NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50 and 52

[NRC–2004–0006]

RIN 3150–AH29

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

AGENCY: Nuclear Regulatory Commission.

ACTION: Supplemental proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend 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 proposed amendments would 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.

DATES: Submit comments on this supplemental proposed rule by September 24, 2009. Submit comments specific to the information collections aspects of this supplemental proposed rule by September 9, 2009. Comments received after the above dates will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after these dates.

ADDRESSES: You may submit comments by any one of the following methods. Comments submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. You may submit comments on the information collections by the methods indicated in the Paperwork Reduction Act Statement of this document.

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.Gallagher@nrc.gov.*

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, *Attn:* Rulemakings and Adjudications Staff.

E-mail comments to: Rulemaking.Comments@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415–1966.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. during Federal workdays. (Telephone (301) 415–1966).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415–1101.

You can access publicly available documents related to this document using the following methods:

NRC's Public Document Room (PDR): The public may examine publicly available documents at the NRC's PDR, Public File Area O–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee.

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FOR FURTHER INFORMATION CONTACT:
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SUPPLEMENTARY INFORMATION:

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I. Background

During the last few 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,'' (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 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.

Regulatory Guide 1.174 further clarifies that in implementing these principles, the NRC expects that all safety impacts of the proposed change are evaluated in an integrated manner as part of an overall risk management approach in which the licensee is using risk analysis to improve operational and engineering decisions broadly by identifying and taking advantage of opportunities to reduce risk; and not just to eliminate requirements that a licensee sees as burdensome or undesirable.

II. Rulemaking Initiation

The process described in RG 1.174 is applicable to changes to plant licensing bases. As NRC experience with the 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 promulgated 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.

The NRC also decided to examine 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. These 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, (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)' '' (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,'' (March 3, 2004; ML040490133). The Commission provided direction in a SRM dated July 1, 2004, (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 reactor coolant system (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 should increases in frequency require licensees to restore the facility to its original design basis or make other compensating changes, the backfit rule (10 CFR 50.109) would not apply.

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, the Commission directed the NRC staff to publish the proposed rule for public comment after making certain changes. The most significant change requested by the Commission was to require that after implementing the alternative § 50.46a requirements, *all* subsequent plant changes made by a licensee would be evaluated by the licensee's risk-informed process to ensure that they met all of the requirements in § 50.46a. Another change requested by the Commission was to address the issue of seismic loading of degraded piping during very large earthquakes and to solicit public comments on the subject.

On November 7, 2005, (70 FR 67598), the proposed rule was published in the **Federal Register** (FR) with a comment period of 90 days. On December 6, 2005, the Nuclear Energy Institute [1] (NEI) requested that the comment period be extended for 30 additional days. NEI stated that additional time was needed to prepare high quality comments that reflected an industry consensus perspective. On December 20, 2005, the

[1] All utilities licensed to operate commercial nuclear power plants in the United States are members of NEI.

Westinghouse Owners Group (WOG) submitted a letter endorsing the NEI extension request. On January 18, 2006, the NRC extended the comment period by 30 days to expire on March 8, 2006. As directed by the Commission in its SRM on SECY–05–0052, the NRC staff addressed the seismic issue by preparing a report entitled ''Seismic Considerations for the Transition Break Size'' (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 that stakeholders understood the NRC's intent and interpretation of the proposed rule and two public meetings were held on June 28, 2006, and August 17, 2006, to discuss public comments received on the proposed rule.

After evaluating all written public comments and comments received at the public meetings, 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, (ML063190465) the ACRS provided its evaluation of the draft final rule. In its November 16, 2006, letter to the Commission, the ACRS recommended that the rule not be issued in its 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 (ML072220595) in response to SECY–07–0082, the Commission approved NRC staff recommendations for a revised priority and approach for addressing the ACRS concerns and completing the final rule. On April 1, 2008, the NRC staff provided the Commission with its planned schedule (ML080370355) for completing the rule.

As the NRC staff proceeded to modify the rule in response to the ACRS recommendations and the Commission's direction, numerous substantive changes were made to the requirements in the draft final rule. After consideration of the extent of these changes, the NRC has decided to provide another opportunity for public comment focusing on the revised proposed rule, in order to provide public stakeholders with another opportunity to review and comment on the new language. Because of the interrelated nature of the regulatory requirements, the NRC is republishing the entire 10 CFR 50.46a proposed rule to allow public comments on the changed requirements and on other closely-related regulatory provisions.

III. Description of November 2005 Proposed Rule

The proposed rule published on November 7, 2005, (70 FR 67598) would divide the current spectrum of LOCA break sizes into two regions. The division between the two regions is delineated by a ''transition break size'' (TBS). [2] 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 RCS pipe. Break area associated with the TBS is not based upon a double-ended offset break. Rather, it is based upon the inside area of a single-sided circular pipe break.

Pipe breaks in the smaller break size region are considered more likely than pipe breaks in the larger break size region. Consequently, each break size region is subject to different ECCS requirements, commensurate with likelihood of the break. LOCAs in the smaller break size region must be analyzed by the methods, assumptions, and criteria currently used for LOCA analysis; accidents in the larger break size region will be analyzed by less conservative assumptions based on their lower likelihood. Although LOCAs for break sizes larger than the transition break would become ''beyond design-basis accidents,'' the proposed rule would require licensees to maintain the ability to mitigate all LOCAs up to and including the DEGB of the largest RCS pipe during all operating configurations.

Licensees who perform LOCA analyses using the risk-informed alternative requirements could find that their plant designs are no longer limited by certain parameters associated with previous DEGB analyses. Reducing the DEGB limitations could enable 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 required accident analyses. Potential design changes include modification of containment spray designs, modifying core peaking factors, modifying setpoints on accumulators or removing some from service, eliminating fast starting of one or more emergency diesel generators, increasing power, *etc.* Some of these design and operational changes could increase plant safety because a licensee could modify its systems to better mitigate the more likely small-break LOCAs. Other design changes, such as increasing power, could cause increases in plant risk. Accordingly, the risk-informed § 50.46a option would establish risk acceptance criteria to ensure the risk acceptability of all subsequent facility changes. The proposed rule required that *all* future facility changes [3] made by licensees after adopting § 50.46a be evaluated by a risk-informed integrated safety performance (RISP) assessment process that has been reviewed and approved by the NRC via the routine process for license amendments.[4] The RISP assessment process would ensure that the cumulative effect of all plant changes involved acceptable changes in risk and was consistent with other criteria from RG 1.174 to ensure adequate defense-in-depth, safety margins and performance measurement. Licensees with an approved RISP assessment process could make certain facility changes without NRC review if they met § 50.59 [5] and § 50.46a requirements, including the criterion that risk increases cannot exceed a ''minimal'' level. Licensees could make other facility changes after NRC approval if they met the § 50.90 requirements for license amendments and the criteria in § 50.46a, including

[2] Different TBSs for pressurized water reactors and boiling water reactors would be established due to the differences in design and operation between those two types of reactors.

[3] The scope of changes subject to the change criteria in § 50.46a(f) of the proposed rule would be greater than the changes currently subject to § 50.59, which applies only to changes to ''the facility as described in the FSAR.'' The change criteria in the proposed rule would apply to all facility and procedure changes, regardless of whether they are described in the Final Safety Analysis Report (FSAR).

[4] Requirements for license amendments are specified in §§ 50.90, 50.91 and 50.92. They include public notice of all amendment requests in the **Federal Register** and an opportunity for affected persons to request a hearing. In implementing license amendments, the NRC typically prepares an appropriate environmental analysis and a detailed NRC technical evaluation to ensure that the facility will continue to provide adequate protection of public health and safety and common defense and security after the amendment is implemented.

[5] Requirements in § 50.59 establish a screening process that licensees may use to determine whether facility changes require prior review and approval by the NRC. Licensees may make changes meeting the § 50.59 requirements without requesting NRC approval of a license amendment under § 50.90.

the criterion that total cumulative risk increase cannot exceed a ''small'' threshold. Potential impacts of the plant changes on facility security would be evaluated as part of the license amendment review process.

The NRC would periodically evaluate LOCA frequency information. Should estimated LOCA frequencies significantly increase such that the risk associated with pipe breaks larger than the TBS is unacceptable, the NRC would undertake rulemaking (or issue orders, if appropriate) to change the TBS. In such a case, the backfit rule (10 CFR 50.109) would not apply. If previous plant changes were invalidated because of a change to the TBS, licensees would have to modify or restore components or systems as necessary so that the facility would continue to comply with § 50.46a acceptance criteria. The backfit rule (10 CFR 50.109) would also not apply to these licensee actions.

IV. Discussion of Public Comments

The NRC received comments on the proposed rule from six nuclear power plant licensees, four nuclear industry organizations, two reactor vendors, and an NRC employee. The comments provided by NEI were specifically endorsed by the WOG, the Boiling Water Reactors Owners Group (BWROG), and three nuclear power plant licensees. The NRC considered all comments in formulating the revised proposed rule language. The NRC also received comments from a nuclear engineering professor on the expert elicitation process for determining the relationship between pipe break frequency and pipe size that was used as the baseline for selecting the transition break size. Although these comments were submitted for NUREG–1829 (Draft Report), ''Estimating Loss-of-Coolant Accident (LOCA) Frequencies Through the Elicitation Process'' (ML051520574), they were also considered in the development of the § 50.46a final rule.

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), Public File Area 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.

Comments addressed six different general topics: selection of the TBS, the effect of seismic considerations on the TBS, thermal-hydraulic ECCS analyses, probabilistic risk analysis, applicability of the backfit rule, and comments on questions posed by the Commission. The comments are discussed below by topic area.

A. Comments on Selection of the TBS

Comment. NEI stated that the TBS proposed for boiling water reactors (BWRs) is overly conservative and may unnecessarily limit or preclude benefits for BWRs. They suggested 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. The BWROG supported a reduced TBS for BWRs consistent with the 95th percentile TBS noted from the expert elicitation (*i.e.,* without additional conservatisms).

NRC response. The proposed TBS for BWRs is currently 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″ range, and are similar in size to the 95th percentile estimates from the expert elicitation process results 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. 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 (*i.e.,* a complete severance of the pipe). 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 feedwater or recirculation pipes. For these reasons, the NRC continues to believe that the TBS for BWRs should 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 have been made in the revised proposed rule.

Comment. The Nuclear Energy Institute, the Westinghouse Owners Group (WOG) and a reactor licensee stated 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 hot leg pipe, and the TBS for the cold leg should be based on the largest connecting cold leg pipe. These are logical break sizes and avoid the arbitrary nature of the size of the connecting pipe on the hot leg being also applied to breaks on the cold leg. If no attached piping is connected to the cold leg, the cold leg TBS should be the same as the hot leg TBS. The WOG stated that the NRC and the industry should take the opportunity of this rule change to determine the appropriate transition break size and not settle for a rule that is needlessly conservative. Because the rulemaking cannot easily be changed in the future as new information becomes available, the TBS should be based on sound technical facts and expert opinions with some margin for uncertainties and unknowns that could show up in the future and erode margins. It is not appropriate to set the TBS on the basis of where the most benefit would be realized because this may change tomorrow and there will be no easy recourse. The WOG also said that the Commissioners have recommended a design basis LOCA cut-off frequency of 10^{-5} per reactor year, which corresponds to a break size of about a three or four-inch diameter effective break (for PWRs). The WOG believes that selecting a TBS equal to the largest attached piping (8- to 12-inch diameter break) is very conservative. However, the WOG has conducted thermal-hydraulic and risk analyses that show that there are substantial potential benefits for PWR plants even with this larger TBS. The WOG agreed that setting the transition break size at the sizes of the piping attached to the RCS loop is reasonable because it will provide significant benefit while providing substantial margin to account for uncertainties or any new information that may become available on break size vs. frequency. The requirement that plants must still be able to mitigate breaks larger than the TBS provides even more margin.

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 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 the hot leg from the cold leg break frequencies. The commenters did not provide additional information or technical data that justifies different break frequencies or use of a smaller TBS on the cold leg piping. Thus, no changes to the PWR TBS were made in the revised proposed rule.

B. Comments on Seismic Considerations Related to the TBS

The TBS specified by the NRC in the November 7, 2005, proposed rule did not include an adjustment to address the effects of seismically-induced LOCAs. (*See* 70 FR at 67604.) On December 20, 2005, the NRC released a report discussing seismic considerations for the transition break size (''Seismic Considerations for the Transition Break Size'', December 2006; ML053470439). The NRC requested specific public comments on the effects of pipe degradation on seismically-induced LOCA frequencies and the potential for affecting the selection of the TBS. These public comments were considered in the final, published report (NUREG–1903, ''Seismic Considerations for the Transition Break Size'', February 2008; ML080880140).

Comment. NEI, WOG, BWROG, and a reactor licensee all commented that the proposed TBS need not be further adjusted due to seismic considerations. NEI indicated that the NRC's December 20, 2005, report demonstrates that the seismically-induced LOCA frequency contribution is less than the 10^{-5} per reactor year guideline used by the NRC in determining the TBS. NEI further commented that median seismic capacities for both the primary piping system and primary system components are higher than most other safety related power plant components within the nuclear power plant. Because of these relative capacities, NEI said the seismic risk from very large, low probability earthquakes would be controlled by consequential safety component failure. In addition, NEI stated that the creation of the TBS by itself does not produce a physical change in the plant that would result in an appreciable change in seismic risk. The WOG, the BWROG, and a reactor licensee endorsed the NEI comments. WOG included an additional comment which stated that the NRC's December report indicated that seismic loading will only have a small (10 per cent) effect on the LOCA frequencies estimated by the NRC expert panel (NUREG–1829, Draft report, June 2005) and that effect is well within the uncertainty bounds of the frequency estimate of the panel. Furthermore the NRC has already included a very substantial margin above the break size that would correspond to a LOCA frequency of 10^{-5} per reactor year. Therefore, seismic effects should not change the transition break size.

NRC Response. The NRC agrees with the commenters' conclusion that the TBS defined in the proposed rule need not be adjusted further to account for the effects of seismically induced LOCAs in piping greater than the TBS. 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 rare (10^{-5} per year) earthquakes.

The NRC report NUREG–1903, ''Seismic Considerations for the Transition Break Size'' (February 2008; ML080880140) considered the potential contribution from two mechanisms: direct piping failures and indirect failures. Direct failures are those pipe ruptures that result when the combined earthquake loadings and normal stresses exceed the strength of the pipe. The report concluded that direct failures from earthquakes with return frequencies of 10^{-5} per year and 10^{-6} per year would not be expected unless cracks on the order of 30 percent through-wall and approximately 145 degrees around the piping circumference were present at the time of the earthquake. The NRC reviewed its experience with flaws in reactor coolant system piping to assess whether cracks of this magnitude have ever been found in RCS main loop piping, or if other information suggests that cracks of this magnitude are likely. The NRC considered both fabrication induced flaws and service induced flaws. No large fabrication flaws have ever been reported. If large fabrication flaws were present and were not detected by the initial fabrication inspections and subsequent in-service inspections, it would be expected that some would have grown through-wall over time as a result of fatigue or other mechanisms and would have been discovered through leakage. This has not been observed even though most plants have been in operation for more than 20 years.

