together these form the systematic risk assessment; that the systematic risk assessment is one input to the risk-informed analysis, which also includes defense-in-depth, safety margins, and performance measurement.

**Comment:** The last sentence in Section C.3 is not clear. Is this statement referring to proceduralized operator actions (e.g., securing containment spray or switching over to hot leg recirculation), which may or may not reduce CDF/LERF, or is it referring to actions that would be

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used to mitigate loss of ECCS due to the effects of debris (e.g., turning on a reactor coolant pump to blow debris out of the core)? [ECON1-8]

**NRC Response:** The NRC disagrees with the comment. The guidance simply and clearly states that operator actions that impact the risk results should be described. No distinction is made about the specific type of actions or whether they involve procedures. Guidance on modeling human actions is provided in the ASME PRA Standard.

**Comment:** Paragraph C.8 requires licensees to justify using containment overpressure with respect to NPSH computations. Containment pressure is also used in gas void calculations. Is justification for using overpressure required for other aspects of the evaluation besides NPSH computations? [ECON1-14]

**NRC Response:** The NRC is developing guidance for use of containment overpressure. The NRC has evaluated the use of containment accident pressure in the calculation of NPSH and has published draft guidance on its use at ML13015A437. Although this guidance is not final at this time the NRC is working to incorporate it into RG 1.82 via reference. For the calculation of gas voiding across a debris bed, the NRC is not applying similar guidance. However, the NRC expects that any overpressure credited to prevent or limit voiding be justified using conservative evaluation methods.

**Comment:** Paragraph C.9.b states that the licensee should determine when an initiating event could result in debris loads that are predicted to cause head losses greater than those shown to be acceptable. "Debris loads" should be clarified to state that it includes all debris types (including chemical precipitates). [ECON1-19]

**NRC Response:** The NRC does not agree with the comment. Paragraph C.9.a of the DG, which is just ahead of the paragraph referred to, said: "The analyst should define a range of loads, debris types, debris combinations, debris arrival sequences, and interactions with chemicals in the fluid where the strainer is not expected to fail." The NRC believes that this clearly says that all types of debris should be considered, and the chemical interactions also considered. This language has been retained in paragraph B-2.a of Appendix B to the RG.

**Comment:** It states that licensee can skip paragraphs C.10 through C.13 if a simplified approach is used but in paragraph 9a. it sends the licensee to C.11 and C.13. Please clarify. [STP2-44]

**NRC Response:** The NRC agrees that the DG was confusing and moved the detailed approach to Appendix A and the simplified approach to Appendix B of the final RG.

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**Comment:** In paragraph C.6.c, clarify that the effects of latent debris may be neglected when testing demonstrates no impact on strainer performance. [STARS2-5]

**NRC Response:** The NRC disagrees with this comment. The guidance requires the analyst to evaluate the effects of latent debris. As with any other potential debris source, the analyst may show that the effects of certain debris types are negligible. The guidance requires the evaluation of all debris sources and allows potential sources that will not affect strainer performance to be eliminated from further consideration.

**Comment:** The example provided in the first paragraph of Section C.2, "(e.g., fine and compact debris filling the void space of a fibrous debris bed)", isn't clear. A better example might be that the maximum failure quantity of debris downstream of the strainer wouldn't cause failure of ex-vessel components due to blockage or wear. [ECON1-5]

**NRC Response:** The NRC agrees with this comment. The example in the guidance was revised to be more general.

**Comment:** The second paragraph of Section C.2 provides an example where a particular failure mode (RHR heat exchanger blockage) was screened out based on a bounding analysis, but the degradation effects of debris still need to be considered. Although this is a valid point, the example is probably not the best choice. A better example might be something along these lines: 1. ECCS pump failures due to gas voids were screened out since the calculated void fraction under bounding conditions was determined to be less than 2%. 2. Even though the pumps won't fail directly due to gas voids, the void fraction must still be considered due to the effect on NPSH required (as discussed in Regulatory Guide 1.82). [ECON1-6]

**NRC Response:** The NRC acknowledges that the example provided by the commenter would be a reasonable alternative but believes the existing example is suitable.

**Comment:** In paragraph C.2.d, the concept of exceeding "ex-vessel limits" is suggested. Could the staff provide some examples of what an "ex-vessel limit" is, or define the term? [PWROG2-18]

**NRC Response:** The NRC disagrees with this comment. There is already an example immediately following the use of this term.

