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Draft Rule Conceptual Basis and Draft Rule Language for Proposed Rulemaking

Risk-Informed Revision to Emergency Core Cooling Requirements (10 CFR 50.46).

The Nuclear Regulatory Commission (NRC) is making available a draft rule conceptual basis and draft rule language for a new 10 CFR 50.46a and conforming changes to §§ 50.34, 50.46, 50.46a (to be redesignated as 50.46b), 50.109 and 10 CFR Part 50, Appendix A, Criterion 35. The amended regulations would permit power reactor licensees to implement a voluntary risk-informed alternative to the current requirements for analysis of emergency core cooling systems (ECCS) in 10 CFR 50.46. Under this risk-informed alternative, the NRC would establish requirements, in a new 50.46a, which would divide the existing spectrum of LOCA pipe break sizes up to the double-ended rupture of the largest reactor coolant system pipe into two regions. Each region would be subject to different ECCS analysis requirements, commensurate with likelihood of the break.

The availability of the draft rule conceptual basis and draft rule language is intended to inform stakeholders of the current status of the NRC's activities to risk-inform 10 CFR 50.46, but the NRC is not soliciting formal public comments on the information at this time. This early draft rule conceptual basis and draft rule language may be incomplete in one or more respects and may be subject to significant revisions during the rulemaking process. The NRC has scheduled a public meeting for August 17, 2004, at which stakeholders are invited to inform the NRC of possible nuclear power plant modifications that might be sought under such a rule and their associated costs and benefits. The NRC plans to use this information in preparing the regulatory analysis for the proposed rule. The NRC is not soliciting formal public comments on this draft rule conceptual basis and draft rule language. No stakeholder requests for a comment period will be granted at this stage in the rulemaking process. Public comments will be requested on the proposed rule at a later date in accordance with the rulemaking provisions of the Administrative Procedures Act.

The NRC may update the rule conceptual basis or draft rule language periodically. Updated versions will be posted on the NRC rulemaking web site; http://ruleforum.llnl.gov.

Draft Rule Conceptual Basis and Draft Rule Language for Proposed Rulemaking

Risk-Informed Revision to Emergency Core Cooling Requirements (10 CFR 50.46).

Executive Summary

The NRC is proposing to change its requirements for the design and analysis of emergency core cooling systems (ECCS) at nuclear power reactors. Current NRC requirements (§50.46) on the ECCS were established to mitigate the consequences of the worst-case hypothetical accident scenario, which is a loss-of-reactor coolant accident (LOCA) caused by the catastrophic failure of the largest pipe in the reactor coolant system. Engineering and risk studies over the years have shown that the likelihood of such large pipe break accidents is very low. The Commission believes that the current ECCS performance requirements, based on such unrealistic scenarios, result in significant design and operational constraints, and consequently, impose a regulatory burden that is disproportionate with the risk contribution of these events. The proposed revisions to §50.46 are intended to remedy this disproportion by allowing licensees more flexibility in the treatment of low risk LOCAs, and, as a result, greater flexibility in design and operations while still assuring adequate protection of public health and safety.

The NRC's approach to the rule revision is to divide the current LOCA break spectrum into two regions based upon the estimated frequency of occurrence of breaks. Breaks in the more likely region will be subject to the same regulatory requirements as today as well as other qualitative factors. Break areas in the less likely region are judged to be very low in frequency and would be addressed by less rigorous requirements. Licensees will, however, still be required to demonstrate mitigation capability for all break sizes up to and including an area equivalent to the double ended break of the largest pipe in the reactor coolant system using the less rigorous requirements.

A licensee that wishes to adopt the alternative ECCS requirements and make changes to the plant design or operations will be required to submit a risk-informed license amendment for staff review and approval. The amendment must use a probabilistic risk assessment (PRA) to demonstrate that any resulting change in risk is small. The amendment must also show that safety margins are maintained, that defense in depth is maintained, and that a monitoring program is in place that assures that the basis for the proposed changes will be maintained. Licensees who adopt the alternative will also be required to periodically update their PRA to ensure that the effects of cumulative changes on risk are not significant.

Should estimates of LOCA frequency change in the future such that a licensee's basis for changes made under the rule are invalidated, the licensee would be required to make changes to the plant or operations such that compliance is restored. In such cases, the Backfit Rule (10 CFR 50.109) would not apply.

Risk-Informing Rules on Large Break Loss-of-Coolant Accidents

Conceptual Outline for Risk-Informed 10 CFR 50.46

Outline

I. Background

The Commission published a Policy Statement on the Use of Probabilistic Risk Assessment (PRA) on August 16, 1995 (60 FR 42622). In the policy statement, the Commission stated that the use of PRA technology should be increased in all regulatory matters to the extent supported by the state of the art in PRA methods and data, and in a manner that complements the deterministic approach and that supports the NRC's defense-in-depth philosophy. PRA evaluations in support of regulatory decisions should be as realistic as practicable and appropriate supporting data that is not designated as sensitive unclassified information should be publicly available. The policy statement also stated that in making regulatory judgments, the Commission's safety goals for nuclear power reactors and subsidiary numerical objectives should be used with appropriate consideration of uncertainties. In addition to quantitative risk estimates, the defense-in-depth philosophy is invoked in risk-informed decision-making as a strategy to ensure public safety given there exists both unquantified and unquantifiable uncertainty in engineering analyses (both deterministic and risk assessments). The primary need with respect to defense-in-depth in a risk-informed regulatory system is guidance to determine which measures are appropriate and how good these should be to provide sufficient defense-in-depth.

Risk insights can clarify the elements of defense-in-depth by quantifying their benefit to the extent practicable. Although the uncertainties associated with the importance of some elements of defense-in-depth may be substantial, the quantification of the resulting safety enhancement can aid in determining how best to achieve defense-in-depth. Decisions on the adequacy of, or the necessity for elements of defense should reflect risk insights gained through identification of the individual performance of each defense system in relation to overall performance.

To implement the Commission Policy Statement, the NRC developed guidance on the use of risk information for reactor license amendments and issued Regulatory Guide (RG) 1.174. This RG provided guidance on an acceptable approach to risk-informed decision-making consistent with the Commission's policy, including a set of key principles. These principles and their supporting elements include: (1) be consistent with the defense-in-depth philosophy; (2) maintain sufficient safety margins; (3) allowable changes must result in only a small increase in core damage frequency or risk (consistent with the intent of the Commission's Safety Goal Policy Statement); and (4) incorporate monitoring and performance measurement strategies.

II. Rulemaking Initiation

The process described in RG 1.174 is applicable to individual changes to plant licensing bases. As experience with the process and applications grew, the Commission recognized that further development of risk-informed regulation would require changes to the regulations themselves. The application of risk information to support changes to the regulations has been studied extensively by the Commission as documented in SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR Part 50 - 'Domestic Licensing of Production and Utilization Facilities,' " dated December 23, 1998, and SECY-00-0198, "Status Report on Study of Risk-Informed Changes to the Technical Requirements of 10 CFR Part 50 (Option 3) and Recommendations on Risk-Informed Changes to 10 CFR 50.44 (Combustible Gas Control)," dated September 14, 2000. As discussed in these papers, the NRC staff recommended that risk-informed approaches to the technical requirements within Part 50 be developed. The Commission decided to undertake both risk-informed changes to the existing treatment requirements for safety systems and components and changes to the technical requirements of Part 50. A final rule providing risk-informed treatment requirements (10 CFR 50.69) is expected to be published in late 2004. The first risk-informed revision to the technical requirements of Part 50 consisted of changes to the combustible gas control requirements in 10 CFR 50.44; 68 FR 54123 (September 16, 2003).

As part of the Option 3 study of risk-informing technical requirements in Part 50, another topic that NRC staff decided to examine was the requirements for large break loss of coolant accidents (LOCAs) (see SECY-00-0198, SECY-01-0133 and SECY-02-0057). A number of possible changes were considered; including changes to General Design Criteria (GDC) 35 and changes to §50.46 acceptance criteria, evaluation models, and functional reliability requirements. The NRC also proposed to refine previous estimates of LOCA frequency for various sizes of LOCAs to more accurately reflect the current state of knowledge with respect to the mechanisms and likelihood of primary coolant system rupture.

Industry interest in a redefined LOCA was shown by filing of a Petition for Rulemaking (PRM 50-75) by the Nuclear Energy Institute (NEI) in February 2002. Notice of that petition was published in the *Federal Register* for comment on April 8, 2002 (67 FR16654). The petition requested the NRC to amend §50.46 and Appendices A and K to allow an option [to the double-ended rupture of the largest pipe in the reactor system] for the maximum LOCA break size as "up to and including an alternate maximum break size that is approved by the Director of the Office of Nuclear Reactor Regulation." Seventeen sets of comments were received, mostly from the power reactor industry in favor of granting the petition. A few stakeholders were concerned about potential impacts on defense-in-depth or safety margins if significant changes were made to reactor designs based upon use of a smaller break size.

During public meetings, industry representatives expressed interest in a number of possible changes to licensed power reactors resulting from redefinition of the large break LOCA. These include: power uprates; fuel management improvements; elimination of potentially required actions for postulated sump blockage issues; and changes to required number of accumulators, diesel start times, sequencing of equipment, and valve stroke times; among others.

The Commission SRM of March 31, 2003, on SECY-02-0057, approved most of the staff recommendations related to possible changes to LOCA requirements and also directed the NRC staff to prepare a proposed rule that would provide a risk-informed alternative maximum break size. The NRC initially began to prepare a proposed rule responsive to the SRM direction. However, after holding two public meetings the NRC found that there were significant differences between stated Commission and industry interests. The original concept in SECY-98-300 for Option 3 was to make risk-informed changes to technical requirements in all of Part 50. The March 2003 SRM, as it related to LOCA redefinition, preserved design basis functional requirements (i.e., retaining installed structures, systems and components), but allowed relaxation in more operational aspects, such as sequencing of loads. The Commission supported a rule that allowed for operational flexibility, but prohibited risk-informed removal of installed safety systems and components. Stakeholders expressed varying expectations about how broadly LOCA redefinition should be applied and in the extent of changes to equipment that might result, based upon their understanding of the intended purpose of the Option 3 initiative.

Thus, in order to reach a common understanding about the objectives of the LOCA redefinition rulemaking, the NRC staff requested additional direction and guidance from the Commission in SECY-04-0037, "Issues Related to Proposed Rulemaking to Risk-Inform Requirements Related to Large Break Loss-of-Coolant Accident (LOCA) Break Size and Plans for Rulemaking on LOCA with Coincident Loss-of Offsite Power," (March 3, 2004). The Commission provided direction in a SRM dated July 1, 2004. The Commission stated that the staff should determine an appropriate risk-informed alternative break size and that breaks larger than this size should be removed from the design basis event category. The Commission indicated that the proposed rule should be structured to allow operational as well as design changes and should include requirements for licensees to maintain capability to mitigate the full spectrum of LOCAs up to the double-ended guillotine break of the largest reactor coolant system pipe. The Commission stated that the mitigation capabilities for beyond design-basis events should be controlled by NRC requirements commensurate with the safety significance of these capabilities. The Commission also stated that LOCA frequencies should be periodically reevaluated and should increases in frequency require licensees to restore the facility to its original design basis or make other compensating changes, the backfit rule (10 CFR 50.109) would not apply. Regarding the current requirement to assume a loss-of-offsite power (LOOP) coincident with all LOCAs, the Commission directed that the NRC staff first evaluate the Boiling Water Reactor Owners Group pilot exemption request before proceeding with a separate rulemaking on that topic.

III. Planned Action

The Commission is considering an alternative set of risk-informed requirements with which licensees may voluntarily chose to comply in lieu of meeting the current emergency core cooling system requirements in 10 CFR 50.46. Using the alternative ECCS requirements will provide some licensees with opportunities to change other aspects of facility design. The overall structure of the risk-informed alternative is described below. The initial focus for this rulemaking is on operating plants. The Commission does not now have enough information to develop generic ECCS evaluation requirements appropriate to potentially wide versions of new designs for nuclear power reactors. Promulgation of a similar rule applicable to future plants may be undertaken separately, at a later time, as the Commission's understanding of advanced reactor designs increases. The potential rule changes discussed in this document would only apply to nuclear power reactors which currently hold operating licenses.

