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NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50 and 52

RIN 3150-AH29

[NRC-2004-0006]

Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations that govern domestic licensing of production and utilization facilities and licenses, certifications, and approvals for nuclear power plants to allow current and certain future power reactor licensees and applicants to choose to implement a risk-informed alternative to the current requirements for analyzing the performance of emergency core cooling systems (ECCS) during loss-of-coolant accidents (LOCAs). The amendments will also establish procedures and acceptance criteria for evaluating certain changes in plant design and operation based upon the results of the new analyses of ECCS performance. This action also completes all activities associated with a petition for rulemaking filed by the Nuclear Energy Institute (NEI) (PRM-50-75).

DATES: *Effective Date:* [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER.*]

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Federal e Rulemaking Portal: Go to http://www.regulations.gov and search for documents filed under Docket ID NRC-2004-0006. Address questions about NRC dockets to Carol Gallagher (301) 415-5905; e-mail Carol.Gallager@nrc.gov.

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SUPPLEMENTARY INFORMATION:

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I. Background

During the last 11 years, the NRC has had numerous initiatives underway to make improvements in its regulatory requirements that would reflect current knowledge about reactor risk. The overall objectives of risk-informed modifications to reactor regulations include:

(1) Enhancing safety by focusing NRC and licensee resources in areas commensurate with their importance to health and safety;

(2) Providing NRC with the framework to use risk information to take action in reactor regulatory matters, and

(3) Allowing use of risk information to provide flexibility in plant operation and design, which can result in reduction of burden without compromising safety, improvements in safety, or both.

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 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 (on core damage frequency and containment performance) should be used with appropriate consideration of uncertainties.

To implement the policy statement, the NRC developed guidance on the use of risk information for reactor license amendments and issued Regulatory Guide (RG) 1.174, “An Approach for Using Probabilistic Risk Assessments in Risk-Informed Decisions on Plant Specific Changes to the Licensing Basis,” (Agencywide Document Access and Management System (ADAMS) Accession No. ML023240437). 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 are discussed in RG 1.174 and include:

(1) Being consistent with the defense-in-depth philosophy

(2) Maintaining sufficient safety margins

(3) Allowing only changes that result in no more than a small increase in core damage frequency or risk (consistent with the intent of the Commission's Safety Goal Policy Statement); and

(4) Incorporating monitoring and performance measurement strategies.

The process described in RG 1.174 is applicable to changes in plant licensing bases. As NRC experience with the risk-informed process and applications grew, the NRC recognized that further development of risk-informed regulation would require making changes to the regulations. In June 1999, the Commission decided to implement risk-informed changes to the technical requirements of Part 50. The first risk-informed revision to the technical requirements of Part 50 consisted of changes to the combustible gas control requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.44 (68 FR 54123; September 16, 2003). Other risk-informed regulations issued later by the NRC include § 50.48(c) on fire protection (69 FR 33550; June 16, 2004), § 50.69 on special treatment requirements for systems, structures, and components (69 FR 68047; Nov. 22, 2004), and § 50.61 on fracture toughness requirements for protection against pressurized thermal shock events (75 FR 13; January 4, 2010).

In February 2002, NEI submitted a petition for rulemaking (PRM 50-75) requesting that the NRC revise ECCS requirements by redefining the large break LOCA (ADAMS Accession No. ML020630082). Notice of that petition was published in the *Federal Register* (FR) for public comment on April 8, 2002 (67 FR 16654). The petition requested the NRC to amend § 50.46 and Appendices A and K of Part 50 to allow licensees to use as an alternative to the double-ended rupture of the largest pipe in the reactor coolant system (RCS), “an alternate maximum break size that is approved by the Director of the Office of Nuclear Reactor Regulation.” Detailed information regarding the NRC’s resolution of this petition is provided in Section V, of this document.

Before the NEI petition was submitted, the NRC staff had already begun its own investigation of the feasibility of a risk-informed ECCS rule. Specifically, the NRC examined the ECCS requirements for large break LOCAs. A number of possible changes were considered, including changes to General Design Criterion (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. 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. Possible changes include: containment spray system setpoint changes; fuel management improvements; optimization of plant modifications and operator actions to address postulated sump blockage issues; power uprates; and changes to the required number of accumulators, diesel start times, sequencing of equipment, and valve stroke times.

The Staff Requirements Memorandum (SRM), of March 31, 2003 (ADAMS Accession No. ML030910476), on SECY-02-0057, "Update to SECY-01-0133, 'Fourth 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 50.46 (ECCS Acceptance Criteria)'" (ADAMS Accession No. ML020660607), approved most of the NRC 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 began to prepare a proposed rule responsive to the SRM direction. However, after holding two public meetings, the NRC found that there were differences between stated Commission and industry interests.

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," dated March 3, 2004; (ADAMS Accession No. ML040490133). The Commission provided direction in an SRM dated July 1, 2004, (ADAMS Accession No. ML041830412). The Commission stated that the NRC 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 (DEGB) of the largest RCS 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 that future increases in LOCA frequencies may require licensees to restore the facility to its original design basis or make other compensating changes. The Commission further stipulated that these changes should not be subject to the backfit rule (10 CFR 50.109).

II. Progression of Rulemaking

On March 29, 2005, in SECY-05-0052, "Proposed Rulemaking for 'Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements'," the NRC staff provided a proposed rule to the Commission for its consideration. In an SRM on July 29, 2005 (ADAMS Accession No. ML052100416), the Commission directed the NRC staff to publish the proposed rule for public comment after making certain changes.

On November 7, 2005 (70 FR 67598), the proposed rule was published in the FR with a comment period of 90 days. In response to two different stakeholder requests, on January 18, 2006, the NRC extended the public comment period by 30 days to March 8, 2006.

As directed by the Commission in its SRM on SECY-05-0052, the NRC staff addressed the effect of seismic events on the selection of the transition break size by preparing a report entitled "Seismic Considerations for the Transition Break Size" (ADAMS Accession No. ML053470439). This report was posted on the NRC's rulemaking web site and a notice of its availability and opportunity for public comment was published in the FR on December 20, 2005 (70 FR 75501). A public workshop was held on February 16, 2006, to ensure before the comment period closed that stakeholders understood the NRC's intent and interpretation of the proposed rule. Additional public meetings were held on June 28, 2006, and August 17, 2006, to discuss public comments.

After evaluating public comments, the NRC completed draft final rule language that addressed nearly all commenters' concerns. On October 31 and November 1, 2006, the NRC staff met with the Advisory Committee on Reactor Safeguards (ACRS) to discuss the draft final rule. In a letter dated November 16, 2006 (ADAMS Accession No. ML063190465), the ACRS provided its evaluation of the draft final rule. The ACRS recommended that the rule not be issued in its then current form. The ACRS recommended numerous changes to the rule, primarily to increase the defense-in-depth provided for large pipe breaks. The NRC staff evaluated the ACRS recommendations, and in SECY-07-0082, "Rulemaking to Make Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements; 10 CFR 50.46a "Alternative Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors" (May 16, 2007), sought additional guidance from the Commission on the priority of the rule and on the issues raised by the ACRS. In its August 10, 2007, SRM (ADAMS Accession No. ML072220595), the Commission responded by approving NRC staff recommendations for a revised priority and approach for addressing the ACRS concerns and completing the final rule.

As the NRC modified the rule in response to the ACRS recommendations and the Commission's direction, the NRC staff made many substantive changes to the requirements. After considering the extent of these changes, the NRC decided to provide an additional opportunity for public stakeholders to review and submit comments on the revised rule language. The NRC published the supplemental proposed rule in the FR on August 10, 2009 (74 FR 40006). In this document, the NRC addressed the public comments on the initial proposed rule and explained the bases for the subsequent changes made to the rule language.

On August 18, 2009, NEI requested a 120-day extension to the public comment period. The NRC granted the extension request by extending the comment period for all stakeholders until January 22, 2010. The NRC evaluated public comments received on the supplemental proposed rule and prepared a draft final rule which was made publicly available on May 12, 2010, and posted on www.regulations.gov. The NRC held a public meeting on June 4, 2010, to discuss resolution of public comments and the draft final rule language with stakeholders. The NRC then prepared the final rule.

The NRC staff conducted its final briefings of the ACRS subcommittee and full committee on September 22 and October 7, 2010, respectively. The ACRS recommended approval of the final rule for operating reactors in a letter dated October 20, 2010 (ADAMS Accession No. ML102850279), but concluded that it was premature to extend the proposed rule to new reactors at this time. However, the ACRS also recommended that if new reactors are to be included in the final rule, new reactor facility changes enabled by § 50.46a may not result in a significant decrease in the level of safety provided by the new reactor design. The ACRS further stated that this requirement should be extended to determining the allowable time for operating in configurations without a demonstrated capability to mitigate a large LOCA. The NRC agrees with these ACRS recommendations and has modified the rule to make these recommended provisions applicable to all new reactors licensed under Part 52. Further details on applying this rule to new reactor designs are provided in subsequent sections of this FR document.

III. Final Action

A. Overview

The final rule establishes an alternative set of risk-informed requirements (10 CFR 50.46a) with which licensees may choose to comply in lieu of meeting the current emergency core cooling system requirements in 10 CFR 50.46. Using these alternative ECCS requirements will provide some licensees with opportunities to change various aspects of facility design and operation.

As was the case in the initial and supplemental proposed rules, the final rule divides the current spectrum of LOCA break sizes into two regions. The division between the two regions is delineated by the transition break size (TBS). The first region includes small size breaks, up to and including the TBS. The second region includes breaks larger than the TBS, up to and including the DEGB of the largest reactor coolant system pipe. These larger breaks are considered to have a much lower likelihood than the smaller breaks in the first region. Under the new rule, the ECCS design requirements for breaks smaller than the TBS remain the same as the requirements for all breaks under the current 10 CFR 50.46 ECCS rule. By contrast, under the new rule, the ECCS design requirements for the pipe breaks larger than the TBS may be analyzed using less conservative assumptions based on their lower likelihood. Although LOCAs for break sizes larger than the transition break will become “beyond design-basis accidents”, these breaks will still be subject to regulatory control. The final rule will require that licensees maintain the ability to mitigate all LOCAs, up to and including the DEGB of the largest reactor coolant system pipe. However, mitigation analyses for LOCAs larger than the TBS need not assume the loss-of-offsite power or the occurrence of a coincident single failure. Licensees will also be allowed to credit the use of non-safety-grade systems.

Licensees who perform LOCA analyses using the risk-informed alternative requirements may find that their plant design or operation is no longer limited by certain parameters associated with previous DEGB analyses. Reducing the DEGB limitations will allow some licensees to propose a wide scope of design or operational changes up to the point of being limited by some other parameter associated with any of the other required accident analyses. Potential design changes include containment spray system setpoint changes; fuel management improvements; optimization of plant modifications and operator actions to address postulated sump blockage issues; power uprates; and changes to the required number of accumulators, diesel start times, sequencing of equipment, and valve stroke times. Some of these design and operational changes could increase plant safety because a licensee could modify its systems to better mitigate the more likely smaller LOCAs. Other changes, such as increasing power, could increase the overall risk of inadvertent release of radioactive material.

The risk-informed § 50.46a option includes risk acceptance criteria for evaluating future design changes to ensure that any risk increases are acceptably small. These acceptance criteria are consistent with the guidelines for risk-informed license amendments in RG 1.174 and ensure both the acceptability of the changes from a risk perspective and the retention of sufficient defense-in-depth, safety margins, and performance monitoring. The requirements for the risk-informed evaluation process are discussed in detail in Section III.E of this document.

The NRC will also periodically evaluate LOCA frequencies. Should estimated LOCA frequencies increase, causing a significant increase in the risk associated with breaks larger than the TBS, the NRC will undertake rulemaking (or issue orders, if appropriate) to change the TBS. The new rule includes changes to the Backfit Rule, 10 CFR 50.109, indicating that a backfitting analysis need not be prepared for changes the NRC may make to the TBS. If previous plant changes are invalidated because of a change made to the TBS, licensees will have to modify or restore components or systems or make offsetting changes to other parts of the plant so that the facility will continue to comply with 10 CFR 50.46a acceptance criteria. The new § 50.46a rule in paragraph (d)(4), states that the Backfit Rule will also not apply to such licensee actions.

Changes to 10 CFR Title I which are accomplished by this final rule are a new 10 CFR 50.46a, and conforming changes to existing 10 CFR §§ 50.34, 50.46, 50.46a (redesignated as § 50.46b), 50.109, 10 CFR Part 50, Appendix A, General Design Criteria 17, 35, 38, 41, 44 and 50, and 10 CFR §§ 52.47, 52.79, 52.137, and 52.157.

B. <u>Determination of the Transition Break Size</u>

To help establish the TBS, the NRC developed pipe break frequencies as a function of break size using an expert opinion elicitation process for degradation-related pipe breaks in typical BWR and PWR reactor coolant systems (NUREG-1829; “Estimating Loss-of-Coolant Accident (LOCA) Frequencies through the Elicitation Process” March 2008; ADAMS Accession No. ML082250436). The elicitation process is used for quantifying phenomenological knowledge when data or modeling approaches are insufficient. The elicitation focused solely on determining event frequencies that initiate from unisolable primary system side failures related to material degradation.

A baseline TBS was established from the expert elicitation results for each reactor type (i.e., PWR and BWR) that corresponded to a break frequency of once per 100,000 reactor years ($1X10^{-5}$, or 10^{-5} per reactor year). The NRC then considered uncertainty in the elicitation process, other potential mechanisms that could cause passive component failure that were not explicitly considered in the expert elicitation process, and the higher susceptibility to rupture/failure of specific locations in the RCS by adjusting the TBS upwards to account for these factors. Other mechanisms that contribute to the overall LOCA frequency include LOCAs resulting from failures of non-passive components and LOCAs resulting from low probability events (e.g., earthquakes of magnitude larger than the safe shutdown earthquake and dropped heavy loads). These LOCAs have a strong dependency on plant-specific factors.

LOCAs caused by failure of non-passive components, such as stuck-open valves and blown out seals or gaskets have a greater frequency of occurrence than LOCAs resulting from the failure of passive components. LOCAs resulting from the failure of non-passive components would be small-break LOCAs, when considering the size of the opening that could result should components fail open or blow out (e.g., safety valves, pump seals). LOCAs resulting from stuck-open valves are limited by the size of the auxiliary pipe. In some PWRs, there are large loop isolation valves in the hot and cold leg piping. However, a complete failure of the valve stem packing is not expected to result in a large flow area, because the valves are back-seated in the open configuration. Based on these considerations, non-passive LOCAs are relatively small in size and are bounded by the selected TBS.

LOCAs could also be caused by dropping heavy loads that could cause a breach of the RCS piping. During power operation, personnel entry into the containment is typically infrequent and of short duration. The lifting of heavy loads that if dropped would have the potential to cause a LOCA or damage safety-related equipment is typically performed while the plant is shut down. The majority of heavy loads are lifted during refueling when the primary system is depressurized, further reducing the risk of a LOCA and a loss of core cooling. If loads are lifted during power operation, they would not be loads similar to the heavy loads lifted during plant shutdown, e.g., vessel heads and reactor internals. In addition, the RCS is inherently protected by surrounding concrete walls, floors, missile shields, and biological shielding. Thus, the contribution of heavy load drops to overall LOCA frequency is not considered to be significant and does not affect the TBS.

Seismically-induced LOCA break frequencies can vary greatly from plant to plant because of factors such as site seismicity, seismic design considerations, and plant-specific layout and spatial configurations. Seismic break frequencies are also affected by the amount of pipe degradation occurring prior to postulated seismic events. Seismic PRA insights have been accumulated from the NRC Seismic Safety Margins Research Program and the Individual Plant Examination of External Events submittals. Based on these studies, piping and other passive RCS components generally exhibit high seismic capacities and, therefore, are not significant risk contributors. However, these studies did not explicitly consider the effect of degraded component performance on the risk contributions. Therefore, the NRC conducted a study to evaluate the seismic performance of undegraded and degraded passive system components (NUREG-1903, "Seismic Considerations for the Transition Break Size," February 2008), (ADAMS Accession No. ML080880140). This effort examined operating experience, seismic PRA insights, and models to evaluate the failure likelihood of undegraded and degraded piping. The operating experience review considered passive component failures that have occurred as a result of strong motion earthquakes in nuclear and fossil power plants as well as other industrial facilities. No catastrophic failures of large pipes resulting from earthquakes between 0.2g and 0.5g peak ground acceleration have occurred in power plants. However, piping degradation could increase the LOCA frequency associated with seismically-induced piping failures. The NUREG-1903 report evaluated seismic loadings on degraded piping and concluded that a large, pre-existing crack on the order of 30 percent through-wall and 145 degrees around the piping circumference would have to be present during a large, rare earthquake (i.e., frequency of occurrence equivalent to 10^{-5} or 10^{-6} per year) in order for pipe failure to occur. The NRC concluded that the likelihood of flaws large enough to fail during such a seismic event is sufficiently low that the TBS need not be modified to address seismically-induced direct piping failures. In reaching its conclusion, the NRC considered the comments received as well as historical information related to piping degradation and the potential for the presence of cracks sufficiently large that pipe failure would be expected under loads associated with these rare (i.e., 10^{-5} per year) earthquakes.

Indirect failures are primary system ruptures that are a consequence of failures in non-primary system components or structural support failures (such as a steam generator support). Structural support failures could then cause displacements in components that stress and in turn, fail the piping. The NRC performed studies on two plants to estimate the conditional pipe failure probability due to structural support failure given a large, rare earthquake (i.e., 10^{-5} to 10^{-6} per year). The results indicated that the conditional failure probability of the piping was on the order of 0.1. These studies used seismic hazard curves from NUREG-1488, “Revised Livermore Seismic Hazard Estimates for Sixty-Nine Nuclear Power Plant Sites East of the Rocky Mountains, April 1994 (ADAMS Accession No. ML052640591). More recent studies were completed by the Electric Power Research Institute (EPRI) on three plants using updated seismic hazard estimates. The updated seismic hazard increases the peak ground acceleration at some sites. The highest pipe failure probability calculated for the three plants in the industry analyses was 6 $X10^{-6}$ per year. However, the NRC noted in its report that indirect failure analyses are highly plant-specific. Therefore, it is possible that example plants assessed in the NRC and EPRI analyses are not limiting for all plants.

The NRC has considered the importance of indirect failures on the selection of the TBS. For the cases considered in both the EPRI and NRC studies, the likelihood of indirectly induced piping failures resulting from major component support failures is less than 10^{-5} per reactor year, the frequency criterion used to select the TBS. Also, the median seismic capacities for both the primary piping system and primary system components are typically higher than other safety related components within the nuclear power plant. Because of these relative capacities, it is expected that a seismic event of sufficient magnitude to cause consequential failure within the primary system would also induce failure of components in multiple trains of mitigation systems, or even induce multiple RCS pipe breaks. Consequently, the risk contribution from seismically-induced indirect failures is expected to depend more heavily on the relative fragilities of plant components and systems than the size of the TBS. Therefore, the NRC believes that adjustment to the TBS for seismically-induced indirect LOCAs is also not warranted.

The final consideration in selecting the TBS was actual piping system design (e.g., sizes) and operating experience. For example, due to system configuration and operating environment, certain piping is considered to be more susceptible to degradation and failure than other piping in the same size range. For PWRs, the range of pipe break sizes determined from the various statistical aggregations of expert opinion was 6 to 10 inches in diameter (i.e., inside dimension) for the 95th percentile. This is only slightly smaller than the PWR surge lines, which are attached to the RCS main loop piping and are typically 12- to 14-inch diameter Schedule 160 piping (i.e., 10.1 to 11.2 inch inside diameter piping). The RCS main loop piping is in the range of 30 inches in diameter and has substantially thicker walls than the surge lines. The expert elicitation panel concluded that this main loop piping is much less likely to break than other RCS piping. The shutdown cooling lines and safety injection lines may also be 12- to

14-inch diameter Schedule 160 piping and are likewise connected to the RCS. The difference in diameter and thickness of the reactor coolant piping and the piping connected to it forms a reasonable line of demarcation to define the TBS. Therefore, to capture the surge, shutdown cooling, and safety injection lines in the range of piping considered to be equal to or less than the TBS, the NRC specified the TBS for PWRs as the cross-sectional flow area of the largest piping attached to the RCS main loop.

For BWRs, the range of pipe sizes determined from the various statistical aggregations of expert opinion was approximately 13 to 20 inches equivalent diameter for the 95th percentile. The information gathered from the elicitation for BWRs also showed that the estimated frequency of pipe breaks dropped markedly for break sizes beyond the range of approximately 18 to 20 inches. After evaluating BWR designs, it was determined that typical residual heat removal piping connected to the recirculation loop piping and feedwater piping is about 18 to 24 inches in diameter. These pipe sizes are consistent with break sizes beyond which the pipe break frequency is expected to decrease markedly below 10^{-5} per year. It was also recognized that the sizes of attached pipes vary somewhat among plants. Thus, for BWRs, the TBS is specified as the cross-sectional flow area of the larger of either the feedwater or the RHR piping inside primary containment.

Because the effects of TBS breaks on core cooling vary with the break location, the NRC evaluated whether the frequency of TBS breaks varies with location and whether TBS breaks could, therefore, vary in size with location. In PWRs, the pressurizer surge line is only connected to one hot leg and the pipes attached to the cold legs are generally smaller than the surge line. The cold legs (including the intermediate legs) also operate at slightly cooler temperatures such that thermally-activated degradation mechanisms would be expected to progress more slowly in the cold leg than in the hot leg. The frequency of occurrence of a break of a given size is composed of both the frequency of a completely severed pipe of that size (a complete circumferential break) plus the frequency of a partial break of that size in an equal or larger size pipe (a partial circumferential or longitudinal break). Therefore, the NRC evaluated an option where the TBS for the hot and cold legs would be distinctly different by considering the frequency contributions of these two break components: (1) complete breaks of the pipes attached to the hot or cold legs at the limiting locations within each attached pipe, and (2) partial breaks of a constant size, as appropriate for either the hot or cold leg, at the limiting locations within the hot or cold legs. The NRC attempted to estimate the appropriate size of the partial break component for the TBS by reviewing the expert elicitation results to determine the frequencies of occurrence of partial breaks within hot and cold legs that would be equivalent to the frequency of a complete surge line break. The NRC found that frequencies of occurrence of partial breaks of a given size are generally lower for the cold leg than for the hot leg. However, other than this general trend, the elicitation results do not contain sufficient information to adequately quantify differences among the hot leg, cold leg, and surge line pipe break frequencies. Because it was not possible to establish a smaller partial break TBS criterion in the hot or cold legs, the NRC concluded that the TBS associated with partial breaks in the hot and cold legs should remain equivalent in size to the internal cross sectional area of the surge line. Similarly, the elicitation results do not contain sufficient detail to quantify break frequency differences among the BWR recirculation, residual heat removal, and feedwater system piping. Thus, a smaller partial break TBS criterion also could not be established for BWR recirculation piping.

The NRC also evaluated whether TBS breaks should be analyzed as single-ended or double-ended breaks. To address this issue, the NRC reviewed the expert elicitation process and the guidance given to the experts in developing their frequency estimates. The NRC concluded that the expert elicitation LOCA frequency estimates correspond to a break area having an equivalent circular diameter at each break size. This correspondence is representative of a single-ended break. Additionally, the experts based their estimates on knowledge of postulated failure mechanisms in pressure boundary components and not on the flow rates emanating from the breaks. The flow rates are governed by the break location and system configuration which determines whether reactor coolant will be discharged from both ends of the break.

The current design basis analysis for light water reactors requires analysis of a DEGB of the largest pipe in the RCS. Under the new rule, all breaks up to and including the TBS will be analyzed under existing requirements. A possible reason for specifying the TBS for PWRs as double-ended could be that a complete break of the pressurizer surge line would result in reactor coolant exiting both ends of the break. Although this occurs initially during a LOCA, core cooling requirements are dominated by the flow rate of coolant exiting from the hot leg side of the break, with much less contribution from the flow rate of coolant exiting from the pressurizer side. Therefore, specifying the TBS break as an area equivalent to a double-ended break of the surge line would be overly conservative. For BWRs, the effect of a double-ended break area is also considered to be overly conservative. The selected TBS for BWRs is based on the larger of the residual heat removal or main feedwater lines attached to the main recirculation piping. A single-ended break in these lines would bound double-ended breaks of the smaller lines in the reactor recirculation and feedwater system. Therefore, the NRC concluded that treating the TBS as a single-ended break reasonably characterizes the expert elicitation results and represents the flow rates associated with postulated pipe breaks within the RCS.

For the TBS to be valid at a particular facility, the rule requires that licensee to demonstrate that the generic assumptions or bounding aspects of the approaches and analysis used to determine the NUREG-1829 and NUREG-1903 results are applicable. For example, the licensee should show that design, configuration, operation, and maintenance of the primary pressure boundary piping systems larger than the TBS (e.g., hot and cold legs in PWRs) are consistent with the assumptions, approach, and limitations associated with the NUREG-1829 and NUREG-1903 studies. Also, the licensee should demonstrate that aging management programs for these systems follow acceptable industry practice or have been approved by the NRC.

In addition, the final rule requires the licensee to demonstrate that proposed plant modifications do not significantly increase the LOCA pipe break frequency estimates generated during the expert elicitation and used as the basis for the TBS. For example, the expert elicitation panel did not consider the effects of power uprates in deriving the break frequency estimates. Further, the expert elicitation panel assumed that future plant operating characteristics would remain consistent with past operating practices. The NRC recognizes that significant plant changes may change plant performance and relevant operating characteristics to a degree that they might impact future LOCA frequencies. Therefore, after a facility has adopted § 50.46a, the final rule requires the licensee to ensure that the TBS remains applicable to the facility by reviewing all subsequent plant changes to ensure that those changes do not significantly increase LOCA pipe break frequencies.

As discussed previously, the baseline TBS was selected to account for uncertainties and failure mechanisms leading to pipe rupture that were not considered in the expert elicitation process. As the NRC obtains additional information that may tend to reduce those uncertainties or allow for more structured consideration of degradation mechanisms, the NRC will assess whether the TBS (as defined in § 50.46a) should be adjusted. Also, the NRC will continue to assess failure precursors identified through operating experience to determine whether adjustments should be made to the TBS. The NRC may initiate rulemaking (or issue orders) to revise the TBS to account for this new information.

Nevertheless, the selected TBS values are within the range supported by the expert elicitation estimates when considering the uncertainty inherent in processing the degradation-related frequency estimates. The NRC believes that the TBS values specified in the final rule are sufficiently conservative to compensate for possible future increases in either break frequencies or failure precursors. Therefore, the NRC expects that the TBS values will remain stable and that any future LOCA frequency reevaluations are unlikely to require the NRC to increase the TBS and cause licensees to undo plant modifications made after implementing § 50.46a.

C. Evaluation of the Plant-Specific Applicability of the Transition Break Size

As previously discussed in Section III.B of this document, the NRC has published two reports, NUREG-1829 (ADAMS Accession No. ML082250436), and NUREG-1903 (ADAMS Accession No. ML080880140) that form part of the technical basis used to select the TBS for BWR and PWR plants. NUREG-1829 used expert elicitation to develop generic LOCA frequency estimates of passive system failures as a function of break size for both BWR and PWR plants and considered normal operational loading and transients expected over a 60-year plant life. NUREG-1903 assessed the likelihood that rare seismic events would induce primary system failures larger than the postulated TBS. NUREG-1903 evaluated both direct failures of flawed and unflawed primary system pressure boundary components and indirect failures of system components and supports that could lead to primary system failures. Because both the NUREG-1829 and NUREG-1903 studies did not develop bounding estimates, unique plant attributes may result in plant-specific LOCA frequencies that are greater than reported in either NUREG-1829 or NUREG-1903. Consequently, the NRC has included a requirement that applicants wishing to implement § 50.46a conduct an evaluation to demonstrate that the results in NUREG-1829 and NUREG-1903 are applicable to their individual plants.

This evaluation applies only to primary system piping and other primary pressure boundary components that are large enough to result in LOCA break sizes larger than the TBS. This evaluation is also only applicable to aspects of facility design and operation affecting compliance with ECCS requirements and does not pertain to design-bases or operational procedures associated with other aspects of the facility licensing basis.

This evaluation to demonstrate the applicability of NUREG-1829 requires that § 50.46a applicants first demonstrate that the applicable plant systems adhere to the facility's licensing basis. Additionally, the evaluation requires that licensees consider the effects of unique, plant-specific attributes on the generic LOCA frequencies developed in NUREG-1829. Licensees must then evaluate the effect of proposed plant changes on both direct and indirect system failures to demonstrate that NUREG-1829 results remain applicable after the proposed changes have been implemented. After a licensee is approved to implement the new § 50.46a requirements, it is necessary to evaluate the effect of future proposed plant changes to demonstrate that NUREG-1829 results remain applicable after enacting the future changes.

The evaluation to demonstrate the applicability of the NUREG-1903 is focused on the assessment of both direct and indirect piping failures. The regulatory acceptance criteria that are established in paragraphs (c)(1)(i) and (c)(3)(i) of the final rule for demonstrating the applicability of the NUREG-1903 results require the licensee to demonstrate that the total frequency of seismically-induced direct and indirect failures of piping larger than the TBS at the facility is significantly less than 10^{-5} per year. In addition, because the frequency of indirect failure is highly plant-specific and NUREG-1903 only considered the frequencies associated with two different plants, this limited analysis does not provide a sufficient technical basis for allowing generic changes to the seismic design, testing, analysis, qualification, and maintenance requirements (i.e., seismic design basis) associated with any component under § 50.46a . Therefore, licensees may not make any changes to components that would alter their seismic design basis unless such changes are justified using a plant-specific analysis to assess the change in risk associated with seismically-induced failures of the relevant component and/or system that results from the proposed plant changes.

After receiving approval to implement the final § 50.46a requirements, it is also necessary for licensees to demonstrate that the NUREG-1903 results remain applicable and that the frequency of seismically-induced direct and indirect piping failures remains acceptable after implementing all future facility changes.

The NRC is preparing guidance for conducting the plant-specific evaluation to demonstrate the applicability of both the NUREG-1829 and NUREG-1903 results, such that the TBS described herein, is also applicable. Draft regulatory guide DG-1216, ''Plant-Specific Applicability of the Transition Break Size Specified in 10 CFR 50.46a" (ADAMS Accession No. ML100430352), was published in June 2010 for public comment. This guidance identifies the scope, provides acceptable methods, and identifies acceptance criteria for evaluating the results of the evaluation to determine the applicability of NUREG-1829. The guidance also provides an evaluation framework and acceptance criteria to demonstrate the applicability of the NUREG-1903 assessment of direct piping failures. This framework identifies the analysis scope and considerations, provides several options for conducting the analysis, and describes a systematic approach for each option. One important step is to determine whether the NUREG-1903 results can be used directly or if a plant-specific analysis is required to determine the limiting flaw sizes under rare seismic loading.