With respect to service induced flaws, the NRC also considered the potential for known degradation mechanisms to induce cracks of the critical size. For BWRs, intergranular stress corrosion cracking (IGSCC) is the only mechanism that has been shown to produce large cracks. However, regulatory and industry programs have been in place for many years to specifically address this mechanism and as a result, IGSCC is being effectively managed. In PWRs, a number of partly through-wall flaws and a small number of through-wall flaws have been discovered and have been attributed to primary water stress corrosion cracking (PWSCC). To date, all flaws discovered were considerably smaller than flaws that would lead to failure under 10^{-5} and 10^{-6} per year earthquake loadings. PWR plant owners have established programs to address PWSCC in susceptible reactor coolant system piping welds. They are inspecting these welds more frequently and, in most cases, are applying mitigation techniques to manage PWSCC. The NRC is working with the American Society of Mechanical Engineers (ASME) to establish a regulatory framework for improved inspection and mitigation of PWSCC in these welds. The NRC expects that these measures will ensure that PWSCC will be effectively managed. As a result of the above considerations, the NRC considers the likelihood of flaws large enough to fail under 10^{-5} and 10^{-6} per year earthquake loadings to be sufficiently low that the TBS need not be modified to address seismically induced direct failures.

Indirect failures are primary system pipe 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 the piping and result in pipe failure. The NRC performed studies on two plants to estimate the conditional pipe failure probability due to structural support failure given a low return frequency earthquake (10^{-5} to 10^{-6} per year). The results indicated that the conditional failure probability 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; ML052640591). More recent indirect failure 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 6×10^{-6} per year. Although the EPRI failure probability was higher than either of the two cases calculated by the NRC, the result is still lower than the TBS selection guideline of 10^{-5} per reactor year. 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, as noted in the public comments, 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, adjustment to the TBS for seismically induced indirect LOCAs is also not warranted.

Comment. In the proposed rule, the NRC stated that the final rule might include requirements for licensees to perform plant-specific assessments of seismically-induced pipe breaks and, if necessary, implement augmented in-service inspection plans before implementing the alternative ECCS requirements. NEI, WOG, BWROG, and a reactor licensee all commented that plant specific assessments 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. NEI indicated that the NRC's December 20, 2005 report, ''Seismic Considerations for the Transition Break Size'' demonstrates that the seismically induced LOCA frequency contribution is less than the 10^{-5} per reactor year guideline limit used by the NRC in determining the TBS. NEI further commented that indirect LOCA seismic studies had been performed by EPRI for a limited number of plants using more recent seismic hazard estimates than those used in the NRC's December study. The EPRI study estimated that the indirect LOCA probability was less than 10^{-5} per year for the plants examined. The EPRI study found that although the latest seismic hazard has increased for some parts of the central and eastern United States, there are several mitigating phenomena that have been established within the new plant seismic program which tend to counter much of that increase. NEI also stated that for a risk informed application, the change in risk should be the primary metric for decision making. The change in risk relative to seismic events is estimated to be negligible based upon the fact that the TBS threshold does not directly impact either the seismic hazard or the plant seismic fragilities. The WOG, the BWROG, and a licensee all endorsed the NEI comments. WOG included an additional comment which stated that the NRC's December report indicated that seismic loading will only have a small (~10 percent) effect on the LOCA frequencies estimated by the NRC expert panel (NUREG–1829 Draft Report, June 2005) and that effect is well within the uncertainty bounds of the frequency estimate of the panel. A reactor licensee had an additional comment that plant specific assessments to determine the frequency of seismically induced pipe breaks would be very difficult to complete. The licensee said that because pipe inspection and repair are such an integral part of plant operations, after a plant seismic assessment was completed, its conclusions would then be prejudiced by implementation of piping inspection and repair programs. The commenter did not explain in detail how the results would be prejudiced. The commenter also suggested that more technically valid piping failure probabilities might be obtainable through an extensive research program, but noted it is questionable whether this would provide additional risk insights.

NRC response. The NRC disagrees with the commenters that plant specific assessments of seismically induced pipe breaks are not necessary before implementing the alternative ECCS requirements. As discussed in the previous comment, although seismic considerations do not significantly affect TBS selection, the generic nature of the seismic risk 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 seismic-induced unflawed piping failure was much less than 10^{-5} per year. However, a general conclusion about the likelihood of seismic-induced flawed 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 extremely 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 (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 criteria used for selecting the TBS in the proposed rule. Because seismic analyses and, in particular, indirect failure estimates are highly plant and site specific (as noted in NUREG–1903 and in ACRS comments), 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. Depending upon the results of the plant specific assessment, it may be necessary to implement augmented in-service inspection plans. As discussed below in Section V.C. of this document, the NRC is currently preparing guidance for conducting these plant-specific assessments (''Plant-Specific Applicability of 10 CFR 50.46 Technical Basis,'' February 2009; ML090350757).

C. Comments on Thermal-Hydraulic Analysis

Comment. Both NEI and WOG recommended that the proposed new reporting requirement in § 50.46a(g)(1)(i) of a 0.4 percent change in oxidation as the threshold for reporting a change, or the sum of changes, in calculated clad oxidation be changed from 0.4 percent to 2.0 percent. WOG noted that the rationale for selecting 0.4 percent is that it is the same, on a percentage basis, as the existing peak cladding temperature (PCT) change reporting requirement. WOG also stated that this rationale is only true if one considers the range of interest of PCT as 0 to 2200 degrees Fahrenheit (°F) [(50 °F/2200 °F) × (17 percent) = 0.4 percent]. If instead, one considers the range of interest of PCT as 1700–2200 °F or 1800–2200 °F, from the perspective of transient oxide build-up, this same rationale gives a significance threshold of 1.7 or 2.1 percent. On this basis, WOG recommended that the significance threshold for changes in oxidation be revised to 2.0 percent.

WOG also noted that changes in oxidation are much more difficult to estimate than changes in peak cladding temperature because oxidation is an integrated parameter based on the temperature transient versus time, whereas PCT is a point value. If the significance threshold for oxidation is not adjusted as recommended above, it is anticipated that the new oxidation reporting requirement will require more frequent re-analyses than the current regulations require, with no commensurate benefit to the public health and safety.

NRC response. The basis for the 0.4 per year oxidation change is that the ratio of the reporting threshold value to the change in oxidation from a ''normal'' operating level of 4 percent (based on a twice-burned oxidation thickness of 65 µ for Zircalloy-4) to a maximum level of 17 percent should be the same as the ratio of the reporting threshold value to the change from the normal operating cladding temperature of 600 °F to the allowed PCT of 2200 °F. On that basis the oxidation change of 0.4 percent was chosen. The trend toward thinner cladding material raises the initial oxidation percentage even closer to the maximum local oxidation limit and reduces the margin for change in predicted oxidation.

Additionally, the NRC agrees with the WOG comment that calculating oxidation is more time-consuming than calculating PCT. However, the NRC believes WOG is incorrect in stating that not reducing the significance threshold for reporting changes in calculated oxidation will cause the need for performing additional oxidation calculations. The significance threshold for reporting to the NRC only affects the frequency of reporting and has no effect on the need to do reanalysis. Reanalysis is necessary when licensees discover errors or make changes to analytical codes.

The Commission has directed the NRC staff 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 will soon issue an Advance Notice of Proposed Rulemaking (ANPR) seeking public comments on a planned regulatory approach. 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. As these new acceptance criteria are being established, the NRC will also make conforming changes to § 50.46a as necessary for both below and above TBS breaks. As a consequence, the NRC now believes that the need for a reporting requirement in § 50.46a associated with errors or changes in ECCS analysis methodology would be more appropriately addressed in the ongoing § 50.46(b) proceeding. Accordingly, the changes to the oxidation reporting requirements in the initial proposed rule have been removed from the revised proposed rule.

Comment. Framatome commented that the analysis or case requirements in § 50.46a(e)(2) for beyond the transition break size evaluations are excessive. The desire for this portion of the regulation is to establish in a reasonable way that the plant remains able to mitigate a large break LOCA. It is unnecessary and inconsistent to elevate the consideration of break size effects beyond that of other portions or aspects of the evaluation that are to be treated as reasonable values. Under the proposed rule language, a full § 50.46 evaluation will be required for breaks of area less than the TBS. The results for these analyses can be extended to the smaller break sizes in the greater than TBS spectrum with assurance. Combining a reasonable selection of discharge coefficient (0.6) with the use of the 1994 ANS decay heat standard would roughly equate a 14-inch schedule 160 pipe area (0.7 ft^2), treated as below the TBS, with a 1.4 ft^2 break, treated as a beyond TBS break. Similarly, at the upper end of the break spectrum, what used to be considered as an 8 to 9 ft^2 break of the cold leg will be the equivalent of a historical 5 ft^2 break. The requirement to perform sensitivity studies to identify a worst case break between these two limits seems unwarranted. It would be reasonable to just perform the full double area break or at most that break and one intermediate break. The only sensitivity required should be relative to break location. Historically, break location can have a substantial influence on the calculated results. This should be resolved prior to the greater than TBS calculation either by sensitivity studies or by reference to appropriate historical analyses. The concern can be allayed by either altering the rule so that the identification of the most severe break size is not required or by inserting the concept of reasonable confidence that breaks within the beyond TBS spectrum will not pose consequences substantially more severe than those of the calculations performed.

The WOG stated that for NRC-approved best-estimate or Appendix K evaluation models, the requirement for analyzing a spectrum of break sizes is unwarranted. The BWROG said that the requirement to re-validate over 30 years of experience with performing large break LOCA analysis to confirm ''for a number of postulated LOCAs of different sizes and locations * * * that the most severe postulated LOCAs * * * are analyzed'' is unnecessarily burdensome and appears to serve no specific technical need. Current best-estimate large break LOCA models, which are benchmarked to testing data, have yielded no insights that would invalidate the previous analytical experience and knowledge. WOG concluded that this provision in the rule language should be removed.

NRC response. The NRC disagrees with the commenters on the need for analyzing a spectrum of break sizes. The proposed rule language was selected because there are two peak cladding temperatures, one that occurs below the TBS and one that occurs above the TBS. The peak above the TBS may not occur for the DEGB, but rather, for a break area in the range of 0.6 to 0.8 times the DEGB area. Because there can be a fairly large temperature difference between that break and the DEGB, use of the DEGB could be non-conservative. The NRC also believes that the language of the rule provides considerable flexibility in implementation (relative to the stated comments) because the requirement is to analyze a ''number of postulated LOCAs * * * sufficient to provide assurance that the most severe LOCAs * * * are analyzed''. The use of historical analyses is not precluded. No changes were made in the revised proposed rule.

Comment. NEI commented that in § 50.46a(e)(2) on ECCS analysis methods, one requirement is that ''comparisons to applicable experimental data must be made.'' NEI stated that other approaches such as comparison of results to accepted analysis techniques or to textbook approaches are also appropriate and suggested that the requirement be reworded to state that ''sufficient justification'' must be provided.

NRC response. The NRC disagrees with this commenter. Computer code-to-code comparisons are not adequate because all codes have uncertainty in their results. Only code-to-data comparisons can be used to accurately assess code uncertainties. Similarly, computer code results cannot be validated by comparison to ''textbook approaches'' because no simple textbook approaches exist for modeling the highly complex thermal-hydraulic phenomena associated with pipe break analyses. No changes were made in the revised proposed rule.

Comment. WOG submitted four options for how to perform ECCS analysis in the beyond-TBS region to assist the NRC staff in developing the regulatory guide for implementing the § 50.46a rule.

NRC Response. The NRC will evaluate the WOG ECCS analysis options and will provide additional implementation guidance in the associated regulatory guide.

Comment. The BWROG stated that it supports applying the requirements of § 50.46a(b)(1) to reactors with MOX [mixed oxide] fuel.

NRC response. The proposed § 50.46a is intended to be an alternative to the current ECCS requirements in § 50.46. Because § 50.46 does not address the use of mixed oxide fuel, the NRC believes that the commenter's proposal is beyond the scope of this rulemaking. The NRC did not make changes in the revised proposed rule to address MOX fuel.

Comment. Proposed § 50.46a(e)(2): The following sentence should be moved from its current location to just in front of the sentence beginning, ''These calculations * * *'': ''The evaluation must be performed for a number of postulated LOCAs of different sizes and locations 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.'' This relocated sentence should begin a new paragraph. These changes will properly group the more detailed analysis requirements.

NRC response. The NRC agrees that movement of the noted sentence improves the rule presentation. In the revised proposed rule, this sentence has been relocated as the commenter suggested, but the structure of § 50.46a(e)(2) was not modified.

Comment. In proposed § 50.46a(e)(2), the NRC should clarify the requirements for licensee documentation to be maintained onsite versus generic documentation in or supporting a licensing topical report.

NRC response. In the revised proposed rule, the NRC modified § 50.46a(e) to require that analysis methods for all LOCAs ''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.'' Thus, the documentation requirements for analysis methods used for breaks larger than the TBS are the same as for analysis methods used for breaks smaller than the TBS. The purpose of this change is to increase confidence in the ability to mitigate breaks greater than the TBS, as recommended by the Advisory Committee on Reactor Safeguards.

Comment. In proposed § 50.46a(e)(2), the NRC states that these calculations [for breaks larger than the TBS] may take credit for the availability of offsite power and do not require the assumption of a single failure. It should also be noted that availability of equipment is not limited to safety-related equipment.

NRC response. The NRC agrees that the suggested language is more descriptive and has incorporated the change into that last sentence of § 50.46a(e)(2).

Comment. For PWR LOCAs below and above the TBS, the mitigating systems and equipment are the same for the full spectrum of LOCAs. Although non-safety LOCA mitigation systems/components may be applicable in the context of BWR LOCA analysis, this is not the case for PWRs. If this element of the proposed regulation (allowing the use of non-safety grade systems) is intended to address a situation that is only applicable to BWRs, then it should not be required for PWRs.

NRC response. The element of the proposed regulation—allowing the use of non-safety grade systems—noted by the commenter is not intended to address a situation that is only applicable to BWRs. Although PWR plants may not currently have non-safety systems that could be credited for LOCA mitigation (for breaks larger than the TBS), modifications could be made in the future that facilitate use of non-safety systems. The revised proposed rule would relax existing § 50.46 requirements to allow ECCS analyses of breaks larger than the TBS to take credit for both safety-grade and non-safety-grade equipment if such equipment exists, is maintained available and reliable, and is capable of being powered by an on-site source of electrical power.

Comment. The WOG commented that the rule should not contain a requirement for licensees to submit beyond TBS thermal-hydraulic analyses to the NRC for approval. One reactor licensee commented that the proposed rule states that licensees will not be required to submit their beyond-TBS analysis method or application to the NRC for review and approval; instead, the NRC intends to maintain regulatory oversight of these analyses by inspection. That licensee said that although not requiring NRC review and approval has the appearance of a benefit to the licensees, it actually introduces a risk of a regulatory crisis should an inspection identify a deficiency in the beyond-TBS analysis method following implementation. Such an identified deficiency could result in a consequence such as the regulator imposing restrictions on reactor operation. This risk is greater than for the current situation where LOCA evaluation models and applications are pre-approved by the NRC. It would be preferable that NRC review and approval of § 50.46a applications be obtained prior to implementation to avoid such a regulatory crisis. This commenter proposed that the NRC agree to perform a pre-approval of a licensee's beyond-TBS analysis method and application if requested by a licensee.