A. Overview of rule framework

The NRC will establish a risk-informed LOCA break size[1] (smaller than the double-ended guillotine break (DEGB) of the largest reactor coolant system pipe) to divide the current spectrum of LOCA break sizes into two regions. The division between the two regions is delineated by a "transition" break size. Details on selection of the risk-informed LOCA transition break size are presented in Section III.B. The first region includes small pipe breaks up to and including the transition break size. The second region includes breaks larger than the transition break size up to and including the DEGB of largest reactor coolant system pipe. Since pipe breaks in the smaller break size region are considered more likely than pipe breaks in the larger break size region, each region will be subject to different ECCS requirements commensurate with likelihood of the break. Loss-of-coolant accidents in the smaller break size region may be analyzed by the methods, assumptions and criteria presently used for LOCA analysis; accidents in the larger break size region will be analyzed by less stringent methods based on their lower likelihood. Although loss-of-coolant accidents for break sizes larger than the transition break will become beyond design-basis accidents, the NRC would promulgate regulations ensuring that licensees maintain the ability to mitigate all LOCAs up to and including the DEGB of the largest reactor coolant system pipe. Since the NRC would require accident mitigation in the larger break region, these accidents would be separate from severe accidents, which are

[1] Different transition break sizes (diameters) for PWRs and BWRs are being established due to the differences in design between these two types of reactors.

addressed by voluntary industry guidelines. The ECCS requirements for both regions are discussed in Section III.C.

Licensees who perform the new LOCA analyses using the risk-informed alternative requirements may find that their plant designs are no longer limited by certain parameters associated with previous DEGB analyses. Reducing the DEGB limitations could enable licensees to propose a wide scope of design or operational changes up to the point of being limited by some other parameter on any of the required accident analyses. Potential design changes include increasing power, modifying core peaking factors, removing some accumulators from service, eliminating fast starting of one or more emergency diesel generators, etc. Some of these design and operational changes could increase plant safety margins. To ensure that any design and operational changes do not unacceptably reduce plant safety margins or increase risk, the rule will require that any potential increase in risk associated with plant modifications is small and consistent with the Commission's Safety Goal Policy Statement. To this end the risk-informed §50.46 option will establish a design change evaluation process. The evaluation process will generally include the criteria for risk-informed license amendments similar to the criteria contained in Regulatory Guide 1.174. These criteria assure both the acceptability of the changes from a risk perspective and that sufficient defense-in-depth is maintained. The risk evaluation process is described in Section III. D.

The rule would also require that proposed facility changes be reviewed and approved by the NRC via the routine process for risk-informed license amendments[2], including any needed changes to the facility's technical specifications. Potential impacts of the plant changes on facility security would be evaluated as part of the license amendment review process. The plant design change licensing process is discussed in Section III.E.

The NRC will periodically evaluate LOCA frequency information. If estimated LOCA frequencies significantly increase, the NRC will undertake rulemaking (or issue orders, if appropriate) to change the transition break size. In such a case the backfit rule (10 CFR 50.109) would not apply. As the result of changing the transition break size, some licensees may be required to take appropriate action to reduce facility risk to acceptable levels (see Section III.F). In these cases also, the backfit rule (10 CFR 50.109) would not apply.

B. Determination of the transition break size

In SECY-04-0037, the NRC noted that the most appropriate metric for the selection of an alternative maximum break size in lieu of the DEGB specified in §50.46 is the estimated direct LOCA initiating event frequency. In developing a risk-informed approach for ECCS design, the NRC will establish an alternative LOCA break size in lieu of the DEGB. This alternative LOCA break size will define a transition break size (TBS) below which the current 10 CFR 50.46 evaluation requirements will continue to apply and above which a less conservative evaluation

[2] Requirements for license amendments are specified in 10 CFR 50.90. They include public notice of all amendment requests in the *Federal Register*, an opportunity for affected persons to request a public hearing, preparation of an environmental analysis, and a detailed NRC technical evaluation to ensure that the facility will continue to provide adequate protection of public health and safety after the amendment is implemented.

of ECCS adequacy would be permitted up to the DEGB. LOCA analyses for break sizes equal to or smaller than the transition size should be applied to all locations in the reactor coolant system; e.g., for pipes whose inside pipe diameter is larger than the transition break size, breaks up to the transition break size must be analyzed to find the limiting break location. To help establish this transition LOCA break size, the NRC developed LOCA frequencies as a function of break size using an expert elicitation process for generic BWR and PWR passive-system LOCAs. A TBS will be established using these LOCA event frequencies in consideration with other significant contributing factors that were not explicitly addressed in the expert elicitation process. These other factors include consideration of active-system LOCAs, low-frequency events and transients (e.g., large seismic and waterhammer loadings), and externally-induced LOCAs (e.g., heavy-load drop). It is also important to account for uncertainties in the expert elicitation process, plant-specific operating experience and configuration, and possible future changes in plant design characteristics when establishing the transition LOCA break size.

There have been several previous studies documented in WASH-1400, NUREG-1150, and NUREG/CR-5750 that have developed pipe break frequencies as a function of break size. The earliest studies (WASH-1400 and NUREG-1150) suffered from a lack of commercial nuclear operating experience. More recent study (NUREG/CR-5750) only considered the LOCA frequency associated with precursor leaks events and did not separately evaluate the effects of known degradation mechanisms. No previous study comprehensively evaluated the LOCA frequency contributions on non-piping components other than steam generator tube ruptures. Because of these limitations, these earlier studies are not sufficient to develop a TBS for use within 10 CFR 50.46.

In establishing LOCA event frequencies as a function of break size, the NRC used an expert elicitation process with a panel of 12 experts as documented in SECY-04-0060. The LOCA frequency contributions from pipe breaks in the reactor coolant pressure boundary as well as non-piping passive failures were considered in this study. Non-piping passive failure contributions were evaluated in reactor coolant pressure boundary components including the pressurizer, reactor vessel, steam generator, pumps, and valves as appropriate for BWR and PWR plant-types. Total LOCA frequencies under normal operational loading and transients expected over a 60 year reactor operating life have been developed separately for PWR and BWR plant-types. These frequencies represent generic values applicable to the currently operating commercial nuclear reactor fleet. Uncertainty in the frequency estimates and variability among the experts' results were also examined. A number of sensitivity analyses were also conducted to examine the robustness of the LOCA frequency estimates to assumptions made during the analysis of the experts' responses.

The LOCA frequency estimates developed using this process are consistent with operating experience and exhibit trends that are expected based on an understanding of passive system failure processes. This is important because it is expected from the results that the most significant LOCA frequency contribution occurs from degradation-induced precursors such as cracking and wall thinning. The LOCA frequency estimates are also comparable to prior LOCA frequency estimates. However, previous studies (e.g. WASH-1400, NUREG-1150, and NUREG/CR-5750) indicate that the smaller size pipes are one to two orders of magnitude more likely to break than are the largest size pipes. The expert elicitation LOCA frequency results in SECY-04-0060 indicate an even greater difference between small and large breaks. As expected, there is also significant uncertainty associated with the final LOCA frequency estimates due to both individual expert uncertainty and variability among the experts' responses. The estimates also depend on certain assumptions used to process the expert's input. The overall conclusions of the expert elicitation process found that the final LOCA frequency estimates are sensitive to the method used to analyze the panelists' inputs.

Consistent with the Commission SRM on SECY-04-0037 and using the results of the expert elicitation process, the NRC staff selected a pipe break frequency having approximately a 95th percentile probability of 1E-5/reactor year (1 occurrence in 100,000 reactor years) as a starting reference point for the TBS. The expert elicitation process considered only passive system LOCAs under normal operational conditions. It considered neither active-system LOCAs nor other rare event-induced LOCA break frequencies. The NRC is currently assessing the extent to which active-system LOCAs and seismically-induced LOCA break frequencies need to be factored into the results of the expert elicitation process. For active system LOCAs, the NRC will address the differences between BWR and PWR plants for such events as stuck-open relief valves, and failure of motor-operated valves to close under design-basis accident conditions. The NRC is also evaluating the impact of NUREG/CR-3895 that discussed the potential for small-break LOCAs causing a severe waterhammer that might lead to a large-break LOCA.

In addition, the NRC is evaluating the contribution of seismically-induced LOCA frequencies. Classical experiential data, design rules, and laboratory testing demonstrate the robustness of nuclear systems under safe shutdown earthquake loading in undegraded passive component systems. However, passive system failure frequency increases as both the loading severity and the level of degradation increase. Therefore, the NRC is evaluating the impact of expected degradation over plants' operating period on the passive component fragilities. Additionally, the significance of seismic-induced LOCA frequencies due to features uniquely associated with BWR and PWR plants are also being considered. For instance, in PWR plants, the reactor coolant pressure boundary is composed of thick-walled components (e.g., reactor vessel, steam generators, reactor coolant pumps) connected by relatively short lengths of piping in contrast with BWR plants that contain relatively long lengths of piping in the reactor coolant pressure boundary (e.g., main steam, feedwater, and reactor recirculation systems). In addition, the reactor coolant pressure boundaries in BWR plants are susceptible to more known degradation mechanisms (e.g., flow-assisted corrosion, intergranular stress-corrosion cracking, and thermal fatigue). These inherent differences may cause BWR plants to be more susceptible to seismically-induced LOCAs. Other plant-specific factors also play an important role in determining the seismic failure frequency including (1) differences in seismicity at various plant sites, (2) plant response characteristics (i.e., safe-shutdown earthquake stresses in the piping relative to the safe-shutdown earthquake ground accelerations), and (3) margins between linear and non-linear stresses in the piping system. Because of these potentially considerable plant-specific differences and the effect of passive system degradation, the NRC currently cannot conclude that seismically-induced failure frequencies are generically insignificant.

The NRC approach for the selection of the TBS is to use the frequency estimates of various degradation-related pipe breaks as a starting reference. The frequencies for degradation-related breaks represent generic information, broadly applicable for indicating the trend of the frequency as the break size increases. Based on the example provided in the Commission SRM on SECY 04-0037, a target initiating frequency of occurrence of 1E^{-5}/reactor-year is used for the generic TBS selections. As stated above, there are other important considerations in estimating overall frequencies, in addition to the degradation-related frequency estimates, including:

(1) Active LOCAs, such as stuck-open valves and blown out seals or gaskets. Many active LOCAs have a greater frequency of occurrence than that for pipe breaks, but are generally small-break (SB) LOCAs, when considering most components which can fail open or blow out (e.g., safety valves, pump seals). Certain manways have larger gaskets than the seals on pumps, but are captured in recesses that do not allow a large resulting flow area, even if the gasket completely blows out.

(2) Seismically-induced LOCAs, both with and without material degradation. Seismically-induced break frequencies vary from plant to plant due to siting and design considerations and are affected by the amount of degradation occurring prior to postulated seismic events.

(3) Other large loads, including waterhammer. There are usually no significant waterhammer loads that can occur in primary system piping during normal conditions; however, there is one waterhammer scenario which can apparently occur in PWR cold legs following SBLOCAs. This is discussed in detail in NUREG/CR-3895. The NRC is working to better characterize the expected waterhammer and the piping rupture margin.

If any of these considerations are significant (of the same order of magnitude or greater) compared to the degradation-related frequencies, they need to be included in the TBS selections.

Another consideration in making TBS selections is the overall effect they may have in providing an additional level of defense-in-depth, taking into account the uncertainties in predicted break frequencies. For example, specific piping known to have higher-than-normal degradation, including PWR surge lines and BWR feedwater lines should be considered.

Recognizing that the expert elicitation responses were aggregated using several methods to evaluate sensitivities, the NRC made several estimates of the pipe sizes which correspond to a frequency of degradation-related failure of 1E-5/reactor year. For BWRs, to address active-system and externally-induced LOCAs, unexpected events and transients, plant-specific considerations, and other uncertainties, the preliminary TBS selection is 20 inches. This size bounds most of the piping attached to the RCS in BWRs. It also represents a selection providing a significant level of confidence that a $1E^{-5}$/reactor year degradation-related frequency is not exceeded. For PWRs, to address active-system and externally-induced LOCAs, unexpected events and transients, plant-specific considerations, and other uncertainties, the preliminary TBS selection is 14 inches. This size bounds most of the piping attached to the reactor coolant system in PWRs. It also represents a selection providing a significant level of confidence that a $1E^{-5}$/reactor year degradation-related frequency is not exceeded.