**Comment:** DG-1322 does not provide an acceptable approach for draft rule paragraph (e)(1)(iii) consider results and insights from PRA [PWROG2-1]

**NRC Response:** The NRC agrees with this comment and has clarified the RG.

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**Comment:** DG-1322 does not provide an acceptable approach for draft rule paragraph (e)(1)(iv) PRA approach scope, level of detail, and technical adequacy. [PWROG2-2]

**NRC Response:** The NRC disagrees with this comment. The RG clearly provides guidance on scope, including hazards, initiating events, and plant operational modes. The RG refers to RG 1.200 regarding technical adequacy.

**Comment:** DG-1322 does not provide an acceptable approach for draft rule paragraph (e)(2)(ii) PRA scope, etc. are commensurate with the reliance on risk information [PWROG2-3]

**NRC Response:** The NRC disagrees with the comment. The RG refers to RG 1.174 for guidance on this aspect of the risk-informed analysis.

**Comment:** DG-1322 does not provide an acceptable approach for draft rule paragraph (e)(2)(iii) PRA review process [PWROG2-4]

**NRC Response:** The NRC agrees with the comment and has added submittal guidance to the RG.

**Comment:** DG-1322 does not provide an acceptable approach for draft rule paragraph (e)(2)(iv) description and basis of evaluations to satisfy (e)(1)(i) and (ii) [PWROG2-5]

**NRC Response:** The NRC agrees with the comment and has added submittal guidance to the RG.

**Comment:** DG-1322 does not provide an acceptable approach for draft rule paragraph (e)(3) NRC approval [PWROG2-6]

**NRC Response:** The NRC does not agree with the comment, which it interprets as saying that the RG should have guidance on 10 CFR 50.46c(e)(3). Paragraph (e)(3) is about what NRC must find in order to approve the application. However, guidance was added to this RG regarding reporting and corrective action, which is discussed in paragraph (e)(3).

**Comment:** DG-1322 does not provide an acceptable approach for draft rule paragraph (m)(4)(vii) for operating licenses (other parts deal with design certification and COLAs - not directly applicable to PWROG scope) [PWROG2-7]

**NRC Response:** The NRC agrees with this comment and has added guidance to this RG on reporting and corrective action.

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**Comment:** It might make more sense to move Paragraph C.9 after Paragraph C.13 and modify it to specify that where simplified methods are used, some of the preceding paragraphs will not be applicable. [ECON1-16]

**NRC Response:** The NRC agrees that the draft guide was confusing. The final RG was reorganized to improve the information flow. The detailed and simplified approaches were moved to separate appendices.

**Comment:** Paragraph C.9.a refers to Paragraphs C.11 and C.13, although the first paragraph in Section C.9 states that these steps can be skipped. Note, however, that it is necessary to perform some level of analysis for chemical effects even with the simplified approach. [ECON1-18]

**NRC Response:** The NRC agrees that the draft guide was confusing. The final RG was reorganized to improve the information flow. The detailed and simplified approaches were moved to separate appendices.

**Comment:** The first sentence in Paragraph C.9.c appears to be a repeat of Paragraph C.9.a and can probably be deleted. [ECON1-20]

**NRC Response:** The NRC agrees that the draft guide was confusing. The final RG was reorganized to improve the information flow. The detailed and simplified approaches were moved to separate appendices.

**Comment:** In C.10, recommended editorial change: "The output of this approach is a calculated head loss value [delete "and in-vessel debris load"] for each scenario." The remainder of C.10 is focused on strainer head loss, so in-vessel debris loads should be addressed elsewhere. [ECON1-21]

**NRC Response:** The NRC agrees and made the suggested edit.

**Comment:** A significant portion of the guidance in C.11, C.12 and C.13 apply to the simplified approach. [ECON1-22]

**NRC Response:** The NRC agrees that the draft guide was confusing. The final RG was reorganized to improve the information flow. The detailed and simplified approaches were moved to separate appendices.

**Comment:** It is recommended that paragraph C.6.c, which discusses chemical effects and debris penetration, be deleted, as these are discussed in C.11 and C.12, respectively. [ECON1-12]

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**NRC Response:** The NRC agrees that the draft guide was confusing. The final RG was reorganized to improve the information flow. The detailed and simplified approaches were moved to separate appendices.