NRC response. The NRC has changed the proposed rule to require NRC review and approval of analysis methods used to evaluate plant response to LOCAs larger than the transition break size. The purpose of this change is to increase confidence in the ability to mitigate breaks greater than the TBS, as recommended by the ACRS.

Comment. NEI, a reactor vendor, and a reactor licensee requested that M5 cladding (M5) be specified as an approved fuel cladding material in existing § 50.46(a) and in proposed § 50.46a(b)(1) to avoid the need for requesting an exemption to allow its use. The reactor vendor stated that because M5 is currently being used in 11 nuclear power reactors of varying designs across the United States, it is obvious that M5 is an acceptable and desirable cladding material. The BWROG stated that § 50.46a should be made available to reactors with alternate cladding materials.

NRC response. As previously discussed, the Commission directed the NRC staff to initiate a separate rulemaking effort to amend § 50.46(b) to address the use of advanced cladding alloys. The NRC is considering cladding specific issues in that proceeding and will also incorporate appropriate conforming changes to § 50.46a. 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 facilitate the licensing review of advanced cladding alloys such as M5. The NRC plans to issue an ANPR during the summer of 2009 to solicit public comments on a planned regulatory approach. In the interim, the NRC will continue to evaluate the use of cladding materials other than Zircalloy or ZIRLO on a case-by-case basis.

D. Comments Related to Probabilistic Risk Assessment

1. Summary

The initial proposed rule required that *all* future facility changes [6] made by licensees after adopting § 50.46a be evaluated by a risk-informed integrated safety performance (RISP) assessment process that has been reviewed and approved by the NRC via the routine process for license amendments.[7] (*See* 70 FR 67612–67615.) Most of the commenters on the proposed rule stated that current regulatory processes that control changes to the facility are adequate and therefore, there is no need for the RISP change control process. In comments generally supported by all nuclear industry commenters, NEI argued that the controls on the existing licensing basis make it virtually impossible to make significant adverse changes to the risk profile of the plant without being required to submit a license amendment request for prior NRC review and approval. NEI concluded that the only item that might be missing from the current framework that would provide additional assurance that the licensee is appropriately maintaining the risk profile of the facility after adoption of § 50.46a would be a requirement that the licensee periodically assess the cumulative impact of facility changes to the risk profile.

Industry commenters also considered the proposed rule's unbounded scope of the facility changes requiring a RISP assessment to be an unnecessary burden and some argued that this requirement is potentially adverse to safety. In this regard, the commenters said that because most facility changes have no material safety significance, requiring a RISP assessment of facility changes beyond even the criteria established in current regulations, such as in § 50.59, would add a wide range of activities and components to the licensing basis that were never reviewed or ever intended to be reviewed by the NRC. Thus, licensees would be forced to divert valuable resources from monitoring plant safety to tracking a multitude of items that have no safety or risk significance. A few commenters recognized that most facility changes could be dispositioned with a qualitative RISP assessment but argued that there would still be cost associated with the performance and documentation of the assessment.

All commenters stated that the rule should not include the operational restriction that all allowable at-power configurations be demonstrated to meet the ECCS acceptance criteria. The suggested alternatives ranged from reducing the restrictions and placing them under licensee control to eliminating them entirely. The commenters argued that:

(1) Existing plant configuration control programs, including technical specifications and implementation of the maintenance rule, provide sufficient controls to ensure that implementation of § 50.46a will not lead to plant operation in high risk configurations;

(2) Because of the low frequency of breaks greater than the TBS there should be a minimum of associated operating restrictions;

(3) Any operating restrictions for breaks larger than the TBS need to be commensurate with risk contribution of these larger break sizes; and

(4) Operating restrictions would remove or reduce any potential benefit that licensees might gain from the adoption of § 50.46a.

NRC summary response. The NRC believes that a risk-informed change process is a necessary component of this rule because this rule would permit changes to facility design bases that would not be allowed under current regulations. The current regulatory processes that control facility changes are not adequate to control risk-informed plant changes that would be allowed under § 50.46a. However, the NRC has modified the risk-informed change process considerably by reducing the scope of facility changes for which a risk assessment is required. The NRC considered requiring all facility changes to be evaluated as risk informed changes and permitting licensees to make all facility changes, with some exceptions, that satisfy the criteria in § 50.59 or other NRC regulations without prior NRC review and approval. The ACRS commented that requiring the change in risk from all facility changes to be compared to the acceptable risk increase criteria was a significant departure from RG 1.174 guidance and other past risk-informed applications. The ACRS recommended that this proposal be reviewed for its implications.

Instead of requiring risk assessment of all future facility changes, the revised proposed rule would require risk assessments for only those facility changes enabled by the new ECCS requirements for pipe breaks greater than the TBS. This change would

[6] The scope of changes subject to the change criteria in § 50.46a(f) of the proposed rule would be greater than the changes currently subject to § 50.59, which applies only to changes to ''the facility as described in the FSAR.'' The change criteria in the proposed rule would apply to all facility and procedure changes, regardless of whether they are described in the FSAR.

[7] Requirements for license amendments are specified in §§ 50.90, 50.91 and 50.92. They include public notice of all amendment requests in the **Federal Register** and an opportunity for affected persons to request a hearing. In implementing license amendments, the NRC typically prepares an appropriate environmental analysis and a detailed NRC technical evaluation to ensure that the facility will continue to provide adequate protection of public health and safety and common defense and security after the amendment is implemented.

reduce unnecessary burden and bring the change control process into conformance with RG 1.174 and other risk-informed rules and licensing actions. Two previous risk-informed regulations promulgated by the NRC (*i.e.,* §§ 50.69 and 50.48(c)) have included similar requirements related to the use of PRA and risk-informed principles to demonstrate the acceptability of facility changes enabled by new, risk-informed regulations before being implemented by licensees.

The revised proposed rule defines facility changes enabled by § 50.46a as changes to the facility, technical specifications, and procedures that satisfy the revised ECCS analysis requirements in § 50.46a but do not satisfy the ECCS analysis requirements in § 50.46. A risk-informed analysis, consistent with that described in RG 1.174, shall be applied to facility changes enabled by the rule. The risk-informed framework established in RG 1.174 permits licensees to propose several individual changes to a facility's licensing basis that have been evaluated and will be implemented in an integrated fashion. Some facility changes proposed by licensees may not be enabled by the rule but may lead to a risk decrease. RG 1.174 permits integrated (bundled) changes in risk to be compared to the acceptance guidelines from RG 1.174 in order to encourage changes that reduce risk. The NRC has retained this guidance in § 50.46a(f)(2)(iv) which would permit the change in risk from changes enabled by the rule to be combined with the change in risk from other plant changes unrelated to the rule for the purpose of demonstrating that the change in risk from all changes made under the rule meets the acceptance criteria.

In addition to reducing the scope of facility changes to which the risk-informed change process must be applied, the NRC has discarded the acronym ''RISP'' in favor of the simpler ''risk-informed'' label because the elements and processes described by the RISP are the elements and processes that make up a risk-informed evaluation.

The NRC considered whether to simplify the risk-assessment process further by relying primarily on current regulations to identify which facility changes a licensee must submit for prior NRC review and approval. The ACRS commented that the NRC should use risk criteria to determine whether a licensee should submit a change enabled by the rule for review and approval. Subsequently, the NRC retained the criteria specifying the maximum risk increase for a change that a licensee may make without prior NRC review and approval. This requirement frees licensees and the NRC from the burden of evaluating and accounting for the many individual facility changes that do not have a significant impact on risk while retaining NRC review and approval for changes that might pose a safety concern.

In response to comments received on the operational restrictions in the proposed rule, the NRC has decided that restrictions must remain on plant operation in configurations where it has not been demonstrated that breaks larger than the TBS can be mitigated, but the restrictions will be modified. The proposed rule prohibited at-power operation in any configuration without the demonstrated ability to mitigate a LOCA larger than the TBS. The revised proposed rule would restrict at-power operation in such a configuration to not exceed a total of fourteen days in any 12 month period. Rather than requiring licensees to use risk methods to determine how long such operation would be permitted, what actions would be required, and how the controls would be implemented, in the republished proposed rule the NRC is specifying a time limit that simplifies implementation without sacrificing flexibility and introducing unnecessary burden. The NRC believes it is unlikely that licensees would experience circumstances when they would consider operating in such a condition for more than fourteen days but feels that maintaining the restriction is necessary.

Although the LOCA frequencies on which the TBS are founded indicate that the expected frequency of breaks larger than the TBS is low, these frequencies are estimates derived from an expert elicitation process. The NRC has addressed the associated uncertainty, in part, by incorporating other elements into the selection of the TBS while recognizing that facility changes permitted by the rule could reduce the capability to mitigate some accidents that would currently be mitigated. The NRC concluded that the consequence of a challenge to the facility from an unmitigated break larger than the TBS is severe enough to warrant some confidence that the break could be mitigated.

Although the NRC currently has no guidance explicitly applicable to determine an acceptable time interval for operation without mitigation capability for a beyond-TBS LOCA, some related guidance is available. Previously, the NRC determined that events having at least a 10^{-7} probability per year should generally be taken into consideration in facility design. This approach is reflected in NUREG–0800, ''Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants.'' Events taken into consideration in facility design are design basis events and must meet the regulations specifying the required ability to mitigate the event. This guideline indicates that events with a frequency less than 10^{-7} per year need not be considered in facility design. Applying this criterion to develop an acceptable time interval during which a beyond-TBS LOCA might not be successfully mitigated yields about 4 days per year. Regulatory Guide 1.177, ''An Approach for Plant-Specific Risk-Informed Decisionmaking; Technical Specifications,'' provides risk guidelines that are routinely used to judge the acceptability of time intervals that safety-related equipment can be unavailable. Applying the RG 1.177 criterion yields about 18 days. Neither of these guidelines is fully applicable to this configuration. The 10^{-7} annual probability was developed to identify events external to the plant that need not be included in the design basis and is not specifically applicable to internal events such as LOCAs. Regulatory Guide 1.177 guidelines are normally applied to an operating configuration when mitigation capability would still be available although a single failure might fail that capability. Nevertheless, they provide an indication that an acceptable period of time should be measured in days.

The NRC chose fourteen days as the appropriate limit on how long a plant can operate in a configuration not demonstrated to meet the ECCS acceptance criteria for LOCA break sizes larger than the TBS. The NRC believes that fourteen days should be sufficient to allow completion of on-line maintenance activities relied on to ensure high reliability for safety systems while providing adequate protection of public health and safety, consistent with the low frequency of these LOCAs. The NRC believes that a longer time period for operating in such a plant condition would not be consistent with its stated goal of retaining the ability to successfully mitigate the full spectrum of LOCAs and would not adequately address uncertainties in the evaluation used to select the TBS. Conversely, a shorter time period could lead to significant burden to the industry with no clear safety benefits and, if maintenance activities were adversely affected, a possible reduction in safety. Therefore, the NRC will limit the allowed time period for operation in an unanalyzed condition to fourteen days to ensure that mitigation capability is maintained except for occasional, brief periods necessary to perform online maintenance of mitigation structures, systems and components.

The NRC concludes that the fourteen day operational restriction would protect public health and safety, provide adequate time for licensees to perform beneficial maintenance activities, be commensurate with the safety significance of LOCAs with a break size larger than the TBS and 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.''

The NRC agrees with commenters that operational restrictions could reduce the benefits that may be derived from adopting § 50.46a, but the NRC believes that this reduction in benefits is necessary and prudent to ensure that some capability to successfully mitigate LOCAs larger than the TBS is retained consistent with the risk of these events.

As an example, because the new § 50.46a ECCS analysis requirements provide relief from the single failure criterion for pipe breaks larger than the TBS, they could permit a facility to increase power to the extent that flow from both low pressure safety injection trains would be required to fully mitigate beyond-TBS breaks. However, the operational restriction in the re-noticed proposed rule would require that such a facility reduce power to a level where injection from one train is sufficient to mitigate beyond-TBS breaks if the second train is inoperable or is removed from service for preventative maintenance for longer than fourteen days. The plant would be permitted to operate at the increased power level at all other times.

2. Discussion of Specific Comments

Comment. The RISP process would be an extreme regulatory burden on licensees and the NRC to implement. Five reactor licensees said they would not implement the proposed rule because of excessive burden.

NRC response. The NRC disagrees with the commenters that the burden to develop and implement a risk-informed evaluation process as described in the initial proposed rule is an extreme regulatory burden because many elements of a risk-informed evaluation process should already exist at power reactors. However, as discussed above, the NRC has substantially reduced the scope of facility changes requiring a risk-informed evaluation. The revised proposed rule now would require a risk-informed evaluation as described in RG 1.174 which is consistent with the risk-informed evaluations required by other risk-informed applications and regulations. The NRC believes that the burden associated with implementing a risk-informed evaluation program would be offset by the flexibility provided by the new ECCS analysis requirements that will permit facility changes that were not permitted by the previous ECCS analysis requirements.

Comment. The risk-informed evaluation process emphasizes insignificant facility changes. The proposed change control requirements would require the NRC to be in the business of individually reviewing a myriad of insignificant facility changes. The risk acceptance criteria for allowing minimal risk changes appear to be contrary to the stated goal of enhancing safety. It seems illogical to adopt more restrictive requirements on safeguards for beyond design basis events than exist for design basis events.

NRC response. The NRC disagrees that the proposed rule's requirements would lead to the NRC individually reviewing insignificant facility changes. Facility changes that are enabled by the new ECCS requirements may lead to a wide range of estimated increases in risk, from immeasurably small to very large. The NRC has established an acceptance criterion that specifies the total amount of risk increase that would be considered acceptable from changes made under this rule. The revised proposed rule also includes a provision that prior NRC review is not required for individual facility changes that cause no more than a minimal increase in risk when compared to the overall plant risk profile. As discussed below, the NRC would consider any increase that is less than ten percent of the total acceptable risk increase to be minimal. The revised proposed rule includes these criteria to prevent NRC review of insignificant changes while retaining the capability to review facility changes that might pose a safety concern before implementation.

Comment. The scope of the required PRA is excessive. One commenter stated that the PRA scope requirements of § 50.46a(f)(4)(i) in the proposed rule appear excessive and should instead use text from NRC policy regarding PRA scope requirements relative to an application, *i.e.* ''* * * the PRA scope is such that all operational modes and initiating events that could change the regulatory decision substantially are included in the model quantitatively.'' Another commenter stated that requirements for PRA should not be prescribed in the rule. Standards and processes exist to establish requirements for PRA technical adequacy (*e.g.,* RG 1.174, RG 1.200, ASME PRA standard). A peer-reviewed internal events PRA that meets RG 1.200 should be sufficient for § 50.46a implementation. A final commenter stated that a requirement for shutdown PRAs is not appropriate because of the low risk associated with shutdown configurations at BWRs. Requirements for seismic PRAs are also inappropriate because these constitute a typically small fraction of the overall risk for most plants.

NRC response. The NRC does not agree with commenters that the scope of the required PRA is excessive and has made no changes to the PRA requirements in the revised proposed rule. Further, the NRC believes that the proposed rule language regarding PRA scope requirements provided by one of the above commenters is consistent with the language in both the proposed and the revised proposed rules. Thus, the commenter's text was not incorporated into the revised proposed rule.