It should be noted that seismic loading and waterhammer loading may affect the overall break frequency distributions and could increase the TBSs. The work remaining to complete regarding the final TBS selections includes: incorporating the results of the generic evaluation of seismic margins in primary piping and evaluating the cold leg waterhammer piping margins and vulnerability. The results from this effort are not expected to cause the preliminary TBS to be changed substantially, although some adjustments may be necessary.

C. <u>Alternative ECCS analysis requirements and acceptance criteria</u>

As discussed below, commensurate with the lower frequency of breaks beyond the transition break size, the NRC regulations will relax requirements associated with the rigor and conservatism of the analyses performed to ensure that long-term cooling and a coolable core geometry is maintained in the event of a LOCA**.**

The NRC expects that most PWRs may be able to uprate power, depending upon plant-specific equipment capabilities, such as steam generator capacity. BWRs, which tend not to be LOCA-limited, may not be able to uprate power but may be able to relax technical specifications and reduce analysis as well as operations and maintenance costs.

C.1. Acceptable methodologies and analysis assumptions

NRC requirements in 10 CFR 50.46 state:

> *Each boiling or pressurized light-water nuclear power reactor fueled with uranium oxide pellets within cylindrical zircaloy or ZIRLO cladding must be provided with an emergency core cooling system (ECCS) that must be designed so that its calculated cooling performance following postulated loss-of-coolant accidents conforms to the criteria set forth in paragraph (b) of this section. ECCS cooling performance must be calculated in accordance with an acceptable evaluation model.*...

An evaluation model is defined as:

> ...*the calculational framework for evaluating the behavior of the reactor coolant system during a postulated loss-of-coolant accident (LOCA). It includes one or more computer programs and all other information necessary for application of the calculational framework to a specific LOCA, such as mathematical models used, assumptions included in the programs, procedure for treating the program input and output information specification of those portions of analysis not included in computer programs, values of parameters, and all other information necessary to specify the calculational procedure*.

The currently approved methodologies are either best-estimate analysis tools that realistically describe the behavior and account for modeling uncertainty, as described in paragraph (a)(1)(ii) of the regulation or those that utilize the required and acceptable features established in Appendix K to 10 CFR Part 50. All analysis methodologies must be reviewed and approved by NRC for use by a licensee. The revised rule will not change any of the analysis requirements for breaks in the region up to and including the transition break size.

The worst break size and location in the region beyond the transition break size must be identified and analyzed using an appropriate analysis methodology approved by the NRC. Although preferred, these methodologies need not be currently approved, realistic (best-estimate) evaluation models. Therefore, a licensee may opt to submit a methodology for review and approval for use in analyzing breaks in the region beyond the transition break size. It is expected that the level of conservatism of the methodology would be less than those evaluation models used to analyze breaks in the region up to and including the transition break size, and the level of NRC review would not be as rigorous.

In 10 CFR 50.46, it is required that LOCAs be analyzed assuming the worst single failure and concurrent with LOOP. In addition, only credit for safety systems is permitted. The NRC proposes to retain these restrictions for the region up to and including the transition break size. In the region beyond the transition break size, credit may be taken for operation of any and all equipment supported by availability data, along with use of nominal operating conditions rather than technical specification limits. This would also include use of actual fuel burnup in decay heat predictions and actual operating peaking factors. The most significant difference would be the relaxation of the requirement that a single failure be imposed in the region beyond the transition break size.

As work is finalized on LOCA-LOOP and the technical basis is established, the rule could be amended to offer this relaxation if appropriate.

It is feasible that a licensee may use a best-estimate methodology for analyzing breaks in the region beyond the transition break size, since such methodologies have already been approved for many plants and would yield the most margin. When using a best-estimate methodology, a licensee must evaluate the uncertainty of the calculation.

Currently, 50.46 says, "...*when calculated ECCS cooling performance is compared to the criteria set forth in paragraph (b) of this section, there is a high level of probability that the criteria would not be exceeded*." What constitutes a *high level of probability* has never been delineated in the rule. The position taken in RG 1.157 has been that 95% constitutes an acceptably high probability.

The rule will require a high probability level as the statistical acceptance criteria for breaks in the region up to and including the transition break size. For breaks in the region beyond the transition break size, it is reasonable to reduce the level of probability of predicting conditions within the acceptance criteria. In this case, a probability at a reduced level such as 70% is deemed acceptable.

Reducing the required probability level of capturing the acceptance criteria for the break sizes beyond the transition break size, has an effect similar to allowing higher acceptance criteria at a high probability level. It is just a matter of keeping a consistent set of criteria but using different levels of achieving the criteria. Note that a 70% value of peak cladding temperature (PCT) indicates that the probability of the hot pin in the core exceeding the PCT calculated is 30%—this does not imply that 30% of the core is over the PCT calculated. The amount of core damage is not predicted specifically since it will depend on the peaking factors of the core. The PCT reported is that of the hot pin only. The clad temperature of the average pin is not reported.

C.2. Acceptance criteria

In 10 CFR 50.46(b), licensees are required to demonstrate using an approved methodology that for the limiting LOCA, the following acceptance criteria are met:

PCT of 2200 °F;
maximum local cladding oxidation (MLO) of 17%;
maximum hydrogen production -- core wide cladding oxidation (CWO) of 1%;
maintenance of coolable geometry; and
maintenance of long-term cooling.

The PCT limit is important due to the behavior of cladding oxidation as temperature increases. Temperatures above approximately 2200 °F result in rapid decreases in cladding ductility. As the break size definition for a design basis accident decreases, cladding oxidation becomes more limiting. Small breaks result in extended periods of time at moderate temperatures, in the range of 1800 °F, which can produce oxidation levels as great or greater than short time spans at slightly higher temperatures. The limit on hydrogen production also remains important as the break size decreases for the same reason as retaining the maximum local oxidation limit, that is, long periods and moderately high temperatures cause greater clad oxidation and hydrogen production.

The above acceptance criteria will be maintained for the region up to and including the transition break size. In the region beyond the transition break size, the rule will require:

maintenance of coolable geometry;
maintenance of long-term cooling.

Commensurate with a lower frequency of occurrence, the acceptance criteria are less prescriptive for breaks beyond the transition break size. The PCT and LCO criteria ensure that the clad will be ductile when quenched during a LOCA. Loss of ductility would potentially result in fragmentation of the fuel and loss of a coolable geometry. This change will allow a licensee to submit data or other justification to demonstrate that the core will remain in a coolable geometry in the event of a LOCA. Without submission of adequate justification, the NRC will continue to use the 2200 °F and 17% limits for PCT and LCO, respectively.

C.3. Analysis of record and reporting requirements

In 50.46(a)(3)(i) licensees are required to report to NRC when any single change or error correction results in a change in calculated PCT of 50°F, or the sum of the absolute values of the changes in PCT equals or exceeds 50°F. Reports must be filed on an annual basis, or within 30 days when the above limits are reached. This ensures that the methodology used by the licensee is that reviewed and approved by the NRC, and that the changes made to the plant or operation of the plant do not appreciably change the ECCS response. Once 50 °F is reached, the licensee must submit its analysis for review by NRC.

When the ECCS rule was first promulgated, the industry and the agency did not expect SBLOCAs to be risk-significant. Therefore, the regulations focused on LBLOCA. In LBLOCAs, oxidation is a simple function of temperature. Therefore, oxidation is not expected to change if the calculated PCT does not change. The PCT reporting requirement was adequate to control changes to ECCS analyses. However, in SBLOCAs, time at temperature is just as important as temperature in determining oxidation. An additional reporting requirement will be added such that if the change in the calculated oxidation, or the sum of the absolute values of the changes, equals or exceeds 0.4% oxidation, the change must be reported to the NRC. This makes the oxidation reporting requirement the same on a percentage basis as the current temperature change requirement.

The reporting requirement will be established for the two regions, up to and beyond the transition break size, separately.

D. Determining the adequacy of proposed plant modifications

If a licensee chooses to implement the voluntary option under 10 CFR 50.46(a), structures, systems, and components (SSC) required to mitigate design bases accidents for breaks less than the defined TBS will still need to meet the current 10 CFR 50.46 requirements. SSCs needed to provide mitigative capability for LOCAs with break sizes greater than the TBS will have to meet the new risk-informed criteria. The introduction of the second region with less stringent requirements provides an opportunity for the licensee to improve its design by focusing on the most risk-significant prevention and mitigation areas while reducing the burden in areas where there is less risk. For licensees to take advantage of the optional rule, they must submit for NRC review a description of the proposed plant modifications, the evaluation of the effect of these changes on the plant, and a description of how these modifications meet the criteria listed below.

Changes proposed under this rule must meet the following risk-informed principles:

1) Except as allowed under this rule, the proposed modifications must meet the current regulations unless the changes are explicitly related to a requested exemption (i.e., a “specific exemption” under 10 CFR 50.12).

2) The proposed modifications must retain sufficient defense-in-depth.

3) The proposed modifications must maintain sufficient safety margins.

4) When proposed modifications result in an increase in core damage frequency (CDF) or large early release frequency (LERF), the increases must be small.

5) The effect of the proposed modifications must be monitored using performance measurement strategies.

Each of these principles is to be considered in the risk-informed integrated decision making process. Licensees are expected to implement these issues as follows:

* All safety effects of the proposed modifications are to be evaluated in an integrated manner as part of an overall risk management approach in which the licensee is using risk analysis to improve operational and engineering decisions broadly by identifying and

taking advantage of opportunities to reduce risk and not just to eliminate requirements the licensee sees as undesirable. For those cases when risk increases are proposed, the benefits must be described and be commensurate with the proposed risk increases. The approach used to identify changes in requirements should be used to identify areas where requirements should be increased as well as where they can be reduced.

* Increases in estimated CDF and LERF resulting from proposed plant modifications will be limited to small increments. The cumulative effect of all such changes will be tracked by licensees and considered in the decision making process. Data, methods, and assessment criteria used to support regulatory decisionmaking in a manner consistent with RG 1.174 must be well documented.

Given these principles of risk-informed decision making, licensees are to follow a four-element approach to evaluating the acceptability of proposed changes.

Step 1: Define the proposed change

The licensee must identify those aspects of the plant's design or licensing bases that will be affected by the proposed changes, including but not limited to rules and regulations, final safety analysis report (FSAR), technical specifications, license conditions, and licensing commitments. The NRC will treat all plant modifications made under this rule as a collective change for purposes of comparing the total increase in risk to numerical criteria. The licensee must identify all SSCs, procedures, and activities that are covered by the proposed plant modifications being evaluated and must consider the original reasons for including each program requirement.

In developing the risk information required by this rule and assessing impacts from proposed changes, licensees may identify SSCs that become highly risk significant based on the proposed changes but that are not currently subject to regulatory requirements or that are subject to a level of regulation that is not commensurate with their risk significance. It is expected that licensees will propose plant modifications that will subject these SSCs to an appropriate level of regulatory oversight, consistent with the risk significance of each SSC.

Step 2: Perform engineering analyses

The NRC has developed an approach to analyzing and evaluating proposed plant modifications under this rule. This approach supports NRC's desire to base its decisions on the results of traditional engineering evaluations, supported by insights (derived from use of PRA methods) about the risk significance of the proposed modifications. Decisions concerning proposed changes are to be reached in an integrated fashion, considering traditional engineering and risk information. The scope and quality of the engineering analyses conducted by licensees to justify the proposed plant changes must be appropriate for the nature and scope of the changes. The analyses should reflect the actual design, construction, and operational practices of the plant. Licensees must evaluate proposed plant modifications with regard to assuring that adequate defense-in-depth and safety margins are maintained, and that proposed increases in CDF or LERF are small. The effect of the proposed plant modifications on affected equipment functionality, reliability, and availability must be determined. Appropriate consideration of uncertainty must be given in analyses and interpretation of findings, including using a monitoring program, feedback, and corrective action to address significant uncertainties.

a. Defense-in-depth

The defense-in-depth philosophy traditionally has been applied in reactor design and operation to provide multiple means to accomplish safety functions and prevent the release of radioactive material. It has been and continues to be an effective way to account for uncertainties in equipment and human performance. The evaluation must consider the effect of the proposed plant modifications on barriers (both preventive and mitigative) to core damage, containment failure or bypass, and the balance among defense-in-depth attributes. Maintenance of adequate defense-in-depth for operating nuclear power plants is an important part of the foundation for the protection of public health and safety. The NRC considers that consistency with the philosophy of defense-in-depth is maintained if the following are met:

* A reasonable balance is preserved among prevention of core damage, prevention of containment failure (early and late), and consequence mitigation.