D. Alternative ECCS Analysis Requirements and Acceptance Criteria

The final rule requires licensees to analyze ECCS cooling performance for breaks up to and including a double-ended rupture of the largest pipe in the RCS. These analyses must be performed by methods acceptable to the NRC and must demonstrate that ECCS cooling performance conforms to the acceptance criteria set forth in the rule. For breaks at or below the TBS, § 50.46a(e)(1) specifies requirements identical to the existing ECCS analysis requirements set forth in § 50.46. However, commensurate with the lower probability of breaks larger than the TBS, § 50.46a(e)(2) of the rule specifies less conservatism for the analyses and associated acceptance criteria for breaks larger than the TBS. LOCA analyses for break sizes equal to or smaller than the TBS must be applied to all locations in the RCS to find the limiting break location. LOCA analyses for break sizes larger than the TBS must also be applied to all locations in the RCS (but using less conservative assumptions) to find the limiting break size and location. This analytical approach is consistent with current NRC regulatory positions and industry practice.

1. Acceptable methodologies and analysis assumptions.

Under existing § 50.46 requirements, prior NRC approval is required for ECCS evaluation models. The requirement for prior NRC approval of evaluation models is retained in § 50.46a(e). Acceptable evaluation models are currently of two types - those that realistically describe the behavior of the RCS during a LOCA, and those that conform with the required and acceptable features specified in Appendix K to Part 50. Appendix K evaluation models incorporate conservatism as a means to justify that the acceptance criteria are satisfied by an ECCS design. In contrast, the realistic or best-estimate models attempt to accurately simulate the expected phenomena. As a result, comparisons to applicable experimental data must be made and uncertainty in the evaluation model and inputs must be identified and assessed. This is necessary so that the uncertainty in the results can be estimated so that when the calculated ECCS cooling performance is compared to the acceptance criteria, there is a high level of probability that the criteria will not be exceeded. Appendix K, Part II, contains the documentation requirements for evaluation models. All of these existing requirements are included in § 50.46a(e)(1) of the final rule for breaks at or below the TBS.

As currently required under § 50.46, the ECCS analysis performed with a model other than one based on Appendix K must demonstrate with a high level of probability that the acceptance criteria will not be exceeded. The position taken in RG 1.157 has been that 95 percent probability constitutes an acceptably high probability. Section 50.46a(e)(1) of the final rule retains this high level of probability as the statistical acceptance criterion.

Final §§ 50.46a(e)(1) and (e)(2) require that the worst break size and location be calculated separately for breaks at or below the TBS and for breaks larger than the TBS up to and including a double-ended rupture of the largest pipe in the RCS. Different methodologies, analytical assumptions, and acceptance criteria may be used for each break size region. Consistent with current § 50.46 requirements, licensees are required to analyze breaks at or below the TBS by assuming the worst single failure concurrent with a loss-of-offsite power and only crediting operability of safety systems. For breaks larger than the TBS, licensees may take credit for operation of both safety and non-safety systems (subject to system availability as supported by operating experience or test data) provided that onsite power can be reliably provided to that equipment through manual actions within a reasonable time after a loss-of-offsite power. All non-safety equipment that is credited for analyses of breaks larger than the TBS must be identified as such and listed in the plant technical specifications. The assumptions of loss-of-offsite power and the worst single failure are not required in these analyses because breaks larger than the TBS are very unlikely and therefore, less margin is needed. The requirement to provide onsite power to non-safety equipment in a reasonable time following a loss-of-offsite power (e.g., approximately 30 minutes) is a defense-in-depth consideration for severe accident management.

2. Acceptance criteria.

ECCS acceptance criteria in § 50.46a(e)(3) for breaks at or below the TBS are the same as those currently required in § 50.46. Therefore, licensees must use an approved methodology to demonstrate that the following acceptance criteria are met for the limiting LOCA at or below the TBS:

- Peak cladding temperature (PCT) less than 2200°F;

- Maximum local cladding oxidation (MLO) less than 17 percent;
- Maximum hydrogen production -- core-wide cladding oxidation less than one percent;
- Maintenance of coolable geometry; and
- Maintenance of long-term cooling.

Commensurate with the lower probability of occurrence, the acceptance criteria in § 50.46a(e)(4) for breaks larger than the TBS are less prescriptive:

- Maintenance of coolable geometry, and
- Maintenance of long-term cooling.

The final rule allows licensees flexibility in establishing appropriate metrics and quantitative acceptance criteria for maintenance of coolable geometry. A licensee's metrics and acceptance criteria must realistically demonstrate that coolable core geometry and long-term cooling will be maintained. However, unless data or other valid justification criteria are provided, licensees should use 2200°F and 17 percent for the limits on PCT and MLO, respectively, as metrics and quantitative acceptance criteria for meeting the rule. Other less conservative criteria would be acceptable if properly justified by licensees.

Currently, the NRC is working to revise the ECCS acceptance criteria in § 50.46(b) to account for new experimental data on cladding ductility and to allow for the use of advanced cladding alloys. The NRC expects that this rulemaking (Docket ID NRC-2008-0332) will establish new cladding embrittlement acceptance criteria in § 50.46(b) for design basis LOCAs. When these new acceptance criteria are established, the NRC will also make any necessary conforming changes to § 50.46a for pipe breaks below and above the TBS.

3. Restriction of reactor operation.

Paragraph 50.46a(e)(5) allows the Director of the Office of Nuclear Reactor Regulation to impose restrictions on reactor operation if it is determined that the evaluations of ECCS cooling performance are not consistent with the requirements for evaluation models and analysis methods specified in final §§ 50.46a(e)(1) through (e)(4). Non-compliance may be due to factors such as lack of a sufficient data base upon which to assess model uncertainty, use of a model outside the range of an appropriate data base, use of models inconsistent with the requirements of Appendix K of Part 50, or discovery of phenomena unknown at the time of approval of the methodology. Lack of compliance with methodological requirements would not necessarily mean that the ECCS capability is unacceptable, but only that the analysis results using the methodology in question cannot be relied upon to demonstrate compliance with the appropriate acceptance criteria. Thus, depending upon the specific circumstances, it might be necessary for the NRC to impose restrictions on operation until these issues are resolved. This requirement is included in the final rule for consistency with the current ECCS regulations as specified in existing § 50.46(a)(2).

E. Risk-Informed Changes to the Facility, Technical Specifications, or Procedures

Licensees who adopt § 50.46a will use a risk-informed evaluation process to demonstrate, before implementation, that facility changes will satisfy the risk-informed acceptance criteria in § 50.46a(f). Changes that must be evaluated are specified in § 50.46a(d)(3) and include all "enabled" changes that satisfy the alternative ECCS analysis requirements in § 50.46a but do not satisfy the current ECCS analysis requirements in § 50.46.

Licensees are required to periodically maintain and upgrade the PRA used in the risk assessments and ensure that over time all changes made under § 50.46a continue to meet the risk-informed acceptance criteria. If necessary, § 50.46a(g)(1)(ii) requires the licensee to propose steps and a schedule to bring the facility back into compliance with the acceptance criteria in § 50.46a(f).

The risk-informed evaluation is required to demonstrate that increases in plant risk (if any) meet appropriate risk acceptance criteria, defense-in-depth is maintained, adequate safety margins are maintained, and adequate performance-measurement programs are implemented. The NRC believes that all changes to a plant, its technical specifications, or its procedures which are based upon the analyses of ECCS performance permitted under § 50.46a(e)(2) – with the exception of those changes permitted under § 50.46a(f)(1) – must be reviewed and approved by the NRC for two reasons. First, a wide range of changes could be implemented under § 50.46a, which, if improperly implemented by licensees, could result in significant adverse impacts on public health and safety or common defense and security. NRC review and approval will provide verification that a licensee has properly evaluated each proposed change against the acceptance criteria in § 50.46a. Second, changes involving technical specifications must receive NRC review and approval in the form of a license amendment, as required by the Atomic Energy Act of 1954, as amended. Accordingly, the NRC's final rule requires NRC review and approval of all changes initiated under § 50.46a(f)(2).

A licensee who wishes to make certain future changes that are enabled by the rule without prior NRC review and approval (i.e., via self-approval) must submit for review its risk-informed process that will be used in evaluating the acceptability of these changes as described in § 50.46a(c)(1)(vi). A licensee who will only make a single or a few changes enabled by the rule need not submit a risk-informed self-approval process. Instead, that licensee must only submit its risk-informed evaluation of each change it has requested. Acceptance criteria for self-approved changes enabled by the rule are described in § 50.46a(f)(1). Each licensee should evaluate its approach to implement § 50.46a to determine whether the self-approval process is its preferred alternative. If a licensee's initial application to implement § 50.46a did not include a self-approval process, that licensee may, at any later time, submit another license amendment requesting approval of a risk-informed self-approval process.

After one or more changes enabled by the rule have been implemented, licensees must periodically update its risk-informed evaluation of the changes to ensure that the acceptance criteria in § 50.46a(f), as applicable, continue to be met.

1. Requirements for the risk-informed evaluation.

The final rule is based upon the regulatory premise that the acceptability of all licensee-initiated changes made under the rule must be judged in a risk-informed manner. The risk-informed assessment process must include methods for evaluating compliance with the risk criteria, defense-in-depth criteria, safety margin criteria, and performance measurement criteria in § 50.46a(f). These attributes have been identified by the Commission as a necessary set of risk evaluation tools to ensure that changes to the facility do not endanger public health and safety.

Compliance with the risk criteria plays a key role in the regulatory structure of the rule. A risk assessment must be used to determine the change in risk associated with facility changes. Inasmuch as PRA methodologies are generally recognized as the best approach for conducting risk assessments suitable for making decisions in areas of potential safety significance, § 50.46a(f)(4) of the final rule requires that a technically adequate PRA be used to demonstrate compliance with the requirements of § 50.46a if the change being assessed could substantively increase risk. Sections 50.46a(f)(4)(i) through (iv) set forth the four general attributes of an acceptable PRA for the purposes of this rule. However, the NRC recognizes that non-quantitative PRA assessment methodologies and approaches could also be used to complement or supplement the quantitative aspects of a PRA, especially when performance of a quantitative PRA methodology of the level needed to support a particular plant modification decision is not justifiable because the safety significance of the decision does not warrant the level of technical sophistication inherent in a PRA. Accordingly, § 50.46a(f)(5) establishes the minimum requirements for risk assessment methodologies other than PRA. This requirement provides flexibility for licensees to use the non-PRA risk methodology (or combination of different methodologies) when these methodologies produce results that are sufficient to determine that the risk acceptance criteria in the rule have been met.

2. Aggregation of plant changes when evaluating changes in risk

Licensees often make changes to the facility, technical specifications, and procedures. Some changes that the licensees may make after adopting this rule would not have been permitted without the new § 50.46a ECCS requirements (enabled changes). Other changes would be unrelated insofar as the basis of the changes and NRC approval, when necessary, will rely on regulations, guidelines, or facility priorities that do not depend on the new ECCS requirements in § 50.46a. Unrelated changes will indirectly influence the change in risk of the § 50.46a related changes because they change the risk profile of the facility. If unrelated changes are combined (bundled) with enabled changes in evaluating the § 50.46a change in risk estimates, the result will typically be different than if the unrelated changes are considered as part of the baseline risk associated with the current design and operation of the facility. Regulatory Guide 1.174 permits bundling changes (referred to as combined changes in RG 1.174) and provides additional acceptance guidelines that must be met when combining unrelated plant changes that might decrease risk together with a group of enabled changes to evaluate the total change in risk for comparison to the acceptance guidelines.

The NRC believes that allowing bundling of unrelated changes into the § 50.46a change in risk estimates will encourage licensees to use risk-informed methods to take advantage of opportunities to reduce risk, and not just eliminate requirements that a licensee deems as undesirable. However, in some situations, bundling could mask the creation of significant risk outliers. To ensure that outliers are not created, and that the additional guidelines in RG 1.174 are appropriately applied, the rule will not permit bundling of unrelated changes with enabled changes without NRC review and approval. Therefore, the final § 50.46a(f)(2)(iii) allows changes not enabled by § 50.46a to be combined (bundled) with changes enabled by § 50.46a in the calculation of the change in risk when a licensee submits an application for a change under 50.90.

3. NRC approval of a licensee process for making changes to a licensee's facility or procedures without NRC review and approval.

As a general matter, the licensee must obtain NRC review and approval (through a license amendment application) for any changes to the facility, technical specifications, or procedures that may be implemented under § 50.46a. However, the NRC believes that there is a subset of plant and procedure changes that would be made possible by § 50.46a involving minimal changes in risk which also have no significant impact upon defense-in-depth capabilities. Prior NRC review and approval of these changes on an individual basis is unnecessary *if* the NRC has previously concluded that the licensee has an adequate technical process for appropriately identifying this subset of changes. In the NRC's view, plant changes which involve minimal changes in risk and have no significant impact upon defense-in-depth (and do not involve a change to the technical specifications), by definition, do not result in significant issues involving public health and safety or common defense and security.

Expending licensee resources to prepare an application for approval of plant changes involving minimal changes in risk and NRC resources to review and approve these applications is not an efficient use of resources. Rather, the NRC believes that if it reviews and approves in advance the licensee's processes (including the adequacy of the licensee's PRA and other risk assessment methods) and criteria for identifying changes which are both minimal from a risk standpoint and do not significantly affect defense-in-depth or plant physical security, then there is no need to review and approve each of the changes individually. Further, the NRC believes that these minimal changes are unlikely to impact the built-in capability of the facility to resist security threats. Accordingly, the NRC is including an approach in § 50.46a(f)(1) allowing a licensee to obtain “pre-approval” of a process for identifying minimal plant and procedure changes made possible under § 50.46a.

Section § 50.46a(f)(1) states that a licensee may self-approve changes based upon the provisions of this section without prior review and approval if the stated requirements in paragraphs (f)(1) and (f)(3) of this section are met. The rule also states that the provisions of the existing § 50.59 change process continue to apply. Licensees with a pre-approved § 50.46a(f)(1) change process will be allowed to make facility changes without NRC approval if they met both § 50.59 and § 50.46a requirements. Compliance with the current § 50.59 requirements is necessary to ensure that facility changes made without NRC approval do not result in plant conditions that could impact public health and safety. Compliance with the § 50.46a(f) requirements for risk assessments is required to ensure that facility changes result in acceptable changes in risk, that adequate defense-in-depth is maintained, that safety margins will be maintained, and that adequate performance-measurement programs are implemented.

4. Risk acceptance criteria for plant changes.

Section 50.46a(f)(2)(ii) requires that the total increases in risk are very small and that the overall plant risk remains small. The NRC believes that this requirement is a necessary element for ensuring that changes which are permitted by the final § 50.46a ECCS analyses do not result in a greater change in risk than intended by the Commission.

a. Risk estimate.

To satisfy the Commission's requirement in §§ 50.46a(f)(2)(ii) that the total increases in risk are very small requires that the change in risk for each facility change be evaluated and shown to meet the acceptance guidelines. If a series of changes are made over time, § 50.46a(f)(2)(iii) requires that cumulative effect of these changes be evaluated and shown to meet the acceptance criteria. Section 50.46a(f)(2)(iii) also permits changes in risk from facility changes not enabled by § 50.46a to be combined by the licensee with facility changes that are enabled by this section for the purposes of meeting the acceptance guidelines. Taken together, this combined (bundled) group of enabled changes and unrelated changes is referred to as the changes made *under* § 50.46a. For each change requiring a risk-informed evaluation, the total change in risk from all facility changes made *under* the rule after adopting § 50.46a must be evaluated and compared to the "very small" acceptance criterion when the change is first made, then with each subsequent enabled change that results in a greater than minimal increase in risk, and again after each time that the PRA is changed through periodic maintenance and upgrading. Requiring that the total change in risk from all facility changes made under the rule after the adoption of § 50.46a be compared to the § 50.46a acceptance criteria instead of allowing the changes in risk to be partitioned and individually compared to the acceptance criteria ensures that the total risk increase for all changes, as they are implemented over time, does not constitute more than a very small increase in risk. If the total increase in the applicable risk metrics were not compared to the acceptance criteria, a number of changes in which each individual change's risk increase is kept below the rule's risk acceptance criteria could, considered cumulatively, result in a significant increase in risk. A significant increase would not satisfy the Commission’s criteria that the overall plant risk remains small. Also, comparing the risk increase from each change to the acceptance criteria independently of all previous changes would render the use of the ‘‘very small" criterion inadequate to monitor and control increases in risk from a series of plant changes implemented over time.

Comparing the total risk increase to the risk increase criterion, and allowing bundling of unrelated changes in the change in risk estimate, will support the NRC’s philosophy that, consistent with the principles of risk-informed integrated decision making, licensees will have a risk management philosophy in which risk insights are not just used to systematically increase risk, but also to help reduce risk where appropriate and where it is shown to be cost effective.

b. Acceptance criteria.

In § 50.46a(f)(2)(ii), core damage frequency (CDF) and large early release frequency (LERF) are used as surrogates for early and latent health effects, which are used in the Commission’s Policy Statement on Safety Goals (51 FR 30028; August 4, 1986). The NRC has used CDF and LERF in making regulatory decisions for over 20 years. The NRC endorsed the use of CDF and LERF as appropriate measures for evaluating risk and ensuring safety in nuclear power plants when it adopted RG 1.174 in 1997. Since the adoption of RG 1.174, the NRC has had 13 years of experience in applying risk-informed regulation to support a variety of applications, including amending facility procedures and programs (e.g., IST and ISI programs), amending facility operating licenses, making changes to the FSAR, and implementing risk-informed technical specifications. On the basis of this experience, the NRC has determined that CDF and LERF are acceptable measures for evaluating changes in risk as the result of changes to a facility, technical specifications, and procedures, with the exception of certain changes that affect containment performance but do not affect CDF or LERF. Changes that affect containment performance are considered as part of the defense-in-depth evaluation.

The Commission has concluded that changes under this rule shall be restricted to very small risk increases. As discussed in RG 1.174, a very small risk increase is independent of a plant's overall risk as measured by the current CDF and LERF. Increases in CDF of 10^{-6} per reactor year or less, and increases in LERF of 10^{-7} per reactor year or less are very small risk increases for existing reactor facilities. Applicants for new reactor operating licenses under Part 52 may need to supplement these criteria to also meet the requirement that implementing the proposed changes will not result in a significant decrease in the level of safety otherwise provided by the new reactor design.

Since adopting RG 1.174 in 1997, the NRC has applied the quantitative change in risk guidelines to individual plant changes and to sequences of plant changes implemented over time. The NRC has found these guidelines and the CDF and LERF values (when used together with the defense in depth, safety monitoring, and performance measurement criteria) are capable of differentiating between changes, and sequences of changes, that are not expected to endanger public health and safety from those that might.

Section 50.46a(f)(1) permits licensees to make changes under this provision without prior review and approval if the changes involve minimal increases in risk which also have no significant impact upon defense-in-depth capabilities. A minimal risk increase is one which, when considered qualitatively by itself or in combination with all other minimal increases, would never become significant. Logically, a minimal increase is less than the very small increase in CDF and in LERF, and has been chosen as an increase of less than 10^{-7} per reactor year for CDF and an increase in LERF of less than 10^{-8} per reactor year for existing reactor facilities. Although ten changes, each separately considered to be minimal increases, when considered together could exceed the very small criteria, the NRC believes that most of these changes will have a much smaller (and, in some cases, an unmeasurable) increase in risk. Regardless of whether a licensee makes changes under § 50.46a(f)(1) instead of § 50.46a(f)(2), the total cumulative risk including all the individually minimal risk increases as well as any increases approved by the NRC under § 50.46a(f)(2), must be considered in the periodic reporting required by § 50.46a(g)(1)(ii). If a licensee implements an unexpectedly large number of minimal risk changes, the periodic reporting requirements in § 50.46a(g)(2) will provide adequate notice to ensure that the NRC is aware of potentially significant changes (or any collective impact), so that the NRC may undertake additional oversight actions as deemed necessary and appropriate.

5. Defense-in-depth.

Section 50.46a(f)(3)(i) requires that the risk-informed evaluation demonstrate that defense-in-depth is maintained. Defense-in-depth is an element of the NRC's safety philosophy that employs successive measures to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility. As conceived and implemented by the NRC, defense-in-depth provides, among other things, redundancy in addition to a multiple barrier approach against fission product releases. Defense-in-depth continues to be an effective way to account for uncertainties in equipment and human performance. The NRC has determined that retention of adequate defense-in-depth must be ensured in all risk-informed regulatory activities.

6. Safety margins.

Section 50.46a(f)(3)(ii) requires that adequate safety margins be retained to account for uncertainties. These uncertainties include phenomenology, modeling, plant construction, and plant operation. The NRC's concern is that plant changes could inappropriately reduce safety margins, resulting in an unacceptable increase in risk or challenge to plant systems, structures and components (SSCs). This provision ensures that an adequate safety margin exists to account for these uncertainties, such that there are no unacceptable results or consequences (e.g., structural failure) if an acceptance criterion or limit is exceeded.

7. Performance measuring programs.

Section 50.46a(f)(3)(iii) requires that adequate performance measurement programs and feedback strategies be implemented to ensure that the risk-informed evaluation continues to reflect actual plant design and operation. The risk-informed evaluation includes the risk assessment, maintenance of defense-in-depth, and maintenance of adequate safety margins. This section requires that the monitoring programs be designed to detect degradation of SSCs before plant safety is compromised. Permitting degradation to advance until plant safety could be compromised would be inconsistent with the NRC's regulatory responsibility of protecting public safety. The NRC expects that licensees will integrate existing programs for monitoring equipment performance and other operating experience both on their site and throughout industry with the performance measuring programs required by this section.

F. Leak Detection Requirements

In its SRM on SECY-07-0082, the Commission directed the NRC staff to increase the defense-in-depth provided by the rule against large pipe breaks. The SRM also directed the NRC staff to evaluate various approaches for enhancing the rule with requirements for enhanced leak detection methods. The NRC determined that enhanced leak detection capability could improve defense-in-depth for LOCAs larger than the TBS by reducing the likelihood of pipe breaks in the large break region. Thus, § 50.46a(d)(2) of the final rule requires that, "The licensee shall have leak detection systems available at the facility and shall implement actions as necessary to identify, monitor and quantify leakage to ensure that adverse safety consequences do not result from primary pressure boundary leakage from piping and components that are larger than the transition break size."

Because § 50.46a makes no changes to the design basis of piping and components that are smaller than the TBS, the requirements of § 50.46a(d)(2) only apply to piping and components that are larger than TBS. The NRC recognizes that leakage detection methods that satisfy these requirements may not be capable of determining whether the source of leakage is from piping or a component that is larger or smaller than the TBS. Discrimination between leaks in pipes larger or smaller than the TBS is unnecessary as long as enhanced leak detection is provided for all beyond-TBS piping.

In response to a recommendation made by the Davis-Besse Lessons Learned Task Force (DBLLTF), (see memorandum from Arthur T. Howell to William F. Kane, ''Degradation of the Davis-Besse Nuclear Power Station Reactor Pressure Vessel Head Lessons-Learned Report; September 30, 2002; ADAMS Accession No. ML022740211) the NRC evaluated whether it should impose tighter reactor coolant leakage limits and new leakage monitoring requirements on licensees. Specifically, the DBLLTF Recommendation 3.1.5(1) was that the NRC should determine whether PWR plants should install online enhanced leakage detection systems on critical plant components which could detect leakage rates of significantly less than 1 gallon per minute. The NRC's evaluation identified techniques that could improve localized leak detection and on-line monitoring and also identified several areas of possible improvements to leakage detection requirements that could provide increased confidence that plants are not operated at power with reactor coolant pressure boundary leakage. Although the NRC concluded that there was not a sufficient basis to require the technical specification on allowable leakage to be reduced for existing licensees through a backfit, the NRC recommended updating Regulatory Guide 1.45 on leak detection.

In May 2008, the NRC finalized Revision 1 to Regulatory Guide 1.45, "Guidance on Monitoring and Responding to Reactor Coolant System Leakage" which provides new guidance on improved leak detection methods. RG 1.45, Revision 1, incorporates progress in reactor coolant pressure boundary leakage detection technology; addresses the effect on radiation monitoring, and, subsequently, on leak detection, from reduced reactor coolant activity levels due to improved fuel integrity; and incorporates lessons learned from operating experience. Revision 1 also provides detailed guidance for timely detection and location of leaks, continuous monitoring, quantifying and trending leak rates, assessing safety significance of leakage, and specifying plant actions following confirmation of an adverse trend in the unidentified leak rate. Revision 1 describes acceptable leakage detection systems and methods, using risk-informed and performance-based criteria to the extent practical. It retains the recommendations for monitoring of sump level or flow, airborne particulate activity, and condensate flow rate from air coolers. Other supplementary detection methods are recommended for use where and when appropriate.

The NRC has concluded that by implementing the guidance in Regulatory Guide 1.45, Revision 1, licensees who choose to comply with § 50.46a will have improved monitoring and response to leaks in the reactor coolant system sufficient to satisfy the requirements of § 50.46a(d)(2).

G. Operational Requirements

The final rule includes six specific operational requirements that apply to licensees who are approved to implement § 50.46a. These requirements are set forth in § 50.46a(d) and remain in effect as long as the facility is subject to the § 50.46a alternative ECCS requirements until such time as the licensee permanently ceases operations by submitting the decommissioning certifications required under § 50.82(a). They are:

1. Maintain ECCS models and/or analysis methods that demonstrate compliance with the ECCS acceptance criteria.

2. Maintain reactor coolant leak detection equipment available at the facility and identify, monitor, and quantify leakage to ensure that adverse safety consequences do not result from leakage from piping and components larger than the transition break size.

3. Perform a risk-informed evaluation for each potentially risk-significant change (or group of changes) to the facility enabled by or made under § 50.46a.

4. Periodically confirm that the cumulative risk impact of changes to the facility made under § 50.46a continue to meet the acceptance criteria.

5. Do not operate the plant for more than a “short time” in any 12-month period in an at-power operating configuration that has not been demonstrated to meet the ECCS acceptance criteria for breaks larger than the TBS.

6. Perform an evaluation to determine the effect of all planned facility changes and do not implement any facility change that would invalidate the applicability to the facility of the results in NUREG-1829 and NUREG-1903.

Each of the six operational requirements is discussed in detail below.

1. Maintain ECCS models and/or analysis methods that demonstrate compliance with the ECCS acceptance criteria.

Section 50.46a(d)(1) requires that calculated results of licensee ECCS models and/or analysis methods must demonstrate compliance with the ECCS acceptance criteria throughout the operating lifetime of the plant. Licensees must also update ECCS models and/or analysis methods by modifying them as needed to address any plant design changes affecting ECCS performance during this time period.

2. Section 50.46a(d)(2) requires licensees to maintain reactor coolant leak detection equipment available at the facility and identify, monitor, and quantify leakage to ensure that adverse safety consequences do not result from leakage from piping and components larger than the transition break size.

This requirement for enhanced leak detection capability was previously discussed in section III.F, of this document. Enhanced leak detection must be provided for all primary piping and components (excluding the reactor vessel) whose rupture could result in a break larger than the TBS.

3. Perform a risk-informed evaluation for each change (or group of changes) to the facility enabled by or made under § 50.46a.

In addition to meeting all other applicable requirements, a risk-informed evaluation required by § 50.46a(d)(3) must be performed for changes enabled by or made under § 50.46a. If a licensee has a change methodology that was submitted under § 50.46a(c)(1)(vi) and approved by the NRC, that licensee can make some changes without NRC approval as long as the acceptance criteria in § 50.46a(f)(1) are met. Otherwise, the licensee is required to submit the results of its risk-informed evaluation for NRC review and approval in a license amendment request subject to the requirements of § 50.90. The licensee must retain the results of all risk-informed evaluations made under § 50.46a(f)(1) and periodically submit a summary of the results to the NRC as required under § 50.46a(g)(1)(iii).

4. Periodically assess the cumulative effect of changes to the facility made under § 50.46a.

Key components of risk-informed regulation are the monitoring of changes in plant risk and updating the risk assessment and/or plant design activities and processes which are the subject of the risk assessment. Section 50.46a(d)(4) requires that after adopting § 50.46a, a licensee must periodically maintain and upgrade the risk assessments (both PRA and non-PRA) required under §§ 50.46a(f)(4) and (f)(5). It is necessary that the PRA be maintained to reflect all plant changes; such as modifications, procedure changes, or changes in plant performance data. Other factors that could change the risk-assessments, such as changes to LOCA frequencies or seismic hazards, must also be included as part of the PRA maintenance. This maintenance enables the licensee to demonstrate that the total increases in CDF and LERF after adopting § 50.46a continue to meet the acceptance criteria in § 50.46a(f)(2). The risk assessments must also continue to meet the minimum quality requirements in §§ 50.46a(f)(4) and (f)(5) to support reasoned decision making under the rule.

The final rule specifies that the maintenance and upgrading be conducted periodically "but no less often than once every four years." The NRC believes that this is an appropriate period because the uncertainty of risk changes occurring during the period is tolerable and unlikely to lead to high risk situations as a result of the implementation of plant changes. The NRC's determination is based upon the stringent acceptance criteria governing changes made under § 50.46a, the existing deterministic criteria in the technical requirements in Part 50, and the criteria utilized in determining the acceptability of plant changes.

If the assessment of the cumulative effect of changes made under the rule demonstrates that the acceptance criteria in § 50.46a(f)(2) are not met, § 50.46a(g)(1)(ii) requires the licensee to develop steps and a schedule to bring the facility design and operation back into compliance with the acceptance criteria. These actions may include (but are not limited to) corrections to the risk analyses to demonstrate compliance, implementation of facility changes to offset adverse changes in risk, or reversal of changes previously made under the provisions of § 50.46a(f). The NRC believes that this requirement provides appropriate flexibility for the licensee to determine the actions necessary to ensure continued compliance with the § 50.46a(f) acceptance criteria, and is consistent with the concept of performance-based regulation.

5. Do not operate the plant for more than a short time in an operating configuration that has not been demonstrated to meet the ECCS acceptance criteria for breaks larger than the TBS.

A short time for an operating reactor whose construction permit was issued before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR], is either a total of fourteen (14) days in any 12-month period or an alternative proposed by the licensee and approved by the NRC. The final rule does not define a short time for a new reactor design (i.e., a future operating reactor whose license is issued under Part 52 of this chapter). Instead the rule requires the applicant or licensee, as applicable, to propose a time period constituting a "short time" for its plant by demonstrating that there is not a significant decrease in the level of safety otherwise provided by the design.

As previously discussed in the supplementary information of this document, the final rule includes restrictions on plant operation in configurations where licensees have not demonstrated that LOCAs larger that the TBS will be mitigated. The initial proposed rule (November 2005) would have completely prohibited at-power operation in any configuration without the demonstrated ability to mitigate a beyond-TBS LOCA. The final rule restricts operation in such a configuration to a short time in any 12 month period. A short time for existing operating reactors is either 14 days in 12 months or an NRC-approved alterative time the NRC believes it is unlikely that licensees will experience circumstances where they would consider operating in such a condition for more than 14 days, but has concluded that the establishing a limit on the allowable time is necessary to support the defense-in-depth philosophy. The rule allows using an alternative to the 14 days per 12 months limit because risk-informed evaluations could be developed to determine a different plant specific limit. Even though the LOCA frequencies on which the TBS is founded indicate that the expected frequency of breaks larger than the TBS is low, the restriction is needed because there are large uncertainties associated with these frequency estimates. The Commission concluded that the consequences of a challenge to the facility from an unmitigated break larger than the TBS are severe enough to warrant confidence that the break can be mitigated.