The required overall characteristics of the PRA (and the non-PRA risk assessment) are included in the rule because these characteristics have been determined to be necessary to support decision making and inclusion of the characteristics in the rule provides clarity and predictability. The revised proposed rule does not prescribe how it will be determined whether a licensee's risk-assessment complies with these characteristics. The process to evaluate the suitability of each licensees' risk assessment will be described in the regulatory guide associated with this rule. This process will include staff-endorsed industry standards and the peer review process currently used by the NRC to evaluate the technical adequacy of PRAs supporting license amendment requests.

Comment. The requirement to update the PRA at a frequency no less often than once every two refueling cycles is potentially burdensome. An alternative would be to require that after every second refueling cycle, that the need for a PRA update is assessed and that appropriate action be initiated.

NRC response. The commenter's suggestion that the need for a PRA update be first assessed and appropriate action then be taken is consistent with the revised proposed rule. Section 50.46a(f)(2)(iv) would require that the PRA reasonably represent the current configuration of the plant. If a PRA continues to reasonably represent the configuration of the plant after a periodic review, the update requirement could be satisfied with a simple conclusion that changes to the PRA are not needed. The NRC believes that an update interval no longer than two operating cycles is not unduly burdensome; thus, the PRA update periodicity was not changed in the revised proposed rule.

Comment. The description of the risk-informed process should not be included in the application for a license amendment to implement § 50.46a. NEI provided complete alternative rule language in its comments. At the June 28, 2006, public meeting to clarify the comments, NEI emphasized that the proposed rule provided in their comments did not require that the RISP process be submitted for review because they felt that such a review was unnecessary. Although this comment was not formally submitted, several other participants at the June 2006 public meeting agreed with this comment.

NRC response. The NRC disagrees with the comment that a description of a licensee's risk-informed assessment process need not be submitted for NRC review as part of the licensee's application to adopt § 50.46a. However, the NRC believes that the amount and complexity of the process description that must be submitted will vary appropriately depending on which, and how many, facility changes enabled by the rule a licensee chooses to make.

As discussed, the NRC has revised the proposed rule by reducing the requirement that all future facility changes be evaluated using a risk-informed evaluation to only requiring that facility changes enabled by the rule be evaluated. Licensees who make limited facility changes under the rule, may chose to not submit a request to make future facility changes enabled by the rule without prior NRC approval as would be permitted in paragraph (c)(1)(iv). Licensees who make one or more risk-informed submittals without requesting the authority permitted under § 50.46a(c)(1)(iv) would only need to demonstrate that the process used to evaluate the specific change(s) described in each submittal provides confidence that the requirements of § 50.46a(f)(2) are satisfied. The content of these submittals is expected to be similar to, and consistent with, risk-informed license amendment requests currently accepted for review by the NRC.

A licensee requesting authority to make future changes without NRC review as permitted by § 50.46a(c)(1)(iv) must submit for NRC review and approval additional information, *i.e.,* the licensee's process including its risk assessment models and methods that will be used for making future risk-informed changes. Section 50.46a(c)(3)(iii) provides that the NRC may approve an application if, in part, the licensee's risk-informed evaluation process is adequate for determining whether the acceptance criteria in § 50.46a(f) have been met. As described in RG 1.174, the technical acceptability of a PRA should be commensurate with the application for which it is intended; the level of detail required of the PRA should be sufficient to model the impact of the proposed change; and the effects of the changes should be appropriately accounted for. A licensee's submittal to make future changes must provide sufficient information on both the risk assessment models and how future changes will be reflected in these models, to allow the NRC to conclude that the requirement in § 50.46a(c)(3)(iii) is met.

Comment. Requirements on late containment failure should be removed. It is inappropriate to require licensees to retain a level of mitigation for late containment failure and late radiological releases, because these releases constitute a very small fraction of overall plant risk. Therefore, these references should be removed.

NRC response. The NRC is proposing changes in the revised proposed rule that would make this topic moot. The commenter was remarking on the parenthetical ''(early and late)'' that was added to the containment related defense in depth element described in RG 1.174 when three of the elements were incorporated as acceptance criteria in the proposed rule. The NRC has removed the defense-in-depth acceptance criteria in the revised proposed rule, including the reference to early and late containment failures, but has retained the general criterion that defense-in-depth be maintained.

The NRC will continue to follow the guidelines in RG 1.174 to address defense-in-depth when evaluating whether a licensee has satisfied the rule criterion that defense-in-depth has been maintained. The RG 1.174 guidelines for defense-in-depth in risk-informed applications have been used successfully by the NRC for more than a decade and do not need further clarification through rulemaking. Retaining the defense-in-depth guidelines in a regulatory guide instead of promulgating acceptance criteria in the rule would also allow the NRC to more effectively update its guidance as new information becomes available or if the Commission changes its policy.

Comment. Section 50.46a(f)(4) contradicts § 50.46a(f)(5). One commenter stated that § 50.46a(f)(4) implies that only a PRA meeting the requirements of the following paragraphs may be used in the risk-informed assessment. This was seen as contradictory to § 50.46a(f)(5), which allows non-PRA risk assessment methods.

NRC response. The NRC disagrees that the rule language is contradictory. The relevant phrase in § 50.46a(f)(4) states that ''* * * to the extent that a PRA is used in the risk-informed assessment, it must * * *,'' meet the following PRA requirements. If a PRA need not be used according to § 50.46a(f)(1)(i) and (f)(2)(ii), and a PRA is not used, then non-PRA risk assessment methods that satisfy the requirements in § 50.46a(f)(5) may be used. No changes were made in the revised proposed rule.

Comment. Performance monitoring is already covered by Appendix B to Part 50. One commenter stated that the proposed requirement for a monitoring program designed to detect and prevent degradation of systems, structures, and components (SSCs) before plant safety is compromised is unnecessary. The commenter stated that 10 CFR Part 50, Appendix B, Criterion XVI for corrective action already contains this requirement.

NRC response. The NRC does not agree. Appendix B to 10 CFR Part 50 applies to safety-related SSCs and activities. The risk-informed decision process includes risk models that consider a much broader set of accidents and can credit a larger set of equipment and actions to mitigate these accidents than the set of safety-related equipment or actions. The NRC believes that performance measurement is an important part of risk-informed decision making that must be applied irrespective of the classification of an SSC or activity as ''safety-related.'' The performance monitoring requirement remains in the revised proposed rule.

Comment. Power uprates and relaxation of the single failure criteria for breaks larger than a TBS LOCA could result in a situation when all emergency power supplies are needed to successfully mitigate a break larger than the TBS when accompanied by a loss-of-offsite power. The potential consequences of relying on the availability of offsite power supply in a deregulated environment or a requirement to have both divisions of onsite power available (without single failure capability) to mitigate the uprated reactor accident would not appear to be offset by any compensatory factors.

NRC response. The NRC agrees that licensees who adopt § 50.46a could potentially make changes to the facility such that all emergency onsite power supplies were required to demonstrate successful mitigation of a break larger than the TBS when accompanied by a loss-of-offsite power. Such an operating configuration would not be permitted by the current regulations. Licensees who adopt § 50.46a would have the flexibility to make facility changes that would not normally be permitted by current ECCS regulations but must comply with all the requirements of § 50.46a. One requirement is to demonstrate that all changes made under the rule meet the risk acceptance criteria in § 50.46a(f) before the facility change may be implemented. Another requirement is that the change in risk from all changes to the facility must be periodically assessed and steps must be taken if the result exceeds the acceptance criteria in § 50.46a(f)(2). If changes to the plant-specific emergency power configuration and/or grid reliability over time result in risk increases exceeding the acceptance criteria, the plant changes that would permit this operating configuration may not be implemented, or other steps must be taken to reduce overall facility risk.

However, in response to the ACRS recommendation in the November 16, 2006, letter from Graham Wallis to Chairman Dale E. Klein, (ML063190465), to increase the level of defense-in-depth provided by the rule for mitigating LOCAs larger than the TBS, the NRC has modified the revised proposed rule with respect to the availability of onsite electrical power. The NRC has added the requirement that all equipment needed to mitigate pipe breaks larger that the TBS must be designed so that onsite power can be provided to the equipment. Onsite power may be provided automatically or as the result of manual actions taken by facility staff within a time frame that provides mitigation of damage and accident consequences. Although the ECCS analyses for pipe breaks larger than the TBS may still assume the availability of offsite power, the availability of onsite power to the necessary equipment provides additional defense-in-depth for postulated large break accidents.

E. Comments Related to the Applicability of the Backfit Rule

Comment. Commenters stated that the proposed rule provision limiting the applicability of the backfit rule is unnecessary. These commenters stated that the rule requires maintaining a mitigation capability up to the largest LOCA, regardless of the size of the TBS. The NRC should either apply the backfit rule to future changes in the TBS, or define a set of criteria defining how and when the NRC would determine that the TBS is no longer acceptable. Licensees should be provided with a great deal of latitude on achieving compliance following any change in the TBS, with the goal being that risk requirements are achieved with a reasonable mix of prevention and mitigation.

NRC response. The NRC disagrees, for the most part, with the comments on this question. Because the estimated low LOCA frequency and corresponding low risk of large LOCAs is necessary to maintain assurance of public health and safety with this risk-informed regulation, the NRC believes that the exclusion of TBS changes from the backfit rule must be maintained in case future changes in estimated LOCA frequency require changes to the TBS.

With respect to a commenter's argument about the continuing regulatory requirement for LOCA mitigative capability beyond the TBS, the NRC notes that even though mitigative capability is retained, the proposed beyond-TBS mitigative capability is reduced, as compared to the capability required under the current ECCS rule. In developing the proposed rule, the NRC recognized the open-ended nature of the backfit exclusion. The NRC attempted to develop criteria for assessing whether new information mandates a change to the TBS. Unfortunately, the NRC was unable to develop relatively clear criteria and it was concluded that adoption of generalized criteria for constraining the NRC in future changes to the TBS would not prove useful or practical. Thus, the proposed rule did not set forth proposed criteria for assessing whether new information mandates a change to the TBS. The NRC notes that no commenter suggested any criteria for assessing the need for, or desirability of, changes to the TBS based upon new information.

The NRC agrees that the proposed amendment should provide licensees with substantial flexibility to determine the manner in which they would come back into compliance with applicable regulatory requirements following any future change in the TBS. Licensees who must take actions to come back into compliance need not return the plant to the precise conditions and circumstances in effect immediately before implementation of the § 50.46a regulation. Rather, licensees should be afforded the flexibility of deciding what actions to implement to comply with a revised TBS. Further, as one of the commenters suggests, the overall goal of any actions taken to restore compliance is to achieve a reasonable mix of prevention and mitigation. The NRC will consider making this clear in implementing guidance. For these reasons, the NRC has decided to adopt the exclusion of future TBS changes from the backfit rule by retaining the provisions of proposed §§ 50.46a(m) and 50.109(b)(2) in the revised proposed rule.

Comment. Proposed §§ 50.109(b)(2) and 50.46a(d)(5) should not be adopted, and any changes to the TBS should be accomplished by rulemaking, and evaluated under the backfit rule. Excluding future changes to the TBS from compliance with the backfit rule would defeat the goal of regulatory stability embodied in the backfit rule and may result in changes that are not cost-justified.

NRC response. The NRC disagrees with the comment that the NRC's three reasons for excepting TBS changes and any consequent licensee reanalyses and changes from the backfit rule do not address how the objectives of the backfit rule are met. On the contrary, the NRC's first reason (consideration of costs and benefits in a regulatory analysis) and the third reason (flexibility may reduce impacts of changes in the TBS) directly address the underlying objectives of the backfit rule. In addition, the second reason (application of the backfit rule favors incremental increases in risk) is relevant to the backfit rule's ''substantial increase in protection'' criterion. A backfitting standard that limits increases in protection to public health and safety or common defense and security to those which are both substantial and cost-justified, but ignores (or allows) incremental decreases in protection without restriction does not seem to be a justifiable regulatory approach. Hence, the NRC believes that adoption of criteria to control these incremental decreases is justifiable and appropriate, even if inconsistent with the objective of regulatory stability, which is, arguably, the primary objective of the backfit rule.

Finally, the NRC agrees that the goal of regulatory stability is not negated by the fact that a licensee's decision to comply with § 50.46a rule would be optional or voluntary. On the contrary, the NRC believes that regulatory stability should be an important factor in developing a rule. However, the NRC disagrees with the commenter's implicit assertion that, absent consideration under the backfit rule, regulatory stability would not be appropriately considered in any future revisions to the TBS. As the NRC stated in the statement of considerations in the proposed rule, a regulatory analysis would be required for any revision to the TBS. (See 70 FR 67617–67618.) This regulatory tool provides an appropriate means of ensuring that regulatory stability is considered by the NRC when determining whether to revise the TBS.

Comment. The NRC should not adopt the backfitting exclusion provision in § 50.46a(d), which would require that any facility changes made necessary by the maintenance and upgrading of risk assessments, would not be deemed to be backfitting.

NRC response. The NRC disagrees with this comment, which was part of a broader comment opposing the proposed rule's provision excluding from backfit consideration changes to a plant and its procedures that are necessitated by any future TBS changes mandated by the NRC (*see* the immediately-preceding comment analysis). The commenter did not provide a separate basis supporting its position that licensee changes necessitated by the periodic risk assessment maintenance and upgrading (as contrasted with NRC-mandated TBS changes) should be subject to backfitting consideration.

The NRC believes that the policy and regulatory considerations with respect to backfitting of changes stemming from future TBS changes are irrelevant to the policy and regulatory considerations with respect to backfitting of changes required to maintain compliance with updated risk analyses. The NRC regards plant changes necessitated by periodic risk assessments under § 50.46a to be analogous (from a backfitting standpoint) to the 120-month updating of inservice inspection (ISI) and inservice testing (IST) under § 50.55a(f) and (g). Under those provisions, a licensee must update its ISI and IST program every 120 months to the latest version of the ASME Code in effect 12 months before the beginning of the next inspection interval. The NRC has stated that the 120-month updating does not constitute backfitting, in part because the regulatory requirement for updating is known to the operating license applicant before it receives its license, which addresses the policy of regulatory stability and predictability embodied in the backfit rule. *See* 69 FR 58804, 58817 (third column) (October 1, 2004); 67 FR 60520, 60536–60537 (September 26, 2002). This logic also applies to the periodic risk assessment maintenance and upgrading under § 50.46a(d)(4) and any necessary licensee actions necessary to maintain compliance with the relevant 50.46a acceptance criteria. The NRC also notes that § 50.46a does not prescribe any specific manner or approach for achieving compliance following the periodic risk assessment maintenance and upgrading under § 50.46a(d)(4); this performance-based approach to regulation affords the licensee substantial flexibility and gives the licensee control over how best to achieve compliance. This further tends to reduce the impact of § 50.46a(d)(4) on licensees, which is an implicit objective of the backfit rule. For these reasons, the NRC declines to adopt the commenter's recommendation.

Comment. The fact that the proposed rule provides an alternative or voluntary approach for LOCA analysis does not negate either the backfit rule itself or the policy of regulatory stability.