**Comment:** Add the following in the first sentence in C4: “. . . utilize integrated models to evaluate strainer and downstream system performance, including the following submodels for . . .” [STP2-26, SNC2-7]

**NRC Response:** The NRC agrees with this comment and has clarified the RG as appropriate.

**Comment:** The end of the sentence in C.13.f is “and analogies of . . .” Complete the sentence to indicate the scope of acceptable bases for the penetrated debris effects model. [STARS2-8, PWROG2-30]

**NRC Response:** The NRC agrees and completed the sentence: “and analogies of similar systems and models.”

**Comment:** In the References, add, “Generic Safety Issue (GSI)-191, Assessment of Debris Accumulation on PWR Sump Performance,” which is discussed in Section B on page 3. [STARS2-14, STP2-96]

**NRC Response:** The NRC agrees with the comment and has added this reference.

**Comment:** Consider adding RG 1.177 under “Related Guidance” if changes to the TS are being proposed as part of the risk-informed approach. [STP2-6]

**NRC Response:** The NRC does not agree with the comment because RG 1.177 addresses changes to limiting conditions for operation completion times and changes to surveillance intervals. 10 CFR 50.46c includes requirements for monitoring, reporting, and corrective action, similar to those required for the ECCS analyses. A licensee may request a technical specification related to debris, but this is not within the scope of the RG. No change was made to the RG as a result of this comment.

**Comment:** In C.1: As a minimum, any scenario or group of scenarios meeting all the following four ---. In the second paragraph in same sections, “When the licensee demonstrates, qualitatively or quantitatively ---“does this statement apply to state in third paragraph “As a minimum---“? [STP2-13]

**NRC Response:** The NRC notes that the third paragraph provides an *example* set of screening criteria an analyst might use for the screening allowed in the second paragraph. No substantive

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change was made to the RG as a result of this comment, although the fourth screening criterion was re-worded for clarity.

**Comment:** Paragraph C.9. Allows the user to skip steps C.10. through C.13. while paragraph C.9.a. refers the user to paragraph C.11. It is recommended that the reference to paragraph C.11. in paragraph C.9.a. be deleted. [STP2-43]

**NRC Response:** The NRC disagrees with the comment. The references to the skipped sections are appropriate because these aspects still need to be considered. The NRC agrees that the draft guide was confusing. The final RG was reorganized to improve the information flow. The detailed and simplified approaches were moved to separate appendices.

**Comment:** In the third paragraph of paragraph C.1, a quote is begun on the first line, and never closed. A close-quote should be added at the appropriate location. [PWROG2-12]

**NRC Response:** The NRC agrees with this comment and has added the "close quote."

**Comment:** In paragraph C.17.c, in the last sentence, consider the following change: "...are addressed by the next element so they do not have to be addressed ..." [PWROG2-13]

**NRC Response:** The NRC incorporated the suggested edit.

**Comment:** In paragraph C.17.d, in the first sentence, consider the following change: "... new common cause failure mechanisms are to be assessed and addressed." [added "to be" before "assessed"] [PWROG2-14]

**NRC Response:** The NRC incorporated the suggested edit.

**Comment:** In the 5th paragraph under "Background," change "In response to GL 2004-02, a number of licensees ..." to "In response to GL 2004-02, most licensees ..." Also change the next sentence "For example, some ..." to "For example, most ..." [ECON1-2, STP2-7] In that same sentence, replace "the debris of which is considered less likely to reach or impede flow through the strainers" with "which is generally less problematic with respect to strainer performance." In the final sentence, change "...validated models for strainer performance operating under complex conditions" to "...validate models for strainer performance under complex operating conditions." [ECON1-2]

**NRC Response:** The NRC disagrees that this editorial change is needed and did not change the RG as a result of this comment.