As discussed above, a short time for new reactor designs shall be proposed by the licensee and be approved by the NRC. In addition to meeting all the risk-informed acceptance criteria for existing operating reactors, new reactor licensees must also demonstrate that the allowable outage period does not cause a significant decrease in the level of safety otherwise provided by the design. The additional limitation is needed because new reactors are expected to have significantly lower risk profiles from the current operating reactor fleet and the NRC does not want new reactors to significantly increase the overall risk profile of the plant during operation.

6. Perform an evaluation to determine the effect of all planned facility changes and do not implement any facility change that would invalidate the applicability to the facility of the results in NUREG-1829 and NUREG 1903.

For the TBS to properly apply to a specific facility, an evaluation must be performed to demonstrate that the results of the two generic studies on which the TBS is based are applicable to that particular facility. But after the initial evaluation has demonstrated the applicability of the NUREG-1829 and NUREG-1903 results, a licensee could make significant facility changes that would invalidate the initial evaluation. Therefore, after a facility has adopted § 50.46a, the final rule requires the licensee to ensure that the TBS remains applicable to the facility by reviewing all subsequent plant changes to ensure that the facility is not modified to the extent that the results of the NUREG-1829 and NUREG-1903 studies no longer apply. The NRC believes it is likely that a licensee's existing configuration management program, that contains a process to control plant changes made under § 50.59, "Changes, Tests and Experiments" could be modified, through screening or evaluation, to identify future plant changes made which may invalidate the applicability of the NRC's generic studies.

H. Reporting Requirements

1. ECCS Analysis reporting requirements.

Section 50.46a(g)(1)(i) sets forth reporting requirements with respect to changes or errors in LOCA evaluation models. For each change to or error discovered in an ECCS evaluation model or analysis method or in the application of such a model that affects the calculated results, the licensee shall report the nature of the change or error and its estimated effect on the limiting ECCS analysis to the NRC at least annually as specified in § 50.4. If the change or error is significant, the 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 § 50.46a requirements. The 30-day period ensures sufficient time for the licensee to complete its evaluation, explain the changes, and determine the course of action necessary to address compliance issues. For breaks smaller than the TBS, a significant change is one which results in a calculated peak fuel cladding temperature different by more than 50 degrees Fahrenheit 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 degrees

Fahrenheit. This requirement is the same as in § 50.46. The NRC will also apply these reporting criteria to LOCAs involving pipe breaks larger than the TBS unless a specific alternative is proposed by a licensee and is approved by the NRC.

2. Risk assessment reporting requirements.

Section 50.46a(g)(1)(ii) sets forth reporting requirements with respect to maintaining and upgrading the PRA as required by § 50.46a(d)(4). When updating and upgrading the PRA, § 50.46a(g)(1)(ii) requires the licensee to report changes to the NRC within 60 days if the acceptance criteria in §§ 50.46a(f)(2)(ii) are exceeded. This provision also requires the report to include a schedule for implementation of any corrective actions necessary to bring plant operation or design back into compliance with the acceptance criteria. The 60-day period ensures sufficient time for the licensee to complete its evaluation and explanation of the changes and determine the course of action necessary to address adverse changes in risk, while not unduly delaying the report to the NRC and thereby delaying NRC oversight. The NRC believes it should be informed of the licensee's implementation schedule so the NRC can ensure that the licensee takes corrective action on a timely basis, consistent with the safety significance of the change.

Section 50.46a(g)(1)(iii) requires periodic reports of changes that required a risk-informed evaluation under § 50.46a(d)(3) and were implemented without prior NRC approval under paragraph (f)(1) of this section. This process is comparable in many respects to the § 50.59 process which requires similar reports.

Section 50.46a(g)(2) contains reporting requirements for design certification applicants and applicants for and holders of design approvals. If errors in the submitted or approved ECCS evaluation models are discovered, they must be reported to the NRC in accordance with the requirements in § 50.46a(g)(2)(i), for LOCAs at or below the TBS and § 50.46a(g)(2)(ii), for LOCAs larger than the TBS. In this paragraph the NRC has modified the rule language that was published in the supplemental proposed rule to specify the time period for making these reports. The reporting requirements and time periods specified in the § 50.46a final rule are now consistent with the reporting requirements in § 50.46(a)(iii). Errors must be reported to the NRC and to any applicant or licensee referencing the design approval or design certification at least annually. Significant errors must be reported within 30 days. These reporting requirements continue until the later of either the termination or expiration of the design certification; or the termination of the last license directly or indirectly referencing the design certification.

I. Documentation Requirements

Section 50.46a(h) of the final rule requires that licensees maintain records sufficient to demonstrate compliance with § 50.46a requirements. When making plant changes under § 50.46a(f) and when updating its PRA and/or other risk assessments, licensees are required to document the bases for concluding that the acceptance criteria in §§ 50.46a(f)(1) and (f)(2) are satisfied and that they continue to be satisfied throughout the operating lifetime of the facility. Licensees are required under Part II of Appendix K to Part 50 to document the bases of evaluation models used to perform ECCS calculations. Licensees must document the time spent in an operating configuration not demonstrated to meet the ECCS acceptance criteria in § 50.46a(c)(3) to demonstrate compliance with the time limits in paragraph (d)(5) of this section. Licensees must also document plant design changes made under § 50.46a by updating the Final Safety Analysis Report in accordance with the requirements in § 50.71(e). All documentation could be reviewed during NRC inspections and/or audits.

J. Submittal and Review of Applications

1. Initial application for implementing alternative § 50.46a requirements.

When a licensee first applies to adopt the alternative § 50.46a requirements, that licensee must submit an application under § 50.90 for NRC review and approval of a license amendment request. The initial application must contain the information specified in §§ 50.46a(c)(1)(i) through (viii), as applicable. This includes information related to the applicability to the facility of the NUREG-1829 and NUREG-1903 results (and consequently the TBS); information identifying the ECCS analysis methods to be used; information explaining the risk-informed basis for any alternative “short time” period proposed for use by existing operating reactors under paragraph (d)(5); information explaining the risk-informed basis for the “short time” period under paragraph (d)(5) proposed for new reactor designs; information describing the risk-informed evaluation for all changes enabled by or made under the rule (enabled changes plus bundled unrelated changes) and proposed in the application; information describing the proposed process for making risk-informed changes without prior NRC approval (if the applicant is seeking approval of such a process); information describing non-safety equipment to be credited for compliance with the ECCS acceptance criteria in § 50.46a(e), and information describing how the leak detection program satisfies the criteria in § 50.46a(d)(2). A licensee's initial change from its existing ECCS analysis need not be reviewed by the licensee under the provisions of § 50.59 because the rule requires NRC review and approval of the initial license amendment application to implement the alternative § 50.46a requirements. After the § 50.46a evaluation models and initial ECCS LOCA analyses are established by approval of the § 50.46a license amendment, subsequent changes to ECCS analyses will be controlled by the existing process in § 50.59 (which provides criteria for determining which changes are within the licensee's authority) and the requirements in § 50.46a(g) for reporting when changes to evaluation models and analysis methods (whether from correction of errors or changes) are significant. The initial application may request one or more facility changes.

Paragraph (c)(1)(iii) allows operating reactor applicants who wish to determine compliance with paragraph (d)(5) by proposing a time period other than 14 days, to submit for NRC approval the appropriate length of time constituting a “short time.” Paragraph (c)(1)(iv) requires new reactor applicants under Part 52 of this section, to provide in the initial application the length of time constituting a "short time" for the allowable outage time for certain plant equipment under paragraph (d)(5).

The initial application may also include a request for NRC approval of a process for evaluating the acceptability of future facility changes enabled by § 50.46a using the provisions in paragraph (f)(1) of this section. If approval of a process for evaluating future changes is requested, the application must include the information described in § 50.46a(c)(1)(vi).

2. Subsequent applications for plant changes under § 50.46a.

After NRC approval of a licensee's initial license amendment application addressing ECCS analyses and the risk-informed evaluation processes, licensees may submit individual license amendment applications for plant changes under § 50.90. These individual license amendment applications must contain:

a. The information required by § 50.90;

b. Information from the risk-informed evaluation demonstrating that the risk criteria, defense-in-depth criteria, safety margins, and performance monitoring criteria in §§ 50.46a(f)(2) and (f)(3) are met;

c. Information demonstrating that the ECCS acceptance criteria in §§ 50.46a(e)(3) and (e)(4) are met; and

d. Information demonstrating that the proposed change will not increase the LOCA frequency of the facility by an amount that will invalidate the applicability to the facility of the NUREG-1829 and NUREG-1903 reports (and consequently the TBS).

After reviewing the individual plant change license amendment application, the NRC may approve the change if it complies with the above criteria and all other applicable NRC regulations, including the current requirements for plant physical security. In addition, the NRC will evaluate potential impacts of the proposed change on facility security to ensure that the change does not significantly reduce the “built-in capability" of the plant to resist security threats, thus ensuring that the change is not inimical to the common defense and security and provides adequate protection to public health and safety.

Licensees who have not submitted a request for NRC approval of a process for evaluating the acceptability of future changes enabled by § 50.46a using the provisions in paragraph (f)(1) of that section may make such a request at any time by submitting a license amendment application containing the information described in paragraph (c)(1)(vi).

K. Applicability to New Reactor Designs

Based on information currently available, new reactor designs may have similar piping materials, similar service conditions and operational programs, similar piping designs, and similar mitigation and control of age-related degradation programs to those found in currently operating plants. There are several new LWR designs for which the NRC expects that the frequency of large LOCAs could be as low as it is at current LWRs. Thus, it could be appropriate to allow applicants to apply the § 50.46a requirements to these future designs. Accordingly, the final rule applies to new LWR designs; i.e. facilities other than those which are currently licensed to operate. Applicants for design certification or combined licenses, holders of combined licenses under 10 CFR Part 52, or any other future licensees of operating light-water reactors who wish to apply § 50.46a must submit an analysis for NRC approval demonstrating why it would be appropriate to apply the alternative ECCS requirements and what the appropriate TBS would be in order for the new design to meet the intent of the § 50.46a rule.

In its analysis, the applicant, holder, or licensee must demonstrate that the proposed reactor facility is similar to reactors licensed before the effective date of the rule. In addressing similarity of the proposed design to reactors licensed before the effective date of rule, the applicant, holder, or licensee will need to address design, construction and fabrication, and operational factors that include, but are not limited to:

(1) The similarity of the piping materials of construction and construction techniques for new reactors to those in the currently operating fleet;

(2) The similarity of service conditions and operational programs (e.g., in-service inspection and testing, leak detection, quality assurance etc.) for new reactors to those for operating plants;

(3) The similarity of piping design, (e.g., pipe sizes and pipe configuration) for new reactors to those found in operating plants;

(4) Adherence to existing regulatory requirements, regulatory guidance, and industry programs related to mitigation and control of age-related degradation (e.g., aging management, fatigue monitoring, water chemistry, stress corrosion cracking mitigation etc.); and

(5) Any plant-specific attributes that may increase LOCA frequencies compared to the results in NUREG-1829 and NUREG-1903.

The analysis must also include a recommendation for an appropriate TBS and a justification that the proposed TBS includes sufficient margin to provide assurance that, when considering the limited availability of data and the uncertainty in the estimation of loss of coolant accident frequency, the estimated frequency of breaks larger than the TBS for all initiators does not exceed 10^{-5} per year. For those new reactor designs that employ design features that effectively increase the break size via opening of specially designed valves to rapidly depressurize the reactor coolant system during any size loss of coolant accident, justification of the relevance of a TBS would also be necessary. The methodology used to determine the proposed TBS should be described in the justification.

It should be noted that all of the preceding discussion in Section III of this supplementary information uses the term “licensee” to describe who might implement the final § 50.46a rule and how the rule would be applied. The NRC has used this term for convenience only to simplify the discussion. The NRC does not intend for this discussion to limit the application of § 50.46a to licensees only. As stated in the final rule language (with certain specified restrictions) and in the section-by-section analysis of the final rule, for reactor designs that are shown to be similar to the designs of currently operating reactors, § 50.46a could be used by applicants for and holders of construction permits, operating licenses, combined licenses, and standard design approvals and applicants for certified designs and for manufacturing licenses.

IV. Discussion of Public Comments on Supplemental Proposed Rule

The NRC received five comment letters on the supplemental proposed rule from two private citizens and two nuclear industry organizations, NEI and the Pressurized Water Reactor Owners Group (PWROG). The NRC considered all public comments in formulating the final rule language. This section summarizes the comments received on supplemental proposed rule and the NRC's responses to those comments. The following comment identification abbreviations are used: NEI = NEI; PWR Owners Group = P, Mark Leyse = ML; and Robert Leyse = RL.

Comments and other publicly available documents related to this rulemaking may be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), Room O-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. Selected documents, including comments, may be viewed and downloaded electronically via the Federal e Rulemaking Portal. Go to http://www.regulations.gov and search for documents filed under Docket ID NRC-2004-0006.

The public comments were related to nine different general topics: selection of the TBS, applicability of generic studies, thermal-hydraulic analysis, probabilistic risk assessment, comments related to existing petitions for rulemaking, enhanced leak detection, applicability to new reactor designs, applicability of the backfit rule, general comments, and comments on three questions posed by the Commission. The comments are discussed below by topic area.

A. Comments on Selection of the TBS

Comment. A commenter stated that the TBS proposed for boiling water reactors (BWRs) is overly conservative and may unnecessarily limit or preclude benefits for BWRs. The commenter reiterated an earlier comment made on the initial proposed rule suggesting that the specified piping for the BWR TBS should be equivalent to the 16-inch schedule 80 piping in the shutdown cooling suction line inside containment. (NEI-A1-1, Part A)

NRC response. The NRC disagrees with the commenter's view. The TBS for BWRs is based on the cross-sectional area of the larger of either the shutdown cooling residual heat removal (RHR) or feedwater pipes which are connected to the RCS inside containment. These pipe sizes are generally in the 18- to 24-inch range, and are similar in size to the 95th percentile estimates from the expert elicitation for BWRs at a 10^{-5} per year frequency. (It should be noted that the NRC also considered uncertainties in the estimates based on analysis sensitivities of the expert elicitation results, such as the method of aggregating the individual frequency estimates. More specifically, the 95th percentile estimate of BWR break size diameter for the geometric mean aggregation method is approximately 13 inches and the corresponding break size for the arithmetic mean aggregation method is approximately 20 inches.) The actual plant pipe sizes were used as a logical selection criterion; because for a given size break, it is more likely that a break will be circumferentially oriented and result in complete severance of the pipe than a partial break or one that is longitudinally oriented. Therefore, the NRC selected the TBS by considering the actual size of the attached piping, rather than by selecting a single break size value which would conservatively bound all plant configurations. For BWRs, the pipes connecting to the RCS, other than the largest reactor recirculation piping or main steam line piping, are the feedwater and RHR piping. Also, these pipes are large enough so that a single-ended break of one of them will generally bound the total cross-sectional discharge area for a double-sided break in smaller size piping that is connected to the feedwater or recirculation systems. The commenter provided no technical basis for its recommended alternative TBS and provided no data or analyses to demonstrate that the NRC made any logical or technical errors in its method used to select the BWR TBS. For these reasons, the NRC has determined that the TBS for BWRs will be based on the cross-sectional area of the larger of either the feedwater or RHR lines inside containment. No changes to the BWR TBS were made in the final rule.

Comment. A commenter reiterated an earlier comment made on the initial proposed rule by stating that for pressurized water reactors (PWRs) with large piping connected to both the hot and cold legs, the TBS for the hot leg should be based on the largest connecting pipe on the hot leg, and the TBS for the cold leg should be based on the largest connecting pipe on the cold leg. For PWRs with no large piping connected to the cold legs, it should be acceptable to use the TBS for the hot leg for both hot and cold legs. (NEI-A1-1, Part B)

NRC response. In developing the basis for the PWR TBS, the NRC not only used the mean break frequency estimates from the expert elicitation but also included additional allowances for various uncertainties. To address uncertainties in the elicitation process, the 95th percentile estimates of break size diameter were used. Further, the methods of aggregating the individual elicitation frequency estimates were evaluated for sensitivities. For PWRs, the break size at a 10^{-5} per year frequency using the geometric mean method is approximately 6 inches, and the corresponding break size for the arithmetic mean method is approximately 10 inches. This is similar in size to the cross-sectional area of the largest pipe attached to the main reactor coolant loop on which the TBS is ultimately based. The largest attached piping in PWRs is generally in the 12- to 14-inch nominal pipe size range (with inside diameters corresponding to 10.1 to 11.2 inches), and typically corresponds to the surge line which is attached to the hot leg. However, on some Combustion Engineering and Babcock and Wilcox plants, the largest attached pipes may be the RHR, safety injection, or core flood lines, which may not be similarly attached to the hot leg. However, as stated in the statement of considerations for the initial proposed rule (see 70 FR at 67603-67606), the NRC selected only one size which would uniformly apply for all locations in the RCS piping because the expert elicitation did not provide sufficient detail to distinguish between the hot leg and cold leg break frequencies. The commenter did not provide additional information or technical data that justifies different break frequencies or use of a smaller TBS on the cold leg piping and provided no data or analyses to demonstrate that the NRC made any logical or technical errors in its method used to select the PWR TBS. Thus, no changes to the PWR TBS were made in the final rule.

B. Comments on Applicability of Generic Studies Supporting the TBS

Comment. A commenter reiterated an earlier comment made on the initial proposed rule, stating that plant-specific assessments of the effect of seismically-induced breaks should not be required to demonstrate that seismically-induced pipe breaks do not significantly affect the likelihood of pipe breaks larger than the TBS. The commenter stated that EPRI studies demonstrated the negligible contribution of the indirect seismically-induced LOCA risk and reiterated that such an assessment is not necessary given the negligible contribution to the overall LOCA frequency. The commenter noted that § 50.46a(3)(c)(i) of the supplemental proposed rule retained the requirement for such a plant specific assessment. (NEI-A1-9)

NRC response. The NRC disagrees with the commenter's view that plant-specific assessments of seismically-induced pipe breaks should not be required to demonstrate that the seismically-induced pipe breaks do not significantly affect the likelihood of pipe breaks larger than the TBS. Although seismic considerations did not significantly affect TBS selection, the plant-specific nature of the seismic studies requires an applicant to demonstrate that these studies are applicable to its plant and site. The NUREG-1903 study did generically conclude (based on operating experience, probabilistic risk assessment insights, experimental testing, and analysis) that the likelihood of seismically-induced unflawed piping failure was much less than 10^{-5} per year. However, a general conclusion about the likelihood of both seismically-induced flawed direct piping and indirect piping failure could not be reached for all plants.

Twenty-six plant-specific calculations were conducted in NUREG-1903 using available seismic hazard assessments for plants east of the Rocky Mountains (i.e., from NUREG-1488; April, 1994) and piping stress and material information obtained from historical leak-before-break applications. These calculations indicated that large circumferential flaws (i.e., greater than 30 percent of the piping wall thickness for a flaw approximately 145 degrees around the piping circumference) would be required before failure would occur due to earthquakes with a return frequency of 10^{-5} or 10^{-6} per year. However, the plant-specific conditions used in the calculations were not chosen to bound conditions at all nuclear power plants. Additionally, some plants may have updated seismic hazard, piping stress, material property, or other information used in the flawed piping evaluation. Thus, the NUREG-1903 results may not be applicable to every plant.

The ACRS, in its letter dated November 16, 2006 (ADAMS Accession No. ML063190465), also noted that seismic hazards are very plant specific. The ACRS further recommended that licensees who adopt § 50.46a should demonstrate that the results developed by the NRC bound the likelihood of seismically-induced failure at their plants. The Committee further stated that licensees may have to perform additional calculations to demonstrate a comparable robustness of flawed piping. The ACRS recommendations are consistent with the limitations of the NUREG-1903 study as noted above. It would also be inconsistent with the Commission's intent to allow the relaxation of ECCS requirements at a plant with a seismically-induced large break LOCA frequency greater than the 10^{-5} per reactor year criterion used for selecting the TBS.

Because seismic analyses, and in particular direct and indirect piping failure estimates, are highly plant and site specific, the NRC believes that it is necessary for a licensee to demonstrate that its seismic LOCA frequency is sufficiently low before implementation of the alternative ECCS requirements. Consistent with the ACRS recommendations, the Commission also provided explicit direction[1] to the NRC staff to "… require licensees to justify that the generic results in the revised NUREG-1829, 'Estimating Loss-of-Coolant Accident Frequencies through the Elicitation Process,' are applicable to their individual plants." Because the analyses conducted in NUREG-1903 were not bounding and the results are plant-specific, the NRC has decided, consistent with its treatment of NUREG-1829, to also require licensees to justify that the NUREG-1903 results are applicable. Thus, licensees of plants choosing to implement § 50.46a are required by paragraph (c)(1)(i) of the rule to ensure that the total frequency of seismically-induced direct and indirect failures of piping larger than the TBS remains significantly less than 10^{-5} per year. As a consequence, the final rule is consistent with the Commission's direction.

Some additional rule limitations result from the treatment of indirect failures in NUREG-1903. Indirect failures are primary system ruptures that are a consequence of failures in non-primary system components or structural support failures (such as a steam generator support). Structural support failures resulting from seismic events could then cause displacements in components that stress and in turn, fail the piping. The NRC, in NUREG-1903, performed studies on two plants to estimate the conditional pipe failure probability due to structural support failure given a large, rare earthquake (i.e., 10^{-5} to 10^{-6} per year). The results indicated that the conditional failure probability of the piping was on the order of 0.1 such that the total failure probability is on the order of 10^{-6} to 10^{-7} per year. These results are consistent with more recent studies completed by EPRI on three plants. However, the NRC noted in NUREG-1903 that because seismically-induced indirect failure risks are highly plant-

[1] See memorandum from A.L. Vietti-Cook to L.A. Reyes, "Staff Requirements – SECY-07-0082 - Rulemaking To Make Risk-Informed Changes To Loss-Of-Coolant Accident Technical Requirements; 10 CFR 50.46a, "Alternative Acceptance Criteria For Emergency Core Cooling Systems For Light-Water Nuclear Power Reactors", dated August 10, 2007, ADAMS Accession No. ML072220595.

specific, it is possible that the small number of plants assessed in the NRC and EPRI analyses are not limiting. Consequently, the limited analysis of indirect piping failures does not provide a sufficient technical basis for allowing generic changes to the seismic design, testing, analysis, qualification, and maintenance requirements (i.e., seismic design basis) associated with any component under § 50.46a. Therefore, licensees may not make any changes to components that would alter their seismic design basis unless these changes are justified using a plant-specific analysis to assess the change in risk associated with seismically-induced failures of the relevant component and/or system that results from the proposed plant changes.

No change was made to the rule as a result of the comment.

Comment. A commenter noted that the NRC included in the revised proposed rule a requirement that licensees wishing to implement § 50.46a conduct an evaluation to demonstrate that the results in NUREG-1829 and NUREG-1903 are applicable in their plants. The commenter also stated that the further expectation for re-evaluation of applicability of NUREG-1829 and NUREG-1903 after making plant changes embeds a continuous process in the rule such that implementation costs (demonstrating plant-specific applicability of NUREG-1829 and NUREG-1903) and associated reporting requirements will have the potential to limit industry-wide implementation of § 50.46a. Therefore, the commenter recommends that some limitation on continuously ensuring applicability needs to be developed. The commenter also stated that a simplified method to ensure the applicability of NUREG-1829 and NUREG-1903 needs to be developed for use by licensees adopting § 50.46a. (P-1.3, P-5)

NRC Response. The NRC agrees with the commenter that implementation costs for demonstrating the plant-specific applicability of NUREG-1829 and NUREG-1903 could affect licensee implementation of § 50.46a. Since the decision to implement § 50.46a is voluntary, the NRC recognizes that licensees will choose to apply for plant changes enabled by this rule based upon a comparison of the benefit associated with the intended changes and the implementation and operational costs.

The NRC also recognizes the need to develop guidance for an approved method that plants can use to justify the applicability of the NUREG-1829 and NUREG-1903 results[2]. The NRC is currently developing guidance for conducting these plant-specific assessments and published draft regulatory guide, DG-1216, ''Plant-Specific Applicability of the Transition Break Size Specified in 10 CFR 50.46a,'' (ADAMS Accession No. ML100430352), in June 2010 for public comment. This guidance identifies the scope, provides acceptable methods, and identifies acceptance criteria for evaluating the results of the evaluation to determine the applicability of NUREG-1829. The guidance also provides an evaluation framework and acceptance criteria to demonstrate the applicability of the NUREG-1903 assessment of direct piping failures. This guidance will also allow licensees to estimate this portion of the costs associated with implementing § 50.46a.

Also, the NRC will solicit interest in a pilot study to evaluate the appropriateness of the regulatory positions contained within the guidance. A pilot study would allow licensees to more accurately assess the associated implementation costs. This planned pilot study, and public comments associated with the draft regulatory guidance, may also provide a basis for revising the regulatory guidance so that implementation costs are minimized while the evaluation still provides reasonable assurance that the TBS in § 50.46a is applicable.

Also as indicated by the comment, the NRC has included in the final rule a specific requirement to ensure that the initial evaluation performed to demonstrate the applicability of NUREG-1829 and NUREG-1903 is not invalidated when future changes are made to the licensee's facility. It is likely that the licensee's existing configuration management program,

[2] See the Commission's SRM on SECY-07-0082, " Rulemaking To Make Risk-Informed Changes To Loss-Of-Coolant Accident Technical Requirements; '10 CFR 50.46a - Alternative Acceptance Criteria For Emergency Core Cooling Systems For Light-Water Nuclear Power Reactors'", dated August 10, 2007, ADAMS Accession No. ML072220595.

that contains a process to control plant changes made under § 50.59, could be modified, through screening or evaluation, to identify future plant changes made which may invalidate the applicability of the NRC's generic studies. However, due to the variety of approaches licensees use to evaluate facility changes, other options may be available to ensure that the initial evaluation is not invalidated by future plant changes. It is up to each licensee to decide how to best implement this requirement.

The NRC also notes that although the information submitted in initial applicability demonstration will require a more extensive evaluation, it is expected that subsequent plant change evaluations will require much less effort.

For these reasons, the NRC agrees with the comment, but made no change to the rule as a result of the comment.

C. <u>Comments on Thermal-Hydraulic Analysis</u>

Comment. A commenter noted that the supplemental proposed rule language in § 50.46a(e) was changed to require NRC review and approval of analysis methods used to evaluate plant thermal-hydraulic response to LOCAs larger than the TBS. The commenter recommended that these models should be available for inspection, but that prior NRC review and approval of these models for beyond design-basis events should not be required. The commenter believes this would be consistent with the classification of breaks larger than the TBS as being beyond design-basis accidents and that fewer NRC resources would be required if prior approval is not required. Therefore, the commenter recommended that prior approval of beyond-TBS analysis methods be included as an option at the discretion of the vendor or licensee. (P-6)

NRC Response. The NRC disagrees with the commenter's recommendation. The proposed language in § 50.46a(e) was changed in response to recommendations from the Advisory Committee on Reactor Safeguards (ACRS). In a letter dated November 16, 2006, following review of an earlier draft final rule, the ACRS recommended that the final rule be modified to increase defense in depth. In that same letter, the ACRS also recommended that prior review and approval by the NRC of the analysis methods used for beyond-TBS breaks should be required. Such a requirement would increase confidence in the ability to mitigate breaks larger than the TBS. The NRC also considered the resource implications for review of methods used for breaks larger than the TBS. The NRC noted that the most significant changes in analysis requirements for breaks greater than the TBS are credit for offsite power and removal of the single failure assumption. Currently approved LOCA analysis methodologies can be readily adapted to take advantage of these changes without a significant resource impact. Further simplification of existing analysis methods by licensees would be expected to introduce greater uncertainty in the results and thereby reduce confidence in the ability to mitigate breaks larger than the TBS. In such a case, the increased review resources are warranted. The NRC has therefore retained the requirement in the final rule for prior review and approval of ECCS analysis methods for all break sizes.

Comment. A commenter noted that in the supplemental proposed rule, the NRC retained the requirement in § 50.46a(e)(2) that evaluations of ECCS cooling performance for LOCAs larger than the TBS must utilize comparisons to applicable experimental data. The commenter reiterated comments made on the initial proposed rule, stating that other approaches, such as comparison of results to accepted analysis techniques or to text book approaches, are also appropriate. The "sufficient justification" clause allows for a demonstration of the calculational approach that is appropriate to the importance of the phenomena without the specific requirement to benchmark data. (NEI-A1-10)

NRC Response. The NRC disagrees with the commenter. Analysis methods for large break LOCA have been largely developed on the basis of empirical correlations that were derived from a limited data range and for a specific application. The NRC expects the extent and rigor of the experimental validation for greater than TBS evaluations may differ from the design basis evaluations, but the Commission does not agree that textbook or code to code comparisons alone can provide sufficient justification for an analysis method. The NRC has therefore retained the requirement for comparison of the analysis results to applicable experimental data in the final rule.

Comment. A commenter stated that the new draft rulemaking language introduces a new requirement in § 50.46a(e)(2) that non-safety-related equipment can only be credited if "onsite power can be readily provided through simple manual actions to equipment that is credited in the analysis." The commenter stated that the requirement that all equipment credited to mitigate pipe breaks larger than TBS must be designed so that onsite power can be provided automatically or as the result of simple manual actions, is contrary to the notion that the beyond-design basis LOCAs can be analyzed without assuming a coincident LOOP. The commenter stated that this new requirement places additional burden on the licensee if non-safety-related equipment is to be credited for the mitigation of the LOCA greater than the TBS and that this will likely require additional analysis and modification of existing equipment and procedures to comply with this new requirement. (P-7)

NRC Response. The NRC disagrees with the commenter's interpretation. The requirement in § 50.46a(e)(2) to provide onsite power to all equipment credited for breaks larger than the TBS does not require licensees to consider the time necessary to provide the onsite power when analyzing beyond TBS breaks. To analyze breaks larger than the TBS, the analysis may assume the immediate availability of offsite power. The requirement that the equipment be designed so that onsite power can be provided through simple manual actions (within approximately 30 minutes) is for the purposes of severe accident management. Furthermore, given current plant designs, the NRC expects that this requirement will have no burden impact unless a plant makes significant changes to existing core designs or ECCS configuration. In these circumstances, the NRC believes that it reasonable to enhance defense-in-depth by assuring the ability to provide onsite power capability to accident mitigation equipment. This requirement has therefore been retained in the final rule.

Comment. In the supplementary information published with the supplemental proposed rule, the NRC requested stakeholder comment on whether § 50.46a should retain the coolable geometry ECCS acceptance criterion for beyond-TBS breaks (NRC Question 3). Two commenters recommended that the option to use the coolable geometry criterion be retained because it would provide flexibility, could reduce the analysis scope and cost for beyond TBS compliance, and would increase the likelihood that a licensee could find implementation of this rule to be beneficial. (P-9, NEI-A2-3)

NRC Response. The NRC agrees with the commenters that maintaining the coolable geometry acceptance criterion for beyond TBS breaks will provide some flexibility for beyond TBS compliance. The criterion has been retained in the final rule.