* Over-reliance on programmatic activities to compensate for weaknesses in plant design is avoided.

* System redundancy, independence, and diversity are preserved commensurate with the expected frequency, consequences of challenges to the SSC, and uncertainties.

* Defenses against potential common cause failures are preserved, and the potential for the introduction of new common cause failure mechanisms is assessed.

* Independence of barriers is not degraded.

* Defenses against human errors are preserved.

* The intent of the GDC in Appendix A to 10 CFR Part 50 is maintained.

For break sizes above the TBS, the proposed revision to 10 CFR 50.46 would allow credit for all injection trains in demonstrating successful accident mitigation (i.e., meeting the ECCS criteria in 10 CFR 50.46a), due to the low frequency of the very large pipe breaks and the reliability of the emergency core cooling systems.

The NRC believes that credit for all trains (i.e., analysis of the LOCA without assumption of a single train failure for break sizes larger than the TBS) would be justified by risk calculations that show the effect on CDF and LERF to be low for any and all proposed plant modifications under this rule. However, the insights of this risk calculation are largely driven by the low initiation frequency now assumed for these break sizes, and the insights do not directly address considerations of uncertainty and the remaining effect on defense-in-depth and safety margins, since there will be some periods where the success criteria will not be met for these LOCAs (i.e., one ECCS train will not be available due to planned maintenance or random failure). During these periods when the full ECCS complement is not available, it is possible that LOCAs larger than the TBS could lead to core damage. To assure that sufficient safety margin remains with respect to a severe accident that would result in significant offsite consequences, for defense-in-depth purposes a licensee must also ensure that the combination of a LOCA break size larger than the TBS and a failure (such as the failure of an ECCS train to inject) would not be expected to result in significant challenge to the reactor vessel and the containment. This analysis would be reviewed by NRC as part of the justification for defense-in-depth. It is expected that severe accident evaluation methods currently being employed by the industry and NRC would be adequate to perform such evaluations.

b. Safety margins

The engineering evaluation should assess whether the impact of the proposed change is consistent with the principle that sufficient safety margins are maintained. The licensee is expected to choose the method of engineering analysis appropriate for evaluating whether sufficient safety margins would be maintained if the proposed change were implemented. An acceptable set of guidelines for making that assessment is summarized below. Other equivalent acceptance guidelines may also be used. Sufficient safety margins are maintained if:

* Codes and standards or their alternatives acceptable to the NRC are met for risk-significant SSCs needed to prevent or provide mitigative capability for LOCAs greater than the TBS.

* Safety analyses include sufficient margin to account for analysis and data uncertainty.

c. Numerical acceptance criteria

The risk-acceptance criteria herein are based on principles and expectations for risk-informed regulation as described in RG 1.174. Part of those principles and expectations is that the effect of the changes proposed can be measured in a quantitative manner, hopefully in a realistic manner, but if not, then in a conservative one. If proposed changes are not directly modeled in a licensee's PRA, then the PRA should be modified to reflect the design feature, or it should be demonstrably shown that the proposed change has, at worst, no or only a very small negative effect on core damage frequency, equipment reliability, containment failure, and emergency planning.

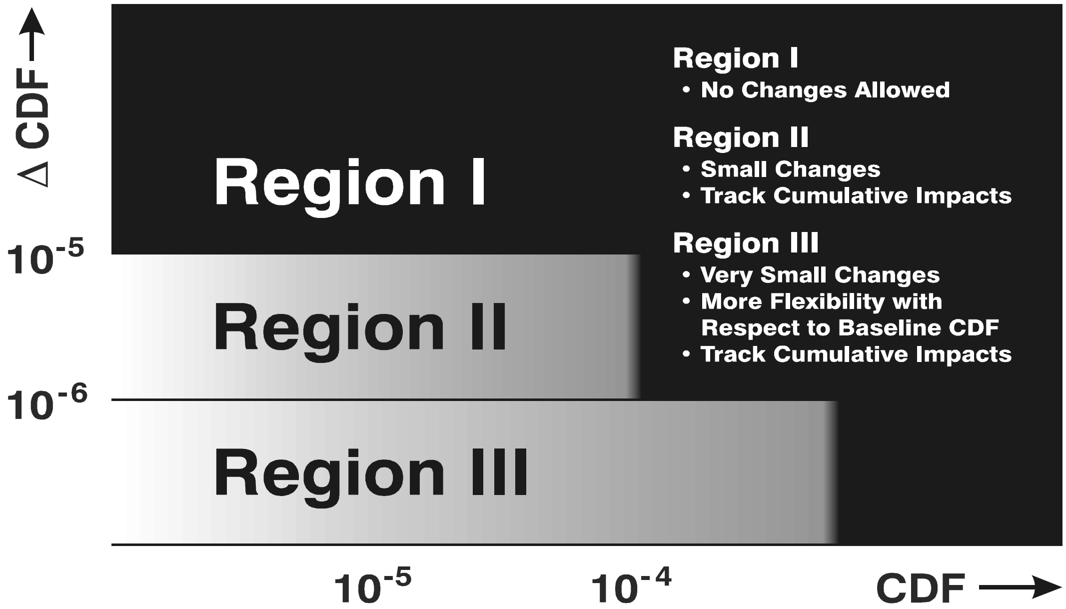

Figure 1. Acceptance Criteria* for Core Damage Frequency (CDF)

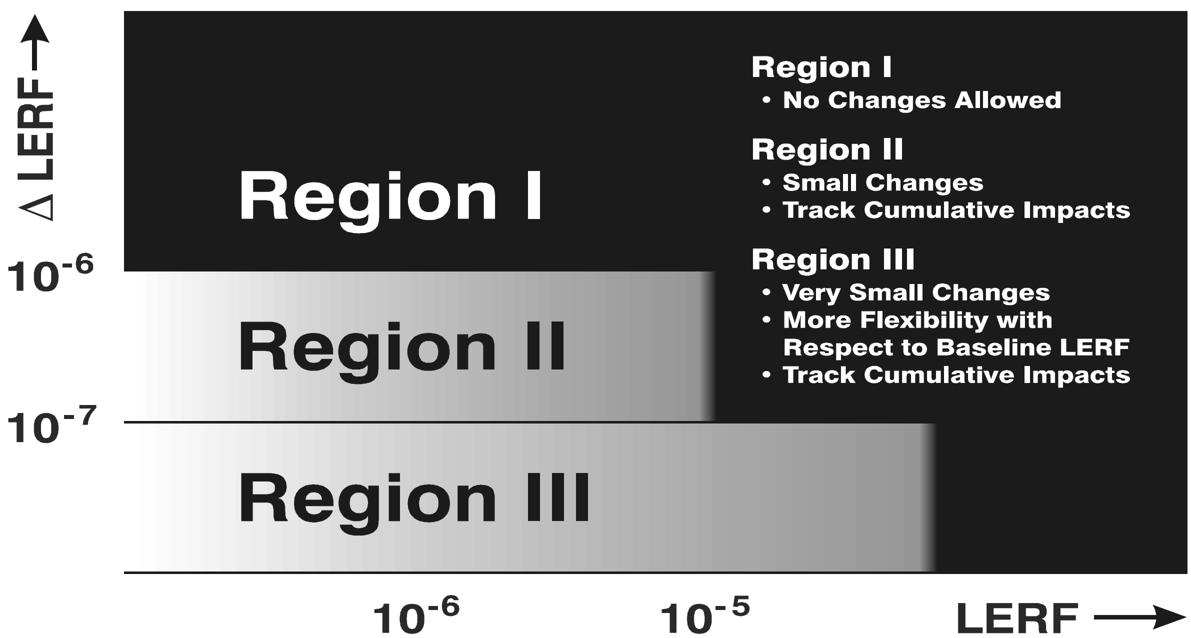

Figure 2 Acceptance Criteria* for Large Early Release Frequency (LERF)

* The analysis will be subject to increased technical review and management attention as indicated by the darkness of the shading of the figure.

As illustrated in Figures 1 and 2, there are two sets of numerical acceptance criteria, one based on CDF and one for LERF. Both sets are applicable:

* If the application clearly can be shown to result in a decrease in CDF, the proposed plant modification will be considered to have satisfied the relevant principle of risk-informed regulation with respect to CDF. The NRC will carefully evaluate proposed plant modifications where the effects of plant modifications are traded off against each other (e.g., plant modifications leading to CDF decreases are paired with plant changes leading to CDF increases), especially in situations where large uncertainties exist.

* When the calculated total increase in CDF from all plant modifications proposed under this regulation is very small (i.e., less than $1x10^{-6}$ per reactor year), the proposed plant modifications will be considered regardless of the calculation of the total CDF (Region III).

* When the calculated total increase in CDF from all plant modifications proposed under this regulation is in the range of $1x10^{-6}$ to $1x10^{-5}$ per reactor year, applications will be considered only if it can be reasonably shown that the total CDF is less than $1x10^{-4}$ per reactor year (Region II) .

* When the calculated total increase in CDF from all plant modifications proposed under this regulation is greater than $1x10^{-5}$ per reactor year, the proposed plant modifications normally would not be considered by the NRC (Region I).

AND

* If the application clearly can be shown to result in a decrease in LERF, the proposed plant modification will be considered to have satisfied the relevant principle of risk-informed regulation with respect to LERF. The NRC will carefully evaluate proposed plant modifications where the effects of plant modifications are traded off against each other (e.g., plant modifications leading to LERF decreases are paired with plant modifications leading to LERF increases), especially in situations where large uncertainties exist.

* When the calculated total increase in LERF from all plant modifications proposed under this regulation is very small (i.e., less than $1x10^{-7}$ per reactor year), the proposed plant modifications will be considered regardless of the calculation of the total LERF (Region III).

* When the calculated total increase in LERF from all plant modifications proposed under this regulation is in the range of $1x10^{-7}$ to $1x10^{-6}$ per reactor year, applications will be considered only if it can be reasonably shown that the total LERF is less than $1x10^{-5}$ per reactor year (Region II).

* When the calculated total increase in LERF from all plant modifications proposed under this regulation is greater than $1x10^{-6}$ per reactor year, the proposed plant modifications would not normally be considered by the NRC (Region I).

These acceptance guidelines provide assurance that the proposed increases in CDF and LERF are small and are consistent with the intent of the Commission's Safety Goal Policy Statement. Plant modification requests will be subject to an NRC technical and management review that will become more intensive when the calculated results are closer to region boundaries.

Early containment failure is addressed with the LERF guidelines but late containment failure has been addressed in most current risk-informed applications under the defense-in-depth guidelines. Because of the potential range of changes that may be permitted by this rulemaking, the NRC may request additional quantitative information on late containment failure from the licensee to support the resolution of the qualitative defense-in-depth guidelines.

The criteria above are applicable for full power, low power, and shutdown operation for both internal and external events. However, during certain shutdown operations when the containment function is not maintained, the LERF criterion as defined above is not practical. In those cases, licensees may use more stringent baseline CDF criteria to maintain an equivalent risk profile or may propose an alternative criterion to LERF that meets the intent that proposed modifications result in, at most, a small increase in CDF or risk, consistent with the Commission's Safety Goal Policy Statement.

Licensees are responsible for determining the effect that proposed plant modifications would have on important risk-informed decisions made previously. The basis for this includes American Society of Mechanical Engineers (ASME) "Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications," ASME RA-S-2002, December 5, 2003, which states that a process shall exist to evaluate the impact of a PRA change on previously implemented risk-informed decisions that relied upon PRA information and that affect the safe operation of the plant. The NRC had no objection to this requirement in its review of the ASME Standard described in RG 1.200. Therefore, a licensee must evaluate the effect that implementation of proposed plant modifications will have on risk-informed licensing actions previously approved by the NRC. If the risk-informed decisions were adversely affected, the licensee must remedy the concerns based on the implementation and monitoring program associated with each risk-informed licensing action.

d. Additional requirements

Separate from 10 CFR 50.46, using a TBS instead of the rupture of the largest pipe in the reactor coolant system can affect several other rules, technical specifications, regulatory issues and other aspects of the design and operation of a plant (e.g., structural requirements for containment and piping, operating procedures, emergency operating procedures, evacuation plans, equipment surveillance and maintenance, and alarm setpoints). The NRC has determined that constraints must be placed on proposed plant modifications to assure that engineering principles and safety margins are retained consistent with risk-informed decision making. The NRC, after considering the underlying uncertainties in the estimated frequency of rare events, the inherent uncertainties associated with both engineering evaluations and the underlying assumptions of the revised §50.46, has identified certain plant design capabilities and operational characteristics that should not be changed or might be adversely affected through implementation of the alternative requirements to §50.46. The staff has identified several criteria for evaluating the acceptability of proposed changes to the facility and operating procedures, and are as follows:

- The proposed changes do not eliminate the capability to mitigate LOCAs larger than the TBS up to and including the double-ended rupture of the largest pipe in the reactor coolant system.