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**Comment:** Recommend editing the final paragraph in C.4 to say, "Integrated models should account for uncertainty in parameters and phenomenological models, as well as [delete "for"] the frequency of initiating events (e.g., frequency of large break LOCAs) [delete: and intensity of those events (e.g., size of the pipe break causing a LOCA)]." The term "intensity" in this context is not clear, and it is not clear how the size of a pipe break represents intensity. [ECON1-9]

**NRC Response:** The NRC re-wrote the RG section on uncertainty and refers to NUREG-1855 to a great extent.

**Comment:** Recommend editing the first sentence of C.5 to say, "The licensee should develop descriptions of the as-built and as-operated nuclear power plant, including the [delete the parenthetical and "system evaluated by"] phenomenological, physical, and mathematical models identified under Paragraph C.4 of this RG. [ECON1-10]

**NRC Response:** The NRC made the requested change.

**Comment:** In C.9, recommended edits: "This option would not [add "necessarily"] seek to calculate time-dependent flow conditions at the strainer or in the vessel..." "a. The licensee should define a range of [add "debris"] loads, debris types, debris combinations..." [ECON1-17]

**NRC Response:** This sentence was removed from the RG, so the recommended edit was not applicable.

**Comment:** In C.13.b, delete "(g)" after "15 grams:" [ECON1-23]

**NRC Response:** The NRC agrees with this comment and has clarified the RG as appropriate.

**Comment:** In C.13.d: "The licensee should develop a model for [delete "debris penetration"] [insert "downstream"] effects ... In particular, the licensee should properly account for the [delete "fraction of debris ... for the amount of in-vessel] [insert "flow split to containment sprays and the boil-off flow rate when calculating"] debris accumulation [insert "in the core"]. [ECON1-24]

**NRC Response:** The NRC agrees with this comment and has clarified the RG as appropriate.

**Comment:** In C.13.e: "Chemical effects should be considered in the [insert "downstream effects"] evaluation [delete the rest of the sentence]. [ECON1-25]

**NRC Response:** The NRC agrees with this comment and has clarified the RG as appropriate.

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**Comment:** In C.13.f: "The licensee should evaluate the validity of the [delete "penetrated debris"] [insert "downstream"] effects model, relying, for example, on tests, empirical data, and analogies of [insert "other systems"]. [ECON1-26]

**NRC Response:** The NRC agrees with this comment and has clarified the RG as appropriate.

**Comment:** In C.14, editorial change: "The licensee should combine the submodels for ... chemical interactions with debris, debris [delete "strainer"] penetration, and [delete "in-vessel"] [insert "downstream"] effects ..." [ECON1-27]

**NRC Response:** The NRC agrees with this comment and has clarified the RG as appropriate.

**Comment:** In paragraph C.16.c.(4), change "... and tests conditions ..." to "... and test conditions ..." [ECON1-35]

**NRC Response:** The NRC agrees with this comment and has clarified the RG as appropriate.

**Comment:** A citation should be added for "Example Pressurized Water for the Reactor Defense-in-Depth Measures for GSI-191, PWR Sump Performance" in Section C.17.e. [ECON1-36]

**NRC Response:** The NRC notes that the citation is provided when that document is first referred to in the RG; no change was made to the RG as a result of this comment.

**Comment:** In C.20, the following editorial change is suggested: "For example, if a licensee's evaluation credits the removal of [replace "Marinite" with "a problematic type of insulation"], the licensee ..." [ECON1-39]

**NRC Response:** The NRC agrees with this comment and has made this change.

### n. Other Comments

**Comment:** In C.20: SECY-12-0093 required all licensees to report to the NRC staff the chosen methodology that the licensee would voluntarily adopt to address the Generic Regulatory Issue described in GSI-191 and GL 2004-02. Please explain how this does not meet "Backfit" requirements per 10CFR50.109(a)(1). [STP2-95]

**NRC Response:** The NRC has concluded that this comment is not within the scope of the comments requested on the draft regulatory guide. The guidance is simply that. It does not require anything. Since the guidance is not a requirement it cannot be construed as a backfit.

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**Comment:** Both the industry and the NRC need to be assured that a PRA can be successfully integrated with deterministic models that comports with the peer-reviewed PRA modeling approaches. If there are new PRA modeling approaches that are necessary, the existing ASME/ANS PRA Standard may not be adequate to ensure the necessary level of PRA technical adequacy without resources to perform focused PRA peer reviews. A pilot program would identify such issues and suggest solutions. [PWROG2-42]

**NRC Response:** The NRC partially agrees with this comment. Pilot programs can be valuable in identifying issues and good practices associated with new methods or applications of existing methods to new circumstances. The existing PRA guidance is adequate to define high level requirements for the use of PRA in the evaluation of debris effects on long-term cooling such that technical adequacy is assured.