Comment. A commenter stated that § 50.46a(e) includes the requirements for smaller than TBS breaks as well as for breaks larger than the TBS. The commenter reasoned that if an applicant who uses § 50.46a needs the smaller than TBS requirements as well, it seems that it would be administratively cleaner for § 50.46a to refer to the § 50.46(b) requirements for smaller than TBS breaks, assuming the requirements are the same in both places. (P-12)

NRC Response. The NRC agrees with the commenter that it would be possible to reference the § 50.46(b) requirements in § 50.46a with regard to breaks less than the TBS. It is the NRC's intent for breaks smaller than (or equal to) the TBS, that the loss of coolant accident (LOCA) analysis and acceptance criteria be the same regardless of the option (i.e., § 50.46 or § 50.46a) selected by a licensee to demonstrate the adequacy of ECCS performance. Such a scheme would facilitate consistency between the two options when changes are made in the future to the criteria for breaks smaller than the TBS. The NRC believes, however, that there are benefits to rules being all inclusive as well. When a rule is all inclusive, a licensee or applicant has a clearer view of the totality of the requirements. The NRC believes that there is a greater chance of misinterpreting rule requirements when a rule refers to requirements specified in whole, or in part, in other regulations. Therefore, the final rule will retain the same structure as in the proposed rule.

Comment. A commenter asserted that § 50.46a should not be promulgated until after the ECCS acceptance criteria in § 50.46(b) are modified to account for new experimental data on cladding ductility so that conforming changes can be made to § 50.46a as necessary for both below and above TBS breaks. The commenter stated this is because the current ECCS acceptance criteria in § 50.46(b) are non-conservative and facility changes proposed by licensees adopting § 50.46a will likely result in more demanding reactor operating conditions that may further stress the fuel, or result in small break LOCAs becoming limiting. (ML-2)

NRC Response. The NRC disagrees with the commenter's assertion. The Commission specifically considered this issue[3] and decided that the § 50.46a rulemaking could proceed prior to completing the revisions to § 50.46(b) on cladding ductility. The NRC believes that significant changes in core design under § 50.46a (such as power uprates) that could result in more demanding operating conditions would involve several years of lead time prior to the submission of a license amendment. Even if the § 50.46(b) rulemaking is not finalized by the time a § 50.46a application is submitted, the NRC review of any such application would be conducted in light of the information that is forming the basis for the revised § 50.46(b) criteria. Using this information, the NRC can ensure that safety margin for fuel clad integrity is conservatively included in any proposed design. No changes were made in the final rule.

[3] See the SRM on SECY-07-0082, "Rulemaking To Make Risk-Informed Changes To Loss-Of-Coolant Accident Technical Requirements; 10 CFR 50.46a, "Alternative Acceptance Criteria For Emergency Core Cooling Systems For Light-Water Nuclear Power Reactors", dated August 10, 2007, ADAMS ML072220595.

D. Comments Related to Probabilistic Risk Assessment

Comment. Many commenters objected to the prescriptive restriction in § 50.46a(d)(5) that the allowable time for operating in a configuration not demonstrated to meet the acceptance criteria in § 50.46a(e)(4) may not exceed a total of 14 days in any 12-month period. The commenters raised numerous objections. The primary objection was that current risk-informed management infrastructure including the maintenance rule provides adequate controls to manage the risk of the low-safety-significant configuration in question. Another objection was that the requirement for additional controls is contrary to how technical specifications are currently defined, and that implementation would be excessively complex and would divert resources from more risk-significant activities. A commenter also stated that the existing operational restrictions on equipment to mitigate greater than TBS LOCAs are based on the traditionally conservative ECCS analyses and are more than sufficient to provide reasonable assurance that the same equipment can mitigate breaks larger than the TBS, as analyzed in the reasonably conservative mitigating analysis. (P-1.1, P-4, P-4.1, P-4.2, P-4.3, P-4.4, P-4.5, NEI-A1-3.1, NEI-A1-3.2, NEI-A1-3.3)

NRC Response. The NRC disagrees with the commenters' premise that the plant operating configurations controlled by existing technical specifications and risk-management infrastructures are the same as the operating configurations controlled by § 50.46a(d)(5). The commenters discuss existing risk-management infrastructure activities associated with the maintenance rule (§ 50.65) and Risk Management Technical Specification (RMTS) initiative 4b. These existing risk-management infrastructures control activities when capability to mitigate accidents is reduced but the required function is not lost. In contrast, § 50.46a(d)(5) controls activities when some function required to mitigate breaks larger than the TBS is lost or unavailable. RMTS initiative 6 addresses loss of function, but the methodology has not been implemented and differs substantially from the existing infrastructure. To allow licensees to use other NRC-approved approaches, the final rule was changed by adding language in § 50.46a(d)(5) that will allow licensees to propose an alternative plant-specific evaluation and operational control mechanism.

The NRC has incorporated the relatively low-safety-significance of the loss of the capability to mitigate LOCAs greater than the TBS into the rule by permitting a limited time period in operation when this mitigating capability is unavailable. The NRC has concluded that a total unavailability not to exceed 14 days in any 12-month period would protect public health and safety and provide adequate time for licensees to perform beneficial maintenance activities. As described in the supplemental proposed rule (74 FR 40015), the NRC developed the 14 days per 12 months criterion based on related, existing NRC guidelines and has concluded that this time period provides adequate protection of public health and safety. The NRC agrees with the commenter that current standard technical specifications do not include cumulative time limits but such limits have been used when necessary. Although somewhat more complex than current technical specifications, a cumulative limit is included in the final rule because the allowable out of service time has been justified on the basis of an acceptable annual increase in risk. As a result, the allowable out of service time has been specified as a cumulative annual limit to remain consistent with the basis upon which it was established.

The NRC recognizes that alternative evaluations might demonstrate that a different time period measurement or criterion that does not accumulate the time on a per year basis might be consistent with the Commission's intent that mitigation capability be retained for the full spectrum of LOCA events "commensurate with the safety significance of these capabilities." Therefore, the NRC has modified the rule to permit licensees to propose alternative, plant-specific evaluations and operational control mechanisms commensurate with the mitigation capability available if supported by an acceptable risk-informed evaluation of the configuration-specific risk, defense-in-depth, and safety margins. After obtaining approval, licensees could implement the alternative approach.

The NRC also disagrees with the commenter's assertion that current LOCA analyses are sufficiently conservative that LOCAs up to the double-ended rupture of the largest pipe can always be mitigated with the original ECCS equipment after implementing any plant changes enabled by § 50.46a. Section 50.46a (e)(2) describes the analysis and § 50.46a(e)(4) provides acceptance criteria that licensees must use to demonstrate that LOCAs up to the double-ended rupture of the largest pipe can be mitigated after implementing changes enabled by § 50.46a. If a licensee demonstrates that the same equipment required to mitigate a break up to the TBS size continues to be capable of mitigating a break up to the double ended rupture of the largest pipe after implementing all its changes enabled by § 50.46a, there would be no operation in an unanalyzed condition and no burden imposed by the requirement. No changes were made to the rule in response to this comment.

Comment. One commenter stated that the proposed rule language will add significant costs to the § 50.59 facility change process. The requirement in § 50.46a(f)(1) would require a licensee to establish a process or program to perform risk evaluations for all changes at the facility, including those not enabled by § 50.46a but performed in accordance with § 50.59. (P-2)

NRC Response. The NRC agrees with the commenter that the supplemental proposed rule appears to have changed the facility change process established by § 50.59, but this was caused by an error in the cross references in the rule. Section 50.46a(f)(1)(ii) of the supplemental proposed rule incorrectly referred to § 50.46a(c)(1)(iii) instead of the correct reference to § 50.46a(c)(1)(iv). The incorrect reference to § 50.46a(c)(1)(iii) could have been interpreted to require a risk-informed evaluation for any plant change that a licensee intends to make without prior NRC approval including all changes made under § 50.59. The NRC has changed the rule to correct the error. The correct reference to § 50.46a(c)(1)(vi) now clarifies that a risk-informed evaluation is only required for changes enabled by § 50.46a that a licensee intends to make without prior NRC approval.

Comment. Several commenters noted that acceptable increases in risk must be "very small" instead of "small" and argued that this criterion departs from and conflicts with RG 1.174. The "very small" criterion establishes an acceptable risk increase that is smaller than the maximum increase permitted by RG 1.174 guidance and does not include consideration of the magnitude of the baseline risk estimates. The commenters believe that "small" should be used instead of "very small" to be consistent with RG 1.74 guidelines. Differing views were expressed regarding the related topic in NRC Question 1 about whether any increase in risk should be allowed under § 50.46a. Another commenter argued that no risk increase should be allowed because uncertainties in PRA success criteria calculations caused by alleged inadequacies in NRC and industry ECCS analysis models imply that total risk is currently very high and should not be further increased. Commenters stated that risk increases consistent with RG 1.174 should be allowed. One commenter argued that not allowing any risk increase was contrary to the Commission's PRA policy statement. (P-3.1, NEI-A1-4, NEI-A2-1, NEI-A1-4)

NRC Response. The NRC disagrees that the "very small" criterion conflicts with the RG 1.174 guidance although not all options in the RG are used. RG 1.174 defines "very small" increases in CDF and LERF and provides guidance to be used to determine the acceptability of facility changes that cause these risk increases. The NRC intends to apply the RG 1.174 guidance applicable to "very small" increases in CDF and LERF. Consistent with RG 1.174 guidance for "very small," the rule does not require a licensee to calculate the baseline CDF and LERF from all plant operating modes and all possible initiating events and show that the baseline estimates are less than10^{-4} per year and 10^{-5} per year, respectively.

In the SRM to SECY-07-0082, the Commission directed the staff to limit the total increase in risk from changes implemented under § 50.46a to "very small." As described in the supplemental proposed rule (74 FR 40033), a very small risk increase is independent of a plant's baseline risk (unless there are indications that a plant's risk is exceptionally high) and the same criterion can be used by all licensees. Beyond disagreeing with the Commission's direction, the commenters provided no new bases and provided no new data or analyses to demonstrate that the NRC made any logical or technical error by selecting the "very small" risk increase as the appropriate criterion in this rulemaking; thus, the rule was not changed.

The NRC decided to retain the proposed acceptance criteria arising from changes enabled by § 50.46a as "very small" rather than reduce the criteria to risk neutral or a risk decrease. The NRC believes permitting only very small risk increases addresses, in part, the individual commenter's concern that the uncertainty about the total risk levels should preclude further risk increases because relatively low baseline risk estimates cannot be used to justify greater risk increases. Risk increases will be permitted by the rule when they are part of an acceptable risk-informed evaluation which is clearly consistent with the PRA policy statement.

Comment. A commenter noted that "minimal" is not used in RG 1.174 and, if it is used in the § 50.46a rule, it should be defined in the rule. The commenter also stated that the rule implied that "minimal" was the same as "very small." (P-3.2)

NRC Response. The NRC disagrees that "minimal" should be defined in the rule beyond its current use as a description of the acceptance criterion identifying changes the licensee may make without prior NRC approval. Quantitative guidelines that the NRC uses to implement acceptance criteria in a rule are typically contained in guidance documents. The NRC agrees that the rule language and the supplementary information published with the supplemental proposed rule implied that "minimal" could have the same guideline value as "very small" for plants with total CDF/LERF estimates below $10^{-4}/10^{-5}$ per year.

During its evaluation of comments on the supplemental proposed rule, the NRC concluded that the phrase in § 50.46a(f)(1)(ii), “minimal compared to overall plant risk,” would introduce a relative criterion that differs from the fixed “very small” criterion in paragraph (f)(2)(ii). The NRC has concluded that a specific value (defined in other regulatory documents) for all plants is desirable to define acceptable “very small” risk increases and believes a specific value for all plants is also desirable to define “minimal.” The NRC has removed the phrase “comparable to overall plant risk” from § 50.46a(f)(1)(ii) of the final rule. To implement this rule, the NRC will use the same self-approval guidelines as described in RG 1.205 which specify CDF and LERF guideline values of 10^{-7} and 10^{-8} per year, respectively.

Comment. Several commenters argued that the requirement in proposed § 50.46a(f)(4)(i) that the PRA must address initiating events "... for all modes of operation including low power and shutdown” would require the expenditure of resources on some initiators and modes of operation that are not significant to the implementation of this rule. The commenters identified shutdown operation and large LOCAs during shutdown operations, as examples of PRA analyses that would introduce substantial regulatory uncertainty. (P-8, NEI-A1-6)

NRC Response. The NRC disagrees with the claim that substantial regulatory uncertainty is introduced by the supplemental proposed rule language in § 50.46a(f)(4)(i) that would result in unnecessary evaluation of all initiators and modes of operation. A basic tenet of risk-informed evaluations is that the change in risk estimates need to reflect the risk impact of proposed facility changes for all initiating events and on all modes of operation which might be affected by the proposed action. Another basic tenet is that qualitative or bounding evaluations may be used where applicable. RG 1.174 describes these tenets and they have been successfully applied to all risk-informed activities.

Changes in risk caused by facility changes enabled by this rule may be qualitatively evaluated if the impact on risk is insubstantial, or a bounding evaluation may be used if the results are acceptable. Qualitative evaluations concluding that the risk from unquantified initiators and operating modes need only show that the change in risk from a proposed change is insubstantial because a rigorous estimate of the baseline risk is not necessary for "very small" increases. If the impact on risk of a facility change cannot be shown to be insubstantial and cannot be bounded, then effort will be required to develop appropriate PRA models for the applicable initiating events and operating modes. No changes were made in the final rule in response to this comment.

Comment. A commenter recommended that the reporting of changes resulting in no more than a minimal increase in risk in proposed § 50.46a(g)(3) be deleted. The commenter argues that § 50.59 already requires licensees to submit a report to the NRC at least every 24 months that summarizes the changes that were made that did not require a license amendment. (NEI-A1-5)

NRC Response. The NRC disagrees with the commenter that all changes enabled by § 50.46a would necessarily be reportable under § 50.59. Section § 50.46a(a)(3) states that LOCAs involving breaks larger than the TBS are beyond design basis events. The NRC believes that some facility changes that may be enabled by the new rule would no longer be reportable under § 50.59 because the change might no longer affect design basis events. Therefore, the NRC's final rule retains the reporting requirements in § 50.46a(g)(3) because these requirements will ensure the reporting of all potentially risk significant facility changes made under the rule. The report periodicity is purposely selected to be the same as the § 50.59 reporting requirement, so one report may include both types of changes.

Comment. A commenter proposed that a specific periodicity for PRA maintenance and upgrade in § 50.46a(d)(4) be replaced with the requirements in Section 1-5, PRA configuration control, in the American Nuclear Society (ANS)/American Society of Mechanical Engineers (ASME) PRA Standard. (NEI-A1-7)

NRC Response. The NRC disagrees with the commenter. The ASME/ANS standard referred to by the commenter is endorsed by the NRC in Revision 2 of RG 1.200, "An Approach For Determining The Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities." Revision 2 endorsed the ASME/ANS RA-Sa-2009, "Standard for Level 1/Large Early Release Frequency Probabilistic Risk Assessment for Nuclear Power Plant Applications," Addendum A to RA-S-2008, February 2009. New revisions of RG 1.200 and the ASME/ANS standard are periodically issued.

The NRC believes that the configuration and control requirements in § 50.46a(d)(4) are consistent with the ANS/ASME standard but disagrees that the standard requirements can replace the requirements in § 50.46a(d)(4) and has not changed the paragraph in the final rule. The configuration control requirements in Section 1-5 in the ANS/ASME standard describe how a PRA is to be maintained and upgraded. Section 50.46a(d)(4) describes how a properly maintained and upgraded PRA is to be used to support the risk-informed evaluations required by the final rule.

Comment. One commenter stated that the cumulative change in risk evaluation in § 50.46a(f)(2)(iii) is an unnecessary and inefficient use of NRC and licensee resources. The commenter argued that many other risk-informed applications have been implemented with no such requirement, and experience has demonstrated that this issue has not arisen. (NEI-A1-8)

NRC Response. The NRC disagrees that evaluation of the cumulative change in risk is unnecessary. The NRC also disagrees that other risk-informed applications have been implemented with no requirements related to cumulative impact of changes proposed over time. The commenter simply asserts that "many" other risk-informed applications have been implemented without this requirement and did not provide any examples.

Any process that allows facility changes to be spaced out over time must consider requirements to ensure that the process as a whole is consistent with the intent of the evaluations of individual plant changes so that the process cannot be bypassed or inadvertently misapplied solely by sequencing plant changes in a different manner. Previous risk-informed applications address the cumulative impact on risk of changes made over time. Risk-informed in service inspection, risk-informed in service testing, and risk-informed integrated containment leak rate testing applications all compare the risk associated with the new program with the risk associated with the original deterministic program requirements that were replaced. Additional changes made later in time are also evaluated against the risk associated with the deterministic program requirements that were replaced, not the latest risk-informed program requirement. Risk-informed allowed outage time extensions evaluate the proposed changes against no outage time, even if the time interval is extended step wise in subsequent applications spaced over a period of time. Section 50.69 clarifies that changes to special treatment requirements may be implemented system by system over time, but the acceptance criteria are applied to the total change as each system is added. Both RMTS initiatives 4b and 5b require the licensee to assess the cumulative risk impact over time and implement corrective actions if unanticipated risk increases are identified.

The final rule requirement in § 50.46a(f)(2)(iii) to evaluate the cumulative impact of plant changes is written to be effectively identical to the requirement in the § 50.48(c) which incorporates similar requirements in NFPA-805 Section 2.4.4.1, Risk Acceptance Criteria. This similarity permits the methodology developed to implement § 50.48(c) to be used as applicable to support § 50.46a.

Comment. A commenter stated that § 50.46a(f)(1) of the revised proposed rule would read better as: "The licensee may make changes other than changes to the Technical Specifications without prior NRC approval if ...". Also, § 50.46a(f)(2) would have a complementary change: "For implementing changes to the Technical Specifications or changes that are not permitted under paragraph (f)(1) of this section ...". (P-13)

NRC Response. The NRC agrees with the commenter that licensees may not make changes to the Technical Specifications without NRC approval. This change has been incorporated in the final rule.

Comment. A commenter stated that eliminating the large break LOCA from the design basis, based on its insignificant contribution to plant risk, should be even easier to justify than eliminating requirements for Hydrogen Recombiners (as was done when the risk-informed § 50.44 rule was issued). (P-1a)

NRC Response. The NRC staff disagrees with the commenter that this rulemaking should be easier to justify than § 50.44 because the risk associated with changes enabled by § 50.46a is substantially different than the risk associated with changes enabled by § 50.44. As summarized in SECY-00-0198 which described the proposed § 50.44, the NRC concluded that, in large volume and sub atmospheric containments, equipment to control combustible gas concentration (e.g., recombiners) does not provide any mitigating capability in accident scenarios affecting risk, so discontinuing associated combustible gas control requirements would not affect risk. In other containment types where hydrogen combustion could cause failures that affect risk, requirements to prevent or mitigate the effect of combustion were retained. In contrast, implementing § 50.46a will permit reducing the LOCA mitigating capability in scenarios that do affect risk and therefore, some increase in risk is expected. The § 50.46a rule is expected to result in plant changes that could increase risk, but the provisions in the rule provide confidence that any increases in risk are very small and acceptable. No changes were made to the rule in response to this comment.

Comment. In response to NRC Topic 1 which solicited public comments on whether the § 50.46a rule should allow plant design changes that cause any increase in plant risk, a commenter stated, “The rule should not allow plant changes that increase risk at all. The NRC should decrease the probabilities of core damage frequency (CDF)” and “the frequency of…accidents leading to significant, unmitigated releases from [the] containment in a time frame prior to effective evacuation of the close-in population such that there is a potential for early health effects” (LERF), rather than increase them.

The commenter made the comment primarily because of the commenter’s assertion that there are deficiencies in the NRC’s and nuclear industry’s ECCS evaluation models that, among other things, indicate the ECCS analysis acceptance criteria of § 50.46(b) are non-conservative. Thus, as a result, the commenter believes that the probabilities assigned to CDF and LERF are erroneous. (ML-3.1, ML-3.2)

NRC Response. The NRC disagrees with the commenter’s position that no risk increase should be allowed by § 50.46a and provides its evaluation of this position below. The NRC’s policy statement on probabilistic risk assessment (60 FR 42622 dated August 16, 1995) encourages greater use of this analysis technique to improve safety decisionmaking and improve regulatory efficiency. In its approval of the policy statement, the Commission articulated its expectation that implementation of the policy statement will improve the regulatory process in three areas: foremost, through safety decisionmaking enhanced by the use of PRA insights; through more efficient use of agency resources; and through a reduction in unnecessary burdens on licensees. RG 1.174 provides an approach for using PRA in risk-informed decisions on plant-specific changes to the licensing basis. RG 1.174 describes the five principles of risk-informed integrated decisionmaking. Impact on risk is only one of the five elements that must be considered when evaluating a proposed change which might increase risk. Specifically, the proposed change must:

- Meet current regulations (presumption of adequate protection)
- Be consistent with the defense-in-depth philosophy

- Maintain sufficient safety margins
- Result in an increase in CDF or risk that is small and consistent with the intent of the Commission's Safety Goal Policy Statement (51 FR 30026; August 4, 1986)
- Be monitored using performance measurement strategies.

The Commission's safety goals (and associated quantitative health objectives) define an acceptable level of risk that is a small fraction (0.1 percent) of other risks to which the public is exposed. The change in risk that will be allowed by this rule thus constitutes a small fraction of an already small fraction of risks to which the public would be exposed.

In addition, the inadequacies asserted by the commenter in the NRC's requirements for ECCS evaluation models and ECCS acceptance criteria are now being reviewed by the NRC in its evaluation of PRM-50-93 and in the ongoing rulemaking to establish improved ECCS acceptance criteria in § 50.46(b). If the NRC determines that changes should be made to the ECCS rules, appropriate changes will be made to the regulations in both §§ 50.46 and 50.46a. No changes were made to the rule in response to this comment.

E. <u>Comments Related to Existing Petitions for Rulemaking</u>

Comment. A commenter asserted that there are deficiencies in the NRC's and the nuclear industry's ECCS evaluation models and acceptance criteria that need to be reviewed and corrected before the NRC promulgates 10 CFR 50.46a. The commenter stated that the NRC has acknowledged that under proposed § 50.46a, it is likely that the NRC will find requests for additional power uprates at pressurized water reactors (PWRs) acceptable. The commenter further stated that the uprates will clearly decrease safety margins, even for breaks below the TBS and may result in small break LOCAs becoming limiting. Thus, the commenter asserts that the NRC must not revise its regulations to:

> (1) allow for "design changes, such as increasing power that could cause increases in plant risk;

(2) "divide the current spectrum of LOCA break sizes into two regions and make each break size region subject to different ECCS requirements where the larger break size region would be analyzed by less conservative assumptions based on the lower likelihood of larger breaks; or

(3) allow break sizes larger than the transition break to become "beyond design-basis accidents," even if the proposed rule would require licensees to maintain the ability to mitigate all LOCAs up to and including the double-ended guillotine break of the largest reactor coolant system pipe during all operating configurations.

The commenter stated that these ECCS evaluation model deficiencies are detailed in a petition for rulemaking (PRM-50-93; ADAMS Accession No. ML093290250) submitted by the commenter. PRM-50-93 asserts that the results of LOFT test LP-FP-2 multi-rod (assembly) severe fuel damage experiment and several other tests (i.e., PBF Severe Damage 1-1, NRU Thermal-Hydraulic Experiment 1, BWR FLECHT Zr2K) demonstrate that the § 50.46(b)(1) peak cladding temperature limit of 2200°F is non-conservative. The commenter also asserted that NRC's denial in 2005 of a petition for rulemaking (PRM-50-76, ADAMS Accession No. ML022240009, May 1, 2002) which argued that both Baker-Just and Cathcart-Pawel zirconium oxidation correlations were non-conservative, was in error because the NRC did not consider the results of the LOFT LP-FP-2 test when making its decision. (ML-1, ML-4, ML-9, ML-10)

NRC Response. The NRC disagrees with the commenter that no changes should be made at the present time to the NRC's ECCS regulations. The § 50.46a alternative requirements include changes to the size of pipe breaks and assumed plant conditions that must be evaluated by licensees (i.e., evaluation model inputs and analysis assumptions), but do not change the requirements for how ECCS evaluation models must be designed. Also, the potential technical issues underlying the inadequacies asserted by the commenter above are the subject of PRM-50-93, which is now being reviewed by the NRC to determine if the NRC's emergency core cooling evaluation model requirements in § 50.46 should be revised. The review of PRM-50-93 is being performed independently from the § 50.46a rulemaking. If the review of PRM-50-93 determines that changes should be made to the ECCS evaluation model requirements, appropriate changes will be made to the regulations in both §§ 50.46 and 50.46a.

Comment. Regarding whether the beyond-TBS acceptance criteria should allow licensees the flexibility to develop new criteria for demonstrating the existence of coolable core geometry, a commenter stated that beyond-TBS acceptance criteria should be the same as the acceptance criteria for TBS and smaller breaks; (i.e., the criteria of § 50.46(b)) The commenter stated that the criteria of maintenance of coolable core geometry and maintenance of long-term core cooling should not be used as a substitute for the criteria of § 50.46(b) for beyond-TBS LOCAs because there are deficiencies in the NRC's and the nuclear industry's ECCS evaluation models that indicate the deterministic criteria of § 50.46(b) are non-conservative. The commenter also stated that using the alternative performance-based criteria of maintenance of coolable core geometry and maintenance of long-term core cooling would be even more non-conservative than using the criteria in § 50.46(b). (ML-6)

NRC Response. The NRC disagrees with the commenter's views that beyond-TBS acceptance criteria should be the same as the acceptance criteria for TBS and smaller breaks, and that the criteria of maintenance of coolable core geometry and maintenance of long-term core cooling should not be used as a substitute for the current acceptance criteria in § 50.46(b) for beyond-TBS LOCAs. The commenter provided no direct arguments or facts directly supporting these assertions. Instead, the assertions are based on the commenter's belief that current NRC and industry ECCS evaluation models are deficient. As previously discussed, the § 50.46a alternative requirements include changes to the size of pipe breaks and assumed plant conditions that must be evaluated by licensees (i.e., evaluation model inputs and analysis assumptions), but do not change the requirements for how ECCS evaluation models must be designed. In addition, the potential technical issues underlying the inadequacies asserted by the commenter are the subject of PRM-50-93 which is now being reviewed by the NRC to determine if the NRC's emergency core cooling evaluation model requirements in § 50.46 should be revised. The review of PRM-50-93 is being performed independently from the § 50.46a rulemaking. If the review of PRM-50-93 determines that changes should be made to the ECCS evaluation model requirements, the NRC will amend both §§ 50.46 and 50.46a.

Comment. The commenter submitted approximately 10 pages of text taken directly from another petition for rulemaking (PRM-50-84, ADAMS Accession No. ML070871368, March 15, 2007) which argued that the current NRC ECCS regulations do not properly incorporate the potential thermal effects of "crud" (corrosion deposits) that may accumulate on reactor fuel cladding during plant operation. PRM-50-84 noted that crud deposits inhibit fuel cooling and would increase the actual fuel temperature of reactor fuel. The commenter stated that thermal resistance of crud layers on fuel cladding significantly affects cladding performance during a LOCA The commenter stated that there is little or no evidence that crud has ever been properly factored into ECCS evaluation calculations for postulated LOCAs for nuclear power plants. (ML-7, ML-8)

NRC Response. Although not clearly stated, the NRC presumes that the commenter believes that there are deficiencies related to crud in the NRC's and the nuclear industry's emergency core cooling (ECCS) evaluation models and acceptance criteria that need to be corrected before the NRC promulgates § 50.46a. The NRC disagrees with the view that no changes should be made at the present time to the NRC's ECCS regulations. The commenter provided no direct arguments or facts directly supporting why the issue of crud was relevant to the changes proposed in the § 50.46a alternative ECCS requirements. Section 50.46a includes changes to the size of pipe breaks and assumed plant conditions that must be evaluated by licensees (i.e., evaluation model inputs and analysis assumptions), but does not change the requirements for how ECCS evaluation models must be designed. The NRC evaluated the potential technical issues noted by the commenter when it resolved PRM-50-84 (see 73 FR 71564; November 25, 2008) and decided to evaluate the thermal effects of crud in the ongoing rulemaking to update the ECCS acceptance criteria in § 50.46(b). The NRC's current plans are to provide a proposed § 50.46(b) rule to the Commission by March 2011. When this rulemaking is completed, any necessary changes to the NRC's requirements for considering crud in ECCS evaluations will be made in both §§ 50.46 and 50.46a.

F. Comments Related to Enhanced Leak Detection

Comment. A commenter recommended that § 50.46a(d)(2) pertaining to leak detection for pipes larger than the TBS, be deleted because leakage detection methods cannot determine if the source of the leakage is from a component that is larger than the TBS and also because there already are adequate Technical Specification requirements on leakage. (P-1.2)

NRC Response. The NRC disagrees with the commenter's recommendation. Section 50.46a(d)(2) requires that, "The licensee shall have leak detection systems available at the facility and shall implement actions as necessary to identify, monitor and quantify leakage to ensure that adverse safety consequences do not result from primary pressure boundary leakage from piping and components that are larger than the transition break size." The NRC believes that increased defense-in-depth against large pipe breaks is needed for plants implementing the alternative ECCS rule. In its SRM on SECY-07-0082, the Commission directed the NRC staff to evaluate various approaches for enhancing the rule with requirements for enhanced leak detection methods. In May 2008, the NRC finalized Revision 1 to Regulatory Guide 1.45, "Guidance on Monitoring and Responding to Reactor Coolant System Leakage" to provide new guidance on improved leak detection methods. The NRC believes that § 50.46a licensees who implement the new RG 1.45 guidance will meet the enhanced leak detection requirements of § 50.46a(d)(2) for improved monitoring and response to RCS leakage. These requirements are expected to reduce the likelihood of a LOCA larger than the TBS.

Because § 50.46a makes no changes to the design basis of piping and components that are smaller than the TBS, the requirements of § 50.46a(d)(2) are only applied to piping and components that are larger than TBS. The NRC recognizes that leakage detection methods that satisfy these requirements may not be capable of determining whether the source of leakage is from piping or a component that is larger or smaller than the TBS. However, the NRC believes that discrimination between leaks in pipes larger or smaller than the TBS is unnecessary as long as all piping larger than the TBS has enhanced detection. No changes were made to the rule in response to this comment.