NRC response. The NRC disagrees with the comment. As discussed elsewhere in the backfitting discussion, the backfit rule's protections apply only when the NRC is imposing (directly or indirectly) a change to the activities authorized by a license; it does not apply when the NRC is providing a regulatory approach as an alternative to compliance with an existing regulatory requirement. As a general matter, the regulatory stability and predictability afforded to a licensee by the backfit rule applies to the scope of activities approved by the license. If a licensee seeks a change to its licensing basis—which is what a transition to a voluntary alternative is—the licensee is seeking to do something that is not within the scope of activities authorized by its license. It is the NRC's view that, in such a circumstance, the licensee has no reasonable expectation that the NRC's criteria for judging the acceptability of that proposed change remains the same as the criteria used by the NRC in judging the original license application. Thus, the protections of the backfit rule do not apply either when a licensee seeks a voluntary change to its licensing basis, or when the NRC develops a voluntary alternative.

Comment. The NRC set forth three justifications for excepting TBS changes from backfitting protection: the consideration of alternatives will occur in the required regulatory analysis; application of the backfitting rule effectively favors increases in risk; and the flexibility provided by the rule will tend to reduce the burden of any changes in the TBS. However, even if these justifications are true, they do not address how the objective of the backfit rule will be met or that this objective does not apply.

NRC response. The NRC disagrees in part with this comment. The NRC views the backfit rule as having three underlying objectives: regulatory stability and predictability for a licensee; reasoned agency decisionmaking (that NRC's decision to impose a backfit is assessed against rational criteria); and transparency of agency decisionmaking (that the reasons for the NRC's determination on the overall backfiting criteria are publicly available). The second and third objectives would be met if the NRC imposes future TBS changes by rulemaking (which is by far the most likely course), inasmuch as such a rulemaking must include preparation of a regulatory analysis. A regulatory analysis which is performed in accordance with the NRC's ''Regulatory Analysis Guidelines'', NUREG/BR–0058, Revision 4 (2004), provides for a disciplined agency decisionmaking process. The draft regulatory analysis is published and made available for public comment as part of the proposed rule. The final regulatory analysis, which addresses public comments, is also made available to the public as part of the final rulemaking. Hence, the NRC believes that the backfit rule's objectives of reasoned decisionmaking and transparency of agency decisionmaking will be satisfied by any rulemaking changes to the TBS. With respect to the first objective of the backfit rule, the NRC recognizes that exclusion of future changes to the TBS from the backfit rule could lead to reduced regulatory stability and predictability because neither the adequate protection, compliance, or substantial safety increase criteria would be binding as checks against unwarranted agency action. However, the NRC believes that this is offset to some extent by two factors. First, by explicitly excluding future TBS changes and necessary changes from the backfit rule, licensees who choose to adopt § 50.46a are aware that the NRC may revise the TBS in the future (the argument here is similar to the Commission's determination that the backfit rule does not apply to rulemakings endorsing more recent editions and addenda of the ASME Code for mandatory use in the 120-month interval process for ISI and IST in §§ 50.55a(f) and (g)). Second, the NRC acknowledges that plant-specific orders imposing TBS changes would not necessarily meet all of the backfit rule objectives. However, the NRC's internal process governing the development and issuance of orders should, at minimum, result in reasoned decisionmaking. Moreover, as is the case with rulemaking changes to the TBS, regulatory predictability for changes to the TBS by order is addressed somewhat by explicitly stating in both §§ 50.109 and 50.46a that the backfit rule does not apply if a revised TBS is imposed by order. These provisions provide notice to licensees considering adoption of § 50.46a of the special backfitting process under § 50.46a. Licensees contemplating adoption of § 50.46a may then factor this limited exclusion from the backfit rule into their decision whether to adopt § 50.46a.

Comment. The Commission-proposed exclusion of TBS changes from backfitting protection would leave licensees who voluntarily adopt § 50.46a without recourse to a backfit appeal process.

NRC response. The NRC disagrees with the comment. Licensees who adopt § 50.46a would continue to have access to the backfitting appeals process with respect to licensee-claims of backfit for all matters other than those attributable to TBS changes.

Further, affected licensees would have an opportunity to raise concerns about the cost and expected benefits of proposed TBS changes, whether the TBS changes are imposed by rulemaking or by order. If the TBS were accomplished through rulemaking, all licensees would have an opportunity to comment on the proposed rule, including the associated regulatory analysis. By contrast, if the NRC imposes a TBS change by order, the affected licensee would have an opportunity to request a hearing on the order. During this hearing any issues could be raised on costs and benefits for the TBS change as applied to that licensee. Although these opportunities do not constitute, strictly speaking, a backfit appeal process, the NRC believes that they are the functional equivalent of a backfit appeal process.

Finally, as noted earlier, it is the NRC's expectation that should it mandate a change in the TBS, that licensees would have substantial discretion and flexibility with respect to how they would address that TBS change. Accordingly, the NRC sees no additional benefit from providing a licensee with a plant-specific backfitting appeal process related to TBS changes in addition to the public comment and hearing opportunities already provided for by law.

F. Comments on Topics Requested by the Commission

In the initial proposed rule, the NRC identified 16 significant topics associated with the proposal and invited the public to submit specific comments on those issues. (*See* 70 FR 6718—6719.)

NRC Topic 1. In proposed § 50.46a(b), the NRC specifically precludes the application of the § 50.46a alternative requirements to future reactors. However, future light water reactors might benefit from § 50.46a. The NRC requests specific public comments regarding whether § 50.46a should be made available to future light water reactors.

Comments. Framatome commented that § 50.46a should be available to nuclear power plants licensed after the publication of the rule that are of similar design to the current generation of operating BWRs and PWRs. Framatome stated that the advanced LWR designs previously certified (ABWR, System 80+, AP 600, AP 1000), under design certification review (ESBWR) and in the pre-review process (US EPR), all fit into this category and can realize benefits from § 50.46a. However, for § 50.46a to apply to a new design, the NRC must first make a determination that the design is substantially similar to currently operating LWRs. The applicability to the new design of the frequency of pipe rupture versus break size curves used as a basis for establishing the TBS in § 50.46a must be established. The WOG stated that future PWRs and BWRs operating with materials, pressures and temperatures similar to operating LWRs should be able to use § 50.46a because there is no technical reason that new plants should have to meet outdated requirements for which existing plants can opt out. The BWROG and three other commenters also stated that § 50.46a should be made available to future light water reactors.

NRC response. The NRC agrees with the commenters who stated that there are no technical reasons which prevent the new § 50.46a regulations from being applied to new light water reactor designs that are similar in nature (with respect to design and expected LOCA pipe break frequency) to current operating reactors. However, it would be difficult to apply the new regulation to certified reactor designs which have already received NRC approval. These design approvals were completed as rulemaking activities for the particular standardized design as of the date of the application, as amended. Changes may not be made to these designs unless the designers choose to resubmit the designs for reevaluation and reopen the design approval/rulemaking process to address § 50.46a. Moreover, it is not clear that these changes could be made under the special backfitting criteria in § 52.63, because it does not appear that there is an issue related to adequate protection, compliance with requirements in effect at the time of certification, reduction of unnecessary burden, providing detailed design information, correcting material errors in the certification information, increasing standardization, or providing a substantial increase in overall safety, reliability, or security.

Three new standardized LWR designs and one resubmitted LWR design are now being considered by the NRC. Although the NRC has not performed a detailed analysis of these new designs in the manner done for establishing the technical basis of this rule for existing designs, the frequency of large LOCAs at these facilities could be as low as it is at current LWRs. Thus, it may be appropriate to apply the alternative § 50.46a requirements to these future designs. Accordingly, the revised proposed rule has been modified to apply to new reactor designs, e.g. facilities other than those which are currently licensed to operate. Applicants for design certification or combined licenses, holders of combined licenses under Part 52, or future licensees of operating new 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 for the new design to meet the intent of § 50.46a.

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 reactor design to current reactor designs licensed before the effective date of the rule, the applicant, holder, or licensee would 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 generic results in NUREG–1829 and NUREG–1903.

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 proposed rule. For 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 be necessary. The methodology used to determine the proposed TBS should be described in the justification. 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. Therefore, based on information currently available, the NRC envisions that the TBS defined in the revised proposed rule could be applicable to the new reactor designs.

In addition, a holder of an operating or combined license for a plant with a currently approved standard design could adopt § 50.46a if the design is demonstrated, by satisfying the five criteria above, to be similar to the designs of plants licensed before the effective date of the rule and the TBS proposed by the licensee is found acceptable by the NRC.

In the revised proposed rule language and elsewhere in this document, whenever the NRC refers to similarity of the designs of new reactors to the designs of current operating reactors, the NRC intends for ''design'' to be broadly interpreted to encompass design, construction and fabrication, and operational factors that should be addressed, at a minimum, by considering the five similarity factors indentified above.

NRC Topic 2. The TBS specified by the NRC in the proposed rule does not include an adjustment to address the effects of seismically-induced LOCAs. NRC is currently performing work to obtain better estimates of the likelihood of seismically-induced LOCAs larger than the TBS. By limiting the extent of degradation of reactor coolant system piping, the likelihood of seismically-induced LOCAs may not affect the basis for selecting the proposed TBS. However, if the results of the ongoing work indicate that seismic events could have a significant effect on overall LOCA frequencies, the NRC may need to develop a new TBS. To facilitate public comment on this issue, a report from this evaluation will be posted on the NRC rulemaking Web site at *http://ruleforum.llnl.gov* before the end of the comment period. Stakeholders should periodically check the NRC rulemaking Web site for this information. [The NRC published the report on December 20, 2005 (70 FR 75501; ML053470439).] The NRC requests specific public comments on the effects of pipe degradation on seismically-induced LOCA frequencies and the potential for affecting the selection of the TBS. The NRC also requests public comments on the results of the NRC evaluation that will be made available during the comment period.

NRC response. Comments received on this topic were previously discussed in Section IV.B. of this document, ''Comments on Seismic Considerations Related to the TBS.'' Because this topic was identified for public comment in the initial proposed rule, the NRC completed and published the study on the risks associated with seismically induced LOCAs larger than the TBS (NUREG–1903, ''Seismic Considerations for the Transition Break Size'' February 2008; ML080880140). The NRC considered the public comments received on seismic considerations in the final version of NUREG–1903. As previously discussed in Section IV.B of this document, the NRC has concluded that no adjustment to the TBS is needed to account for seismically-induced LOCAs.

NRC Topic 3. Depending on the outcome of an ongoing NRC study, the final rule could include requirements for licensees to perform plant-specific assessments of seismically-induced pipe breaks. These assessments would need to consider piping degradation that would not be prejudiced by implementation of the licensee's inspection and repair programs. The assessments would have to demonstrate that reactor coolant system piping will withstand earthquakes such that the seismic contribution to the overall frequency of pipe breaks larger than the TBS is insignificant. The NRC requests specific public comments on this and any other potential options and approaches to address this issue.

NRC response. After this topic was identified, the NRC completed and published the study on the risks associated with seismically-induced LOCAs larger than the TBS (NUREG–1903, ''Seismic Considerations for the Transition Break Size'' February 2008; ML080880140). Comments received on this topic were previously addressed in Section IV.B of this document, ''Comments on Seismic Considerations Related to the TBS.'' The NRC has concluded that applicants wishing to implement the alternative ECCS requirements should conduct a plant-specific assessment of the risk associated with seismically-induced failures of flawed piping. The NRC is currently preparing guidance for conducting these plant-specific assessments (''Plant-Specific Applicability of 10 CFR 50.46 Technical Basis'' February 2009; ML090350757).

NRC Topic 4. The ACRS noted that ''a better quantitative understanding of the possible benefits of a smaller break size is needed before finalizing the selection of the transition break size.'' The TBS to be included in the final rule should be selected to maximize the potential safety improvements. Thus, the NRC is soliciting comments on the relationship between the size of the TBS and potential safety improvements that might be made possible by reducing the maximum design-basis accident break size.

NRC response. No comments were received which specifically addressed the relationship between the size of the TBS and potential safety improvements that might be made possible by reducing the maximum design-basis accident break size. However, the WOG stated, ''It is not appropriate to set the TBS on the basis of where the most benefit is, as this may change tomorrow and there will be no easy recourse.'' This comment and other related issues were previously discussed in Section III.A of this document, ''Comments on Selection of the TBS''. The NRC made no changes to the size of the TBS in the revised proposed rule.

NRC Topic 5. Proposed § 50.46a includes an integrated, risk-informed change process to allow for changes to the facility following reanalysis of beyond design basis LOCAs larger than the TBS. However, because the current regulations in 10 CFR part 50 already have requirements addressing changes to the facility (§§ 50.59 and 50.90), it might be more efficient to include the integrated, risk-informed change (RISP) requirements for plants that use § 50.46a under these existing change processes. The NRC solicits specific public comments on whether to revise existing §§ 50.59 and 50.90 to accommodate the requirements for making facility changes under § 50.46a.

Comments. Three commenters responded directly to this question. One stated that §§ 50.59 and 50.90 should not be revised to accommodate the requirements for making plant changes under § 50.46a. Another stated that § 50.59 requirements could be augmented to address the risk evaluations but that the augmentation was not necessary. The third commenter stated that §§ 50.59 and 50.90 should contain change requirements for § 50.46a but that these requirements should not be the RISP requirements included in the proposed rule.

NRC response. The NRC is not changing §§ 50.59 and 50.90 to include integrated, risk-informed change requirements. The NRC has modified the risk-informed change control process to apply only to facility changes made under the rule, *i.e.,* facility changes enabled by the rule as well as other facility changes unrelated to the rule but bundled together by the licensee for estimating the change in risk. Other facility 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 TBS. The NRC changed the process to more closely follow the process described in RG 1.174, which has been used successfully for a wide variety of risk-informed applications. The NRC has concluded that this risk-informed change control process can be used to successfully and safely implement facility changes enabled by the new TBS LOCA in the § 50.46a final rule.

NRC Topic 6. The proposed rule would rely on risk information. The NRC has included specifically applicable PRA quality and scope requirements in the proposed rule. However, there are other NRC regulations that also rely on risk information (*e.g.* the maintenance rule in § 50.65 and § 50.69 pertaining to alternative special treatment requirements). Consistent with the Commission policy on a phased approach to PRA quality, it might be more efficient and effective to describe PRA requirements (*e.g.,* contents, scope, reporting, changes, *etc.*) in one location in the regulations so that the PRA requirements would be consistent among all regulations. The NRC is seeking specific public comments on whether it would be better to consolidate all PRA requirements into a single location in the regulations so that they were consistent for all applications or to locate them separately with the specific regulatory applications that they support.

Comments. Five commenters recommended that it would be preferable to collect all PRA requirements in a single location in the regulations, but they all also stated that it would be premature to use the § 50.46a rulemaking to combine PRA requirements at the present time. Some commenters argued that different applications have different requirements for the supporting PRA analyses and cautioned that PRA requirements should not be based on the most demanding application.

NRC response. The NRC takes note of the recommendation that PRA requirements be eventually collected into a single location in the regulations. The NRC agrees that the § 50.46a rulemaking is not the appropriate vehicle to achieve this regulatory change. The NRC will include PRA requirements adequate to support this rulemaking in the § 50.46a rule. After the NRC develops broad-based PRA requirements suitable for use on a generic basis in different applications, the NRC will be able to codify these generic PRA requirements in a single regulatory location and could remove the § 50.46a specific PRA requirements (or limit them to existing licensees approved under § 50.46a to avoid backfitting).