**Comment:** SNC encourages future public meetings to discuss resolution of the industry comments so that the final regulatory guide serves in the best interest of safety with clear guidance for industry and NRC reviewers. [SNC2-1]

**NRC Response:** The NRC agrees that public meetings provide good forums for understanding industry and regulatory concerns with guidance documents. However, the NRC does not anticipate holding further public meetings on the draft guidance or the rule prior to publication.

**Comment:** Based on comments above (particularly in paragraphs C.3, C. 14, C. 15), the PWROG re-iterates that before the NRC proceeds with rule promulgation, a pilot program be established to test the development and potential pitfalls of the risk-informed method. If STP is considered a pilot, STP should be considered a "first principles" pilot. Subsequent pilots, "application pilots," will leverage the analytical and testing work performed by STP in their own NRC RG 1.174-like exemption request submittal. [PWROG2-41]

**NRC Response:** The NRC disagrees with the comment. The comment suggests that the rule should not be promulgated until a pilot program is established to help in understanding how the risk-informed method can be best implemented and that the existing pilot should be a "first principles" pilot. The NRC has concluded that adequate information regarding methods for implementing the risk-informed solution have been learned from the initial pilot program. It is unlikely that additional lessons will be learned that will significantly improve the implementation of the risk-informed solution.

**Comment:** In paragraph C.2, while it seems reasonable to identify debris-related failure modes for each system, structure and component (SSC) whose success leads to mitigation of the postulated scenarios, the examples provided indicate the need for deterministic, thermal hydraulic calculations. Such calculations could be burdensome, expensive, and/or uncertain. Depending on the results, it is possible that such calculations could obviate the need for a risk-informed approach by showing there are no credible failure modes of the indicated equipment.

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While bounding analysis is permitted, the level of deterministic calculations in this approach could be prohibitive. One approach would be to perform a failure modes and effects analysis (FMEA), which would be more qualitative and likely involve failure modes that could be screened out without a deterministic calculation. The PWROG recommends that the staff discuss the use of this type of an approach in DG-1322. [PWROG2-17]

**NRC Response:** The NRC partially agrees with the comment. Some calculations used in the analysis may be difficult to perform. However the NRC notes that paragraph C.2 does not require thermal hydraulic modeling. Licensees are free to choose the models or methods that are used to evaluate the failure modes. In some cases failure modes may be screened by demonstrating that the failure could not reasonably occur using reasonable assumptions and logic. The NRC has revised the guidance in the section on uncertainty to reflect the fact that the approach described in NUREG-1855 is an acceptable method for determining the appropriate scope and level of detail for a risk-informed analysis.

**Comment:** With the effort needed to develop the deterministic models discussed in paragraphs C.6 and C.7, is there a possibility that the results from these models could obviate the need for a risk-informed model? For example, if the deterministic model(s) shows that only a small amount of debris is transported to the sump (under various LOCA break size and location assumptions), then using the PRA model might be moot. [PWROG2-26]

**NRC Response:** The NRC agrees with this comment. If a licensee develops models that show that the amount of debris that transports to the strainer or downstream components is inconsequential to long-term cooling a risk-informed methodology may not be required. If the licensee models are acceptable to the staff and are developed in accordance with existing guidance or otherwise accepted by the staff and show that long-term cooling is maintained the licensee should exit the risk-informed process and proceed with a deterministic evaluation. In this case, no licensing action should be required. If the assumptions in the licensee models are more realistic and less conservative than the staff guidance for deterministic evaluations allows, the licensee should continue to use the risk-informed approach which requires the evaluation of uncertainty associated with realistic models.

**Comment:** It seems that the risk assessment should be clearly identified as “an addition to” existing engineering design standards. That is, alternative designs should already comply with design standards such as general design criteria. The risk assessment should then provide additional information to help decision makers choose the best (in their judgment) design choice. [ANON1-9]

**NRC Response:** The NRC partially agrees with this comment. A licensee that implements a risk-informed solution may identify the evaluation as an addition to their design standards. The NRC does not envision making this a requirement. The risk assessment is an addition to a

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plants licensing basis and will be documented/referenced in the UFSAR. It is not the intent of the 50.46c rule to require a risk assessment for plants that can deterministically show compliance with the rule. If a licensee determines that changes to the plant are necessary to comply with 50.46c, they may base the changes on deterministic or risk-informed evaluations as long as they are acceptable to the NRC.