G. Comments Related to Applying § 50.46a to New Reactor Designs

Comment. A commenter stated that the definition for TBS in § 50.46a(a)(5) is valid for reactors licensed before the effective date of the § 50.46a final rule. For reactors licensed after the rule becomes effective, the TBS will "be determined on a plant-specific basis." This would create some uncertainty for the licensee of any new plants that plan to implement § 50.46a because there would be a question about what constitutes an acceptable TBS. (P-11)

NRC Response. The NRC agrees that there is uncertainty as to the size of an acceptable TBS for new reactor designs. The NRC has therefore modified the rule to make the acceptance criterion for the TBS for new reactors more explicit.   However, the NRC also notes that implementing the § 50.46a rule is voluntary. A new reactor licensee may use the rule provided it demonstrates similarity of its design to the design of plants currently operating in the U.S. Based on the information currently available, it would not be possible to define a specific TBS applicable to all new plant designs. Although the NRC has not performed a detailed analysis of the existing new plant designs in the manner used for establishing the technical basis of this rule for the current operating reactor fleet, the NRC recognizes that evolutionary plant designs generally have similar piping materials, service conditions, operational programs, piping configurations, and mitigating systems to those found in the operating fleet. For these evolutionary designs, the TBS defined in the final rule would likely be applicable.

However, evolutionary designs previously certified by the NRC cannot take full advantage of the § 50.46a rule unless the certified design is amended. Nevertheless, a combined license (COL) licensee who references a certified design may request to implement the rule by way of a license amendment. For the evolutionary designs currently being considered by the NRC, an applicant may request to apply the rule as part of the design certification. Or, a subsequent COL applicant referencing the design certification may request NRC approval to comply with § 50.46a. To implement the § 50.46a rule in either case, the recommendation of an appropriate TBS including the supporting analysis must be provided to the NRC for approval.

For new reactor designs that use passive safety features, the concept of dividing the LOCA break spectrum may not provide substantial benefit in that the LOCA mitigating systems for these designs depend on automatic systems that completely depressurize the reactor following the occurrence of any size LOCA in a manner similar to a much larger size pipe break. In addition, relaxing the single-active-failure criterion or allowing offsite power may not provide any substantial benefit to passive new reactors. However, applicants or licensees for new reactor designs that use passive safety features may request to implement the § 50.46a rule by recommending an appropriate TBS and providing supporting analyses to the NRC demonstrating similarity of the new reactor design parameters to those of operating reactors. The NRC review would determine if the design was similar with respect to LOCA frequencies and whether the TBS concept could be implemented in a manner consistent with the intent of the § 50.46a rule.

Overall, the intent for evaluating the TBS on a plant specific basis for new plants is to account for all the new plant design scenarios. At this time, the NRC believes that the remaining uncertainty associated with this approach is reasonable given the diversity in possible new plant designs.

Comment. A commenter noted that for new plants, § 50.46a(f)(2)(iii) stated that new reactors will need to show that a risk change is "very small" by computing the risk metrics CDF and large release frequency (LRF). The risk metric LRF is contained in the § 50.46a rule language even though the staff has not yet decided what risk metrics will be required of new reactors for risk-informed applications. For LRF, that would be less than 10^{-8}/year. The rulemaking language may be in conflict with the staff's final disposition on risk metrics for applications for new plants. (P-3.3)

NRC Response. The NRC agrees with the comment that the rulemaking language regarding the use of the risk metrics of CDF and LRF for new reactors may be premature at this time. Over a period of 16 months, the NRC staff engaged stakeholders regarding the issues related to the use of risk metrics in risk-informed applications for new reactors, and whether it is appropriate to use the same metrics as are currently in use for operating reactors per RG 1.174 and associated guidance, or whether new metrics should be developed. The NRC staff has considered input from stakeholders, and in a Commission policy paper provided options on risk-informed regulatory guidance for new reactors. The NRC believes that it is more appropriate to specify the acceptance criteria in appropriate regulatory guidance once the NRC has fully addressed the use of alternative guidance for new reactor risk-informed applications. The NRC has modified the final rule to use CDF and LERF for all reactors (currently operating and new reactors) as described in the current version of RG 1.174. If, as a result of Commission direction, different guidance is promulgated that describes new metrics to be used for new reactors, the NRC will then make appropriate changes in § 50.46a in a rulemaking.

Comment. Regarding the NRC's request for public comments on the difference in risk acceptance criteria metrics used for currently operating reactors (LERF) and new reactors (LRF), a commenter stated, "The definition of what constitutes a "very small increase" and "minimal increase" for LRF should be a full decade lower than those defined for LERF. However, it would be difficult to determine the values for LERF and LRF and ensure that the probabilities assigned to a "very small increase" and "minimal increase" for LRF would indeed be a full decade lower than those assigned to such an increase for LERF, because the NRC's and nuclear industry's ECCS evaluation models are deficient." The commenter then provided a detailed summary of various asserted deficiencies in the NRC's and industry's ECCS evaluation models which were previously submitted to the NRC for evaluation in PRM-50-93. (ML-5)

NRC Response. The NRC does not agree that it would be difficult to determine the values of LERF and LRF (if it were decided to include this latter metric) to ensure a "very small increase" and "minimal increase" once the NRC agrees on the appropriate risk metric and numerical values to use for new reactors. Significant guidance is provided in consensus industry PRA standards as to what constitutes a *large early release*. Although the NRC and industry have not adopted a uniform definition of *large release*, the NRC has been able to review new standard designs and combined license applications against the Commission's LRF goal because of the generally conservative definitions that each applicant has used to date. The NRC believes it is premature to reach a decision as to whether LRF should be a full decade lower than those defined for LERF as described in the comment. On this matter, the NRC staff has engaged stakeholders regarding the issues related to the use of risk metrics in risk-informed applications for new reactors, and whether it is appropriate to use the same metrics as are currently in use for operating reactors per RG 1.174 and associated guidance, or whether new metrics should be developed. The NRC staff has considered input from stakeholders and in a Commission policy paper provided options on risk-informed regulatory guidance for new reactors. If, as a result of Commission direction, different guidance is promulgated that describes new metrics to be used for new reactors, the NRC will then make appropriate changes to § 50.46a in a rulemaking.

Also, as previously discussed, the NRC is reviewing PRM-50-93 as a separate action. After completing this review, if the NRC determines that revisions are necessary to its ECCS analysis requirements and/or acceptance criteria, it will make appropriate changes in both §§ 50.46 and 50.46a.

Comment. Regarding the NRC's request for public comments on the difference in risk acceptance criteria metrics used for currently operating reactors (LERF) and new reactors (LRF), another commenter stated that extensive NRC and industry efforts regarding treatment of risk metrics for reactors licensed under 10 CFR Part 52 have been underway for over a year, and recommended that these decisions as specific to § 50.46a should be deferred until after the completion of these efforts. (NEI-A2-2)

NRC Response. The NRC agrees with the comment that the rulemaking language regarding the use of the risk metric of LRF (as well as CDF) for new reactors may be premature at this time. On this matter, the NRC staff engaged stakeholders regarding the issues related to the use of risk metrics in risk-informed applications for new reactors, and whether it is appropriate to use the same metrics as are currently in use for operating reactors per RG 1.174 and associated guidance, or whether new metrics should be developed. The NRC staff has considered input from stakeholders and in a Commission policy paper provided options on risk-informed regulatory guidance for new reactors. The NRC staff believes that it is more appropriate to specify the acceptance criteria in appropriate regulatory guidance after the NRC has fully addressed the use of alternative guidance for new reactor risk-informed applications. If, as a result of Commission direction, different guidance is promulgated that describes new metrics to be used for new reactors, appropriate changes will be made in § 50.46a. In the interim, the rule will use the same risk metrics for both operating reactors and new reactors.

Comment: In a letter dated October 20, 2010 (ADAMS Accession No. ML102850279), the ACRS concluded that it was premature to extend the proposed rule to new reactors at this time. The recommendation was primarily based on the concern that new reactors are expected to have significantly different risk profiles from the current operating reactor fleet and that development of appropriate risk metrics and risk acceptance criteria for these designs is still in the conceptual stage. However, the ACRS also recommended that if new reactors are to be included in the final rule, the requirement that new reactor facility changes enabled by the rule may not result in a significant decrease in the level of safety provided by the new reactor design should also apply to determining the allowable time for operating in configurations without a demonstrated capability to mitigate a large LOCA.

NRC response. The NRC partially agrees and partially disagrees with the ACRS recommendations.

The NRC disagrees with the recommendation that the rule not be applied to new reactors. Section III.E.4.b of this FR document states that applicants for new reactor licenses under Part 52 may need to supplement the allowable increases in core damage frequency and large early release frequency to meet the requirement in final rule paragraph (f)(3)(iv) that implementing the proposed plant changes will not result in a significant decrease in the level of safety otherwise provided by the new reactor design. The issue regarding development of appropriate risk metrics and risk acceptance criteria for new reactor designs is now being addressed by the Commission in its review of Commission policy paper SECY-10-0121, "Modifying the Risk-Informed Regulatory Guidance for New Reactors" (ADAMS Accession No. ML102230076). Consistent with the NRC staff recommendation to the Commission (Option 2 in SECY-10-0121), the final § 50.46a rule uses the same risk metrics for new reactors as are currently being used for operating reactors. Should the Commission give the staff direction in response to SECY-10-0121 to use different risk metrics for new reactors that are inconsistent with the option recommended by the NRC staff, the NRC will then make appropriate conforming changes in § 50.46a.

The NRC agrees with the other ACRS recommendation that the requirement that new reactor facility changes enabled by the rule may not result in a significant decrease in the level of safety provided by the design should also be applied to determining the allowable time for operating in configurations without a demonstrated capability to mitigate a large LOCA. The NRC has included these additional requirements in the final rule. With these additions, the NRC believes there are sufficient requirements in the final rule and clarifying provisions in its supporting documentation to continue to recommend that the Commission apply the rule to new reactor designs.

H. Comments Related to the Applicability of the Backfit Rule

Comment. One commenter stated that the provision exempting changes to the TBS from backfit rule evaluation as written in proposed § 50.109(b)(2) should be deleted, because the NRC has not sufficiently justified departure from this part of the regulatory process. The commenter stated further that the backfit rule should apply to all aspects of § 50.46a because it ensures that an appropriate safety focus is maintained and does not dilute licensee and NRC attention and resources unnecessarily. Thus, any subsequent changes to the TBS should be accomplished by rulemaking, and § 50.109 should apply as it does today.

Another commenter stated that the proposed rule would require in § 50.46a(d)(4) that any changes to the PRA, facility, technical specifications, or procedures as a result of PRA maintenance and update "shall not be deemed to be backfitting under any provision of this chapter." This part of the language change appears to be very broad including not just changes to the PRA, but changes to the facility, technical specifications, and operating procedures. By not considering any of these changes to be a "back-fit," the commenter asserted that a licensee would be denied any protection afforded by the Backfit Rule that requires that the NRC staff justify the cost effectiveness of the changes. In addition, the new rulemaking language would continue to exclude future TBS changes from the Backfit Rule. (P-10, NEI-A1-2)

NRC Response. The NRC does not agree with the commenters. The implicit assumption of this comment is that, absent the Backfit Rule, the NRC would not, when changing the TBS via rulemaking, be subject to any regulatory controls to ensure that an appropriate safety focus is maintained and does not result in unjustified expenditures of licensee and NRC resources. The NRC believes that this assumption is incorrect. As discussed in the draft backfitting discussion in the supplementary proposed rule, any change to the TBS via rulemaking would be subject to a regulatory analysis, which is the Federal Government-wide tool for assessing the worth and costs of proposed Federal action. The NRC would perform a regulatory analysis in connection with any rulemaking change to the TBS, even if it did not prepare a backfit analysis. The commenter did not include any analysis of the NRC's rationale, nor did the commenter explain why a properly-performed regulatory analysis would fail to protect stakeholders against unjustified or ill-considered changes to the TBS.

In considering the comment, the NRC realized that the supplemental proposed rule's backfitting discussion did not clearly state why a TBS rule change differs from other rules which are subject to the Backfit Rule's restrictions, such that the Backfit Rule's restrictions should not apply to a TBS rule change. The following discussion explains the NRC's views in this regard.

The NRC believes that when the NRC establishes regulatory requirements using new regulatory concepts and paradigms without a large body of technical information, or without substantial implementation history or experience on the overall regulatory approach, the Backfit Rule is not appropriate in evaluating subsequent changes to the new requirements – at least until the NRC has gained substantial experience in implementing the new requirements. In the

NRC's view, the Backfit Rule's restrictions on changes to NRC requirements are most appropriate where: (i) the technical phenomena and/or issues being addressed in the rulemaking are well-understood; (ii) the analytical methods used in developing the rule's requirements or required to be used in implementing the rule are relatively mature and have some history of use; (iii) there is a large body of data and experience to support the regulatory requirement; (iv) the regulatory area being controlled does not involve requirements governing reasonable assurance; and (v) the regulatory requirement is mandatory, and does not represent a voluntary alternative (*i.e.*, one which may be selected by the affected regulated entity).

After considering the effects of these factors on the possible need for future rulemaking to change the TBS values established in this rule, the NRC concludes that such changes to the TBS should not be subject to the Backfit Rule. This rulemaking, governing the regulatory requirements for evaluating the effectiveness of ECCS systems, is an adequate protection requirement. The NRC has no previous regulatory experience, and there is no implementation experience associated with the concept of risk-informing ECCS requirements using an NRC-established TBS applicable to different classes of plants. The technical basis for estimating the frequency of large pipe break events is not supported by a large body of pipe break failures at operating nuclear power reactors. This lack of actual failures contributes to large uncertainties in the estimated values. Additional operational experience in piping degradation could result in increased estimates of LOCA frequency, potentially affecting the technical bases for the TBS values specified in the final rule. Finally, the proposed regulatory requirement is a voluntary alternative, so that each entity who wishes to comply with the rule may decide on its own whether to choose to comply with the provisions of the proposed rule. This freedom to choose lessens the possibility that an unjustified regulatory burden would actually be incurred by any entity. Accordingly, the NRC has determined that the limited exclusion from the restrictions of the Backfit Rule of possible future changes to the size of the TBS and of associated plant changes needed as a result of changes to the TBS is justified.

The NRC is adding to this supplementary explanation of the NRC's decision not to apply the Backfit Rule to possible future rulemaking changes to the TBS to the backfitting statement in the final rule.

I. General Comments

Comment. A commenter stated "While we believe some revisions to the proposed rule are necessary to achieve an implementable approach, we also believe it is important for NRC to codify the concept of a risk-informed break size. The promulgation of a final rule will demonstrate NRC's continuing commitment to risk-informed performance-based methods and provides a platform for enhanced regulatory stability in the future." (NEI-CL-1)

NRC Response. The NRC agrees with the commenter's view that the promulgation of a final rule will demonstrate NRC's continuing commitment to a risk-informed and performance-based regulatory approach. The final rule may also provide a platform for enhanced regulatory stability in the future. No change was made to the rule as a result of the comment.

Comment. A late comment requested that comments specific to the information collection aspects of the supplemental proposed rule should be accepted until at least 30 days following NRC release of 7 reports prepared for the NRC by the Pennsylvania State University. The commenter asserted that the documents are not available to the public and bear on the requirements for analyzing the performance of emergency core cooling systems (ECCS) during loss-of-coolant accidents (LOCAs). (RL-1)

NRC Response. The NRC disagrees with the commenter's assertion that the information contained in the draft reports cited above must be available for review by the public before the NRC issues a final § 50.46a Risk-Informed ECCS rule. The commenter does not appear to understand the purpose of soliciting comments on the burden associated with the information collection and recordkeeping aspects of the supplemental proposed rule. The commenter provided no information to identify any disputed technical issues related to the § 50.46a rule that depend on information from the referenced documents. The public comment period for comments on information collection aspects of the supplemental proposed rule expired on November 9, 2009, several months before this late comment was received. The commenter provided no information to demonstrate why the referenced documents would have any effect on the information collection aspects of the supplemental proposed rule. The NRC will not reopen the comment period. Nevertheless, the NRC informed the commenter of the public availability status and estimated timeframe for public release of each of the reports in a letter dated April 16, 2010. No change was made to the rule as a result of the comment.

J. Comments on Topics Requested by the NRC

In the supplemental proposed rule (74 FR 40038), the NRC identified 3 topics and invited the public to submit specific comments on those issues.

NRC Topic 1. Although the supplemental proposed rule would permit licensees to make plant changes that result in very small risk increases, the NRC requested stakeholder comments on whether the rule should allow plant changes that increase risk at all. Instead of the risk acceptance criteria allowing very small risk increases, should the risk acceptance criteria in the final rule require that the net effect of plant changes made under § 50.46a be risk neutral or risk beneficial?

Comments. As previously discussed in the PRA comment section IV.D, of this document, differing views were expressed regarding NRC Topic 1 on whether any increase in risk should be allowed under § 50.46a. One commenter argued that no risk increase should be allowed because uncertainties in PRA success criteria calculations caused by alleged inadequacies in NRC and industry ECCS analysis models imply that total risk is currently very high and should not be further increased. The commenter further stated that “[t]he NRC should decrease the probabilities of core damage frequency (CDF)” and “the frequency of…accidents leading to significant, unmitigated releases from [the] containment in a time frame prior to effective evacuation of the close-in population such that there is a potential for early health effects.” Other commenters stated that risk increases consistent with RG 1.174 should be allowed. One commenter argued that not allowing any risk increase was contrary to the Commission’s PRA policy statement.

NRC response. The NRC does not agree with the comments suggesting that the rule should not permit any risk increases. The NRC concluded that the rule’s approach allowing very small risk increases is acceptable because it is consistent with the NRC’s PRA Policy Statement, which permits risk-informed plant changes causing very small increases in risk as long as the Commission’s safety goals are still met.

NRC Topic 2. Because of the difference in the risk acceptance criteria metrics used for currently operating reactors (LERF) and new reactors (LRF), the NRC sought public comments on whether LRF should be the metric of concern in lieu of LERF for new reactor applicants (or licensees) implementing the § 50.46a alternative ECCS requirements. Because the LRF goal for new reactors is a decade lower than the 10^{-5} per reactor year LERF reference value above which a facility would be limited to very small increases, should the definition of what constitutes “very small increase” and “minimal increase” for LRF (for new reactors) be a full decade lower than those defined for LERF (for existing reactors) or should the definition be based on relative change in LRF?

Comments. As previously discussed in the new reactor comment section IV.G, of this document, one commenter noted that for new plants, § 50.46a(f)(2)(iii) of the supplemental proposed rule stated that new reactors will need to show that a risk change is "very small" by computing the risk metrics CDF and large release frequency (LRF). The risk metric LRF is contained in the § 50.46a rule language even though the staff has not yet decided what risk metrics will be required of new reactors for risk-informed applications. For LRF, that would be less than 10^{-8} per year. The rulemaking language may be in conflict with the staff's final disposition on risk metrics for applications for new plants. Another commenter said, "The definition of what constitutes a "very small increase" and "minimal increase" for LRF should be a full decade lower than those defined for LERF. However, it would be difficult to determine the values for LERF and LRF and ensure that the probabilities assigned to a "very small increase" and "minimal increase" for LRF would indeed be a full decade lower than those assigned to such an increase for LERF, because the NRC's and nuclear industry's ECCS evaluation models are deficient." Another commenter stated that extensive NRC and industry efforts regarding treatment of risk metrics for reactors licensed under 10 CFR Part 52 have been underway for over a year, and recommended that these decisions as specific to § 50.46a should be deferred until after the completion of these efforts.

NRC response. Over a period of 16 months, the NRC staff engaged stakeholders regarding the issues related to the use of risk metrics in risk-informed applications for new reactors, and whether it is appropriate to use the same metrics as are currently in use for operating reactors per RG 1.174 and associated guidance, or whether new metrics should be developed. The NRC staff has considered input from stakeholders, and in a Commission policy paper provided options on risk-informed regulatory guidance for new reactors. If, as a result of Commission direction, different guidance is promulgated that describes new metrics to be used for new reactors, appropriate changes will be made in § 50.46a through rulemaking. In the interim, the § 50.46a rule will use the same risk metrics for both operating reactors and new reactors.

NRC Topic 3. In § 50.46a(e)(4)(i) of the supplemental proposed rule, the NRC proposed coolable core geometry as a high level performance-based ECCS analysis acceptance criterion for beyond-TBS LOCAs. Applicants would be allowed to justify appropriate metrics to demonstrate coolable geometry or use the current metrics (i.e., 2,200°F PCT and 17 percent MLO). However, the NRC acknowledged that it would be expensive and time-consuming for industry to develop the necessary experimental and analytical data to justify alternative acceptance criteria as a surrogate for demonstrating coolable geometry. Because of the difficulty in demonstrating alternative metrics, the NRC requested stakeholder comments on whether the final § 50.46a rule should retain the coolable geometry criterion for beyond-TBS breaks.

Comments. As previously discussed in the thermal-hydraulic comment section IV.C of this document, two commenters recommended that the option to use the coolable geometry criterion be retained because it would provide flexibility, could reduce the analysis scope and cost for beyond TBS compliance, and would increase the likelihood that a licensee could find implementation of this rule to be beneficial. Another commenter stated that beyond-TBS acceptance criteria should be the same as the acceptance criteria for TBS and smaller breaks; i.e., the criteria of § 50.46(b). The commenter stated that the criteria of maintenance of coolable core geometry and maintenance of long-term core cooling should not be used as a substitute for the criteria of § 50.46(b) for beyond-TBS LOCAs because there are deficiencies in the NRC's and the nuclear industry's ECCS evaluation models that indicate the deterministic criteria of § 50.46(b) are non-conservative.

NRC response. The final rule will retain the coolable geometry criterion for beyond-TBS breaks so that licensees will have the opportunity to propose and justify new metrics for this region. However, until alternative criteria are conclusively demonstrated to ensure core coolability, the NRC will continue to use the same peak cladding temperature and maximum local oxidation criteria for below-TBS and beyond-TBS breaks.

V. Petition for Rulemaking, PRM-50-75

In February 2002, the Nuclear Energy Institute submitted a petition for rulemaking (PRM-50-75) requesting the NRC to revise ECCS requirements by redefining the large break LOCA (ADAMS Accession No. ML020630082). Notice of that petition was published in the *Federal Register* for public comment on April 8, 2002 (67 FR 16654). However, before the NEI petition was submitted, the NRC staff had already begun its own investigation of the feasibility of a risk-informed ECCS rule. As previously discussed in Section I of this document, in March 2002, the NRC staff made recommendations to the Commission on risk-informing its regulations in SECY-02-0057, "Update to SECY-01-0133, 'Fourth 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 50.46 (ECCS Acceptance Criteria)'" (ADAMS Accession No. ML020660607). Based on these recommendations, on March 31, 2003, the Commission directed the NRC staff to initiate a risk-informed ECCS rulemaking. In this manner, the NRC began to work on a risk-informed ECCS rulemaking before the NRC staff's evaluation of PRM-50-75 was completed.

Eighteen sets of public comments were received on PRM-50-75, mostly from the power reactor industry in favor of granting the petition. Two commenters, the Illinois Department of Nuclear Safety (IDNS) and Robert Leyse (RL) 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. The NRC reviewed all public comments, but because the NRC had already initiated a rulemaking on the petitioner's issue, the Petition Review Board resolved the petition by concluding that the petitioner's request should be considered in the ongoing rulemaking process. On November 6, 2008, the NRC published a document in the FR (73 FR 66000) resolving the petition by considering the petitioner's recommendation in this rulemaking. The PRM-50-75 docket was closed. This rulemaking constitutes the NRC's final action on the substance of the petitioner's request and is consistent, for the most part, with the petitioner's proposal. Accordingly, the NRC has formally addressed only the public comments that were not in support of the petition. These public comment evaluations follow at the end of this section.

Specifically, PRM-50-75 requested the NRC to amend § 50.46 and Appendices A and K of Part 50 to allow licensees to use as an alternative to the double-ended rupture of the largest pipe in the RCS, "an alternate maximum break size that is approved by the Director of the Office of Nuclear Reactor Regulation (NRR)." However, the NRC decided that it would not be advisable for the Director of NRR to specify maximum LOCA break sizes in a case-by-case fashion because of potential problems with determining the level of adequate protection on a design-specific basis and associated difficulties in maintaining fairness and regulatory stability. Therefore, the NRC concluded that the maximum LOCA break size should be determined during a rulemaking in which all stakeholders could participate. This approach resulted in the transition break size concept upon which the § 50.46a rule is based. Thus, the § 50.46a final rule addresses the rulemaking request made by the petitioner, but because the rule does not reflect the rule language submitted in PRM-50-75, the petitioner's request is accepted in part and denied in part. The publication of the final § 50.46a completes all activities associated with PRM-50-75. Documents related to PRM-50-75 are available at http://www.regulations.gov under docket ID: NRC-2002-0018.

Public Comments Opposed to PRM-50-75

Comment. A commenter asserted that nuclear plant operating experience reveals there is no basis for changing the break size rules based upon risk-informed performance-based considerations. (RL-1)

NRC Response. The NRC disagrees with the comment. The NRC's bases for the final rule are set forth in this statement of considerations and the referenced technical documents.

Moreover, in the last 13 years, the NRC has developed and implemented risk-informed, performance-based requirements, as well as using risk-informed methodologies to review licensee requests for changes to their licensing bases. The commenter's assertions are unsupported; the commenter does not say what aspects of nuclear plant operating experience show that there is no basis for a risk-informed LOCA break size rule. In addition, the commenter did not identify any NRC experience in the application of a risk-informed regulatory approach which would reasonably lead one to question the technical or regulatory prudence of using risk-informed approaches generically.

Comment. A commenter asserted that PRM-50-75, with its reliance on LBB [leak-before-break], should be withdrawn. (RL-18)

NRC Response. The NRC disagrees with the commenter's implicit assertion that the § 50.46a rule relies on the concept of leak-before-break as the primary technical basis for the rulemaking. The referenced technical documents forming part of the technical basis for this final rule do not rely heavily on the concept of LBB. The technical basis for this rule is the expert elicitation report (NUREG-1829) which provided the LOCA frequency vs. LOCA break size curves. The experts who prepared this report relied primarily on plant operational experience and their individual knowledge of the various technical aspects of piping degradation mechanisms. The individual experts considered LBB to some degree when making their estimates, but LBB was not the principal consideration. The experts and the NRC are aware that piping degradation under certain circumstances can cause pipes to rupture before exhibiting detectable leakage. The commenter did not provide an explanation of why the NRC's limited reliance on LBB adversely affects the viability of a risk-informed ECCS rule. While it is also true that the final § 50.46a rule requires enhanced leak detection methods to be applied to piping larger than the TBS, this requirement was added to increase the defense-in-depth provided by the rule for the degradation methods in which leakage is a detectable precursor to piping failure; it was not the primary basis for ensuring that pipe breaks larger than the TBS do not present an unacceptable risk to public health and safety. In any event, the NRC may not order withdrawal of PRM-50-75; only the petitioner may withdraw the petition.

Comment. A commenter questioned how the NRC would determine how much reduction in defense-in-depth and safety margins would be acceptable when risk-informing the ECCS requirements to allow plant changes that could reduce licensee costs and also increase risk to the public. (IDNS-1)

NRC Response. The NRC agrees with the commenter that before the § 50.46a rulemaking was initiated, explicit guidance did not exist about how much reduction in defense-in-depth and safety margins would be appropriate for mitigating the very low frequency large pipe breaks. However, during the rulemaking the Commission provided guidance to the NRC staff in a publicly-available SRM and the Advisory Committee on Reactor Safeguards provided its views on defense-in-depth and safety margins in a letter to the Commission.

Assessing changes in overall risk is a universal measure, whereas evaluating changes to defense-in-depth and safety margins is unique to each individual proposed change at a specific facility. To determine the appropriate level of defense-in-depth and safety margins for individual proposed changes at a specific facilities, the NRC based the § 50.46a rule requirements on the existing regulatory guidance in RG 1.174 for ensuring adequate defense-in-depth and safety margins. This guidance has been successfully applied to risk-informed applications for the last 13 years. Paragraphs 50.46a(f)(3)(i) and (ii) incorporate these requirements. Therefore, changes to defense-in-depth and safety margins are evaluated as each facility change is proposed. This allows changes to defense-in-depth and safety margins to be appropriately evaluated for any proposed change based on the difference between the traditional requirements or the plant's current licensing basis and the operating configuration that would exist after the proposed changes. It is not feasible to develop a set of universally applicable decision guidelines for ensuring adequate defense-in-depth and safety margins for all plant changes at all facilities.

Comment. A commenter stated that the 2500 [reactor] years of operating and safety experience cited by the petitioner proves that the present set of regulations and regulatory processes is effective. IDNS says that even though some of the large technological uncertainties have been reduced, there are still large uncertainties involved in risk analysis and that there seems to be a trade-off of uncertainties involved in risk-informing the original rulemaking criteria. (IDNS-2)

NRC Response. The NRC agrees with the commenter that the present regulations and regulatory processes are effective but has concluded that they can be made more efficient. The comment did not provide any details about which uncertainties the commenter believes should preclude risk-informed changes. The NRC gave due consideration to major uncertainties when developing all aspects of the risk-informed ECCS rule. For example, the size of the TBS was developed through a consideration of operating experience and analytical evaluations via an expert elicitation process. The NRC then increased the resulting nominal values to add margin to account for uncertainties associated with the process. Uncertainties regarding thermal-hydraulic analyses were also addressed. Analyses performed in compliance with the prescriptive requirements in Appendix K have been shown to produce significantly conservative results to account for uncertainties. Best-estimate ECCS analysis methods allowed by § 50.46 are specifically required to include an identification and assessment of analysis uncertainties. The total estimated uncertainty must be accounted for in the analysis results, and the results must demonstrate that there is a high probability that the ECCS acceptance criteria will not be exceeded.

Comment. A commenter stated that although the petitioner said that a risk-informed ECCS rule will result in increased plant safety and resource benefits, IDNS sees no examples of the expected safety benefits and doesn't recognize what resource benefits will result. (IDNS-3)

NRC response. Although it is possible that licensees could use this rule to increase safety at individual facilities, the rule does not require that plant changes increase safety. Thus, the NRC agrees with the commenter that the rule may not result in overall safety benefits. As a result, the NRC has placed restrictions in the final rule to ensure that any increases in overall risk are very small and do not exceed other acceptable increases in risk allowed by the NRC in other approved risk-informed applications. The NRC will review and approve each plant change made under this rule involving more than a minimal increase in risk via the license amendment process. All such changes will be noticed for public comment which will allow members of the public an opportunity to request a hearing on issues of significant concern in accordance with NRC's rules in 10 CFR Part 2 governing such requests.