NRC Topic 7. Proposed § 50.46a would include the requirement that all allowable at-power operating configurations be included in the analysis of LOCAs larger than the TBS and demonstrated to meet the ECCS acceptance criteria. Historically, operational restrictions have not been contained in § 50.46 but were controlled through other requirements (*e.g.,* technical specifications and maintenance rule requirements). It might be more practical to control the availability of equipment credited in the beyond design-basis LOCA analyses in a manner more consistent with other operational restrictions. As a result, the NRC is soliciting public comments on the most effective means for implementing appropriate operational restrictions and controlling equipment availability to ensure that ECCS acceptance criteria are continually met for beyond design-basis LOCAs.

Comment. As previously discussed, all commenters stated that the NRC should not include the operational restriction that all allowable at-power operating configurations be demonstrated to meet the ECCS acceptance criteria. Several commenters proposed alternatives ranging from placing limits that might be required in licensee-controlled documentation to eliminating all operational restrictions associated with breaks greater than the TBS. Most commenters stated that operational restrictions negated the relief from the requirement to assume the worst single failure during the evaluation of beyond TBS breaks.

NRC response. As discussed in Section III.D of this document, the NRC has decided that operational restrictions must be retained if it cannot be demonstrated in the analysis of LOCAs larger that the TBS that the ECCS acceptance criteria are met, but the restrictions would be reduced. The proposed rule prohibited at-power operation in a configuration without the demonstrated ability to mitigate a LOCA larger than the TBS. The revised proposed rule would require that at-power operation in such a configuration shall not exceed a total of fourteen days in any 12-month period. The NRC believes that this change will satisfy the Commission's intention that mitigative capability be maintained for all breaks up to the double-ended rupture of the largest reactor coolant pipe and still allow a reasonable amount of time for licensees to make corrective actions needed to restore the plant to a fully analyzed configuration.

NRC Topic 8. Given the Commission's intent (see SRM for SECY–04–0037) that facility changes made possible by this proposed rule should be constrained in areas where the current design requirements ''contribute significantly to the 'built-in capability' of the plant to resist security threats,'' the NRC seeks examples on either side of this threshold (facility changes allowed versus facility changes prohibited), and additionally any examples of facility changes made possible by § 50.46a that could *enhance* plant security and defense against radiological sabotage or attack. The NRC also solicits comments on whether the proposed § 50.46a rule should explicitly include a requirement to maintain plant security when making facility changes under § 50.46a or otherwise rely on a separate rulemaking now being considered by the NRC to more globally address safety and security requirements when making facility changes under §§ 50.59 and 50.90. Any examples of facility changes that involve safeguards information should be marked and submitted using the appropriate procedures.

Comments. On the first question regarding examples of facility changes that should or should not be constrained in areas where the current design requirements ''contribute significantly to the 'built-in capability' of the plant to resist security threats,'' NEI said that the proposed rule would not enable facility changes that reduce plant safety margins as well as the capacity to deal with security threats. NEI stated that the opposite is true because the proposed rule would increase the safety focus on risk-significant events and mitigating equipment, and improve the reliability and availability of this equipment by removing excessive conservatism from the design basis.

On the second question as to whether the § 50.46a rule should contain a security requirement, NEI said that existing change control requirements in the regulations preclude significant reductions in safety or security. The BWROG supported the NEI position on this issue. The WOG stated that the security-related aspects of facility changes that might be enabled by this rule change should be addressed in the evaluation of those specific facility changes. The WOG also stated that the changes to § 50.46a should not be tied to security issues. Making a ''security connection'' to this proposed amendment would introduce needless complications and be counterproductive. Issues related to preserving ''built-in capability'' of the plant to resist threats should be addressed centrally in a single location within the regulations. Maintaining all requirements related to security in one place, either in the regulations or in Commission policy, is the most appropriate way to avoid conflicting information and enhance the ease of change. Progress Energy stated that consideration for security concerns should be included in the consideration of safety concerns to avoid possible negative effects caused by these sometimes competing objectives. However, to simplify the processes and maintain consistency, the safety and security interface should be addressed globally by a separate rulemaking.

NRC response. The NRC agrees with commenters that security requirements should be addressed by regulations separate from those in § 50.46a. The NRC is not adding security requirements to proposed § 50.46a. Security requirements will continue to be addressed by overall security requirements located elsewhere in the regulations. Specifically, 10 CFR 73.58, ''Safety/security Interface Requirements for Nuclear Power Reactors'' of the new Power Reactor Security Rule (74 FR 13926; March 27, 2009), requires licensees to communicate plans for proposed plant changes that could impact plant security to security personnel who are qualified to analyze and identify potentially adverse impacts that the changes may have on safety and/or security programs. After security personnel analyze the changes for potential impacts, the regulation requires the licensee to take appropriate actions to mitigate the security impacts.

NRC Topic 9. Given the potential impact to the licensee (because the backfit rule would not apply) of the NRC's periodic re-evaluation of estimated LOCA frequencies which could cause the NRC to increase the TBS, should the proposed rule require licensees to maintain the capability to bring the plant into compliance with an increased transition break size (TBS), within a reasonable period of time?

Comments. NEI, the BWROG, and the WOG commented that licensees should be provided with a great deal of latitude on achieving compliance following any change in the TBS, with the goal being that risk requirements are achieved with a reasonable mix of prevention and mitigation.

NRC response. The NRC agrees with commenters that the § 50.46a rule should provide licensees with substantial flexibility to determine how they will come back into compliance with applicable regulatory requirements following any future change in the TBS. Licensees who must take actions to come back into compliance need not return the plant to the precise conditions and circumstances in effect immediately before implementation of § 50.46a. Rather, licensees would be afforded the flexibility of deciding what actions they will implement to bring about compliance under any revised TBS. Further, as one of the commenters suggests, the overall goal of any actions taken to restore compliance is to achieve a reasonable mix of prevention and mitigation.

NRC Topic 10. Is the proposed rule sufficiently clear as to be ''inspectable?'' That is, does the rule language lend itself to timely and objective NRC conclusions regarding whether or not a licensee is in compliance with the rule, given all the facts? In particular, are the proposed requirements for PRA quality sufficient in this regard?

Comment. On the question of whether the proposed rule is clear enough to be inspectable, NEI was particularly concerned that the operational restrictions would conflict with the existing technical specifications. The BWROG supported the NEI position on this topic.

NRC response. To reduce potential conflict between plant technical specifications and the operability requirements in § 50.46a, the NRC has also modified operability requirements to allow limited operation (for no more than a total of fourteen days in any 12-month period) in configurations where mitigation of LOCAs larger that the TBS has not been demonstrated. A detailed discussion on the basis for this new provision is provided below in Section V.F of this document, *Operational Requirements.*

Comment. NEI stated that the rule would be difficult to inspect because it overlaps so many existing regulatory requirements. The WOG stated that the risk-informed aspects of the proposed rule, including the PRA quality requirements, should rely on the guidance of RG 1.174 and RG 1.200. The WOG stated that proposed § 50.46a should require no more ''inspectability'' than any other performance-based risk-informed application. Another commenter stated that the NRC should clarify certain aspects of the proposed rule and that the rule appropriately includes language like ''reasonable balance'' that requires a knowledgeable individual to exercise judgment which should be informed by appropriate regulatory guidance documents.

NRC response. The NRC has modified the proposed rule to provide greater operational flexibility and reduce the potential for conflict with plant technical specification requirements that might cause ''inspectability'' problems. Although the WOG stated that the proposed rule would not have inspectability problems if it relied on the guidance in RG 1.174 and RG 1.200, the NRC notes that inspectors may not inspect licensees for compliance with regulatory guides because these guides are not regulatory requirements. The NRC has incorporated the important aspects of RG 1.174 and PRA quality guidance into the revised proposed rule itself so that inspectors would have a clear indication of the § 50.46a requirements. Specific inspection guidance will be developed as necessary after the final rule is published.

NRC Topic 11. Proposed § 50.46a would impose no limitations on ''bundling'' of different facility changes together in a single application. Facility changes which would increase plant risk substantially or create risk outliers could be grouped with other facility changes which would reduce risk so that the net change would meet the risk acceptance criteria. Are the net change in risk acceptance criteria in the proposed rule adequate or should some additional limitations be imposed to avoid allowing facility changes which are known to increase plant risk?

Comments. Several commenters said that ''bundling'' is essential for meeting the objectives of this proposed rule which concerns overall plant risk. Bundling provides licensee management with the necessary flexibility to reallocate resources for implementation of the alternative requirements. The RG 1.174 criteria related to bundling (combined change request in RG 1.174) are sufficient and no additional criteria or restrictions on bundling should be imposed by this proposed rule.

NRC response. The NRC agrees that bundling of facility changes is desirable because it appropriately permits licensees to credit risk beneficial facility changes and encourages licensees to identify and implement facility changes that decrease risk. The NRC also agrees that the guidelines on combined changes in RG 1.174 are sufficient to avoid facility changes which would unacceptably increase plant risk.

NRC Topic 12. Is there an alternative to tracking the cumulative risk increases associated with facility changes made after implementing § 50.46a that is sufficient to provide reasonable assurance of protection to public health and safety and common defense and security?

Comments. Four of the commenters who responded to the question stated that tracking cumulative risk increases was reasonable but they appeared to define cumulative tracking differently than as specified in the requirements of the proposed rule. NEI, whose comments were generally endorsed by most of the 12 commenters, recommended rule text stating ''[t]he licensee shall periodically assess the cumulative effect of changes to the plant design configuration and update as necessary, the PRA and other risk analyses.'' After discussing this proposed text at the June 28, 2006, public meeting, the NRC determined that the recommendation equated tracking cumulative risk increases with periodically updating the PRA and estimating the latest core damage frequency (CDF) and large early release frequency (LERF) using the updated PRA. NEI intended for these latest risk estimates themselves to represent the assessment of the cumulative increase. However, the proposed rule required that some previous estimates of CDF and LERF be subtracted from the latest estimates to obtain the amount by which the CDF and LERF has increased. One of the four commenters added that tracking the cumulative risk increase (as intended by the NRC in the proposed rule) was not necessary because the threshold for risk increase is low enough so that the cumulative effect is not significant. A fifth commenter argued that tracking cumulative risk should not be required by the rule because compliance with the guidance in RG 1.174 should be sufficient to ensure that cumulative risk does not impact the health and safety of the public.

NRC response. The NRC has retained the requirement to track the total risk increases in CDF and LERF made under the proposed rule and has retained the definition of risk ''increase'' as being the amount by which risk increases. RG 1.174 provides guidance on judging the acceptability of proposed facility changes based primarily on the amount by which the facility changes increase CDF and LERF. The NRC has clarified what it has concluded must be tracked in § 50.46a(f)(2)(iv) utilizing the requirement for tracking the cumulative effect on risk of changes made under the NFPA–805 standard which was incorporated by reference into § 50.48(c) (*see,* 69 FR 33536; June 16, 2004). By utilizing the same language in both rules, the NRC intends that the implementation of both rules would be consistent.

The NRC has concluded that the alternative proposed by the commenters (*i.e.* to track cumulative risk by simply updating the PRA) is not acceptable because the latest estimates of CDF and LERF alone provide insufficient information to be used in the risk-informed framework contained in RG 1.174. Two other commenters argued that risk tracking is not needed because controls external to proposed § 50.46a (e.g., in RG 1.174) would ensure that the cumulative effect would not be significant. The commenters provided no basis for their assertions that controls external to the rule would keep increases in risk small enough to ensure protection of public health and safety. RG 1.174 does discuss tracking changes in cumulative risk, but regulatory guides are not enforceable requirements. The NRC has determined that it is necessary to establish a regulatory requirement to track the cumulative risk increases from all changes made under this proposed rule. The NRC continues to believe that risk tracking as described in the proposed rule is needed to ensure that facility changes permitted by the revised ECCS analyses under § 50.46a do not result in greater increases in risk than were intended by the Commission.

NRC Topic 13. The NRC requested specific public comments on the acceptability of applying the change in risk acceptance guidelines in RG 1.174 to the total cumulative change in risk from all changes in the plant after adoption of § 50.46a. Should other risk guidelines be used and, if so, what guidelines should be used?

Comments. As discussed, four commenters proposed tracking cumulative risk increases by periodically updating the PRA, estimating the latest CDF and LERF using the updated PRA, and equating these latest estimates with tracking the cumulative risk increase. Applying this definition for tracking cumulative risk increase, these commenters concluded that the change in risk acceptance guidelines should not be applied to the total cumulative change in risk which would not, under their proposals, be estimated.

In general, most commenters' either explicitly or implicitly recommended that the rule should not include the acceptance criteria that ''the total increases in CDF and LERF should be small and the overall risk should remain small.'' Proposals for alternatives varied. NEI's proposed rule text did not include acceptance criteria related to increases in CDF and LERF. Instead, NEI proposed requiring the licensee to report the results of the updated PRA and other risk analyses to the NRC. One commenter argued that for facility changes enabled by the new § 50.46a, compliance with RG 1.174 should be sufficient. Two commenters stated that risk tracking accomplished by updating the PRA and estimating the latest CDF and LERF can be used to ensure that the total risk as well as the risk from specific initiators or classes of accidents is not increasing.

NRC response. The NRC has retained the requirement in the revised proposed rule that the total change in risk from facility changes, measured as the amount by which CDF and LERF (or LRF for new reactors) increase, be tracked and compared to the RG 1.174 acceptance criteria. However, the NRC has reduced the scope of facility changes that must be tracked from all changes to only those changes made to the plant under § 50.46a. Implementation of all RG 1.174 guidelines can only be achieved using a process that includes an estimate of the cumulative change in risk. Also, consistent with the Commission's direction in the SRM for SECY–07–0082, the NRC has reduced the size of an acceptable risk increase from ''small'' to ''very small''. The revised proposed rule would continue to use the quantitative guidelines in RG 1.174.

NEI's proposal for reporting the latest estimates of CDF and LERF to the NRC after each periodic assessment would not be useful because the NRC has no criteria for determining which CDF and LERF values would be acceptable. It would be a lengthy process to establish such acceptance criteria. Lack of acceptance criteria against which the latest CDF and LERF can be compared will result in different stakeholders applying different criteria to judge the acceptability of the results most likely leading to different conclusions.

The NRC believes that the two comments proposing that the total CDF as well as the CDF from specific initiators or class of accidents could be tracked to ensure that risk from these scenarios is not increasing would satisfy the requirement that the total increase in risk remains very small provided that the appropriate initiators or class of accident is identified (and including LERF or LRF). The commenters did not appear to be proposing that such a constraint be included in the rule, instead they were only making observations on what would be possible. Nevertheless, in an SRM on August 10, 2007, the Commission concluded that only a very small increase in risk is acceptable when implemented according to the requirements in this rule. Requiring that there be no risk increase, as hypothesized by the commenters, is more restrictive than the criteria in the revised proposed rule.

Although the revised proposed rule would permit licensees to make plant changes that result in very small risk increases, the NRC requests stakeholder comments on whether any increase in risk should be allowed. Instead of the risk acceptance criteria allowing very small risk increases, should the acceptance criteria in the final rule require that the net effect of plant changes made under § 50.46a be risk neutral or risk beneficial? The NRC requests stakeholders to provide comments on the use of risk acceptance criteria that would not allow a cumulative increase in risk for plant changes made under § 50.46a.