- The proposed changes do not significantly increase the frequency (or uncertainty in the frequency) of LOCAs in a manner as to alter the basis for selection of the transition break size.

- The proposed changes do not introduce new degradation mechanisms or significantly increase the likelihood or effects of known degradation mechanisms on the RCS pressure boundary.

- The proposed changes do not reduce the likelihood of detecting RCS pressure boundary degradation in plants.

In the course of developing the final §50.46 rule, the NRC will identify any additional plant design or operational characteristics that will not be allowed to be changed through the revised §50.46 process. At this time, the NRC envisions that certain facility and procedure changes may be allowed, whereas others may not be consistent with the rule concept. NRC will be soliciting comments on anticipated uses of the revised §50.46 rule and specific examples of facility and procedure changes that might be proposed.

Licensees should not propose changes to plant equipment and operating practices that do not satisfy the risk-informed acceptance criteria specified in the proposed rule in conjunction with the implementation of the proposed risk-informed ECCS rule. The details for determining the adequacy of proposed plant modifications resulting from implementation of the risk-informed ECCS rule are discussed in Section d (Step 2) above. The risk-informed acceptance criteria include the need to maintain defense-in-depth and adequate safety margins. Examples of regulatory requirements necessary to maintain defense-in-depth would include, but not be limited to, assuring containment integrity.

The revised regulations will require that proposed plant modifications do not eliminate the capability to mitigate LOCAs larger than the TBS up to the double-ended rupture of the largest pipe in the reactor coolant system. Changes in margins associated with mitigating the rupture of the largest pipe in the reactor coolant system may be acceptable whereas changes that eliminate the capability to mitigate the rupture of the largest pipe in the reactor coolant system would not be acceptable. For example, containment spray flow rate might be adjusted based on the transition break size, but the function should not be eliminated.

The revised regulations will also require that proposed plant modifications do not significantly increase pipe break frequency estimates. This would generally include changes that significantly affect the basis for estimates generated during the expert elicitation (Reference SECY-04-0060 dated April 13, 2004, ADAMS Accession Number ML040860129). For example, the expert elicitation panel did not consider the effects of power uprates in deriving the break frequency estimates. The NRC is considering the potential impact of power uprates on break frequency estimates and will address this issue further. Another example of a change that might significantly increase break frequency estimates is modification of the repair/replacement requirements of 10 CFR 50.55a.

The revised regulations will also require that the proposed plant modifications do not reduce the likelihood of detecting piping or RCS boundary degradation. Examples of changes that could be considered unacceptable based on these criteria include significantly reducing inservice inspection requirements of 10 CFR 50.55a(g).

Proposed changes using this option to 10 CFR 50.46 that satisfy the risk-informed acceptance criteria specified in the proposed rule would generally be found acceptable to the Commission. For example, certain changes to technical specification requirements might be acceptable, such as:

- Containment isolation valve closure time might be increased.
- Emergency service water flow to the containment air coolers might be reduced.
- Inservice testing acceptance criteria for the containment spray pumps might be relaxed (e.g., allowing a ±2% instrument accuracy for comprehensive pump test instead of requiring ±½%)

e. Comparisons with numerical acceptance criteria

The different regions of the acceptance criteria require different depths of analysis. Changes resulting in a net decrease in the CDF and LERF estimates do not require an assessment of the calculated baseline CDF and LERF. Sometimes, it may be possible to demonstrate on the basis of an understanding of the contributors and the changes that are being made that the overall effect is indeed a decrease, without the need for a detailed quantitative analysis. However, in many instances more detailed quantitative assessments may be required to demonstrate that the proposed change in risk is a risk reduction.

To demonstrate compliance with the numerical criteria, the level of detail required in the assessment of the values and the analysis of uncertainty related to model and incompleteness issues will depend on both (1) the plant modifications being considered and (2) the importance of the demonstration that increases in CDF and LERF are small. The closer the estimates of CDF or LERF are to their corresponding acceptance criteria, the more detail will be required. In a contrasting example, if the estimated value of a particular metric is very small compared to the acceptance criteria, a simple bounding analysis may suffice with no need for a detailed uncertainty analysis.

Because of the way the acceptance criteria were developed, the appropriate numerical measures to use in the initial comparison of the PRA results to the acceptance criteria are mean values. The mean values referred to are the means of the probability distributions that result from the propagation of the uncertainties on the input parameters and those model uncertainties explicitly represented in the model. While a formal propagation of the uncertainty is the best way to correctly account for state-of-knowledge uncertainties that arise from the use of the same parameter values for several basic event probability models, under certain circumstances, a formal propagation of uncertainty may not be required if it can be demonstrated that the state-of-knowledge correlation is unimportant. This will involve, for example, a demonstration that the bulk of the contributing scenarios (cutsets or accident sequences) do not involve multiple events that rely on the same parameter for their quantification.

The NRC will allow flexibility in how a licensee demonstrates it meets the acceptance criteria, if it can be shown that there are important unquantified benefits that are not reflected in the quantitative risk results. However, care should be taken that there are no unquantified detrimental impacts from the proposed changes, such as an increase in operator burden. In addition, if compensatory measures are proposed to counter the impact of the major risk contributors, even though the impact of these measures may not be estimated numerically, such arguments will be considered in the decision process.

f. PRA requirements

The criteria above are applicable to the sum of risk contributors from full power, low power, and shutdown operation for both internal and external events. Licensees must calculate or address changes in risk estimates to compare to the above criteria for all plant modifications implemented as a result of the 10 CFR 50.46 rulemaking. The PRA to be used to estimate the change in risk associated with proposed plant modifications shall have the following characteristics;

> Address initiating events from sources both internal and external to the plant and for all modes of operation, including low power and shutdown modes that could change the regulatory decision substantially (Plants using risk assessment methods other than PRAs (e.g., the Fire-Induced Vulnerability Evaluation (FIVE) fire methodology) would need to justify that the methods used produce realistically conservative numerical results);
>
> Calculate both core damage frequency and large early release frequency;
>
> Reasonably represent the current configuration and operating practices at the plant;
>
> Be of sufficient technical adequacy and level of detail to provide confidence that the change in risk estimate (and total CDF and LERF as required) adequately reflects the plant and the impact of the proposed plant modifications on risk.

The technical adequacy of the plant-specific PRA will be assessed by the NRC taking into account appropriate standards and peer review results. The NRC has prepared a regulatory guide (RG 1.200) on determining the technical adequacy of PRA results for risk-informed activities and has issued the regulatory guide for trial use. RG 1.200 is intended to reflect and endorse guidance provided by consensus standards committees and nuclear industry organizations. ASME published ASME RA-S-2002, "Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications" (April 5, 2002), and Addenda A to this standard (ASME RA-Sa-2003, December 5, 2003). The NRC staff has reviewed ASME RA-S-2002 and the changes noted in ASME RA-Sa-2003 against the characteristics and attributes for a technically acceptable PRA and provided the staff's position on each requirement in Appendix A in RG 1.200. As consensus standards and related industry programs become available for external events, internal fires, and low power and shutdown modes, these standards and the staff's position on the requirements will be incorporated into RG 1.200. Additional guidance on PRA quality attributes specific to implementation of the new 10 CFR 50.46 rule will be addressed in the RG developed for final rule issuance.

The current schedule for completion of the consensus standards and endorsement by the NRC indicates that the standards on internal fire and low power and shutdown will be endorsed no earlier then 2006. This schedule may be delayed. On December 18, 2003, the Commission provided a SRM regarding stabilizing PRA quality expectations and requirements. In the SRM, the Commission approved implementation of a phased approach to achieving an appropriate quality for PRAs for NRC's risk-informed regulatory decisionmaking. The phased approach was described in an attachment to the SRM and the NRC staff was directed to develop a plan to implement the phased approach. The staff will provide a plan to the Commission detailing the proposed approach. PRA quality treatment for implementation of the revised 10 CFR 50.46 rule will be consistent with the phased quality approach.

The phased approach is needed because not all the guidance documents defining PRA quality are currently available for all the risk contributors. The approach lays out a path, in a phased manner, how risk-informed applications can be implemented while the needed guidance documents defining PRA quality for the risk contributors are developed. Each application will be evaluated against the phased approach path based on the changes being proposed and the scope and quality of the PRA. NRC review will become more focused, and the NRC's confidence in the use of the baseline PRA model to support an application will be greater when the PRA standards and guidance exist for the defined PRA scope for an application. When PRA standards or guidance do not exist for the defined PRA scope or application, the NRC review to achieve the same level of confidence will be more resource intensive. It should be expected that those NRC reviews that are more resource intensive will also take longer to complete.

Plants using risk assessment methods other than PRAs (e.g., FIVE fire methodology) would need to justify that the methods used (1) produce realistically conservative numerical results and appropriate safety insights compared to full-scope PRAs and use sufficiently conservative risk assessments in their delta risk calculation, (2) justify that the method is capable of accurately determining the expected change in CDF or LERF, or (3) justify that the absence of probabilistic risk assessment modeling for this initiator would have no significant effect on the numerical results and insights about the adequacy of the proposed plant changes.

As standards are developed and endorsed, it is expected that the licensee will use a PRA that conforms to those quality standards. If a licensee's base PRA does not conform to the existing endorsed PRA standards for the specific application for the risk-significant contributors, but addresses these contributors by other means (e.g., qualitative arguments or reliance on unquantified compensatory measures), a more extensive NRC review will be implemented. An alternative to extensive NRC review, if standards do not exist or if alternative methods are selected, would be to modify the proposed change to limit the impact of the change to initiators and plant operating modes for which standards exist. The PRA quality plan will define a process with which to schedule and prioritize the reviews of submittals according to how they conform to existing guidance.

g. Uncertainty and methods of analysis

The intent of comparing the PRA results with the acceptance guidelines is to demonstrate with reasonable assurance that when proposed modifications result in an increase in CDF or LERF, the increases are small. This decision must be based on a full understanding of the contributors to the PRA results and the impacts of the uncertainties, both those that are explicitly accounted for in the results and those that are not.

Because they are generally characterized and treated differently, it is useful to identify three classes of uncertainty that are addressed in and impact the results of PRAs: parameter uncertainty, model uncertainty, and completeness uncertainty. Completeness uncertainty can be regarded as one aspect of model uncertainty, but because of its importance, it is discussed separately.

Parameter uncertainties are those associated with the values of the fundamental parameters of the PRA model, such as equipment failure rates, initiating event frequencies, and human error probabilities that are used in the quantification of the accident sequence frequencies. They are typically characterized by establishing probability distributions on the parameter values. It is straightforward and within the capability of most PRA codes to propagate the distribution representing uncertainty on the basic parameter values to generate a probability distribution on the results.

The development of the PRA model is supported by the use of models for specific events or phenomena. In many cases, the industry's state of knowledge is incomplete, and there may be different opinions on how the models should be formulated. For some issues with well-formulated alternative models, PRAs have addressed model uncertainty by using discrete distributions over the alternative models, with the probability associated with a specific model representing the analyst's degree of belief that the model is the most appropriate.

Another approach to addressing model uncertainty has been to adjust the results of a single model through the use of an adjustment factor. However it is formulated, an explicit representation of model uncertainty can be propagated through the analysis in the same way as parameter uncertainty. More typically, however, particularly in the Level 1 analysis, the use of different models would result in the need for a different structure (e.g., with different thermal hydraulic models used to determine success criteria). In such cases, uncertainties in the choice of an appropriate model are typically addressed by making assumptions adopting a specific model.

The effect of using alternative assumptions or models may be addressed by performing appropriate sensitivity studies, or they may be addressed using qualitative arguments, based on an understanding of the contributors to the results and how they are impacted by the change in assumptions or models. The impact of making specific modeling approximations may be explored in a similar manner.