Comment. A commenter stated that if leak-before-break and fracture mechanics methodologies are used to reduce the ECCS requirements, they should be subject to standards for rigor and quality which do not presently exist. This commenter said that PRA standards did exist but have not been unequivocally adopted by the NRC and that neither the ASME PRA standard, the NEI PRA peer review criteria, nor the RG 1.174 guidelines adequately treat pipe cracking issues. The commenter further stated its concern that generic analyses that might be done to support the rule might not be applicable to all facilities given the varying as-built plant configurations and operating histories that could affect pipe failures. Thus, the commenter concluded that insufficient technical work had been performed to support risk-informed rule changes. (IDNS-4)

NRC response. The NRC agrees with the commenter that the technical information available at the time of the comment (June 2002) was insufficient to support rulemaking. To ensure that adequate technical information was available to support a risk-informed ECCS rule, the NRC conducted extensive additional studies to estimate pipe break frequencies as a function of break size (See NUREG-1829, "Estimating Loss-of-Coolant Accident Frequencies Through the Elicitation Process," March 2008; ADAMS Accession No. ML082250436) and to evaluate the seismic effects on piping failures greater than the proposed transition break size (See NUREG-1903, "Seismic Considerations for the Transition Break Size," February 2008; ADAMS Accession No. ML080880140). The NRC addressed the commenter's concern about applying generic information to plants with different designs by adding paragraphs (c)(1)(i) and (d)(6) to the final rule. Paragraph (c)(1)(i) requires the licensee of a facility to demonstrate that the results of the NUREG-1829 and NUREG-1903 studies apply to that facility in the initial application for approval to implement § 50.46a. Once a licensee is approved to implement § 50.46a, paragraph (d)(6) requires that licensee determine the effect of all future facility changes on the evaluation performed pursuant to § 50.46a(c)(1)(i) demonstrating the applicability to the licensee's facility of the generic results in NUREG-1829 and NUREG-1903. Changes that would invalidate this applicability evaluation may not be made. The NRC has also developed draft regulatory guidance (DG-1216, "Plant-Specific Applicability of Transition Break Size Specified in 10 CFR 50.46a") to provide an acceptable method for licensees to demonstrate applicability of the generic transition break size.

The NRC also agrees with the commenter's view that industry consensus standards are important. The NRC referenced consensus standards for maintaining and upgrading PRAs in paragraph (d)(4) of the final rule.

Comment. A commenter said that the petitioner stated the rule would cause changes to containment analyses, including peak accident pressure, but that it did not intend for changes to be made to containment structural integrity. The commenter stated that it was not only interested in containment structural integrity, but also containment capability. The commenter also said that if containment integrity testing is done less often, the margin of safety could be reduced and any such reduction must be technically justified. (IDNS-5)

NRC response. The NRC agrees with the commenter that any reductions to containment capability must be justified. The final § 50.46a rule does not affect the frequency of containment leak testing. The final rule does require containment leak tight capability to be maintained for "realistically" calculated temperatures and pressures for LOCAs larger than the TBS. This requirement could allow leak testing to be performed under slightly less conservative conditions for pipe breaks larger than the TBS. The NRC has determined that this reduction is technically justified because of the low frequency of occurrence of these large LOCAs. No public comments were received during the rulemaking on this proposed determination.

Comment. A commenter asked if the rule would reduce emergency planning zone sizes or reduce the need for emergency planning capability. IDNS stated that such changes would potentially affect public safety and confidence. (IDNS-6)

NRC response. The NRC agrees with the commenter. The final § 50.46a rule makes no change to emergency preparedness requirements.

Comment. Although the petitioner stated that the rule would focus facility design and operation on the more likely safety-significant events, a commenter asked why not focus on both the existing design-basis events and the more likely events? (IDNS-7)

NRC response. The NRC agrees in part with the commenter. The final § 50.46a rule allows licensees to focus resources on the more likely, smaller LOCAs, but still requires that the facility be able to mitigate a break in the largest (design-basis) piping. But because of the lower likelihood of large breaks, the rule allows less conservative assumptions to be used for large break analyses.

Comment. A commenter stated that the probability of a large break LOCA increases with age. The commenter was skeptical of allowing reduced Section XI inservice inspection for aging plants. (IDNS-8)

NRC response. The NRC agrees with the commenter on the importance of considering plant aging. The NRC considered plant aging, existing aging management programs, and in-service inspection programs when establishing the LOCA frequency vs. break size curves in NUREG-1829; and, ultimately in selecting the TBS. However, the NRC disagrees with the commenter that the probability of a large break LOCA increases with age. Effective aging management coupled with adequate inspection based upon increased knowledge of the active degradation mechanisms associated with pressure boundary components, can prevent increases in large break LOCA frequency as plant age increases.

Comment. A commenter asserted that the Davis-Besse reactor head corrosion problem shows that degradation methods are not fully understood and that new ones emerge periodically. The commenter also stated that PRAs cannot now adequately predict boric acid erosion/corrosion and hydrogen explosions in RCS piping. (IDNS-9)

NRC response. The NRC agrees with the commenter that continued operating experience will increase the existing knowledge related to the understanding of degradation mechanisms in primary pressure boundary components. This consideration, along with research and evaluation, is part of the ongoing effort to mitigate existing and future plant challenges. For example, the occurrence of primary water stress corrosion cracking (PWSCC) in pressure boundary piping was first observed in the United States at the V. C. Summer plant in 2000. However, prior to this time, the NRC was aware of the potential of PWSCC through its research programs and also international operating experience. Since the V. C. Summer discovery, NRC and industry-sponsored research has been used to develop and evaluate mitigation measures to provide reasonable assurance that the risk associated with PWSCC in piping systems will remain low. The LOCA frequency estimates developed in NUREG-1829 addressed the effect of boric acid corrosion and the possibility of hydrogen explosions in RCS piping as quite a bit of knowledge exists about these degradation mechanisms. Additionally, the TBS values selected by the NRC were conservatively adjusted to account for uncertainties in the NUREG-1829 evaluation process. In addition, the NRC will reassess LOCA frequencies in 10 year intervals and update the estimates based on knowledge gained since the previous assessment. If estimated LOCA frequencies increase, the NRC will change the size of the TBS, as appropriate.

Comment. A commenter argued against the concept of having voluntary alternative regulations by stating that two alternative sets of regulations will not reduce regulatory burden for the NRC and goes against the NRC strategic objectives of reducing regulatory burden, maintaining public confidence and increasing regulatory efficiency and effectiveness. The commenter stated that having alternative regulations indicates that the nuclear industry is not fully committed to the approach and objected to the petitioner’s argument that having alternative risk-informed technical specification requirements would increase plant safety. The commenter also questioned that if risk-informed technical specifications would increase safety, why would the NRC not require that risk-informed standard technical specifications be implemented at all facilities? (IDNS-10)

NRC Response. The NRC agrees with the commenter’s view that alternative regulations will not reduce regulatory burden for the NRC, but does not agree that alternative regulations are contrary to the NRC strategic objectives of reducing overall regulatory burden, maintaining public confidence and increasing regulatory efficiency and effectiveness. The NRC believes that the alternative rule will provide an opportunity for reducing unnecessary burden for licensees since it relaxes certain analysis assumptions that can result in limitations on operating parameters. With respect to maintaining public confidence and increasing regulatory efficiency and effectiveness, the NRC has already implemented several alternative risk-informed regulatory approaches. The NRC has successfully implemented numerous alternative risk-informed technical specification initiatives. Experience gained from this effort has shown that using risk as a decision making tool improves the NRC's efficiency and effectiveness and reduces burden on both the NRC and licensees. The NRC is now implementing risk-informed regulations on fire protection and pressurized thermal shock. The overall experience the NRC is accumulating with these efforts already shows that alternative requirements can work well without significantly impacting public health and safety or the efficiency and effectiveness of the NRC's regulatory oversight. The NRC believes that such demonstrations, approved by the NRC and monitored to determine if adjustments are needed, can increase public confidence in risk-informed regulation.

The NRC disagrees with the commenter's view that having alternative regulations indicates that the nuclear industry is not fully committed to the risk-informed approach. While comment letters from the nuclear industry disagree with specific aspects of the rule, they are unanimously in support of promulgating a risk-informed ECCS option. Issuing the rule as an alternative regulation allows licensees to choose to implement it at facilities where plant changes under the rule are cost-effective and consistent with the licensee's business plans.

The NRC disagrees with the commenter's implied comment that if risk-informed technical specifications increase safety, the NRC should require all licensees to implement risk-informed standard technical specifications. Regardless of whether risk-informed technical specifications do or do not increase safety, the NRC has determined that adequate protection of public health and safety is provided by both the current standard technical specifications and the new risk-informed technical specification initiatives which licensees may use in certain areas to complement the existing deterministic standard technical specifications. The NRC believes it is important that licensees be given a reasonable amount of flexibility to meet regulatory requirements as long as the overall results of the licensee's actions ensure adequate protection. As a result, the NRC has established the risk-informed technical specification initiatives as a voluntary alternative to the existing standard technical specifications.

Comment. A commenter stated that approving the petition at this time would not have a positive effect on the confidence level of the public that the regulator is keeping a close watch on a complex and potentially hazardous technology. Thus, IDNS recommended that the Commission proceed cautiously. (IDNS-11)

NRC Response. The NRC agrees with the commenter that agency must proceed cautiously while risk-informing its ECCS regulations. Licensees who adopt this alternative rule must periodically reconfirm that changes made to the plant do not invalidate the applicability of the underlying basis for the rule and that the cumulative risk increase does not exceed a very small amount. Also, the NRC plans to reassess the estimates of LOCA frequency that serve as the basis for the rule every 10 years. If LOCA frequencies are found to be increasing, the NRC may increase the size of the TBS. If the TBS is increased, the rule specifies that licensees will have to reevaluate the risk impacts of plant changes they have implemented under § 50.46a to show that they still meet the risk acceptance criteria. If the acceptance criteria are not met, licensees will have to reverse plant changes or make other compensatory changes to satisfy the acceptance criteria.

NRC Overall Response to IDNS comments. The NRC agrees that nearly all of the concerns cited by the IDNS are important issues. None of these comments raised issues that the NRC did not consider during the course of the § 50.46a rulemaking. All of these issues were addressed by the NRC as the risk–informed ECCS rule was being developed. Stakeholder input was sought on these and many other issues throughout the process by three notices in the *Federal Register,* two proposed rules, and four public meetings. The NRC provided IDNS with copies of both proposed rules published during this effort. IDNS submitted no comments objecting to the way the NRC addressed any of these issues during the rulemaking. Thus, the NRC believes that it has successfully addressed the concerns raised by IDNS and that the final § 50.46a rule establishes an appropriate level of balance to allow potential operational benefits to licensees and ratepayers while ensuring adequate protection of public health and safety.

VI. Section-by-Section Analysis of Changes

A. Section 50.34 - Contents of application; technical information

Paragraph (a)(4)(i) of this section specifies that § 50.46a contains alternative ECCS requirements that applicants may choose to apply to reactors whose construction permits were issued before the effective date of the rule. This section also states that applicants for construction permits for facilities which may be issued after the effective date of the rule may also choose to apply the § 50.46a alternative ECCS requirements to preliminary analysis and evaluation of the design if the applicant demonstrates that the facility is similar to the designs of facilities licensed before the effective date of the rule.

Paragraph (a)(4)(ii) of this section, specifies that applicants for construction permits for facilities which may be issued after the effective date of the rule who have not demonstrated that the facility is similar to the designs of facilities licensed before the effective date of the rule may not apply the § 50.46a alternative ECCS requirements in the preliminary analysis and evaluation of the design.

Paragraph (b)(4)(i) of this section specifies that applicants for operating licenses for facilities which may be issued after the effective date of the rule may also choose to apply the § 50.46a alternative ECCS requirements to final analysis and evaluation of the design if the applicant demonstrates that the facility is similar to the designs of facilities licensed before the effective date of the rule.

Paragraph (b)(4)(ii) specifies that applicants for operating licenses for facilities which may be issued after the effective date of the rule who have not demonstrated that the design is similar to the designs of facilities licensed before the effective date of the rule may not apply the § 50.46a alternative ECCS requirements in the final analysis and evaluation of the design.

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

Paragraph (a) of this section specifies that boiling or pressurized light-water nuclear power reactor fueled with uranium oxide pellets with zirconium alloy cladding must be provided with an ECCS. It also specifies that the ECCSs of BWRs and PWRs licensed before the effective date of the rule must be designed under § 50.46 or § 50.46a. Paragraph (a) also specifies that ECCSs of BWRs and PWRs licensed after the effective date of the rule may also choose to comply with the § 50.46a alternative ECCS requirements if the applicant or licensee demonstrates that the design is similar to the designs of LWR facilities licensed before the effective date of the rule.

Paragraph (a)(1)(i) of this section requires that the cooling performance of ECCS for BWRs and PWRs be calculated by an acceptable evaluation model and specifies certain general requirements for acceptable evaluation models that are prepared in accordance with Appendix K to 10 CFR Part 50. These requirements were relocated to this subparagraph but were not modified by this rulemaking.

C. Existing Section 50.46a - Acceptance criteria for reactor coolant system venting systems, is administratively redesignated as Section 50.46b.

D. Section 50.46a - Alternative acceptance criteria for emergency core cooling systems for light-water reactors

A new Section 50.46a is created by this rulemaking. Paragraph (a) of this section provides definitions for terms used in other parts of this section. The definition of *evaluation* *model* in § 50.46a(a)(2) is the same as in § 50.46. The definition of *loss-of-coolant accidents* in § 50.46a(a)(3) is based on the existing definition in § 50.46 but has been modified to indicate that pipe breaks larger than the TBS are beyond design-basis accidents.

The new definitions are:

(a)(1) *Changes enabled by this section*, which means changes to the facility, technical specifications, or procedures which are permitted at a facility whose licensing basis includes § 50.46a but are not permitted at a facility whose licensing basis includes § 50.46;

(a)(4) *Operating configuration*, which is used in § 50.46a(d)(5) to specify plant equipment availability conditions that must be analyzed for conformance with acceptance criteria; and

(a)(5) *Transition break size (TBS)*, which is used to distinguish between requirements applicable to pipe breaks at or below this size from those applicable to pipe breaks above this size.

Paragraph (b)(1) provides the applicability and scope of the requirements of this section. Section 50.46a applies to currently licensed light-water nuclear power reactors (licensed before the effective date of the rule) and to LWRs licensed after the effective date of the rule, whose designs have been demonstrated to be similar to the designs of LWR facilities licensed before the effective date of the rule. Thus, for similar reactor designs (but with some limitations as specified for certain specific provisions), § 50.46a could be used by applicants for and holders of construction permits, operating licenses, combined licenses, and standard design approvals and by applicants for certified designs and for manufacturing licenses. Paragraph (b)(2) specifies that the requirements in Section 50.46a are in addition to any other requirements applicable to ECCSs set forth in 10 CFR 50, with the exception of § 50.46.

Paragraph (c)(1) specifies the contents of initial applications that may be submitted by various entities for approval to implement the alternative ECCS requirements in § 50.46a. Paragraph (c)(1)(i) requires that an application contain a written evaluation demonstrating applicability of the results in NUREG-1829 and NUREG-1903 to the specific facility. To confirm the applicability of NUREG-1903, the applicant must demonstrate that the total frequency of seismically-induced direct and indirect failures of piping larger than the TBS at the facility is significantly less than 10^{-5} per year. Paragraph (c)(1)(ii) requires identification of the NRC-approved analysis methods to be used to comply with the ECCS analysis requirements and acceptance criteria in paragraph (e). Paragraph (c)(1)(iii) requires operating reactor licensees whose construction permits were issued before § 50.46a becomes effective and who wish to establish an allowable outage time other than 14 days for use under paragraph (d)(5) of the rule, to propose the alternative period of time. Paragraph (c)(1)(iv) requires licensees of operating reactors whose licenses may be issued under Part 52 of this chapter (which are expected to be new reactor designs) to propose an appropriate allowable outage time (or "short time") for use under paragraph (d)(5) of the rule. Paragraph (c)(1)(v)(A) requires a description of the risk-informed evaluation used to determine whether proposed change(s) to the facility meet the acceptance criteria for making risk-informed changes in paragraph (f). Paragraph (c)(1)(v)(B) requires operating reactor licensees whose construction permits were issued before § 50.46a becomes effective to submit a description of the risk-informed evaluation (if applicable) used to demonstrate that any proposed alternative outage time (or "short time") for use in paragraph (d)(5) meets the acceptance criteria in paragraph (c)(3)(iii)(B). Paragraph (c)(1)(v)(C) requires licensees of operating reactors whose licenses may be issued under Part 52 of this chapter to provide a description of the risk-informed evaluation used to demonstrate that the proposed outage time (or "short time") for use in paragraph (d)(5) meets the acceptance criteria in paragraph (c)(3)(iii)(C). For both types of licensees, a risk-informed evaluation must be used to demonstrate the reasonableness of the duration of the proposed "short time."

Paragraph (c)(1)(vi) requires entities who wish to make facility design changes enabled by § 50.46a without prior NRC approval to submit a description of the risk-informed evaluation process to be used to determine the acceptability of such changes. Design certification applicants are not subject to this provision, either before or after NRC certification of the design. An applicant for a design certification that has not been approved by the NRC does not need this provision since it is free to change the design specified in its unapproved application at any time. By contrast, the NRC has determined that design certification applicants whose designs have been certified should not be allowed to change the certified designs without NRC review and approval via rulemaking. Allowing the design certification applicant to make changes to the certified design without NRC approval through the rulemaking process would appear to be inconsistent with the underlying concept of design certification as rulemaking and would effectively reduce NRC's regulatory control over the design certification. The NRC has also decided to exclude manufacturing license holders from this option to avoid a reduction of NRC regulatory control over the approved manufacturing design. Under paragraph (c)(1)(vi)(A), the process must include an approach for evaluating each change for compliance with all of the acceptance criteria in paragraphs (f)(1), (f)(2), and (f)(3). Under paragraph (c)(1)(vi)(B), the process must include a description of the PRA model or non-PRA risk assessment methods used to determine compliance with paragraphs (f)(4) and (f)(5).

Paragraph (c)(1)(vii) requires entities who wish to adopt the alternative ECCS requirements in § 50.46a to submit a description of all non-safety equipment to be relied on to mitigate the consequences of a LOCA larger than the TBS. Paragraph (c)(1)(viii) requires entities who wish to adopt the alternative ECCS requirements in § 50.46a to submit a description of the facility's leak detection program demonstrating how the program satisfies the criteria in paragraph (d)(2).

Paragraph (c)(2) states that all applicants other than those holding operating licenses issued before § 50.46a becomes effective (i.e., applicants for a construction permit, operating license, design approval, design certification, manufacturing license, or combined license or holder of a design approval) seeking to implement the requirements of this section shall, in addition to the information that is required by paragraph (c)(1) of this section, submit an analysis demonstrating why the proposed reactor design is similar to the designs of reactors licensed before the effective date of the rule and recommend an appropriate TBS.

Paragraph (c)(3) specifies the acceptance criteria for approval of applications to comply with § 50.46a. Paragraph (c)(3)(i) requires the evaluation submitted under paragraph (c)(1)(i) to demonstrate that the NUREG-1829 and the NUREG-1903 results are applicable to the facility. For NUREG-1903 to apply, the total frequency of seismically-induced direct and indirect failures of piping larger than the TBS must be significantly less than 10^{-5} per year. Paragraph (c)(3)(ii) requires that the method(s) for demonstrating compliance with the ECCS acceptance criteria in paragraphs (e)(3) and (e)(4) of this section meet the requirements in paragraphs (e)(1) and (e)(2). Paragraph (c)(3)(iii)(A) requires that the risk-informed evaluation process proposed for use to make changes enabled by or made under this section be adequate for determining whether the acceptance criteria in paragraph (f) of this section have been met. Paragraph (c)(3)(iii)(B) requires that the risk-informed evaluation process (if applicable) used to justify any proposed alternative time period longer than 14 days for use in paragraph (d)(5), be appropriate by considering the mitigative capability available, the configuration specific risk, the philosophy of defense-in-depth, and adequate safety margins. For operating reactors licensed under Part 52, paragraph (c)(3)(iii)(C) requires that the risk-informed evaluation process used to justify the proposed short time for use in paragraph (d)(5), demonstrate that the proposed time is consistent with the mitigative capability available, the configuration specific risk, the philosophy of defense-in-depth, adequate safety margins, and does not result in a significant decrease in the level of safety otherwise provided by the design. Paragraph (c)(3)(iv) requires that the risk-informed evaluation process (if applicable) used for making self-approved plant changes under paragraph (f)(1) is adequate for determining whether the acceptance criteria in paragraph (f) of this section, have been met. Paragraph (c)(3)(v) requires that all non-safety equipment credited for demonstrating compliance with the ECCS acceptance criteria be identified and listed as such in plant technical specifications if possible at the time the § 50.46a application is approved. Because applicants for and holders of design approvals will not have developed plant technical specifications, the NRC intends to include appropriate provisions in the design approval to ensure that future licensees using these designs list this equipment in plant technical specifications. Paragraph (c)(3)(vi) requires that the reactor design for all applicants other than those holding operating licenses issued before the effective date of the rule be similar to the designs of current operating reactors and that the applicant's proposed TBS includes sufficient margin to provide assurance that, when considering the limited availability of data and the uncertainty in the estimation of loss of coolant accident frequency, the estimated frequency of breaks larger than the TBS for all initiators does not exceed 10^{-5} per year. Paragraph (c)(3)(vii) requires that all other applicable standards and requirements of the Act and the Commission's regulations are met.

Paragraph (d) specifies the requirements for licensees during facility operation after implementing § 50.46a.

Paragraph (d)(1) requires that the ECCS models be maintained to comply with the ECCS acceptance criteria in paragraphs (e)(1) and (e)(2) of this section.

Paragraph (d)(2) requires that the licensee maintain leak detection equipment available at the facility and identify, monitor, and quantify leakage to ensure that adverse safety consequences do not result from leakage from piping or components larger than the TBS.

Paragraph (d)(3) requires that changes to the facility, technical specifications, or procedures enabled by or made under § 50.46a be evaluated by a risk-informed evaluation process which demonstrates that acceptance criteria in § 50.46a(f) are met.

Paragraph (d)(4), requires licensees to maintain and upgrade its PRA analyses no less often than once every 4 years. Maintaining a PRA involves the update of PRA models to reflect facility changes such as plant modifications, procedure changes, or changes in plant performance data. Upgrading a PRA involves incorporating into the PRA models a new methodology or significant changes in scope or capability that impact the significant accident sequences. Risk assessments are required to continue to meet the quality requirements in §§ 50.46a(f)(4) and (f)(5). Licensees are required to take action to ensure that facility design and operation is consistent with the risk assessment assumptions used to meet the acceptance criteria in § 50.46a(f)(2) or (f)(3). Any necessary changes to the facility caused by maintaining or upgrading risk assessments will not be deemed backfitting.

Paragraph (d)(5) requires licensees to control plant operation to ensure that for LOCAs larger than the TBS, operation in a plant operating configuration not demonstrated to meet the acceptance criteria in paragraph (e)(4) may not exceed a short time. A short time for existing operating reactors is either a total of fourteen (14) days in any 12-month period or an alternative time period proposed by the licensee and approved by the NRC. A short time for new reactor designs (i.e., future operating reactors whose licenses are issued under Part 52 of this chapter) must be proposed by the applicant or licensee and approved by the NRC.

Paragraph (d)(6) requires licensees to perform an evaluation to determine the effect of all planned facility changes on the evaluation performed pursuant to § 50.46a(c)(1)(i) demonstrating the applicability to the licensee's facility of the results in NUREG-1829 and NUREG-1903 and prohibits licensees from implementing any facility change which would invalidate that evaluation.

Paragraph (e) contains the ECCS evaluation model requirements, analysis requirements, and acceptance criteria for the two LOCA break size regions.

Paragraph (e)(1) specifies model and analysis requirements for breaks smaller than or equal to the TBS. These requirements are the same as the current requirements for LOCA analysis models in existing § 50.46.

Paragraph (e)(2) specifies model and analysis requirements for breaks larger than the TBS. Methods for evaluating ECCS cooling performance for breaks larger than the TBS must be approved by the NRC. However the analysis for breaks larger than the TBS may be performed using different assumptions than those required for breaks smaller than or equal to the TBS. Analysis of breaks larger than the TBS need not assume a coincident single failure of mitigation equipment or loss-of-offsite power. Non-safety grade equipment may also be credited in analyses of breaks larger than the TBS provided that onsite power can supplied to that equipment in a reasonable time in the event offsite power is lost.

Paragraph (e)(3) provides ECCS acceptance criteria for LOCAs smaller than or equal to the TBS. The criteria are the same as the current requirements in § 50.46(b).

Paragraph (e)(4) provides ECCS acceptance criteria for LOCAs larger than the TBS. These acceptance criteria are based on maintaining a coolable geometry in the core and demonstrating long term cooling capability and are less prescriptive than the criteria presently used for LOCA analysis.

Paragraph (e)(5) provides that the Director of the Office of Nuclear Reactor Regulation or the Office of New Reactors may impose restrictions on reactor operation if ECCS requirements are not met. This paragraph is added to be consistent with existing § 50.46 which also contains this requirement.

Paragraph (f) provides requirements for implementing changes to the facility, technical specifications, and procedures under § 50.46a.

Paragraph (f)(1) specifies that certain entities other than design certification applicants and holders of manufacturing licenses may make changes under § 50.46a without NRC approval if:

(i) The changes are permitted under § 50.59 or § 52.98 (as applicable);

(ii) A risk-informed evaluation process has been submitted by the licensee and reviewed and approved by the NRC under § 50.46a(c)(1)(vi) and (c)(3)(iv); and

(iii) The change does not invalidate the evaluation performed under § 50.46a(c)(1)(i) of the applicability of the results in NUREG-1829 and NUREG-1903 to the licensee's facility.

Paragraph (f)(2) states that for plant changes not permitted under paragraph (f)(1), an application must be submitted to the NRC containing the following information:

(i) For reactor licensees, the information required under § 50.90;

(ii) Information from the risk-informed evaluation demonstrating that the total increases in core damage frequency and large early release frequency are very small and the overall risk remains small, and the risk-informed change criteria in paragraph (f)(3) are met;

(iii) If previous changes have been made under § 50.46a, information from the risk-informed evaluation on the cumulative effect on risk of the proposed change and all previous changes made under this section. If more than one plant change is combined; including plant changes not enabled by this section, into a group for the purposes of evaluating acceptable risk increases; the evaluation of each individual change must be performed along with the evaluation of combined changes;

(iv) Information demonstrating that the ECCS analysis acceptance criteria in paragraphs (e)(3) and (e)(4) are met; and

(v) Information demonstrating that the proposed change will not increase the LOCA frequency of the facility (including the frequency of seismically-induced LOCAs) by an amount that would invalidate the applicability to the facility of the results of the studies (NUREG-1829, "Estimating Loss-of-Coolant Accident (LOCA) Frequencies through the Elicitation Process", March 2008 and NUREG-1903, "Seismic Considerations for the Transition Break Size", February 2008").

Under paragraph (f)(2), design certification applicants are permitted to request an amendment to the design certification for which they submitted the original design certification application, in order to make changes enabled by § 50.46a. The amendment request must be submitted in accordance with applicable requirements including 10 CFR Part 2, Subpart H. In addition, combined license holders referencing certified designs are permitted to request NRC approval of plant-specific departures from the certified design in accordance with the requirements in § 52.98(c).

Paragraph (f)(3) specifies requirements for all plant changes made under § 50.46a. Paragraph (f)(3)(i) requires that defense-in-depth be maintained. Paragraph (f)(3)(ii) requires that adequate safety margins be maintained. Paragraph (f)(3)(iii) requires that adequate performance-measurement programs be implemented and provides criteria on the specific attributes required to meet the performance measurement requirements. Paragraph (f)(3)(iv) specifies that for new reactor license applicants under Part 52, plant changes made under § 50.46a must not result in a significant decrease in the level of safety otherwise provided by the new reactor design.

Although previous paragraph (f)(2) does not require use of PRA in assessing risks associated with the proposed changes, to the extent that PRA is used, paragraph (f)(4) of the rule identifies specific technical requirements for the risk-informed assessment. It 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 would affect the regulatory decision in a substantial manner;

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

(iii) Have sufficient technical adequacy (including consideration of uncertainty) and level of detail to provide confidence that the total risk estimate and the change in total risk estimate adequately reflect the plant and the effect of the proposed change on risk; and

(iv) Be determined, through peer review, to meet industry standards for PRA quality that have been endorsed by NRC.

Paragraph (f)(5) requires that to the extent that risk assessment methods other than PRA are used to develop quantitative or qualitative estimates of changes to risk in the risk-informed evaluation, an integrated, systematic process must be used. All aspects of the analyses must reasonably reflect the current plant configuration and operating practices, and applicable plant and industry operating experience.

Paragraph (g) provides the requirements for making reports to the NRC.

Paragraph (g)(1)(i) requires reporting of all errors or changes to ECCS analyses at least annually as specified in § 50.4. For significant changes or errors, licensees must report within 30 days including a schedule for reanalysis or other action as needed to show compliance with ECCS requirements. Under paragraph (g)(1)(i)(A), for LOCAs involving pipe breaks equal to or smaller than the TBS, significant changes are defined as a change in peak cladding temperature of greater than 50°F. Under paragraph (g)(1)(i)(B), for LOCAs involving pipe breaks larger than the TBS, a significant change is defined as one resulting in a significant reduction in the capability to meet the ECCS acceptance criteria in § 50.46a(e)(4).

Paragraph (g)(1)(ii) sets forth reporting requirements with respect to the PRA maintenance and upgrading that is required by § 50.46a(d)(4). When maintaining and upgrading the PRA, this paragraph requires the licensee to report changes to the NRC within 60 days if the acceptance criteria in §50.46a(f)(2)(ii) are exceeded. This provision also requires the report to include a schedule for implementation of any corrective actions necessary to bring plant operation or design back into compliance with the acceptance criteria.

Paragraph (g)(1)(iii) contains reporting requirements for plant changes made under § 50.46a(f)(1) involving minimal risk (self-approved changes). A short description of these changes must be reported every 24 months.

Paragraph (g)(2) contains reporting requirements associated with design certifications and design approvals. During the lifetime of the standard design, reports must be made to the NRC of all significant errors in the ECCS analyses. Paragraphs (g)(2)(i) and (g)(2)(ii) specify the criteria for significant errors which are the same as the criteria for operating reactors specified in paragraphs (g)(1)(i)(A) and (g)(1)(i)(B).

Paragraph (h) provides documentation requirements for plant changes. Following implementation of § 50.46a, licensees are required to maintain records sufficient to demonstrate compliance with all requirements in § 50.46a and § 50.71.

Paragraphs (i) through (l) are reserved for future use.

Paragraph (m) specifies the actions that must be taken by various entities if the NRC increases the TBS.

Paragraph (m)(1) requires that holders of operating licensees, combined licenses, and manufacturing licenses must re-perform the ECCS analyses required by paragraphs (e)(1) and (e)(2). If the acceptance criteria in paragraphs (e)(3) and (e)(4) are not met, licensees must make changes to the facility to comply with the acceptance criteria. This paragraph also specifies that plant changes made necessary after an increase in the TBS are not deemed to be backfitting under 10 CFR 50.109 or a violation of any finality provision in Part 52.

Paragraph (m)(2) requires that holders of combined licenses referencing a design certification must re-perform the ECCS analyses required by paragraphs (e)(1) and (e)(2). If the acceptance criteria in paragraphs (e)(3) and (e)(4) are not met, licensees must make changes to the facility to comply with the acceptance criteria. This paragraph also specifies that plant changes made necessary after an increase in the TBS are deemed to be in conformance with applicable finality provisions in Part 52.

Paragraph (m)(3) requires that holders of combined licenses referencing a design approval must re-perform the ECCS analyses required by paragraphs (e)(1) and (e)(2). If the acceptance criteria in paragraphs (e)(3) and (e)(4) are not met, licensees must make changes to the facility to comply with the acceptance criteria. This paragraph also specifies that plant changes made necessary after an increase in the TBS are not deemed to be backfitting under 10 CFR 50.109 or a violation of any finality provision in Part 52.