NRC Topic 14. After approval to implement § 50.46a, the proposed rule would require tracking risk associated with all proposed facility changes but would not require a licensee to include risk increases caused by previous risk-informed facility changes that were implemented before § 50.46a was adopted. Licensees who adopt § 50.46a before implementing other risk-informed applications would have a smaller risk increase ''available'' compared to licensees who have already incorporated some risk-informed facility changes into their overall plant risk before adopting § 50.46a. The NRC requests specific public comments on whether this potential inconsistency should be addressed and, if so, how?

Comments. Three commenters stated that these potential inconsistencies in acceptable risk increases should be addressed by deleting the requirement that the cumulative risk increase be tracked and compared to the RG 1.174 acceptance guidelines. The commenters argued that licensees and the NRC have effectively managed incremental risk without the need for this structure and that any facility changes that seek to apply the revised design bases should be evaluated using the same methods proven effective in the past. A fourth commenter agreed with the others but proposed that inconsistencies among licensees created by the order of implementing risk-informed applications could be resolved by allowing a licensee to reestablish the baseline and removing some facility changes from tracking.

NRC response. The NRC is proposing additional changes in the revised proposed rule that would make this topic moot. The proposed rule would have required tracking total risk from all facility changes. This requirement reflected a difficulty uniquely associated with comparing the total risk increases from all facility changes to the acceptance criteria. The revised proposed rule would only require that facility changes made under the rule be tracked. Other risk-informed facility changes referred to in Topic 14 would no longer be included in this change in risk estimate and therefore, the acceptability of those facility changes will be independent of facility changes made under this rule (aside from the indirect affect these facility changes have on the plant's risk profile).

NRC Topic 15. Proposed § 50.46a would require licensees to report every 24 months all ''minimal'' risk facility changes made under § 50.46a(f)(1) without NRC review. Are there less burdensome or more effective ways of ensuring that the cumulative impact of an unbounded number of ''minimal'' changes remains inconsequential?

Comments. Several commenters stated that the § 50.46a(g)(3) report summarizing minimal risk changes every 24 months is redundant to reports required under § 50.59(d)(2) as well as § 50.71(e). Thus, § 50.46a(g)(3) should be deleted. The requirement needlessly focuses licensee and NRC resources directly on a large set of information that by its very definition has no safety or risk significance.

NRC response. The NRC agrees with the commenters that the reporting requirements in proposed § 50.46a(g)(3) could be redundant to other reporting requirements for some facility changes because some changes made under the new rule might be reportable under both § 50.59 and § 50.46a(g)(3). The NRC has determined that breaks larger than the TBS should be removed from the design basis event category. Therefore, the NRC believes that some facility changes that may be made under the new rule would no longer be reportable under § 50.59 because the change would no longer affect design basis events. The NRC is proposing to reduce the scope of facility changes that need to be evaluated under the new provision, from all changes made to the facility after adoption of the rule to only facility changes that are made under the new rule. This change would reduce the number of potentially redundant reports.

To avoid the possibility that potentially risk-significant changes are not reported, the NRC has concluded that all facility changes made under the new rule should be reported because the NRC will rely on the risk evaluation to prevent facility changes that might not be protective of public health and safety. Therefore, the NRC has retained the reporting requirements in § 50.46a(g)(3) because these requirements would ensure the reporting of all potentially risk-significant facility changes made under the proposed rule.

NRC Topic 16. Should the § 50.46a rule itself include high-level criteria and requirements for the risk evaluation process and acceptance criteria described in RG 1.174? If these criteria were included in the regulatory guide only, and not in § 50.46a, how could the NRC take enforcement action for licensees who failed to meet the acceptance criteria?

Comments. Four commenters stated that proposed § 50.46a rule should not contain the high-level criteria and requirements for the risk evaluation process and acceptance criteria described in RG 1.174. These commenters did not specifically propose how the NRC could take enforcement action to ensure compliance with the criteria, but instead asserted that regulatory guidance documents and inspection guidelines are the appropriate places for the risk acceptance criteria.

NRC response. The NRC does not agree with the commenters. The proposed rule would have to contain high-level requirements for the risk evaluation and acceptance criteria to establish the legally enforceable alternative regulatory requirements needed to ensure adequate protection of public health and safety in a manner which maximizes regulatory predictability and stability. The NRC believes that proposed § 50.46a should build upon NRC and industry experience with the key principles of risk-informed decision making set forth in RG 1.174, but notes that RG 1.174 only contains guidance, not requirements. To be enforceable, proposed § 50.46a must contain and does contain high-level requirements relating to risk, defense-in-depth, safety margins, risk, and performance measurement. Specific, detailed guidance on how to meet the high-level requirements will be set forth in regulatory guidance and inspection guidelines, as appropriate.

V. Revised Proposed Rule

A. Overview

The NRC's revised proposed rule would establish an alternative set of risk-informed requirements with which licensees may choose to comply in lieu of meeting the current emergency core cooling system requirements in 10 CFR 50.46. Using the alternative ECCS requirements would provide some licensees with opportunities to change other aspects of facility design.

As was the case in the initial proposed rule, the revised proposed rule divides the current spectrum of LOCA break sizes into two regions. The division between the two regions is delineated by the 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 RCS pipe. Break area for the TBS is not based on a double-ended offset break. Rather, it is based on the inside area of a single-sided circular pipe break. Pipe breaks in the smaller break size region are considered more likely than pipe breaks in the larger break size region. Consequently, each break size region will be subject to different ECCS requirements, commensurate with likelihood of the break. LOCAs in the smaller break size region must be analyzed by the same conservative methods, assumptions, and criteria currently used for LOCA analysis. Accidents in the larger break size region may be analyzed using more realistic methods and assumptions based on their lower likelihood. Although LOCAs for break sizes larger than the transition break would become ''beyond design-basis accidents,'' the revised proposed rule would require that licensees maintain the ability to mitigate all LOCAs up to and including the DEGB of the largest RCS pipe. However, mitigation analyses for LOCAs larger than the TBS need not assume the loss-of-offsite power or the occurrence of a single failure.

Licensees who perform LOCA analyses using the risk-informed alternative requirements may find that their plant designs are no longer limited by certain parameters associated with previous DEGB analyses. Reducing the DEGB limitations could enable licensees to propose a wide scope of design or operational changes up to the point of being limited by some other parameter associated with any of the other required accident analyses. Potential design changes include modification of containment spray designs, modifying core peaking factors, modifying setpoints on accumulators or removing some from service, eliminating fast starting of one or more emergency diesel generators, and increasing power, etc. Some of these design and operational changes could increase plant safety because a licensee could modify its systems to better mitigate the more likely LOCAs. Other changes, such as increasing power, could increase overall risk to the public. The risk-informed § 50.46a option would include risk acceptance criteria for evaluating future design changes to ensure that any risk increases are acceptably small. These acceptance criteria would be consistent with the guidelines for risk-informed license amendments in RG 1.174 and would ensure both the acceptability of the changes from a risk perspective and the maintenance of sufficient defense-in-depth, safety margins, and performance monitoring. The requirements for the risk-informed evaluation process are discussed in detail in Section V.E of this document.

The NRC will periodically evaluate LOCA frequency information. Should estimated LOCA frequencies increase causing a significant increase in the risk associated with breaks larger than the TBS, the NRC would undertake rulemaking (or issue orders, if appropriate) to change the TBS. In such a case, the backfit rule (10 CFR 50.109) will not apply. If previous plant changes are invalidated because of a change to the TBS, licensees would have to modify or restore components or systems as necessary so that the facility would continue to comply with § 50.46a acceptance criteria. The backfit rule (10 CFR 50.109) also would not apply in these cases.

Changes consist of a new § 50.46a and conforming changes to existing §§ 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 §§ 52.47, 52.79, 52.137, and 52.157.

B. Determination of the Transition Break Size

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; 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 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 (1×10^{-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 reactor coolant system (RCS); 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 (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 shutdown. The majority of heavy loads are lifted during refueling evolutions 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 would 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; 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 very 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 10^{-5} or 10^{-6} per year earthquake in order for pipe failure to occur. The NRC concluded that the likelihood of flaws large enough to fail during 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 rare (10^{-5} per year) earthquakes.

Indirect failures are primary system ruptures that are a consequence of failures in nonprimary 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 low return frequency earthquake (10^{-5} to 10^{-6} per year). The results indicated that the conditional probability was on the order of 0.1. These studies used seismic hazard curves from NUREG–1488 (NUREG–1488, ''Revised Livermore Seismic Hazard Estimates for Sixty-Nine Nuclear Power Plant Sites East of the Rocky Mountains, April 1994; ML052640591). More recent studies were completed by 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 6×10^{-6} per year. 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, as noted in the public comments, 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 configuration and operating environment, certain piping is considered to be more susceptible than other piping in the same size range. For PWRs, the range of pipe break sizes determined from the various 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 arithmetic and geometric means of the break sizes having approximately a 95th percentile probability of 10^{-5} per year ranged from values of approximately 13 inches to 20 inches equivalent diameter. The information gathered from the elicitation for BWRs 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 should, 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) operate at slightly cooler temperatures. Thermally-activated degradation mechanisms would be expected to progress more slowly in the cold leg than in the hot leg. Therefore, the NRC evaluated whether it may be appropriate to specify a TBS for the cold leg that would be smaller than the size of the surge line. 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 and would be composed of two 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 proposed rule, all breaks up to and including the TBS would 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 remain valid at a particular facility, future plant modifications must 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. 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. The NRC will expect applicants for plant changes under revised proposed § 50.46a to demonstrate that those changes do not significantly increase break frequencies. As discussed in Section V.C. of this document, the NRC is currently preparing guidance for applicants to use to demonstrate that proposed plant changes do not undermine the § 50.46a technical basis (''Plant-Specific Applicability of 10 CFR 50.46 Technical Basis'' February 2009; ML090350757).

The baseline TBS was adjusted upward 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, and may initiate rulemaking to revise the TBS definition to account for this new information. The NRC will also continue to assess the failure precursors that might be indicative of an increase in pipe break frequencies in BWR and PWR plants to establish whether the TBS would need to be adjusted.

However, these TBS values are within the range supported by the expert elicitation estimates when considering the uncertainty inherent in processing the degradation-related frequency estimates. In addition, the NRC believes that the TBS definitions in the proposed rule would provide necessary conservatism to compensate for possible future increases in break frequencies. The NRC expects that the TBS values would result in regulatory stability because future LOCA frequency reevaluations are less likely to make it necessary for the NRC to change 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 discussed in Section V.B. of this document, the NRC has published two reports, NUREG–1829 (ML082250436), and NUREG–1903 (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 failure 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 nonprimary system components and supports that could lead to primary system failures. Because these studies were not intended to develop bounding estimates, unique plant attributes may result in plant-specific LOCA frequencies due to normal operational and/or seismic loading 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.

The NRC is preparing guidance for conducting the plant specific review to demonstrate the applicability of both the NUREG–1829 and NUREG–1903 results. The scope of this applicability guidance would be limited 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 guidance is applicable to aspects of the facility design affecting compliance with ECCS requirements and would not pertain to design-bases or operational procedures associated with other aspects of the facility licensing basis.

The plant applicability evaluation would require that § 50.46a applicants first demonstrate that the applicable systems in the plant adhere to the current licensing basis. Additionally, the evaluation would require that licensees consider the effects of unique, plant-specific attributes on the generic LOCA frequencies developed in NUREG–1829. The licensee would also 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 revised proposed § 50.46a requirements, it would also be necessary to evaluate the effect of future proposed plant changes to demonstrate that NUREG–1829 results remain applicable after enacting the proposed changes.

An evaluation framework is also provided for determining the applicability of the NUREG–1903 assessment of direct piping failures. This framework identifies the aspects that applicants would consider in a plant-specific analysis, provides several options for conducting the analysis, and describes a systematic approach associated with 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. NUREG–1903 also addressed indirect piping failures caused by rare seismic loading. However, the risk of indirect failure is highly plant-specific and NUREG–1903 only considered the risks associated with two different plants. 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 associated with any component under § 50.46a. Any proposed changes to these criteria would be 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 revised proposed § 50.46a requirements, it would also be necessary for licensees to demonstrate that the NUREG–1903 results remain applicable after implementing proposed changes.

More specific details on how to conduct these applicability reviews are available in a white paper entitled, ''Plant-Specific Applicability of the 10 CFR 50.46 Technical Basis'' February 2009 (ML090350757). Commenters on this revised proposed rule may review this white paper to get a better understanding of the scope of the evaluation being considered by the NRC.

D. Alternative ECCS Analysis Requirements and Acceptance Criteria

The revised proposed rule would require 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 would have to 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) would specify 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 revised proposed 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 would be applied to all locations in the RCS to find the limiting break location. LOCA analyses for break sizes larger than the TBS (but using the more realistic analysis requirements) would also be applied to all locations in the RCS 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. 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 would 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 revised proposed 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 revised proposed rule would retain the high level of probability as the statistical acceptance criterion.

Revised proposed §§ 50.46a(e)(1) and (e)(2) would 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 would be required to analyze breaks at or below the TBS by assuming the worst single failure concurrent with a loss-of-offsite power, limiting operating conditions, and only crediting safety systems. For breaks larger than the TBS, licensees may take credit for operation of any equipment supported by availability data provided that onsite power (either safety or non-safety) 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 would have to be identified as such and listed in the plant technical specifications. Analyses of breaks larger than the TBS could assume nominal operating conditions rather than technical specification limits. This would also include combining actual fuel burnup in decay heat predictions with the corresponding operating peaking factors at the appropriate time in the fuel cycle. The assumptions of loss-of-offsite power and the worst single failure would not be required because breaks larger than the TBS are very unlikely; therefore, less margin would be needed in the analysis of breaks in this region. A capability 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 would be the same as those currently required in § 50.46. Therefore, licensees would be required to use an approved methodology to demonstrate that the following acceptance criteria are met for the limiting LOCA at or below the TBS:

- 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 would be less prescriptive:

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

The revised proposed rule would allow 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. 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.

However, the NRC acknowledges 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 is requesting stakeholder comments on whether the final § 50.46a rule should retain the coolable geometry criterion for beyond-TBS breaks. Retaining coolable geometry would give licensees the option to demonstrate alternative coolable geometry metrics or use the current metric (2200 °F PCT and 17 percent MLO). If the NRC removed the coolable geometry criterion, the beyond-TBS acceptance criteria would be the same as the acceptance criteria for TBS and smaller breaks (2200 °F PCT and 17 percent MLO). The NRC will evaluate stakeholder comments on this question before deciding which beyond-TBS acceptance criteria to include in the final rule.

As previously discussed in Section IV.C of this document, 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 will soon issue an ANPR seeking public comments on a planned regulatory approach. 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. As these new acceptance criteria are established, the NRC will also make conforming changes to § 50.46a as necessary for both below and above TBS breaks.

3. Restriction of Reactor Operation

Section 50.46a(e)(5) would allow 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 revised proposed § 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, models inconsistent with the requirements of Appendix K of Part 50, or phenomena unknown at the time of approval of the methodology. Lack of compliance with methodological requirements would not necessarily result in failure to meet the acceptance criteria of revised proposed §§ 50.46a(e)(3) and (e)(4), but, rather, would provide results that could not 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 revised proposed rule for consistency with the current ECCS regulations, because it is comparable to existing § 50.46(a)(2).