Completeness is not in itself an uncertainty, but a reflection of scope limitations. The result is, however, an uncertainty about where the true risk lies. The issue of completeness of scope of a PRA can be addressed for those scope items for which methods are in principle available, and therefore some understanding of the contribution to risk exists, by supplementing the analysis with additional analysis to enlarge the scope, using more restrictive acceptance criteria, or by providing arguments that, for the application of concern, the out-of-scope contributors are not significant.

While the analysis of parametric uncertainty is fairly mature, and is addressed adequately through the use of mean values, the analysis of the model and completeness uncertainties cannot be handled in such a formal manner. Whether the PRA is full scope or only partial scope, and whether it is only the change in metrics or both the change and baseline values that need to be estimated, it will be incumbent on the licensee to demonstrate that the choice of reasonable alternative hypotheses, adjustment factors, or modeling approximations or methods to those adopted in the PRA model would not significantly change the assessment. This demonstration preferably would take the form of well formulated sensitivity studies, but qualitative arguments may be acceptable. In this context, "reasonable" is interpreted as implying some precedent for the alternative, such as use by other analysts, and also that there is a physically reasonable basis for the alternative. It is not the intent that the search for alternatives should be exhaustive and arbitrary. For the decisions that involve only assessing the change in metrics, the number of model uncertainty issues to be addressed will be smaller than for the case of the baseline values, when only a portion of the model is affected. The alternatives that would drive the result toward unacceptableness should be identified and sensitivity studies performed or reasons given as to why they are not appropriate for the current application or for the particular plant. In general, the results of the sensitivity studies should confirm that the criteria are still met even under the alternative assumptions. Alternatively, this analysis can be used to identify candidates for compensatory actions or increased monitoring. The licensee should pay particular attention to those assumptions that impact the parts of the model being exercised by the proposed changes. Again, the NRC emphasizes that all significant elements of uncertainty be appropriately considered and justified in the licensee's assessment of the proposed plant changes arising from implementation the revised §50.46 rule.

Step 3: Define implementation and monitoring program

Careful consideration should be given by licensees to implementation and performance monitoring strategies. The primary goal for this element is to ensure that no adverse safety degradation occurs because of the plant modifications made under this rule. Therefore, an implementation and monitoring plan must be developed by licensees to ensure that the reliability and availability of SSCs upon which the acceptable change in risk estimates are based continues to reflect the actual reliability and availability. This will help ensure that the conclusions that have been drawn from the engineering evaluations remain valid.

The NRC requires licensees to establish monitoring programs that include a means to adequately track the performance of equipment that, when degraded, can affect the conclusions of the licensee's engineering evaluation and integrated decisionmaking that support the proposed plant modifications. The program should be capable of trending equipment performance after a change has been implemented to demonstrate that performance is consistent with that assumed in the traditional engineering and probabilistic analyses that were conducted to justify the change. This may include monitoring associated with non-safety-related SSCs, if the analysis determines those SSCs to be risk significant. The program should be structured such that (1) SSCs are monitored commensurate with their safety importance (i.e., monitoring for SSCs categorized as having low safety significance may be less rigorous than that for SSCs of high safety significance, (2) feedback of information and corrective actions are accomplished in a timely manner, and (3) degradation in SSC performance is detected and corrected before plant safety can be compromised. The potential effect of observed SSC degradation on similar components in different systems throughout the plant must be considered.

The NRC expects licensees will integrate their monitoring for risk-informed changes with existing programs for monitoring equipment performance and other operating experience on their site and throughout the industry. In particular, monitoring that is performed in conformance with the Maintenance Rule can be used when the monitoring performed under the Maintenance Rule is sufficient for the SSCs affected by the risk-informed application. If the application requires monitoring of SSCs that are not included in the Maintenance Rule, or have a greater resolution of monitoring than the Maintenance Rule, it may be advantageous for a licensee to adjust the Maintenance Rule monitoring program rather than to develop additional monitoring programs for risk-informed purposes. In these cases, the performance criteria chosen should be shown to the NRC to be appropriate for the application in question. When actual conditions cannot be monitored or measured, whatever information most closely approximates actual performance data should be used. For example, establishing a monitoring program with a performance-based feedback approach may combine some of the following activities:

* Monitoring performance characteristics under actual design basis conditions (e.g., reviewing actual demands on emergency diesel generators, reviewing operating experience)

* Monitoring performance characteristics under test conditions that are similar to those expected during a design basis event

* Monitoring and trending performance characteristics to verify aspects of the underlying analyses, research, or bases for a requirement (e.g., measuring battery voltage and specific gravity, inservice inspection of piping)

* Evaluating licensee performance during training scenarios (e.g., emergency planning exercises, operator licensing examinations)

* Component quality controls, including developing pre- and post-component installation evaluations (e.g., environmental qualification inspections, reactor protection system channel checks, continuity testing of boiling water reactor squib valves).

As part of the monitoring program, it is important that provisions for specific cause determination, trending of degradation and failures, and corrective actions be included. Such provisions should be applied to SSCs commensurate with their importance to safety as determined by the engineering evaluation that supports the proposed changes. A determination of cause is needed when performance expectations are not being met or when there is a functional failure of an application-specific SSC that poses a significant condition adverse to performance. The cause determination should identify the cause of the failure or degraded performance to the extent that corrective action can be identified that would preclude the problem or ensure that it is anticipated prior to becoming a safety concern. It must address failure significance, the circumstances surrounding the failure or degraded performance, the characteristics of the failure, and whether the failure is isolated or has generic or common cause implications.

Finally, in accordance with Criterion XVI of Appendix B to 10 CFR Part 50, the monitoring program must identify any corrective actions to preclude the recurrence of unacceptable failures or degraded performance. The circumstances surrounding the failure may indicate that the SSC failed because of adverse or harsh operating conditions (e.g., operating a valve dry, over-pressurization of a system) or failure of another component that caused the SSC failure. Therefore, corrective actions must also consider SSCs with similar characteristics with regard to operating, design, or maintenance conditions. The results of the monitoring need not be reported to the NRC, but should be retained onsite for inspection.

a. Cumulative risk monitoring

As part of evaluation of risk, licensees must understand total plant risk and the effects of the applications made under this rule. In addition to being able to estimate total plant risk, licensees are responsible for tracking total changes in risk (both quantifiable and nonquantifiable) that are due to plant modifications made under this rule to account for the cumulative and synergistic effects of these plant changes. This is consistent with the guidance endorsed by NRC in RG 1.174. A licensee's submittal should include the following:

* the calculated change in risk (total and individual) for all plant modifications made under this rule;

* qualitative arguments that were used to justify the change (if any) and the plant elements affected by these arguments; and

* compensatory measures or other commitments used to help justify the change (if any) and the major plant elements affected.

A discussion should be provided of whether the proposed changes are already included in the base PRA model.

b. Effect of future plant changes on acceptability of §50.46a modifications

Plant modifications currently can be made by licensees using a number of processes (e.g., 50.59, 50.90), only some of which are risk-informed. It is possible that changes made both under risk-informed and non-risk-informed processes eventually could undermine the assumptions underlying the NRC's finding that plant modifications proposed under 10 CFR 50.46 are acceptable (e.g., at this time there is no limit under RG 1.174 to the total differential increase in CDF that a licensee could accrue from successive plant modification proposals under 50.90). Similarly, reliability or availability of SSCs may degrade over time in such a manner that in conjunction with other plant modifications the NRC might not approve the same modifications if they were proposed for the as-operated plant. Therefore, the NRC requires that licensees track plant modifications that could affect plant risk and periodically update their PRAs (at least every two refueling outages) to determine if the analyses and assumptions underlying the acceptability of plant changes made under §50.46a continue to be met. If it is determined that plant modifications, plant operating experience, or new information (plant-specific or nuclear industry wide) adversely and significantly affect the acceptability of modifications made under this rule, it is the responsibility of the licensee to propose immediate steps to remedy the adverse effect.

c. Risk reassessment and reporting requirements

Each licensee must evaluate the impact of changes to the PRA model with respect to any plant design or operational changes that have been implemented under this rule. This reevaluation shall consider all revisions to the PRA conducted as part of a formal update process. The reevaluation must include, but not be limited to, revisions in analysis methods, model scope, data, modeling assumptions, and modifications to reflect plant design or operational changes.

After completion of a formal PRA update, the licensee shall reassess all changes that have been implemented under this rule to determine if the cumulative changes in core damage frequency and large early release frequency still meet the acceptance criteria. The calculation will be performed with the updated PRA model to determine both the individual and cumulative impacts of the changes implemented. This shall be accomplished by determining a new baseline risk in the updated PRA model when the plant changes implemented as part of this rule are removed.

As part of the PRA update, the licensee will determine the cumulative changes in CDF and LERF. If either the cumulative differential CDF or LERF increase by 20% or more, the licensee shall report the change to the NRC. The report must be filed with the NRC no more than 60 days after completing the PRA update, and shall include a description of any corrective actions addressing the change in cumulative CDF and/or LERF and a schedule for implementation or the bases why corrective action is not necessary.

Step 4: Submit proposed plant modifications

To support the NRC staff's conclusion that the proposed plant modifications are consistent with the key principles of risk-informed regulation and NRC staff expectations, the following information must be submitted to the NRC:

* A description of how the proposed plant modifications will affect the design and licensing basis including a description of any changes to onsite physical protection systems and security organizations needed to maintain existing levels of high assurance that activities involving nuclear material are not inimical to the common defense and security and do not constitute an unreasonable risk to the public health and safety or a justification of why no changes are needed.

* A discussion of the evaluation and its results performed by the licensee to determine the potential effect of the proposed plant modifications on plant CDF and LERF.

* A discussion of how the proposed plant modifications meet the criteria and required assessments listed in Step 2 - Engineering Analysis including defense-in-depth and margins.

* A description of the structures, systems, and components affected by the proposed changes, the types of changes proposed, the reason for the changes, and results and insights from an analysis of available data on equipment performance (i.e., all safety impacts of the proposed plant modifications must be evaluated).

*	A reevaluation of pertinent accident analysis and the provisions of 10 CFR Parts 20 and 100, if appropriate.

*	An evaluation of the effect of the proposed changes on defense-in-depth attributes of the plant including a description of the extent to which the proposed change reduces the “built-in capability” of the plant to resist security threats.

*	An evaluation of the effect of the proposed changes on the retention of adequate safety margins at the plant.

*	A description of how the proposed plant modifications will be documented in the plant’s FSAR, technical specifications, and license conditions. This must include proposed changes or enhancements to the regulatory controls for high risk-significant SSCs that are not subject to any requirements or the requirements are not commensurate with the SSC's risk significance.

To support the NRC staff's conclusion that when proposed modifications result in an increase in CDF or LERF, the increase must be small, the following information summarizing the results of the risk assessment must be submitted to the NRC:

- The effects of the change on the dominant sequences (sequences that contribute more than 5% to the risk) in order to show that the proposed change does not create risk outliers and does not exacerbate existing risk outliers.

- An assessment of the change to CDF and LERF, including a description of the significant contributors to the change.

- Information related to assessment of the total plant CDF—the extent of the information required will depend on whether the analysis of the change in CDF is in Region II or Region III as defined in Figure 1.

- Information related to assessment of total plant LERF—the extent of the information required will depend on whether the analysis of the change in LERF is in Region II or Region III as defined in Figure 2.

- Results of analyses that show that the conclusions regarding the impact of the proposed change on plant risk will not vary significantly under a different set of plausible assumptions.

To support the NRC staff's conclusion that the technical adequacy of the PRA used in an application is of sufficient quality, submittal requirements will differ depending on whether consistency with an NRC endorsed standard is proposed as the basis for demonstrating the technical adequacy of the PRA, or if further, more detailed NRC review of any initiating event(s) or operating mode(s) is required. A single submittal may include a PRA with analysis of some initiating events and operating modes based on standards, and others that are not based on standards. Qualitative discussion submitted in lieu of quantitative analyses should adhere to submittal guidelines for analyses not based on standards.

The following information should always be submitted:

- A description all initiating events and the plant operating modes and how each of these can or can not, be affected by the proposed changes.

- A discussion of how each initiating event and operating mode that can be affected by the proposed change is addressed in the risk estimates and the basis for proposing that the PRA is adequate to support the requested change.