E. <u>Section 50.109 - Backfitting</u>.

This section is modified to provide that changes made by the NRC to the TBS and changes made by licensees to continue to comply with § 50.46a are not deemed to be backfitting under 10 CFR 50.109.

F. <u>Appendix A to Part 50 - General Design Criteria for Nuclear Power Plants</u>

Five of the general design criteria contained in Appendix A are modified to remove the requirement to assume a single failure and a loss-of-offsite power in the systems subject to these criteria for pipe breaks larger than the TBS up to and including the DEGB of the largest RCS pipe for those plants implementing §50.46a. The specific criteria are: GDC 17, *Electrical power systems,* GDC 35, *Emergency core cooling*, GDC 38, *Containment heat removal*, GDC 41, *Containment atmosphere cleanup*, and GDC 44, *Cooling water systems*. General Design Criterion 50, *Containment design basis*, is modified to specify that for plants under § 50.46a, leak tight containment capability should be maintained for "realistically" calculated temperatures and pressures for LOCAs larger than the TBS.

G. <u>Section 52.47 - Contents of applications; technical information</u>.

Paragraph (a)(4) of this section is amended to specify the technical information to be submitted in an application for a standard design certification for a nuclear power facility filed separately from the filing of an application for a construction permit or combined license for such a facility.

New paragraph (a)(4)(i) specifies that analyses of emergency core cooling systems and the need for high point vents for standard designs certified after the effective date of the § 50.46a rule must be performed under the requirements of either § 50.46 or § 50.46a (for ECCS performance) and § 50.46b (for reactor coolant system high point vents) if the standard design is demonstrated to be similar to the designs of reactors licensed before the effective date of § 50.46a.

New paragraph (a)(4)(ii) specifies that analyses of emergency core cooling systems and the need for high point vents for standard designs certified after the effective date of the § 50.46a rule must be performed under the requirements of § 50.46 (for ECCS performance) and § 50.46b (for reactor coolant system high point vents) if the standard design is not demonstrated to be similar to the designs of reactors licensed before the effective date of § 50.46a.

H. Section 52.63 - Finality of standard design certifications.

In this section, a new paragraph (a)(1)(viii) is added to make clear that the NRC may amend a standard design certification rule to implement the alternative ECCS requirements in 10 CFR 50.46a, and that such an amendment would not constitute a violation of the issue finality provisions in § 52.63. Inasmuch as § 50.46a(f)(2) only allows the original design certification applicant to request a change to a certified design which is enabled by § 50.46a, the NRC does not believe it is necessary to specify in § 52.63(a)(1)(viii) that such amendments may only be initiated by the original design certification applicant.

I. Section 52.54 - Issuance of standard design certifications.

In this section, paragraph (b) is amended to specify that a design certification rule which is reviewed and approved as meeting the requirements of 10 CFR 50.46a must specify the criteria governing departures that a referencing combined license must meet and that the criteria must ensure that the safety bases for the NRC's approval of the certified design's compliance with § 50.46a (including applicability of the TBS) continue to apply despite the departure.

J. Section 52.79 - Contents of applications; technical information in final safety analysis report.

In this section, paragraph (a)(5) is amended to specify the technical information to be submitted in the final safety analysis report for an application for a combined license for a nuclear power facility.

New paragraph (a)(5)(i) specifies that analyses of emergency core cooling systems and the need for high point vents for plants licensed after the effective date of the § 50.46a rule must be performed under the requirements of either § 50.46 or § 50.46a (for ECCS performance) and § 50.46b (for reactor coolant system high point vents) if the design is demonstrated to be similar to the designs of reactors licensed before the effective date of § 50.46a.

New paragraph (a)(5)(ii) specifies that analyses of emergency core cooling systems and the need for high point vents for plants licensed after the effective date of the § 50.46a rule must be performed under the requirements of § 50.46 (for ECCS performance) and § 50.46b (for reactor coolant system high point vents) if the design is not demonstrated to be similar to the designs of reactors licensed before the effective date of § 50.46a.

K. Section 52.137 - Contents of applications; technical information.

Paragraph (a)(4) of this section is amended to specify the technical information to be submitted in an application for approval of a standard design for a nuclear power facility.

New paragraph (a)(4)(i) specifies that analyses of emergency core cooling systems and the need for high point vents for designs approved after the effective date of the § 50.46a rule must be performed under the requirements of either § 50.46 or § 50.46a (for ECCS performance) and § 50.46b (for reactor coolant system high point vents) if the design is demonstrated to be similar to the designs of reactors licensed before the effective date of § 50.46a.

New paragraph (a)(4)(ii) specifies that analyses of emergency core cooling systems and the need for high point vents for designs approved after the effective date of the § 50.46a rule must be performed under the requirements of § 50.46 (for ECCS performance) and § 50.46b (for reactor coolant system high point vents) if the design is not demonstrated to be similar to the designs of reactors licensed before the effective date of § 50.46a.

L. Section 52.157 - Contents of applications; technical information in final safety analysis report.

Paragraph (f)(1) of this section is amended to specify the technical information to be submitted in the final safety analysis report for an application for issuance of a license authorizing manufacture of nuclear power reactors to be installed at sites not identified in the manufacturing license application.

New paragraph (f)(1)(i) specifies that analyses of emergency core cooling systems and the need for high point vents for a license authorizing manufacture of nuclear power reactors issued after the effective date of the § 50.46a rule must be performed under the requirements of either § 50.46 or § 50.46a (for ECCS performance) and § 50.46b (for reactor coolant system high point vents) if the design is demonstrated to be similar to the designs of reactors licensed before the effective date of § 50.46a.

New paragraph (f)(1)(ii) specifies that analyses of emergency core cooling systems and the need for high point vents for a license authorizing manufacture of nuclear power reactors issued after the effective date of the § 50.46a rule must be performed under the requirements of § 50.46 (for ECCS performance) and § 50.46b (for reactor coolant system high point vents) if the design is not demonstrated to be similar to the designs of reactors licensed before the effective date of § 50.46a.

VII. Availability of Documents

Publicly available documents related to this rulemaking identified below are available to interested persons through one or more of the following methods, as indicated.

Public Document Room (PDR). The NRC PDR is located at 11555 Rockville Pike, Rockville, Maryland 20852.

Regulations.gov (Web). These documents may be viewed and downloaded electronically through the Federal eRulemaking Portal http://www.regulations.gov, Docket number NRC-2004-0006.

NRC's Electronic Reading Room (ERR). The NRC's public electronic reading room is located at www.nrc.gov/reading-rm.html.

DOCUMENT	PDR	WEB	ERR (ADAMS)
Policy Statement on the Use of Probabilistic Risk Assessment, August 16, 1995 (60 FR 42622)	X		
Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessments in Risk-Informed Decisions on Plant Specific Changes to the Licensing Basis"	X		ML023240437
Nuclear Energy Institute Petition for Rulemaking - PRM-50-75, February 6, 2002	X	NRC-2002-0018	ML020630082
Federal Register notice of receipt of PRM-50-75 (67 FR16654), April 8, 2002	X	NRC-2002-0018	
Commission SRM on SECY-02-0057, "Update to SECY-01-0133, 'Fourth 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 50.46 (ECCS Acceptance Criteria)'" March 31, 2003	X		ML030910476
Commission SRM on 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," July 1, 2004	X		ML041830412

Commission SRM on SECY-05-0052, "Proposed Rulemaking for Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements," July 29, 2005	X	X	ML052100416
Initial Proposed Rule (70 FR 67598), November 7, 2005	X	NRC-2004-0006	ML091060434
NRC Report – Seismic Considerations for the Transition Break Size, December 2006	X	NRC-2004-0006	ML053470439
Letter from Graham B. Wallis (ACRS) to Dale E. Klein, "Draft Final Rule To Risk-Inform 10 CFR 50.46, 'Acceptance Criteria For Emergency Core Cooling Systems For Light-Water Nuclear Power Reactors,'" November 16, 2006	X	X	ML063190465
SECY-07-0082 - Rulemaking to Make Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements; 10 CFR 50.46a "Alternative Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors," May 16, 2007	X	X	ML070180692
Commission SRM on SECY-07-0082, August 10, 2007	X	X	ML072220595
Memorandum from Luis A. Reyes to NRC Commissioners, "Plans And Schedule For The Rulemaking On Risk- Informed Changes To Loss-of-Coolant Accident Technical Requirements (April 1, 2008)	X	X	ML080370355
NUREG-1488 - Revised Livermore Seismic Hazard Estimates for Sixty-Nine Nuclear Power Plant Sites East of the Rocky Mountains (April 1994)	X	X	ML052640591
NUREG-1829 - Estimating Loss-of-Coolant Accident (LOCA) Frequencies Through the Elicitation Process (Draft Report; June 2005)	X	X	ML051520574
NUREG-1829 - Estimating Loss-of-Coolant Accident (LOCA) Frequencies Through the Elicitation Process (Final Report; March 2008)	X	X	ML082250436
NUREG-1903 - Seismic Considerations for the Transition Break Size (February 2008)	X	X	ML080880140
Federal Register notice of Resolution and Closure of PRM-50-75 (73 FR 66000), November 6, 2008	X	NRC-2002-0018	
NRC White Paper – Plant-Specific Applicability of 10 CFR 50.46a Technical Basis (February 2009)	X	X	ML090350757
Memorandum from Arthur T. Howell to William F. Kane, "Degradation of the Davis-Besse Nuclear Power Station Reactor Pressure Vessel Head Lessons-Learned Report"; (September 30, 2002)	X	X	ML022740211
Supplemental Proposed Rule (74 FR 40006)	X	NRC-2004-0006	
DG-1216 - "Plant-Specific Applicability of the Transition Break Size Specified in 10 CFR 50.46a," June 2010	X		ML100430356

Proposed Rule Regulatory Analysis	X	NRC-2004-0006	ML052870368
Supplemental Proposed Rule Regulatory Analysis	X	X	ML091050748
Final Rule Regulatory Analysis	X	X	ML103230250
Letter from Said Abdel-Khalik (ACRS) to Gregory B. Jaczko, "Draft Final Rule For Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements (10 CFR 50.46a)," October 20, 2010	X		ML102850279
Letter from R. W. Borchardt to Said Abdel-Khalik (ACRS), "Draft Final Rule for Risk-Informed Changes To Loss-Of-Coolant Accident Technical Requirements (10 CFR 50.46a)," November 19, 2010	X		ML103000161

VIII. Compatibility of Agreement State Regulations

Under the "Policy Statement on Adequacy and Compatibility of Agreement States Programs," approved by the Commission on June 20, 1997, and published in the *Federal Register* (62 FR 46517) on September 3, 1997, this rule is classified as compatibility category "NRC." Agreement State Compatibility is not required for Category "NRC" regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act or the provisions of Title 10 of the *Code of Federal Regulations*. Although an Agreement State may not adopt program elements reserved to NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with the particular State's administrative procedure laws. Category "NRC" regulations do not confer regulatory authority on the State.

IX. Plain Language

The Presidential memorandum dated June 1, 1998, entitled "Plain Language in Government Writing" directed that the Government's writing be in plain language. This memorandum was published on June 10, 1998 (63 FR 31883). The NRC requested comments on the initial proposed rule and on the supplemental proposed rule specifically with respect to the clarity and effectiveness of the language used. No comments were received.

X. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or is otherwise impractical.

In this final rule, the NRC uses the following Government-unique standard: 10 CFR 50.46a. The NRC notes the ongoing development of voluntary consensus standards on PRAs, such as the ASME/ANS RA-Sa-2009 consensus standard on Probabilistic Risk Assessment for Nuclear Power Plant Applications. This Government standard (see 10 CFR 50.46a(f)(4)(iv)) requires the use of industry consensus standards for PRA quality that have been endorsed by the NRC. These standards were selected for use in the final rule based on their applicability to the subject of the desired requirements.

Except for consensus standards on PRA quality, the NRC does not believe that any other existing standards are sufficient to specify the necessary requirements for licensees who wish to modify plant ECCS analysis methods and nuclear power reactor designs based on the results of probabilistic risk analysis. The NRC is not aware of any voluntary consensus standard addressing risk-informed ECCS design and consequent changes in a light-water power reactor facility, technical specifications, or procedures that could be used instead of the proposed Government-unique standard.

XI. Criminal Penalties

For the purposes of Section 223 of the Atomic Energy Act (AEA), as amended, the NRC is issuing the final rule to amend § 50.46, add § 50.46a, redesignate existing § 50.46a as § 50.46b and amend §§ 52.47, 52.79, 52.137, and 52.157 under one or more of sections 161b, 161i, or 161o of the AEA. Willful violations of the rule will be subject to criminal enforcement.

Criminal penalties, as they apply to regulations in Part 50, are discussed in § 50.111 and as they apply to the regulations in Part 52, are discussed in § 52.303.

XII. Finding of No Significant Environmental Impact: Environmental Assessment

The NRC has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule will not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The basis for this determination is as follows:

This action stems from the NRC's ongoing efforts to risk-inform its regulations. The final rule establishes a voluntary alternative set of risk-informed requirements for emergency core cooling systems. The alternative requirements are less stringent in the area of large break loss-of-coolant accidents (LOCAs). Using the alternative ECCS requirements will provide some licensees with opportunities to change various aspects of plant design to increase operational flexibility, increase power, or decrease costs. Licensee actions taken under the rule could either decrease the probability of an accident or increase the probability of an accident by a very small amount. Mitigation of LOCAs of all sizes is still required but with less redundancy and margin for the larger, low probability breaks. Increases in risk, if any, are required to be very small so that adequate assurance of public health and safety is maintained. When considered together, the net effect of the licensee actions is expected to have an insignificant effect on accident probability.

Thus, the final action will not significantly increase the probability or consequences of an accident, when considered in a risk-informed manner. No changes will be made in the types or quantities of radiological effluents that may be released offsite, and there is no significant increase in public radiation exposure because there is no change to facility operations that could create a new or significantly affect a previously analyzed accident or release path.

With regard to non-radiological impacts, no changes will be made to non-radiological plant effluents and there will be no changes in activities that will adversely affect the environment. Therefore, there are no significant non-radiological impacts associated with the final action.

The primary alternative is the no action alternative. The no action alternative, at worst, would result in no changes to current levels of safety, risk, or environmental impact. The no action alternative would also prevent licensees from making certain plant modifications that could be implemented under the rule that could potentially increase plant safety, increase operational flexibility, or decrease costs. The no action alternative would also maintain existing regulatory burdens; in some instances for which there could be little or no safety, risk, or environmental benefits.

The NRC requested the views of the States on the environmental assessment for this rule. No comments were received.

XIII. Paperwork Reduction Act Statement

This final rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, control number 3150-0011.

The burden to the public for these information collections is estimated to average 968 hours per response, including time the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of these information collections, including suggestions for reducing the burden, to the Information Services Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to Infocollects.Resource@NRC.gov and to the Desk Officer, Christine Kymn, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0011), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

XIV. Regulatory Analysis

The NRC has prepared a final regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC and concludes that implementation of this alternative rule can result in the accrual of significant benefits over the remaining lifetimes of certain facilities at which the rule is implemented. Availability of the final regulatory analysis is provided in Section VII of this document. The NRC published draft regulatory analyses with both the initial and the supplemental proposed rules. No comments were received on the proposed or supplemental regulatory analyses.

XV. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the NRC certifies that this rule will not have a significant economic impact on a substantial number of small entities. This final rule will affect only the licensing and operation of currently operating nuclear power plants. The companies that own these plants do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810).

XVI. Backfit Analysis

The NRC has determined that the final 10 CFR 50.46a and the changes in 10 CFR parts 50 and 52 generally do not constitute backfitting as defined in the backfit rule, 10 CFR 50.109(a)(1), or are otherwise in conflict with the various issue finality provisions in part 52. In addition, the NRC has determined that three provisions of the final rule which exclude certain NRC actions from the purview of the backfit rule, *viz*., § 50.109(b)(2); § 50.46a(d)(4), and § 50.46a(m), are appropriate. The basis for each of these determinations follows.

10 CFR 50.46a

The NRC has determined that final § 50.46a rule does not constitute backfitting because it provides a voluntary alternative to the existing requirements in 10 CFR 50.46 for evaluating the performance of an ECCS for light-water nuclear power plants. A licensee may decide to either comply with the requirements of § 50.46a, or to continue to comply with the existing licensing basis of their plant with respect to ECCS analyses. Therefore, the backfit rule does not require the preparation of a backfit analysis for the final 50.46a rule.

Conforming changes in 10 CFR Part 50, Appendix A

The NRC has determined that the conforming changes to several of the general design criteria (GDCs) in Part 50, Appendix A, do not constitute backfitting because the conforming changes make clear that several deterministic-based performance requirements in the relevant GDCs are not applicable when using the risk-informed approach to evaluating emergency core cooling above the transition break size under § 50.46a. The changes to the GDC do not apply to licensees currently subject to (or who have committed to) the GDC and who choose not to use the new, risk-informed ECCS requirements in 10 CFR 40.46a. Thus, the conforming changes facilitate the implementation of the voluntary, risk-informed alternative to the existing ECCS requirements in § 50.46, but do not affect existing licensees who are subject to (or have committed to) the GDC.

Conforming changes in 10 CFR Part 52

The NRC has determined that the conforming changes in Part 52 do not constitute backfitting because they are intended to make clear that, for design approvals, design certifications, combined licenses and manufacturing licenses, the requirements of § 50.46a are a voluntary alternative to the existing requirements in § 50.46 for evaluating the performance of an ECCS for light-water nuclear power plants. An applicant or licensees subject to these Part 52 provisions may decide to either comply with the requirements of § 50.46a, or to continue to comply with the existing licensing basis of their plant with respect to ECCS analyses. By providing this voluntary alternative, there is no conflict with the applicable issue finality provisions in Part 52 (§§ 52.63, 52.98, 52.145, 52.171). Therefore, neither the backfit rule nor any of these finality provisions require the preparation of a backfit analysis or comparable justification for the conforming changes in Part 52.

Three provisions excluding certain NRC actions from the backfit rule

As discussed in Section III.A of this document, the NRC may undertake future rulemaking to revise the TBS based upon re-evaluations of LOCA frequencies occurring after the effective date of a final rule. The NRC is adopting a change to § 50.109(b)(2) to exclude future changes to the TBS from the backfit rule, imposed on a license by either rulemaking or by NRC action taken on a plant specific basis. The NRC has determined that there is no statutory bar to the adoption of such a provision. The NRC also believes that the exclusion of such rulemakings from the backfit rule is appropriate from a policy standpoint.

When the NRC establishes regulatory requirements using new regulatory concepts and paradigms without a large body of technical information, or without substantial implementation history or experience on the overall regulatory approach, the Backfit Rule is not appropriate in evaluating subsequent changes to the new requirements – at least until the NRC has gained substantial experience in implementing the new requirements. In the NRC's view, the Backfit Rule's restrictions on changes to NRC requirements are most appropriate where: (i) the technical phenomena and/or issues being addressed in the rulemaking are well-understood; (ii) the analytical methods used in developing the rule's requirements or required to be used in implementing the rule are relatively mature and have some history of use; (iii) there is a large body of data and experience to support the regulatory requirement; (iv) the regulatory area being controlled does not involve requirements governing reasonable assurance; and (v) the regulatory requirement is mandatory, and does not represent a voluntary alternative (i.e., one which may be selected by the affected regulated entity).

After considering the effects of these factors on the possible need for future rulemaking to change the TBS values established in this rule, the NRC concludes that such changes to the TBS should not be subject to the Backfit Rule. This rulemaking, governing the regulatory requirements for evaluating the effectiveness of ECCS systems, is an adequate protection requirement. The NRC has no previous regulatory experience, and there is no implementation experience associated with the concept of risk-informing ECCS requirements using an NRC-established TBS applicable to different classes of plants. The technical basis for estimating the frequency of large pipe break events is not supported by a large body of pipe break failures at operating nuclear power reactors. This lack of actual failures contributes to large uncertainties in the estimated values. Additional operational experience in piping degradation could result in increased estimates of LOCA frequency, potentially affecting the technical bases for the TBS values specified in the final rule. Finally, the proposed regulatory requirement is a voluntary alternative, so that each entity who wishes to comply with the rule may decide on its own whether to choose to comply with the provisions of the proposed rule. This freedom to choose lessens the possibility that an unjustified regulatory burden would actually be incurred by any entity. Accordingly, the NRC has determined that the limited exclusion from the restrictions of the Backfit Rule of possible future changes to the size of the TBS and of associated plant changes needed as a result of changes to the TBS is justified.

From a practical standpoint, the NRC believes that this exclusion will be unlikely to result in unjustified changes to the TBS. The NRC also does not regard the exclusion as allowing the NRC to adopt cost-unjustified changes to the TBS. The NRC prepares a regulatory analysis for each substantive regulatory action which identifies the regulatory objectives of the action, and evaluates the costs and benefits of proposed alternatives for achieving those regulatory objectives. The NRC has also adopted guidelines governing treatment of individual requirements in a regulatory analysis (69 FR 29187; May 21, 2004). The NRC believes that a regulatory analysis performed in accordance with these guidelines will be effective in identifying unjustified regulatory proposals. The NRC intends to revise the TBS in § 50.46a rarely and only if based upon public health and safety and/or common defense and security considerations. This further decreases the possibility that licensees would actually be subject to unjustified changes to the TBS.

For these reasons, the NRC concludes that the exclusion in § 50.109(b)(2) of future changes to the TBS from the requirements of the backfit rule is appropriate.

As discussed in Section III.E of this document, § 50.46a(d)(4) requires that a PRA used to demonstrate compliance with the risk acceptance criteria in § 50.46a(f)(1) or (f)(2) be periodically re-evaluated and updated, and that the licensee implement changes to the facility and procedures as necessary to ensure that the acceptance criteria continue to be met. To ensure that the re-evaluation and updating of the PRA and any necessary changes to a facility and its procedures under § 50.46a(d)(4) are not considered backfitting, § 50.46a(d)(4) states that such re-evaluation, updating, and changes are not deemed to be backfitting. There is no statutory bar to the adoption of this provision. Furthermore, the NRC believes that this exclusion from the backfit rule is appropriate, inasmuch as application of the backfit rule in this context would effectively favor increases in risk. This is because most facility and procedure changes involve an up-front cost to implement a change which must be recovered over the remaining operating life of the facility in order to be considered cost-effective. For example, assume that after a change is implemented, subsequent PRA analyses suggest that the change should be "rescinded" (either the hardware is restored to the original configuration or the new configuration is not credited in design bases analyses) in order to maintain the assumed risk level. The cost/benefit determination of the second, “restoring” change must address the unrecovered cost of the first change and the cost of the second, “restoring” change. In most cases, application of cost/benefit analyses in evaluating the second, “restoring” change would skew the decision-making in favor of accepting the existing plant with the higher risk. Accumulation of these incremental increases in risk does not appear to be an appropriate regulatory approach. Accordingly, the NRC concludes that the backfitting exclusion in § 50.46a(d)(4) is appropriate.

Section 50.46a(m) provides that if the NRC changes the TBS specified in § 50.46a, licensees who have evaluated their ECCS under § 50.46a shall undertake additional actions to ensure that the relevant acceptance criteria for ECCS performance are met with the new TBSs, and that these licensee actions are not considered to be backfitting. Consequently, the NRC may require licensees to take action under § 50.46a(m) without consideration of the backfit rule. The NRC has determined that there is no statutory bar to the adoption of this provision. The NRC has also determined that the provision represents a justified departure from the principles underlying the backfit rule. The NRC’s decision on this matter recognizes that any future rulemaking to alter the TBS will require preparation of a regulatory analysis. As discussed, the regulatory analysis will ordinarily include a cost/benefit analysis addressing whether the costs of the TBS redefinition are justified in view of the benefits attributable to the redefinition. In addition, the licensee has substantial flexibility under § 50.46a to determine the actions (reanalysis, procedure and operational changes, design-related changes, or a combination thereof) necessary to demonstrate compliance with the relevant ECCS acceptance criteria. The performance-based approach of the final § 50.46a lends substantial flexibility to the licensee and may tend to reduce the burden associated with changes in the TBS. Accordingly, the NRC concludes that the backfitting exclusion in § 50.46a(m) is appropriate.

Paragraph (m) also includes provisions analogous provisions governing how changes to the TBS are to be applied to those combined licenses referencing design certifications and design approvals which the NRC has approved the use of the provisions of § 50.46a. Changes to the TBS for a design certification must be accomplished by rulemaking, but are subject to the finality provisions in applicable provisions of part 52. However, once such TBS changes are made by rulemaking, any referencing COL applicant must use the revised TBS, and any changes necessary to the design would not be considered to be a violation of the finality provisions in §§ 52.63, 52.83 or 52.98.

XVII. Congressional Review Act

Under the Congressional Review Act of 1996, the NRC has determined that this action is a major rule and has verified this determination with the Office of Information and Regulatory Affairs of the Office of Management and Budget. Because major rules are subject to Congressional review, the NRC has specified that the rule will not become effective until 60 days after publication in the *Federal Register* to allow Congress sufficient time to complete its review.

List of Subjects

10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

10 CFR Part 52

Administrative practice and procedure, Antitrust, Backfitting, Combined license, Early site permit, Emergency planning, Fees, Inspection, Limited work authorization, Nuclear power plants and reactors, Probabilistic risk assessment, Prototype, Reactor siting criteria, Redress of site, Reporting and recordkeeping requirements, Standard design, Standard design certification.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR Parts 50 and 52.

PART 50 -- DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

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); Energy policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 194 (2005). Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102-486, sec. 2902, 106 Stat. 3123 (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 § 50.8, paragraph (b) is revised to read as follows:

(b) The approved information collection requirements contained in this part appear in §§ 50.30, 50.33, 50.34, 50.34a, 50.35, 50.36, 50.36a, 50.36b, 50.44, 50.46, 50.46a, 50.47, 50.48, 50.49, 50.54, 50.55, 50.55a, 50.59, 50.60, 50.61, 50.61a, 50.62, 50.63, 50.64, 50.65, 50.66, 50.68, 50.69, 50.70, 50.71, 50.72, 50.74, 50.75, 50.80, 50.82, 50.90, 50.91, 50.120, and appendices A, B, E, G, H, I, J, K, M, N,O, Q, R, and S to this part.

3. 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.

(i) Analysis and evaluation of ECCS cooling performance and the need for high point vents following postulated loss-of-coolant accidents must be performed under the requirements of either § 50.46 or § 50.46a, and § 50.46b for facilities whose construction permits were issued after December 28, 1974, but before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR], and for facilities for which construction permits may be issued after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR] and are demonstrated under § 50.46a(c)(2) to have designs that are similar to the designs of reactors licensed before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR].

(ii) Analysis and evaluation of ECCS cooling performance and the need for high point vents following postulated loss-of-coolant accidents must be performed under the requirements of § 50.46 and § 50.46b for facilities for which construction permits may be issued after

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR] and are not demonstrated under § 50.46a(c)(2) to have designs that are similar to the designs of reactors licensed before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR].

* * * * *

(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.

(i) Analysis and evaluation of ECCS cooling performance following postulated LOCAs must be performed under the requirements of either § 50.46 or § 50.46a, and § 50.46b for facilities whose operating licenses may be issued after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR] and are demonstrated under § 50.46a(c)(2) to have designs that are similar to the designs of reactors licensed before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR].

(ii) Analysis and evaluation of ECCS cooling performance following postulated LOCAs must be performed under the requirements of §§ 50.46 and 50.46b for facilities whose operating licenses may be issued after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR] and are not demonstrated under § 50.46a(c)(2) to have designs that are similar to the designs of reactors licensed before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR].

* * * * *

4. In § 50.46, paragraph (a) is amended by adding an introductory paragraph and revising paragraph (a)(1)(i) 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). The ECCS system must be designed under the requirements of this section or § 50.46a for facilities whose operating licenses were issued before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR]; for facilities whose operating licenses, combined licenses under part 52 of this chapter, or manufacturing licenses under part 52 of this chapter are issued after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR] and are demonstrated under § 50.46a(c)(2) to have designs that are similar to the designs of reactors licensed before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR]; and for design approvals and design certifications under part 52 of this chapter issued after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR] that are demonstrated under § 50.46a(c)(2) to have designs that are similar to the designs of reactors licensed before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR]. The ECCS system must be designed under the requirements of this section for facilities whose operating licenses, combined licenses under part 52 of this chapter, or manufacturing licenses under part 52 of this chapter are issued after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR] and are not demonstrated under § 50.46a(c)(2) to have designs that are similar to the designs of reactors licensed before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR]; and for design approvals and design certifications under part 52 of this chapter that are not demonstrated under § 50.46a(c)(2) to have designs that are similar to the designs of reactors licensed before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR].

(1)(i) The ECCS system must be designed so that its calculated cooling performance following postulated LOCAs 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 LOCAs of different sizes, locations, and other properties sufficient to provide assurance that the most severe postulated LOCAs 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 LOCA. 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.

* * * * *

5. 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*. For the purposes of this section:

(1) Changes enabled by this section means changes to the facility, technical specifications, and procedures that satisfy the alternative ECCS analysis requirements under this section but do not satisfy the ECCS requirements under 10 CFR 50.46.

(2) Evaluation model means the calculational framework for evaluating the behavior of the reactor system during a postulated design-basis 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) 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. LOCAs involving breaks at or below the transition break size (TBS) are design-basis accidents. LOCAs involving breaks larger than the TBS are beyond design-basis accidents.

(4) Operating configuration means those plant characteristics, such as power level, equipment unavailability (including unavailability caused by corrective and preventive maintenance), and equipment capability that affect plant response to a LOCA.

(5) Transition break size (TBS) for reactors licensed before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR] is a break area equal to the cross-sectional flow area of the inside diameter of the largest piping attached to the reactor coolant system for a pressurized water reactor, or the inside diameter of the larger of the feedwater line inside

containment or the residual heat removal line inside containment for a boiling water reactor. For reactors licensed after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR], and for design certifications, design approvals, and manufacturing licenses approved or issued after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR], the TBS will be determined on a plant-specific basis.

(b) *Applicability and scope.*

(1) The requirements of this section may be applied to each boiling or pressurized light-water nuclear power reactor fueled with uranium oxide pellets within cylindrical zircalloy or ZIRLO cladding whose operating license was issued prior to [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR]; to each boiling or pressurized light-water nuclear power reactor fueled with uranium oxide pellets within cylindrical zircalloy or ZIRLO cladding whose operating license, combined license under part 52 of this chapter or manufacturing license under part 52 of this chapter is issued after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR] and whose design is demonstrated under § 50.46a(c)(2) to be similar to the designs of reactors licensed before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR]; and to each boiling or pressurized light-water nuclear power reactor fueled with uranium oxide pellets within cylindrical zircalloy or ZIRLO cladding whose design approval or design certification under part 52 of this chapter is demonstrated under § 50.46a(c)(2) to be similar to the designs of reactors licensed before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR]. The requirements of this section do not apply to 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 paragraphs (e)(3) and (e)(4) of this section, with cooling performance calculated in accordance with an acceptable evaluation model or analysis method under paragraphs (e)(1) and (e)(2) of this

section, 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) *Application*. (1) A construction permit holder or licensee of a facility, or other entity seeking to implement this section shall submit the appropriate application containing the following information:

(i) A written evaluation demonstrating applicability of the results in NUREG-1829, “Estimating Loss-of-Coolant Accident (LOCA) Frequencies through the Elicitation Process”; March 2008 and NUREG-1903, “Seismic Considerations for the Transition Break Size”; February 2008, to the applicant’s facility. The applicant shall confirm that the NUREG-1903 results are applicable by demonstrating that the total frequency of seismically-induced direct and indirect failures of piping larger than the TBS at its facility is significantly less than 10^{-5} per year.