- Identification of permanent plant changes (such as design or operational practices) that have an impact on those things modeled in the PRA but have not been incorporated in the baseline PRA model.

If a plant change has not been incorporated, the licensee should provide a justification of why the change does not impact the PRA results. This justification should be in the form of a sensitivity study that demonstrates the significant accident sequences or contributors were not impacted (remained the same).

For all initiating events and operating modes where the technical adequacy is based on conformance with an NRC-endorsed standard, the following information should be submitted;

- Documentation that the parts of the PRA required to produce the results used in the decision are performed consistently with the standard as endorsed in the appendices of RG 1.200.

  If a requirement of the standard (as endorsed in the appendix to RG 1.200) has not been met, the licensee should provide a justification of why it is acceptable that the requirement has not been met. This justification should be in the form of a sensitivity study that demonstrates that the significant accident sequences or contributors were not impacted (remained the same).

- Identification of the key assumptions and approximations relevant to the results used in the decision-making process. Also include the peer reviewers' assessment of those assumptions. These assessments provide information to the NRC staff in their determination of whether the use of these assumptions and approximations is either appropriate for the application, or whether sensitivity studies performed to support the decision are appropriate.

- A discussion of the resolution of the peer review comments that are applicable to the parts of the PRA required for the application. This may take the form of:

  — a discussion of how the PRA model has been changed, or

  — a justification in the form of a sensitivity study that demonstrates the significant accident sequences or contributors were not impacted (remained the same) by the particular issue.

The standards or peer review process documents may recognize different capability categories or grades that are related to level of detail, degree of plant specificity, and degree of realism. The licensee's documentation is to identify the use of the parts of the PRA that conform to the less detailed capability categories, as well as the limitations this imposes.

For all initiating events and operating modes where the technical adequacy is not based on conformance with an NRC-endorsed standard and require further more detailed NRC review, the following information should be submitted;

- A description of risk assessment methods used to support the proposed change. If the proposed change is in Region I or II as defined in Figures 1 and 2, an estimate of the total CDF and LERF is required to support the proposed change.

- Identification, description, and assessment of the key assumptions and approximations relevant to the results used in the decision-making process. The assessment should provide information to the NRC staff to support their determination of whether the use of these assumptions and approximations is either appropriate for the application, or whether sensitivity studies performed to support the decision are appropriate.

- The event trees and fault trees necessary to support the proposed change. If the proposed change is in Region I or II as defined in Figures 1 and 2, an estimate of the total CDF and LERF is required to support the proposed change.

- A list of operator actions modeled in the PRA that impact the proposed change and their error probabilities. If the proposed change is in Region I or II as defined in Figures 1 and 2, an estimate of the total CDF and LERF is required to support the proposed change.

E. <u>Plant design change licensing process</u>

The rule would require that proposed facility changes be reviewed and approved by the NRC as risk-informed applications in accordance with the existing license amendment process, including any needed changes to the facility's technical specifications. Potential impacts of the changes on facility security will be evaluated as part of the process for performing license amendment reviews. Specifically, the application will be reviewed to ensure that the proposed change does not significantly reduce the "built-in capability" of the plant to resist security threats. In addition, the application will be reviewed to ensure that, for the proposed change to the facility, any changes to onsite physical protection systems and security organizations needed to maintain existing levels of high assurance that activities involving nuclear material are not inimical to the common defense and security and do not constitute an unreasonable risk to the public health and safety are identified or a justification of why no changes are needed.

F. <u>Potential revisions based on LOCA frequency reevaluations</u>

The NRC will periodically evaluate LOCA frequency information. If LOCA frequencies significantly increase, the NRC will undertake rulemaking (or issue orders, if appropriate) to change the transition break size. In such a case, the backfit rule (10 CFR 50.109) would not apply. Likewise, if future reevaluations of LOCA frequency invalidate the bases for facility changes implemented by a licensee, that licensee will be required to take appropriate action to reduce facility risk to acceptable levels; either by reversing the previous facility changes or by making other changes to compensate for the increased risk. In these cases, the backfit rule (10 CFR 50.109) would also not apply.

IV. Draft Rule Language

NOTE: Redline of existing rule language denotes changes.

1. The authority citation for part 50 continues to read as follows:

AUTHORITY: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note). Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5841). Section 50.10 also issued under secs. 101, 185, 68 Stat. 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332).
Sections 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a and Appendix Q also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.C. 5844). Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80 - 50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

2. In § 50.34, paragraphs (a)(4) and (b)(4) are revised to read as follows:

§ 50.34 Contents of application; technical information.

(a) * * * * *

(4) A preliminary analysis and evaluation of the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility and including determination of the margins of safety during normal operations and transient conditions anticipated during the life of the facility, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents. Analysis and evaluation of ECCS cooling performance and the need for high point vents following postulated loss-of-coolant accidents must be performed in accordance with the requirements of § 50.46 or § 50.46a, and § 50.46b of this part for facilities for which construction permits may be issued after December 28, 1974, but before [EFFECTIVE DATE OF RULE]. Such analyses must be performed in accordance with the requirements of § 50.46 and § 50.46(b) for facilities for which construction permits may be issued after [EFFECTIVE DATE OF RULE], and design approvals and standard design certifications under part 52 of this chapter.

* * * * *

(b) * * * * *

(4) A final analysis and evaluation of the design and performance of structures, systems, and components with the objective stated in paragraph (a)(4) of this section and taking into account any pertinent information developed since the submittal of the preliminary safety analysis report. Analysis and evaluation of ECCS cooling performance following postulated loss-of-coolant accidents shall be performed in accordance with the requirements of §§ 50.46 or 50.46a, and 50.46b for facilities for which a license to operate may be issued after December 28, 1974, but before [EFFECTIVE DATE OF RULE]. Such analyses must be performed in accordance with the requirements of § 50.46 and 50.46(b) for facilities for which construction permits may be issued after [EFFECTIVE DATE OF RULE], and design approvals and standard design certifications under part 52 of this chapter.

* * * * *

3. In § 50.46, paragraph (a) is revised by adding an introductory paragraph, and paragraph (a)(1)(i) is revised to read as follows:

§ 50.46 Acceptance criteria for emergency core cooling systems for light-water nuclear power plants.

(a) Each boiling or pressurized light-water nuclear power reactor fueled with uranium oxide pellets within cylindrical zircalloy or ZIRLO cladding must be provided with an emergency core cooling system (ECCS). Reactors whose license to operate were issued after December 28, 1974, but before [EFFECTIVE DATE OF RULE] must be designed in accordance with the requirements of either this section or § 50.46a. Reactors whose construction permits are issued after [EFFECTIVE DATE OF RULE] must be designed in accordance with this section.

(1)(i) The ECCS system must be designed so that its calculated cooling performance following postulated loss-of-coolant accidents conforms to the criteria set forth in paragraph (b) of this section. ECCS cooling performance must be calculated in accordance with an acceptable evaluation model and must be calculated for a number of postulated loss-of-coolant accidents of different sizes, locations, and other properties sufficient to provide assurance that the most severe postulated loss-of-coolant accidents are calculated. Except as provided in paragraph (a)(1)(ii) of this section, the evaluation model must include sufficient supporting justification to show that the analytical technique realistically describes the behavior of the reactor system during a loss-of-coolant accident. Comparisons to applicable experimental data must be made and uncertainties in the analysis method and inputs must be identified and assessed so that the uncertainty in the calculated results can be estimated. This uncertainty must be accounted for, so that, when the calculated ECCS cooling performance is compared to the criteria set forth in paragraph (b) of this section, there is a high level of probability that the criteria would not be exceeded. Appendix K, Part II *Required Documentation*, sets forth the documentation requirements for each evaluation model. This section does not apply to a nuclear power reactor facility for which the certifications required under §§ 50.82(a)(1) have been submitted.

* * * * *

4. Section 50.46a is redesignated as § 50.46b, and a new § 50.46a is added to read as follows:

§ 50.46a Alternative acceptance criteria for emergency core cooling systems for light-water nuclear power reactors.

(a) *Definitions.* Definitions for the purposes of this section:

(1) *Loss-of-coolant accidents (LOCAs)* means the hypothetical accidents that would result from the loss of reactor coolant, at a rate in excess of the capability of the reactor coolant makeup system, from breaks in pipes in the reactor coolant pressure boundary up to and including a break equivalent in size to the double-ended rupture of the largest pipe in the reactor coolant system.

(2) *Evaluation model* means the calculational framework for evaluating the behavior of the reactor system during a postulated loss-of-coolant accident (LOCA). It includes one or more computer programs and all other information necessary for application of the calculational framework to a specific LOCA, such as mathematical models used, assumptions included in the programs, procedure for treating the program input and output information, specification of those portions of analysis not included in computer programs, values of parameters, and all other information necessary to specify the calculational procedure.

(3) *Transition break size* is the discharge area, expressed as a circular opening diameter, above which emergency core cooling system (ECCS) behavior must be analyzed using the model specified in paragraph (c)(2) of this section, and determined to meet the acceptance criteria specified in paragraph (d) of this section. Transition break sizes are specified in Table 1.

(b) *Applicability and scope.*

(1) The requirements of this section apply to each boiling or pressurized light-water nuclear power reactor fueled with uranium oxide pellets within cylindrical zircalloy or ZIRLO cladding for which a license to operate may be issued after December 28, 1974, but before [EFFECTIVE DATE OF RULE], but do not apply to such a reactor for which the certification required under § 50.82(a)(1) has been submitted.

(2) The requirements of this section are in addition to any other requirements applicable to ECCS set forth in this part, with the exception of § 50.46. The criteria set forth in paragraph (d), with cooling performance calculated in accordance with an acceptable evaluation model under paragraph (c), are in implementation of the general requirements with respect to ECCS cooling performance design set forth in this part, including in particular Criterion 35 of appendix A to this part.

(c) Each nuclear power reactor subject to this section must be provided with an ECCS that must be designed so that its calculated cooling performance following postulated loss-of-coolant accidents conforms to the criteria set forth in paragraph (d) of this section.

(1) *ECCS evaluation for LOCAs involving breaks at or below the transition break size.* ECCS cooling performance at or below the transition break size must be calculated in accordance with an acceptable evaluation model that meets the requirements of either section I to Appendix K of this part, or the following requirements, and demonstrate that the acceptance criteria in paragraph (d)(1) are satisfied. The evaluation model must be calculated for a number of postulated loss-of-coolant accidents of different sizes, locations, and other properties sufficient to provide assurance that the most severe postulated loss-of-coolant accidents involving breaks at or below the transition break size are calculated. The evaluation model must include sufficient supporting justification to show that the analytical technique realistically describes the behavior of the reactor system during a loss-of-coolant accident. Comparisons to applicable experimental data must be made and uncertainties in the analysis method and inputs must be identified and assessed so that the uncertainty in the calculated results can be estimated. This uncertainty must be accounted for, so that, when the calculated ECCS cooling

performance is compared to the criteria set forth in paragraph (d) of this section, there is a high level of probability that the criteria would not be exceeded.

(2) *ECCS evaluation for LOCAs involving breaks larger than the transition break size.* ECCS cooling performance for LOCAs involving breaks larger than the transitional break size must be calculated in accordance with an acceptable evaluation model that demonstrates that the acceptance criteria in paragraph (d)(2) are satisfied. The evaluation model must be calculated for a number of postulated loss-of-coolant accidents of different sizes, locations, and other properties sufficient to provide assurance that the most severe postulated loss-of-coolant accidents from the transition break size up to the double-ended rupture of the largest ppe in the reactor coolant system are calculated. The evaluation model must include sufficient supporting justification to show that the analytical technique reasonably describes the behavior of the reactor system during a loss-of-coolant accident from the transition break size up to the double-ended pipe rupture. Comparisons to applicable experimental data must be made and uncertainties in the analysis method and inputs must be identified and assessed so that the uncertainty in the calculated results can be estimated. This uncertainty must be accounted for, so that, when the calculated ECCS cooling performance is compared to the criteria set forth in paragraph (d) of this section, there is a reasonable level of probability that the criteria would not be exceeded.

(d) *ECCS acceptance criteria.* The following acceptance criteria must be used in determining the acceptability of ECCS cooling performance as determined in accordance with paragraph (c).

(1) Acceptance criteria for LOCAs involving breaks at or below the transition break size.