(ii) Identification of the approved analysis method(s) for demonstrating compliance with the ECCS criteria in paragraph (e) of this section.

(iii) For an operating reactor whose construction permit was issued before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR], and whose compliance with paragraph (d)(5) of this section is to be determined by a period of time other than 14 days, the proposed alternative period of time.

(iv) For an operating reactor whose license is issued under Part 52 of this chapter, the length of time constituting a “short time” under paragraph (d)(5) of this section.

(v) A description of the risk-informed evaluation used to:

(A) Demonstrate that the proposed changes to the facility meet the requirements in paragraph (f) of this section;

(B) For an operating reactor whose construction permit was issued before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR], demonstrate that the proposed alternative to period specified in paragraph (d)(5) meets the acceptance criteria in paragraph (c)(3)(iii)(B); or

(C) For an operating reactor whose license is issued under Part 52 of this chapter, demonstrate that the time proposed by the licensee as constituting a “short time” under paragraph (d)(5) meets the acceptance criteria in paragraph (c)(3)(iii)(C).

(vi) A construction permit holder or licensee of a facility, or an entity other than a design certification applicant or a holder of a manufacturing license who wishes to make changes enabled by this section without prior NRC review and approval must submit for NRC approval a process to be used for evaluating the acceptability of these changes; including:

(A) A description of the approach, methods, and decisionmaking process to be used for evaluating compliance with the acceptance criteria in paragraphs (f)(1), (f)(2), and (f)(3) of this section; and

(B) A description of the PRA model and non-PRA risk assessment methods to be used for demonstrating compliance with paragraphs (f)(4) and (f)(5) of this section.

(vii) A description of non-safety equipment that is credited for demonstrating compliance with the ECCS acceptance criteria in paragraph (e) of this section.

(viii) A written evaluation demonstrating how the leak detection program in place at the facility satisfies the criteria in paragraph (d)(2) of this section.

(2) Each applicant, other than one holding an operating license issued before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR], seeking to implement the requirements of this section shall, in addition to the information required by paragraphs (c)(1)(i)-(viii) of this section, submit an analysis demonstrating why the proposed reactor design is similar to the designs of reactors licensed before [INSERT DATE 60 DAYS AFTER DATE OF

PUBLICATION IN THE FR] such that the provisions of this section may properly apply. The analysis must also include a recommendation for an appropriate TBS and a justification that the recommended TBS is consistent with the technical basis for this section.

(3) Acceptance criteria. The NRC may approve an application to use this section if:

(i) The evaluation submitted under paragraph (c)(1)(i) of this section demonstrates the applicability of the NUREG-1829 and NUREG-1903 results to the facility. The NUREG-1903 results are applicable if the total frequency of seismically-induced direct and indirect failures of piping larger than the TBS is significantly less than 10^{-5} per year;

(ii) The method(s) for demonstrating compliance with the ECCS acceptance criteria in paragraphs (e)(3) and (e)(4) of this section meet the requirements in paragraphs (e)(1) and (e)(2) of this section;

(iii) The risk-informed evaluation process(es) used to:

(A) Make changes under this section is adequate for determining whether the acceptance criteria in paragraph (f) of this section have been met;

(B) For an operating reactor whose construction permit was issued before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR], the evaluation submitted under paragraph (c)(1)(v)(B) demonstrates that any short time other than 14 days in any 12-month period that may be proposed for use under paragraph (d)(5) of this section, is consistent with the mitigative capability available, the configuration specific risk, the philosophy of defense-in-depth, and adequate safety margins; or

(C) For an operating reactor whose license is issued under Part 52 of this chapter, the evaluation submitted under paragraph (c)(1)(v)(C) demonstrates that the short time proposed by the licensee for use under paragraph (d)(5) of this section, is consistent with the mitigative capability available, the configuration specific risk, the philosophy of defense-in-depth, adequate safety margins and does not result in a significant decrease in the level of safety otherwise provided by the design.

(iv) If applicable, the risk-informed process proposed for use to make changes under paragraph (f)(1) of this section, is adequate for determining whether the acceptance criteria in paragraph (f) of this section, have been met;

(v) Non-safety equipment that is credited for demonstrating compliance with the ECCS acceptance criteria in paragraph (e) of this section is identified in plant Technical Specifications or appropriate conditions require that future licensees list this equipment in the plant's Technical Specifications;

(vi) For each reactor whose operating license, combined license, standard design approval, manufacturing license, or standard design certification rule is issued after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR], the reactor design is similar to the designs of reactors licensed before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR] and the applicant's TBS includes sufficient margin to provide assurance that, when considering the limited availability of data and the uncertainty in the estimation of loss-of-coolant accident frequency, the estimated frequency of breaks larger than the TBS for all initiators does not exceed 10^{-5} per year; and

(vii) The applicable standards and requirements of the Act and the Commission's regulations have been met.

(d) *Requirements during operation.* A licensee whose application under paragraph (c) of this section is approved by the NRC shall comply with the following requirements as long as the facility is subject to the requirements in this section until the licensee submits the certifications required by § 50.82(a):

(1) The licensee shall maintain ECCS model(s) and/or analysis method(s) meeting the requirements in paragraphs (e)(1) and (e)(2) of this section;

(2) The licensee shall have leak detection systems available at the facility and shall implement actions as necessary to identify, monitor and quantify leakage to ensure that adverse safety consequences do not result from primary pressure boundary leakage from piping and components that are larger than the transition break size.

(3) Changes made under this section must, in addition to meeting other applicable NRC requirements, be evaluated by a risk-informed evaluation demonstrating that the acceptance criteria in paragraph (f) of this section, are met.

(4) The licensee shall periodically maintain and upgrade, as necessary, its risk assessments to meet the requirements in paragraph (f)(4) and (f)(5) of this section. The maintenance and upgrading shall be consistent with NRC-endorsed consensus standards on PRA and must be completed in a timely manner, but no less often than once every four years. Based upon a re-evaluation of the risk assessments after the periodic maintenance and upgrading are completed, the licensee shall take appropriate action to ensure that the acceptance criteria in paragraph (f) of this section, as applicable, are met. The PRA maintenance and upgrading required by this section, and any necessary changes to the facility, technical specifications and procedures as a result of this re-evaluation, shall not be deemed to be backfitting under any provision of this chapter.

(5) For pipe breaks larger than the TBS, operation in a plant operating configuration not demonstrated to meet the acceptance criteria in paragraph (e)(4) of this section may not exceed a short time. A short time for an operating reactor whose construction permit was issued before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR], is either a total of fourteen (14) days in any 12-month period or an alternative proposed by the licensee and approved by the NRC. A short time for an operating reactor whose license is issued under Part 52 of this chapter shall be proposed by the licensee, approved by the NRC, and must

demonstrate that there is not a significant decrease in the level of safety otherwise provided by the design.

(6) The licensee shall perform an evaluation to determine the effect of all planned facility changes and shall not implement any facility change that would invalidate the evaluation performed pursuant to § 50.46a(c)(1)(i) demonstrating the applicability to the licensee's facility of the results in NUREG-1829 and NUREG-1903.

(e) *ECCS Performance*. Each nuclear power reactor or nuclear power reactor design subject to this section must be provided with an ECCS that must be designed so that its calculated cooling performance following postulated LOCAs conforms to the criteria set forth in this section. The evaluation models for LOCAs must meet the criteria in this paragraph, and must be approved for use by the NRC. Appendix K, Part II, to 10 CFR Part 50, sets forth the documentation requirements for evaluation models.

(1) *ECCS evaluation for LOCAs involving breaks at or below the TBS*. ECCS cooling performance at or below the TBS must be calculated in accordance with an evaluation model that meets the requirements of either section I to Appendix K of this part, or the following requirements, and must demonstrate that the acceptance criteria in paragraph (e)(3) of this section are satisfied. The evaluation model must be used for a number of postulated LOCAs of different sizes, locations, and other properties sufficient to provide assurance that the most severe postulated LOCAs involving breaks at or below the TBS are analyzed. The evaluation model must include sufficient supporting justification to show that the analytical technique realistically describes the behavior of the reactor system during a LOCA. 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 (e)(3) of this section, there is a high level of probability that the criteria would not be exceeded.

(2) *ECCS analyses for LOCAs involving breaks larger than the TBS*. ECCS cooling performance for LOCAs involving breaks larger than the TBS must be calculated in accordance with an evaluation model that meets the requirements of either section I to Appendix K of this part, or the following requirements, and must demonstrate that the acceptance criteria in paragraph (e)(4) of this section are satisfied. The evaluation model must include sufficient supporting justification to show that the analytical technique realistically describes the behavior of the reactor system during a LOCA. 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 (e)(4) of this section, there is a high level of probability that the criteria would not be exceeded. The evaluation model must be used for a number of postulated LOCAs of different sizes, locations, and other properties sufficient to provide assurance that the most severe postulated LOCAs larger than the TBS up to the double-ended rupture of the largest pipe in the reactor coolant system are analyzed. These calculations may take credit for the availability of offsite power and do not require the assumption of a single failure. Availability of safety-related or non-safety-related equipment may be assumed if supported by plant-specific data or analysis, and provided that onsite power can be readily provided through simple manual actions to equipment that is credited in the analysis.

(3) *Acceptance criteria for LOCAs involving breaks at or below the TBS*. The following acceptance criteria must be used in determining the acceptability of ECCS cooling performance:

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

(ii) *Maximum cladding oxidation*. The calculated total oxidation of the cladding must not at any location exceed 0.17 times the total cladding thickness before oxidation. As used in this paragraph, 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 must 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 must 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 must 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 must 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 must be maintained at an acceptably low value and decay heat must be removed for the extended period of time required by the long-lived radioactivity remaining in the core.

(4) *Acceptance criteria for LOCAs involving breaks larger than the TBS*. The following acceptance criteria must be used in determining the acceptability of ECCS cooling performance:

(i) *Coolable geometry*. Calculated changes in core geometry must 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 must be maintained at an acceptably low value and decay heat must be removed for the extended period of time required by the long-lived radioactivity remaining in the core.

(5) *Imposition of restrictions*. The Director of the Office of Nuclear Reactor Regulation or the Office of New Reactors may impose restrictions on reactor operation if it is found that the evaluations of ECCS cooling performance submitted are not consistent with paragraph (e) of this section.

(f) *Changes to facility, technical specifications, or procedures*. A construction permit holder, licensee, or other entity who wishes to make changes enabled by this section, to the facility, facility design, or procedures or to the technical specifications shall perform a risk-informed evaluation.

(1) A construction permit holder or licensee of a facility, or entity other than a design certification applicant or a holder of a manufacturing license may make changes enabled by this section, other than changes to the technical specifications, without prior NRC approval if:

(i) The change is permitted under § 50.59 for holders of operating licenses, combined licenses that do not reference a design certification, design approval, or manufacturing license (per § 52.98(b)), or combined licenses that reference a design approval; permitted under § 52.98(c) for holders of combined licenses that reference a design certification; or permitted under § 52.98(d) for holders of combined licenses that reference a manufacturing license;

(ii) The risk-informed evaluation process described in paragraph (c)(1)(vi) of this section demonstrates that any increases in the estimated risk are minimal and the criteria in paragraph (f)(3) of this section are met; and

(iii) The change does not invalidate the evaluation performed pursuant to paragraph (c)(1)(i) of the applicability of the results in NUREG-1829 and NUREG-1903 to the applicant's facility.

(2) For implementing changes which are not permitted under paragraph (f)(1) of this section, the construction permit holder or licensee of a facility, or other entity must submit the appropriate application. The application must contain:

(i) For reactor licensees, the information required under § 50.90;

(ii) Information from the risk-informed evaluation demonstrating that the total increases in core damage frequency and large early release frequency are very small and the overall risk remains small and the criteria in paragraph (f)(3) of this section are met;

(iii) If previous changes have been made under § 50.46a, information from the risk-informed evaluation on the cumulative effect on risk of the proposed change and all previous changes made under this section. If more than one plant change is combined; including plant changes not enabled by this section, into a group for the purposes of evaluating acceptable risk increases; the evaluation of each individual change shall be performed along with the evaluation of combined changes;

(iv) Information demonstrating that the criteria in paragraphs (e)(3) and (e)(4) of this section are met; and

(v) Information demonstrating that the proposed change will not increase the LOCA frequency of the facility by an amount that would invalidate the applicability to the facility of the results of NUREG-1829,"Estimating Loss-of-Coolant Accident (LOCA) Frequencies through the

Elicitation Process", March 2008, and NUREG-1903, "Seismic Considerations for the Transition Break Size", February 2008").

(3) All changes made under this rule must meet the following criteria:

(i) Adequate defense in depth is maintained;

(ii) Adequate safety margins are retained to account for uncertainties;

(iii) Adequate performance-measurement programs are implemented to ensure the risk-informed evaluation continues to reflect actual plant design and operation. These programs shall be designed to detect degradation of the system, structure or component before plant safety is compromised, provide feedback of information and timely corrective actions, and monitor systems, structures or components at a level commensurate with their safety significance; and

(iv) For new reactor license applicants under Part 52, will not result in a significant decrease in the level of safety otherwise provided by the new reactor design.

(4) *Requirements for risk assessment - PRA.* Whenever a PRA is used in the risk-informed evaluation, the PRA must, with respect to the area of evaluation which is the subject of the PRA:

(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 would affect the regulatory decision in a substantial manner;

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

(iii) Have sufficient technical adequacy (including consideration of uncertainty) and level of detail to provide confidence that the total risk estimate and the change in total risk estimate adequately reflect the plant and the effect of the proposed change on risk; and

(iv) Be determined, through peer review, to meet industry standards for PRA quality that have been endorsed by the NRC.

(5) *Requirements for risk assessment other than PRA*. Whenever risk assessment methods other than PRAs are used to develop quantitative or qualitative estimates of changes to risk in the risk-informed evaluation, an integrated, systematic process must be used. All aspects of the analyses must reasonably reflect the current plant configuration and operating practices, and applicable plant and industry operating experience.

(g) *Reporting*.

(1) Licensees. (i) Each licensee shall estimate the effect of any change to or error in evaluation models or analysis methods or in the application of such models or methods to determine if the change or error is significant. For each change to or error discovered in an ECCS evaluation model or analysis method or in the application of such a model that affects the calculated results, the 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 or 52.3. If the change or error is significant, the 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 § 50.46a 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 paragraphs (e)(3) or (e)(4) of this section is a reportable event as described in §§ 50.55(e), 50.72 and 50.73. The licensee shall propose immediate steps to demonstrate compliance or bring plant design or operation into compliance with § 50.46a requirements. For the purpose of this paragraph, a significant change or error is:

(A) For LOCAs involving pipe breaks at or below the TBS, one which results either in a calculated peak fuel cladding temperature different by more than 50°F 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; or

(B) For LOCAs involving pipe breaks larger than the TBS, one which results in a significant reduction in the capability to meet the requirements of paragraph (e)(4) of this section.

(ii) As part of the PRA maintenance and upgrading under paragraph (d)(4) of this section, the licensee shall report to the NRC if the re-evaluation results in exceeding the acceptance criteria in paragraph (f) of this section, as applicable. The report must be filed with the NRC no more than 60 days after completing the PRA re-evaluation. The report must describe and explain the changes in the PRA modeling, plant design, or plant operation that led to the increase(s) in risk, and must include a description of and implementation schedule for any corrective actions required under paragraph (d)(4) of this section.

(iii) Every 24 months, the licensee shall submit, as specified in §§ 50.4 or 52.3, a short description of each change involving minimal changes in risk made under paragraph (f)(1) of this section after the last report and a brief summary of the basis for the licensee's determination pursuant to § 50.46a(f)(2)(vi) that the change does not invalidate the applicability evaluation made under § 50.46a(c)(1)(i).

(2) *Design certifications; applicants for and holders of design approvals*. Each design certification applicant and each applicant for and holder of a design approval shall estimate the effect of any change to or error in evaluation models or analysis methods or in the application of such models or methods to determine if the change or error is significant. For each change to or error discovered in an ECCS evaluation model or analysis method or in the application of such a model that affects the calculated results, the applicant or holder shall report the nature of the change or error and its estimated effect on the limiting ECCS analysis to the Commission

and to any applicant or licensee referencing the design approval or design certification at least annually as specified in § 52.3. If the change or error is significant, the applicant or holder 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 § 50.46a requirements. A design certification applicant's duty to report under this paragraph continues until the later of either the termination or expiration of the design certification; or the termination of the last license directly or indirectly referencing the design certification. For the purpose of this paragraph, a significant change or error is:

(i) For LOCAs involving pipe breaks at or below the TBS, one which results either in a calculated peak fuel cladding temperature different by more than 50°F 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; or

(ii) For LOCAs involving pipe breaks larger than the TBS, one which results in a significant reduction in the capability to meet the requirements of paragraph (e)(4) of this section.

(h) *Documentation*. Following implementation of the § 50.46a requirements, each entity subject to this section shall maintain records sufficient to demonstrate compliance with the requirements in this section in accordance with § 50.71.

(i) through (l) - [RESERVED]

(m) *Changes to TBS*. If the NRC increases the TBS specified in this section, affected entities shall take the following actions.

(1) O*perating licenses under Part 50, combined licenses under Part 52, and manufacturing licenses*. Each licensee subject to this section (other than a licensee referencing a design certification rule or a design approval complying with the requirements of this section)

shall re-perform the evaluations required by paragraphs (e)(1) and (e)(2) of this section and reconfirm compliance with the acceptance criteria in paragraphs (e)(3) and (e)(4) of this section. If the licensee cannot demonstrate compliance with the acceptance criteria, then the licensee shall change its facility, technical specifications or procedures so that the acceptance criteria are met. The evaluation required by this paragraph, and any necessary changes to the facility, technical specifications or procedures as the result of this evaluation, are not to be deemed to be backfitting under any provision of this chapter or a violation of any finality provision in Part 52.

(2) Design certifications and referencing combined licenses under Part 52. Changes to a TBS for a design certification must be accomplished by rulemaking, in accordance with 10 CFR 52.63(a). Holders of combined licenses referencing a design certification rule shall re-perform the evaluations required by paragraphs (e)(1) and (e)(2) of this section and reconfirm compliance with the acceptance criteria in paragraphs (e)(3) and (e)(4) of this section. If the licensee cannot demonstrate compliance with the acceptance criteria, then the licensee shall change its facility, technical specifications or procedures so that the acceptance criteria are met. These actions are deemed to be in conformance with applicable finality provisions in Part 52.

(3) Design approvals and referencing combined licenses under Part 52. Holders of combined licenses referencing a design approval rule shall re-perform the evaluations required by paragraphs (e)(1) and (e)(2) of this section and reconfirm compliance with the acceptance criteria in paragraphs (e)(3) and (e)(4) of this section. If the licensee cannot demonstrate compliance with the acceptance criteria, then the licensee shall change its facility, technical specifications or procedures so that the acceptance criteria are met. The evaluation required by this paragraph, and any necessary changes to the facility design, technical specifications or procedures as the result of this evaluation, are not to be deemed to be backfitting under any provision of this chapter or a violation of any finality provision in Part 52.

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

§ 50.109 Backfitting.

* * * * *

(b) Paragraph (a)(3) of this section shall not apply to:

(1) Backfits imposed prior to October 21, 1985; and

(2) Any changes made to the TBS specified in § 50.46a or as otherwise applied to a licensee.

* * * * *

7. In Appendix A to 10 CFR Part 50, under the heading, "CRITERIA," Criterion 17, 35, 38, 41, 44, and 50 are revised to read as follows:

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

* * * * *

CRITERIA

* * * * *

Criterion 17--Electrical power systems. An on-site electric power system and an offsite electric power system shall be provided to permit functioning of structures, systems, and components important to safety. The safety function for each system (assuming the other system is not functioning) shall be to provide sufficient capacity and capability to assure that (1) specified acceptable fuel design limits and design conditions of the reactor coolant pressure boundary are not exceeded as a result of anticipated operational occurrences and (2) the core is cooled and containment integrity and other vital functions are maintained in the event of postulated accidents.

The onsite electric power supplies, including the batteries, and the onsite electrical distribution system, shall have sufficient independence, redundancy, and testability to perform their safety functions assuming a single failure, except for loss of coolant accidents involving pipe breaks larger than the transition break size under 10 CFR 50.46a, where a single failure of the onsite power supplies and electrical distribution system need not be assumed for plants under 10 CFR 50.46a. For those pipe breaks only, neither a single failure nor the unavailability of offsite power need be assumed.

Electric power from the transmission network to the onsite electric distribution system shall be supplied by two physically independent circuits (not necessarily on separate rights of way) designed and located so as to minimize to the extent practical the likelihood of their simultaneous failure under operating and postulated accident conditions. A switchyard common to both circuits is acceptable. Each of these circuits shall be designed to be available in sufficient time following a loss of all onsite alternating current power supplies and the other offsite electric power circuit, to assure that specified acceptable fuel design limits and design conditions of the reactor coolant pressure boundary are not exceeded. One of these circuits shall be designed to be available within a few seconds following a LOCA to assure that core cooling, containment integrity, and other vital safety functions are maintained.

Provisions shall be included to minimize the probability of losing electric power from any of the remaining supplies as a result of, or coincident with, the loss of power generated by the nuclear power unit, the loss of power from the transmission network, or the loss of power from the onsite electric power supplies.

*   *   *   *   *

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 pipe breaks larger than the transition break size under 10 CFR 50.46a. For those pipe breaks only, neither a single failure nor the unavailability of offsite power need be assumed.

*   *   *   *   *

Criterion 38--Containment heat removal. A system to remove heat from the reactor containment shall be provided. The system safety function shall be to reduce rapidly, consistent with the functioning of other associated systems, the containment pressure and temperature following any LOCA and maintain them at acceptably low levels.

Suitable redundancy in components and features, and suitable interconnections, leak detection, isolation, and containment capabilities shall be provided to assure that for onsite electric power system operation (assuming offsite power is not available) and for offsite electric power system operation (assuming onsite power is not available) the system safety function can be accomplished, assuming a single failure, except for analysis of loss of coolant accidents involving pipe breaks larger than the transition break size under 10 CFR 50.46a. For those pipe breaks only, neither a single failure nor the unavailability of offsite power need be assumed.

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Criterion 41--Containment atmosphere cleanup. Systems to control fission products, hydrogen, oxygen, and other substances which may be released into the reactor containment shall be provided as necessary to reduce, consistent with the functioning of other associated systems, the concentration and quality of fission products released to the environment following postulated accidents, and to control the concentration of hydrogen or oxygen and other substances in the containment atmosphere following postulated accidents to assure that containment integrity is maintained.

Each system shall have suitable redundancy in components and features, and suitable interconnections, leak detection, isolation, and containment capabilities to assure that for onsite electric power system operation (assuming offsite power is not available) and for offsite electric power system operation (assuming onsite power is not available) its safety function can be accomplished, assuming a single failure, except for analysis of loss of coolant accidents involving pipe breaks larger than the transition break size under 10 CFR 50.46a. For those pipe breaks only, neither a single failure nor the unavailability of offsite power need be assumed.

*   *   *   *   *

Criterion 44--Cooling water. A system to transfer heat from structures, systems, and components important to safety, to an ultimate heat sink shall be provided. The system safety function shall be to transfer the combined heat load of these structures, systems, and components under normal operating and accident conditions.

Suitable redundancy in components and features, and suitable interconnections, leak detection, and isolation 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 analysis of loss of coolant accidents involving pipe breaks larger than the transition break size under 10 CFR 50.46a. For those pipe breaks only, neither a single failure nor the unavailability of offsite power need be assumed.

*   *   *   *   *

Criterion 50--Containment design basis. The reactor containment structure, including access openings, penetrations, and the containment heat removal system shall be designed so that the containment structure and its internal compartments can accommodate, without exceeding the design leakage rate and with sufficient margin, the calculated pressure and temperature conditions resulting from any loss-of-coolant accident. This margin shall reflect consideration of (1) the effects of potential energy sources which have not been included in the determination of the peak conditions, such as energy in steam generators and as required by 10 CFR 50.44 energy from metal-water and other chemical reactions that may result from degradation but not total failure of emergency core cooling functioning, (2) the limited experience and experimental data available for defining accident phenomena and containment responses, and (3) the conservatism of the calculational model and input parameters.

For reactors designed to comply with 10 CFR 50.46a, the structural and leak tight integrity of the reactor containment structure, including access openings, penetrations, and its internal compartments, shall be maintained for realistically calculated pressure and temperature conditions resulting from any loss of coolant accident larger than the transition break size.

* * * * *

PART 52 - LICENSES, CERTIFICATIONS AND APPROVALS FOR NUCLEAR POWER PLANTS

8. The authority citation for part 52 continues to read as follows:

AUTHORITY: Secs. 103, 104, 161, 182, 183, 185, 186, 189, 68 Stat. 936, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2133, 2201, 2232, 2233, 2235, 2236, 2239, 2282); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 594 (2005), secs. 147 and 149 of the Atomic Energy Act.

9. In § 52.47, paragraph (a)(4) is revised to read as follows:

§ 52.47 Contents of applications; technical information

(a) * * *

(4) An analysis and evaluation of the design and performance of structures, systems, and components 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.

(i) Analysis and evaluation of emergency core cooling system (ECCS) cooling performance and the need for high-point vents following postulated loss-of-coolant accidents may be performed under the requirements of either § 50.46 or § 50.46a and § 50.46b of this chapter for designs certified after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR] and demonstrated under § 50.46a(c)(2) of this chapter to be similar to reactor designs licensed before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR], or

(ii) Analysis and evaluation of ECCS cooling performance and the need for high-point vents following postulated loss-of-coolant accidents must be performed under the requirements of §§ 50.46 and 50.46b of this chapter for designs that are not demonstrated under § 50.46a(c)(2) of this chapter to be similar to reactor designs licensed before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR].

* * *

10. In § 52.54, paragraph (b) is revised to read as follows:

§ 52.54 Issuance of standard design certification.

* * *

(b) The design certification rule must specify the site parameters, design characteristics, and any additional requirements and restrictions of the design certification rule. A design certification rule which was reviewed and approved as meeting the requirements of 10 CFR 50.46a must specify the criteria governing departures that a referencing combined license must meet. The criteria must ensure that the safety bases for the NRC's approval of the certified design's compliance with § 50.46a (including applicability of the TBS) continue to apply despite the departure.

* * * * *

11. In § 52.63, paragraph (a)(1)(viii) is added to read as follows:

§ 52.63 Finality of standard design certifications.

(a)(1) * *

(viii) Implements the requirements of 10 CFR 50.46a.

* * * * *

12. In § 52.79, paragraph (a)(5) is revised to read as follows:

§ 52.79 Contents of applications; technical information in final safety analysis report.

(a) * * *

(5) An analysis and evaluation of the design and performance of structures, systems, and components 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.

(i) Analysis and evaluation of ECCS cooling performance and the need for high-point vents following postulated loss-of-coolant accidents must be performed under the requirements of either § 50.46 or § 50.46a and § 50.46b of this chapter for facilities licensed after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR] and demonstrated under § 50.46a(c)(2) of this chapter to be similar to reactor designs licensed before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR], or

(ii) Analysis and evaluation of ECCS cooling performance and the need for high-point vents following postulated loss-of-coolant accidents must be performed under the requirements of §§ 50.46 and 50.46b of this chapter for facilities licensed after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR] and not demonstrated under § 50.46a(c)(2) of this chapter to be similar to reactor designs licensed before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR].

*   *   *   *   *

13. In § 52.137, paragraph (a)(4) is revised to read as follows:

§ 52.137 Contents of applications; technical information.

(a)   *   *   *

(4) An analysis and evaluation of the design and performance of SSCs 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 SSCs provided for the prevention of accidents and the mitigation of the consequences of accidents.

(i) Analysis and evaluation of ECCS cooling performance and the need for high-point vents following postulated loss-of-coolant accidents must be performed under the requirements of either § 50.46 or § 50.46a and § 50.46b of this chapter for designs approved after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR] and demonstrated under § 50.46a(c)(2) of this chapter to be similar to reactor designs licensed before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR], or

(ii) Analysis and evaluation of ECCS cooling performance and the need for high-point vents following postulated loss-of-coolant accidents must be performed under the requirements of §§ 50.46 and 50.46b of this chapter for designs that are not demonstrated under § 50.46a(c)(2) of this chapter to be similar to reactor designs licensed before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR].

* * * * *

14. In § 52.157, paragraph (f)(1) is revised to read as follows:

§ 52.157 Contents of applications; technical information in final safety analysis report.

(f) * * *

(1) An analysis and evaluation of the design and performance of structures, systems, and components 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.

(i) Analysis and evaluation of ECCS cooling performance and the need for high-point vents following postulated loss-of-coolant accidents must be performed under the requirements of either § 50.46 or § 50.46a and § 50.46b of this chapter for facilities licensed after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR] and demonstrated under § 50.46a(c)(2) to be similar to reactor designs licensed before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR], or

(ii) Analysis and evaluation of ECCS cooling performance and the need for high-point vents following postulated loss-of-coolant accidents must be performed under the requirements of §§ 50.46 and 50.46b of this chapter for facilities licensed after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR] and not demonstrated under § 50.46a(c)(2) of this chapter to be similar to reactor designs licensed before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR].

* * * * *

Dated at Rockville, Maryland, this day of , 2010.

For the Nuclear Regulatory Commission.

R. W. Borchardt,
Executive Director for Operations

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.

(i) Analysis and evaluation of ECCS cooling performance and the need for high-point vents following postulated loss-of-coolant accidents must be performed under the requirements of either § 50.46 or § 50.46a and § 50.46b of this chapter for facilities licensed after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR] and demonstrated under § 50.46a(c)(2) to be similar to reactor designs licensed before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR], or

(ii) Analysis and evaluation of ECCS cooling performance and the need for high-point vents following postulated loss-of-coolant accidents must be performed under the requirements of §§ 50.46 and 50.46b of this chapter for facilities licensed after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR] and not demonstrated under § 50.46a(c)(2) of this chapter to be similar to reactor designs licensed before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FR].

* * * * *

Dated at Rockville, Maryland, this day of , 2010.

For the Nuclear Regulatory Commission.

R. W. Borchardt,
Executive Director for Operations

OFFICE	NRR:DPR:PM	NRR:DPR:BC	NRR/DCI	NRR:DRA	NRR:DSS	NRR:DPR:D
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OFFICE	NSIR:D	OGC:NLO	RES:D	NRR:D	EDO	
NAME	JWiggins (JUhle for)	BJones* (GMizuno for)	BSheron (JLyons for)	ELeeds	RBorchardt	
DATE	09/01/10	11/23/10	09/02/10	11/ /10	11/ /10	

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