(i) *Peak cladding temperature*. The calculated maximum fuel element cladding temperature must not exceed 2200F.

(ii) *Maximum cladding oxidation*. The calculated total oxidation of the cladding shall nowhere exceed 0.17 times the total cladding thickness before oxidation. As used in this subparagraph total oxidation means the total thickness of cladding metal that would be locally converted to oxide if all the oxygen absorbed by and reacted with the cladding locally were converted to stoichiometric zirconium dioxide. If cladding rupture is calculated to occur, the inside surfaces of the cladding shall be included in the oxidation, beginning at the calculated time of rupture. Cladding thickness before oxidation means the radial distance from inside to outside the cladding, after any calculated rupture or swelling has occurred but before significant oxidation. Where the calculated conditions of transient pressure and temperature lead to a prediction of cladding swelling, with or without cladding rupture, the unoxidized cladding thickness shall be defined as the cladding cross-sectional area, taken at a horizontal plane at the elevation of the rupture, if it occurs, or at the elevation of the highest cladding temperature if no rupture is calculated to occur, divided by the average circumference at that elevation. For ruptured cladding the circumference does not include the rupture opening.

(iii) *Maximum hydrogen generation*. The calculated total amount of hydrogen generated from the chemical reaction of the cladding with water or steam shall not exceed 0.01 times the hypothetical amount that would be generated if all of the metal in the cladding cylinders surrounding the fuel, excluding the cladding surrounding the plenum volume, were to react.

(iv) *Coolable geometry*. Calculated changes in core geometry shall be such that the core remains amenable to cooling.

(v) *Long term cooling*. After any calculated successful initial operation of the ECCS, the calculated core temperature shall be maintained at an acceptably low value and decay heat shall be removed for the extended period of time required by the long-lived radioactivity remaining in the core.

(2) *Acceptance criteria for LOCAs involving breaks larger than the transition break size.*

(i) *Coolable geometry*. Calculated changes in core geometry shall be such that the core remains amenable to cooling.

(ii) *Long term cooling*. After any calculated successful initial operation of the ECCS, the calculated core temperature shall be maintained at an acceptably low value and decay heat shall be removed for the extended period of time required by the long-lived radioactivity remaining in the core.

(e) *Imposition of restrictions.* The Director of Nuclear Reactor Regulation may impose restrictions on reactor operation if it is found that the evaluations of ECCS cooling performance submitted are not consistent with paragraphs (c) and (d) of this section.

(f) *Changes to facility, procedures, and technical specifications.*

(1) *Submission and approval process*. A licensee may request to make changes to its facility, procedures and technical specifications based upon the reanalysis of ECCS performance permitted under this section, by submitting an application for a license amendment. The application must contain the following information:

(i) A description the proposed change, and a discussion of how the proposed plant or procedure change will affect the design and licensing basis;

(ii) An discussion demonstrating that the criteria in paragraph (f)(2) have been met;

(iii) Identification of the structures, systems and components affected by the proposed change;

(iv) A evaluation demonstrating that 10 CFR Parts 20 and 100 will continue to be met;

(v) A description of the measures taken to assure that the quality and level of detail of the systematic processes that evaluate the plant for internal and external events during normal operation, low power, and shutdown (including the plant-specific probabilistic risk assessment (PRA), margins-type approaches, or other systematic evaluation techniques used to evaluate severe accident vulnerabilities) are adequate for estimating the total core damage frequency (CDF) and large early release frequency (LERF), and the changes to CDF and LERF;

(vi) A description of all initiating events and the plant operating modes, how each of these can or cannot be affected by the proposed changes, how each of the events and operating modes that can be affected by the proposed change is addressed in the risk estimates and the bases for this determination; and

(vii) A list of permanent facility and procedure changes that may have an impact on the PRA but have not been incorporated into the PRA, the bases for not including the changes in the PRA, and a sensitivity study demonstrating that the significant accident sequences or contributors are not affected.

(2) *Acceptance criteria for facility and procedure changes.* The Commission may approve the licensee's request if it determines:

(i) The facility continues to be able to mitigate LOCAs involving breaks larger than the transition break size up to and including a double-ended rupture of the largest pipe in the reactor coolant system;

(ii) The frequency of occurrence of pipe breaks larger than the transition break size at the facility, or the uncertainty in the frequency of occurrence of such pipe breaks, is not significantly changed;

(iii) New reactor coolant system (RCS) pressure boundary degradation mechanisms are not introduced, nor is the likelihood or effect of known degradation mechanisms significantly increased;

(iv) The likelihood of detecting RCS pressure boundary degradation is not reduced;

(v) The total increase in CDF due to all facility and procedure changes permitted as a result of this section is sufficiently small;

(vi) The total increase in LERF due to all facility and procedure changes permitted as a result of this section is sufficiently small;

(vii) An appropriate level of defense in depth is provided by assuring that:

(A) Reasonable balance is provided among prevention of core damage, containment failure (early and late) and consequence mitigation;

(B) Over reliance on programmatic activities to compensate for weaknesses caused by the proposed facility or procedure change is avoided;

(C) System redundancy, independence, and diversity is provided commensurate with the expected frequency of postulated accidents, consequences of postulated accidents, and uncertainties;

(D) Independence of barriers is not degraded;

(E) Defenses against human errors are preserved;

(F) A single failure is not expected to lead to reactor vessel failure; and

(G) Common cause failures are addressed.

(ix) Sufficient safety margins are retained to account for uncertainties;

(3) *PRA Requirements*. A PRA must be used to demonstrate compliance with this section. To the extent that a PRA is used to demonstrate compliance with paragraph (f)(2) of this section, the PRA must:

(i) Address initiating events from sources both internal and external to the plant and for all modes of operation, including low power and shutdown modes, that could change the regulatory decision substantially;

(ii) Calculate both core damage frequency and large early release frequency;

(iii) Reasonably represent the current configuration and operating practices at the plant; and

(iv) Have sufficient technical adequacy and level of detail to provide confidence that the change in total CDF and LERF adequately reflects the plant and the impact of the proposed change on risk.

(4) *Monitoring and Feedback*. Upon approval and implementation of the first facility or procedure change under this paragraph, the licensee shall review changes to the plant, operational practices, and plant operational experience and update the PRA required under paragraphs (f)(2). Thereafter, the licensee shall re-evaluate and update the PRA with respect to any design or operational changes that have been implemented or approved under this section, changes in the PRA model, revisions in analysis methods, model scope, data, modeling assumptions. The re-evaluation and updating must be completed in a timely manner, but no longer than once every two refueling outages. The updated PRA must continue to meet the requirements in paragraph (f)(2). Based upon the PRA, the licensee shall take appropriate action to ensure that all changes accomplished under this section continue to meet the acceptance criteria in paragraph (f)(2).

(g) *Documentation, change control, and records retention.*

(1) *ECCS analysis change*. The first change to the ECCS analysis performed in conformance with this section must be reflected in the ECCS analysis required by § 50.34(b) of this chapter, but need not include a supporting § 50.59 evaluation of the change. Thereafter,

any changes to the ECCS analysis, as described in the FSAR, may be made if the requriements of this section and § 50.59 continue to be met.

(2) *Facility and procedures change*. The licensee shall document the bases for its application under paragraph (f)(1) of this paragraph, and the bases demonstrating compliance with the acceptance criteria in paragraph (f)(2). Upon approval of the change, the licensee shall update the FSAR in accordance with § 50.71(e) of this part.

(h) *Reporting.*

(1) Each licensee shall estimate the effect of any change to or error in evaluation models or in the application of such models to determine if the change or error is significant. For this purpose, a significant change or error is:

(i) One which results in a calculated peak fuel cladding temperature different by more than 50F from the temperature calculated for the limiting transient using the last acceptable model, or is a cumulation of changes and errors such that the sum of the absolute magnitudes of the respective temperature changes is greater than 50°F; and

(ii) For LOCAs at or below the transition break size, one which results in a change in the calculated oxidation, or the sum of the absolute value of the changes in calculated oxidation, equals or exceeds 0.4% oxidation.

(2) For each change to or error discovered in an acceptable evaluation model or in the application of such a model that affects the temperature calculation, the applicant or licensee shall report the nature of the change or error and its estimated effect on the limiting ECCS analysis to the Commission at least annually as specified in § 50.4. If the change or error is significant, the applicant or licensee shall provide this report within 30 days and include with the report a proposed schedule for providing a reanalysis or taking other action as may be needed to show compliance with § 50.46 requirements. This schedule may be developed using an integrated scheduling system previously approved for the facility by the NRC. For those facilities not using an NRC-approved integrated scheduling system, a schedule will be established by the NRC staff within 60 days of receipt of the proposed schedule. Any change or error correction that results in a calculated ECCS performance that does not conform to the criteria set forth in paragraph (d) of this section is a reportable event as described in §§ 50.55(e), 50.72 and 50.73. The affected applicant or licensee shall propose immediate steps to demonstrate compliance or bring plant design or operation into compliance with § 50.46a requirements.

(3) As part of the PRA update under paragraph (f)(4), the licensee shall determine the cumulative changes in CDF and LERF. If either the cumulative CDF or LERF increase by 20% or more, the licensee shall report to the NRC the change. The report must be filed with the NRC no more than 60 days after completing the PRA update, and shall include:

(i) A description of any corrective actions addressing the change in cumulative CDF and/or LERF and a schedule for implementation, or the bases why corrective action is not necessary; and

(ii) A description of any corrective actions required under paragraph (f)(4) of this section and a schedule for implementation.

(i) [RESERVED]

(j) *Changes to transition break size; changes to facility and procedures.* If the transition break size specified in Table 1 of this section applicable to a licensee's nuclear power plant is increased, each licensee subject to this section shall perform the evaluations required by paragraph (c) of this section and reconfirm compliance with the acceptance criteria in paragraph (d). If the licensee cannot demonstrate compliance with the acceptance criteria, then the applicant or licensee must change its facility or procedures so that the acceptance criteria are met. The evaluation required by this paragraph, and any necessary changes to facility and procedures as the result of this evaluation, shall not be deemed to be backfitting under any provision of this chapter.

(k) The requirements of this section are in addition to any other requirements applicable to ECCS set forth in this part. The criteria set forth in paragraph (d), with cooling performance calculated in accordance with an acceptable evaluation model, are in implementation of the general requirements with respect to ECCS cooling performance design set forth in this part, including in particular Criterion 35 of appendix A.

TABLE 1. TRANSITION BREAK SIZES[3] FOR LIGHT WATER COOLED NUCLEAR POWER REACTORS

Reactor Type	
Pressurized Water Reactor	Boiling Water Reactor
14" diameter	20" diameter

[3] The transition break size represents the discharge areas equivalent to the circular opening diameter in Table 1.

ALTERNATIVE TO INCLUDING A BACKFITTING EXCLUSION IN 50.46a FOR TRANSITION BREAK SIZE RULEMAKING

(NOTE: 50.46a(j) contains a backfitting exclusion for licensee's changes to a facility or procedures necessary as a result of a rulemaking change to the transition break size)

5. In § 50.109, paragraph (b) is revised to read as follows:

§ 50.109 Backfitting.

(a) * * * * *
(b) Paragraph (a)(3) of this section shall not apply to:
(1) Backfits imposed prior to October 21, 1985;
(2) Any rulemaking changing the transition break size specified in § 50.46a.

6. In Appendix A to 10 CFR Part 50, under the heading, “CRITERIA,” Criterion 35 is amended to read as follows:

APPENDIX A TO PART 50 -GENERAL DESIGN CRITERIA FOR NUCLEAR POWER PLANTS

• * * * *

CRITERIA

• * * * *

Criterion 35--Emergency core cooling. A system to provide abundant emergency core cooling shall be provided. The system safety function shall be to transfer heat from the reactor core following any loss of reactor coolant at a rate such that (1) fuel and clad damage that could interfere with continued effective core cooling is prevented and (2) clad metal-water reaction is limited to negligible amounts.

Suitable redundancy in components and features, and suitable interconnections, leak detection, isolation, and containment capabilities shall be provided to assure that for onsite electric power system operation (assuming offsite power is not available) and for offsite electric power system operation (assuming onsite power is not available) the system safety function can be accomplished assuming a single failure, except for loss of coolant accidents involving breaks larger the transition break size under § 50.46a, where a single failure need not be assumed using the analytical methods under § 50.46a(c)(2).