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

Licensees who adopt § 50.46a would use a risk-informed evaluation process to demonstrate, before implementation, that facility changes will satisfy the risk-informed acceptance criteria in revised proposed § 50.46a(f). Changes that must be evaluated are specified in revised proposed § 50.46a(d)(3) and would 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. Also, changes in risk from facility changes not enabled by the alternative ECCS requirements could be combined with changes in risk from facility changes enabled by § 50.46a if the licensee chooses to combine the changes in its application of the risk-informed change process defined in the rule. In this case, the changes made under § 50.46a would include those enabled by § 50.46a and those not enabled by § 50.46a but included in the risk-informed application.

Licensees would be 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, revised proposed § 50.46a(g)(2) would require the licensee to propose steps and a schedule to bring the facility back into compliance with the acceptance criteria in § 50.46a(f)(2)(ii) or § 50.46a(f)(2)(iii), as applicable.

The risk-informed evaluation would be 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 would 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 revised proposed rule would require NRC review and approval of all changes initiated under § 50.46a(f)(2).

1. Requirements for the Risk-Informed Evaluation

The revised proposed rule is based upon the regulatory premise that the acceptability of all licensee-initiated changes made under the rule should 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 proposed 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 current approach for conducting risk assessments suitable for making decisions in areas of potential safety significance, § 50.46a(f)(4) of the revised proposed rule would require that a technically adequate PRA be used in demonstrating compliance with the requirements of § 50.46a that would affect the regulatory decision in a substantive manner. 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 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) is written to recognize that non quantitative risk assessment may also be utilized.

a. Probabilistic Risk Assessment Requirements

Sections 50.46a(f)(4)(i) through (iv) set forth the four general attributes of an acceptable PRA for the purposes of this rule. Section 50.46a(f)(4)(i) would require that the PRA address initiating events from internal and external sources, and for all modes of operation, including low power and shutdown, that would affect the regulatory decision in a substantial manner. Failure to consider sources of risk from internal and external events, or from anticipated operating modes, could result in an inaccurate characterization of the level of risk associated with a plant change. Therefore, initiating events from internal and external sources and during all modes of operation would have to be considered by the PRA when the change in risk would affect the regulatory decision, in order to ensure that the effect on risk from licensee-initiated changes is adequately characterized in a manner sufficient to support a technically defensible determination of the level of risk.

Section 50.46a(f)(4)(ii) states that the PRA must reasonably represent the current configuration and operating practices at the plant. A plant's risk may vary as plant configuration and/or plant procedures change. Failure to update the PRA based upon these configuration or procedure changes may result in inaccurate or invalid PRA results. Accordingly, to ensure that estimates of risk adequately reflect the facility for which a decision must be made, the rule would require that the PRA address current plant configuration and operating practices.

Section 50.46a(f)(4)(iii) would require that the PRA have ''sufficient technical adequacy'' including consideration of uncertainty, as well as a sufficient level of detail to provide confidence that the calculated risk and the changes in risk adequately reflect the proposed facility change. The revised proposed rule would require the PRA to consider uncertainty because the decision maker must understand the limitations of the particular PRA that was performed to ensure that the decision is robust and accommodates relevant uncertainties. With respect to level of detail, failure to model the plant (or relevant portion of the plant) at the appropriate level of detail may result in calculated risk values that do not appropriately capture the risk significance of the proposed change.

Finally, § 50.46a(f)(4)(iv) would require that, to the extent that the PRA is used, the PRA must meet NRC-approved industry standards. The NRC has prepared a regulatory guide (RG 1.200) on determining the technical adequacy of PRA results for risk-informed activities. As one step in the assurance of technical quality, the PRA would be subjected to a peer review process assessed against an industry standard or set of acceptance criteria that is endorsed by the NRC. Industry standards for all initiators and operating modes are under development but not yet complete. The NRC will develop review guidelines that endorse criteria for considering the sufficiency of a PRA peer review process for this application in § 50.46(c) if this guidance becomes necessary before industry standards have been completed and endorsed in RG 1.200.

b. Requirements for Risk Assessments Other Than PRA

Risk assessment need not always be performed using PRA. The rule explicitly recognizes the possibility of using risk assessment methods other than PRA to demonstrate compliance with various acceptance criteria in the rule. However, as with PRA methodologies, the NRC believes that minimum quality requirements for PRAs and risk assessments used by a licensee in implementing the rule must be established. Accordingly, § 50.46a(f)(5) would establish the minimum requirement for risk assessment methodologies other than PRA. The NRC believes that this requirement provides flexibility to licensees to use the non-PRA risk methodology (or combination of different methodologies) when these methodologies produce results that are sufficient upon which to base decisions that the various acceptance criteria in the proposed 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 could make after adopting this rule would not have been permitted without the new § 50.46a (related or 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 Section 50.46a. Unrelated changes will indirectly influence the change in risk of the § 50.46a related changes insofar as they change the risk profile of the facility. If unrelated changes are combined with related changes in determining the § 50.46a change in risk estimates (bundling), the result will normally 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. If bundling is permitted, a licensee could implement facility changes that would decrease risk to offset increased risk from § 50.46a enabled changes. These changes would increase the safety of the facility and are expected to result in a reallocation of resources to areas where safety can be improved. Current NRC practice, consistent with RG 1.174, is to compare the total or cumulative risk increase from all related changes, and only related changes, to the acceptance guidelines. RG 1.174 does, however, permit bundling changes (referred to as combined changes in RG 1.174) and provides additional acceptance guidelines that must be met when permitting unrelated plant changes that might decrease risk to be combined together with a group of related changes in a change in risk estimate that would be compared 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 would not permit bundling of changes without previous review and approval. Therefore, the revised, proposed § 50.46a(f)(2)(iv) would allow changes not enabled by § 50.46a to be combined 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 this section. 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 would be 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 license), 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 has proposed 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.

The revised proposed § 50.46a(f)(1) states that a licensee may make 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 revised proposed rule also states that the provisions of § 50.59 would apply. Licensees with a pre-approved change process would be allowed to make facility changes without NRC approval if they met § 50.59 and § 50.46a requirements. Compliance with the § 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, adequate defense-in-depth, that safety margins will be maintained, and that adequate performance-measurement programs are implemented.

4. Risk Acceptance Criteria for Plant Changes

Sections 50.46a(f)(2)(ii) and (f)(2)(iii) would require that the total increases in risk are very small and that the overall plant risk remains small. Two sets of metrics are used to measure risk depending on when the applicant's operating license was issued. For reactors licensed before the effective date of the rule, § 50.46a(f)(2)(ii) would apply and CDF and LERF would be used. For new reactors licensed after the effective date of the rule, § 50.46a(f)(2)(iii) would apply and CDF and large release frequency (LRF) are used. The NRC believes that this requirement is a necessary element for ensuring that changes which would be permitted by the revised § 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 requirements in §§ 50.46a(f)(2)(ii) and (f)(2)(iii) that the total increases in risk are very small would require 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)(iv) would require that cumulative effect of these changes be evaluated and shown to meet the acceptance criteria. Section 50.46a(f)(2)(iv) would also permit 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. The total change in risk from all facility changes made under the rule after the adoption of § 50.46a must be evaluated and compared to the ''very small'' acceptance criterion before each change requiring a risk-informed evaluation and after the periodic PRA 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 would ensure that the total risk increase of all changes, as they are implemented over time, would 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 changes where every individual change's risk increase is kept below the proposed 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 should 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), CDF and 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. After the adoption of RG 1.174, the NRC has had eleven 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 (*e.g.*, power up-rates, license renewals, and changes to the FSAR), and amending technical specifications. On the basis of this experience, for current operating reactors, 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.

For new reactors, CDF and LRF (instead of LERF) would apply as indicated in § 50.46a(f)(2)(iii). For new reactor licensing the Commission has established a goal based on LRF (*see* SRM on SECY–89–102—Implementation of the Safety Goals, June 15, 1990; and SRM on SECY–90–016—Evolutionary Light Water Reactor (LWR) Certification Issues and Their Relationship to Current Regulatory Requirements, June 26, 1990).

The Commission has concluded that changes under this rule should 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.

For new reactors, the same CDF metric is used and the same definition of very small increase (*i.e.,* less than 10^{-6} per reactor year) would be used. The revised proposed rule uses LRF instead of LERF as a metric for new reactors. RG 1.174 provides no guidelines for LRF. The Commission has approved the overall mean frequency of a large release of radioactive material to the environment (LRF) to be less than 10^{-6} per reactor year. The revised proposed rule requires the total increase in LRF to be no more than very small. The NRC proposes that increases in LRF of 10^{-8} per reactor year or less are very small risk increases for new reactors. Because of the difference between the LERF acceptance criteria for existing reactors and the LRF acceptance criteria for new reactors, the NRC is seeking specific public comments on this topic. Additional background information on how the NRC is addressing this issue and how the NRC is soliciting public input on this topic in this revised proposed rule and in other regulatory areas is provided in Section J.2. of this document.

After 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. The NRC believes that applying the LRF guideline for determining very small risk increases would also be protective of public health and safety.

Section 50.46a(f)(1) would permit 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 was 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. Similarly, for new reactor licensing, an increase in LRF less than 10^{-9} per reactor year is a minimal increase. Although ten of these changes could cause the combination of minimal increases to 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), would have to be considered in the periodic reporting required by § 50.46a(g)(2). If a licensee implements an unexpectedly large number of minimal risk changes, the periodic reporting requirements in § 50.46a(g)(2) would 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.

Additionally, although the revised proposed rule would permit licensees to make plant changes that result in very small risk increases, the NRC is requesting 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 final rule require that the net effect of plant changes made under § 50.46a be risk neutral or risk beneficial? The NRC requests stakeholders to provide comments on the use of risk acceptance criteria that would not allow a cumulative increase in risk for plant changes made under § 50.46a.

5. Defense-in-Depth

Section 50.46a(f)(3)(i) would require 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 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) would require that adequate safety margins be retained to account for uncertainties. These uncertainties include phenomenology, modeling, and how the plant was constructed or is operated. The NRC's concern is that plant changes could inappropriately reduce safety margins, resulting in an unacceptable increase in risk or challenge to plant SSCs. This provision would ensure 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) would require 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 adequacy of safety margins. Results from implementation of monitoring and feedback strategies can provide an early indication of unanticipated degradation of performance of plant elements that may invalidate the demonstration by the risk-informed evaluation that the change satisfied all the acceptance criteria. This section would require 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 on their site and throughout industry with the performance measuring programs required by this section.

F. Operational Requirements

The revised proposed rule includes five specific operational requirements that apply to licensees who are approved to implement § 50.46a. These requirements are set forth in § 50.46a(d) and would 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 § 50.46a.

4. Periodically assess the cumulative effect of changes to the plant, operational practices, equipment performance, and plant operational experience.

5. Do not operate the plant for more than fourteen days 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.

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

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

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. 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.

In a Staff Requirements Memorandum dated August 10, 2007, responding to 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' '', the Commission directed the NRC staff to evaluate various approaches for enhancing the 10 CFR 50.46a rule with requirements for improved leak detection methods. This SRM also directed the NRC staff to ''strengthen the assurance of defense-in-depth [provided by the § 50.46a rule] for breaks beyond the transition break size (TBS).''

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 new requirements on licensees in the areas of tighter reactor coolant leakage limits and new leakage monitoring requirements. Specifically, the DBLLTF Recommendation 3.1.5(1) said that the NRC should determine whether PWR plants should install on-line enhanced leakage detection systems on critical plant components which would be capable of detecting leakage rates of significantly less than 1 gallon per minute.

The evaluation identified techniques that could improve localized leak detection and on-line monitoring and 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 reduced technical specification leakage for existing licensees, the NRC recommended updating Regulatory Guide 1.45 on leak detection. This RG was revised in 2008.

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 activity levels of coolant resulting from improved fuel integrity; and incorporates lessons learned from operating experience. The title of the Regulatory Guide 1.45, Revision 1, has been changed from ''Reactor Coolant Pressure Boundary Leakage Detection Systems'' to ''Guidance on Monitoring and Responding to Reactor Coolant System Leakage,'' to reflect its broader scope. Revision 1 provides detailed guidance for timely detection and location of leaks, continuous monitoring, quantifying and trending of leak rates, assessing safety significance, and specifying plant actions following confirmation of an adverse trend in 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.

Paragraph 50.46a(d)(2) in the revised proposed rule contains new enhanced leak detection requirements. Enhanced leak detection is expected to provide increased defense-in-depth against large pipe breaks for licensees who implement the alternative ECCS rule. The NRC has concluded that implementing the guidance in Regulatory Guide 1.45, Revision 1, by licensees choosing to comply with 10 CFR 50.46a will result in improved monitoring and response to leaks in the reactor coolant system and will provide an acceptable method to satisfy the requirements of Section 50.46a(d)(2).

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

In addition to meeting all other applicable requirements, a risk-informed evaluation required by § 50.46a(d)(3) would have to be performed for changes enabled by § 50.46a. If a licensee has a change methodology that was submitted under § 50.46a(f)(1) and approved by the NRC, that licensee could make some changes without NRC approval, if the acceptance criteria in § 50.46a(f)(1) are met. Otherwise, the licensee would be required to submit the results of its risk-informed evaluation for prior NRC review and approval in a license amendment request subject to the requirements of § 50.90. The licensee would have to 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)(3).

4. Periodically assess the cumulative effect of changes to the facility.

Key components of risk-informed regulation are the monitoring of changes in plant risk and feedback to the risk assessment and/or plant design activities and processes which are the subject of the risk assessment. Section 50.46a(d)(4) would require that after adopting § 50.46a, a licensee would be required to periodically maintain and upgrade the risk assessments (both PRA and non-PRA) required under §§ 50.46a(f)(4) and (f)(5). In particular, it is necessary that the PRA be maintained to reflect all plant changes; such as modifications, procedure changes, or changes in plant performance data. This maintenance enables the licensee to demonstrate that the total increases in CDF and LERF (or LRF for new reactors) after adopting § 50.46a continue to meet the acceptance criteria in § 50.46a(f)(2). The risk assessments would have to continue to meet the minimum quality requirements in §§ 50.46a(f)(4) and (f)(5) to support reasoned decision making under the rule.

The revised proposed rule would specify that the maintenance and upgrading be conducted periodically ''but no less often than once every two refueling outages.'' The NRC believes that this is an appropriate period because the uncertainty of risk changes occurring during the two refueling outage period is tolerable and unlikely to result in high risk situations developing 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, as well as the existing deterministic criteria in the substantive technical requirements in Part 50 and the criteria utilized in determining the acceptability of plant changes. The updating period specified in the rule is also comparable to other NRC requirements governing updating and reporting of safety information, e.g., §§ 50.59, 50.71(e).

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)(2) would require 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 total of fourteen days in any 12 month period in an operating configuration that has not been demonstrated to meet the ECCS acceptance criteria for breaks larger than the TBS.

As previously discussed in the supplementary information of this document, the NRC has included restrictions in the revised proposed rule 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 revised proposed rule would restrict operation in such a configuration to not exceed fourteen days in any twelve month period. The NRC believes it is unlikely that licensees will experience circumstances where they would consider operating in such a condition for more than fourteen days, but has concluded that the establishing a limit on the allowable time is necessary to support the defense-in-depth philosophy. 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 some confidence that the break could be mitigated. Thus the revised proposed rule will limit the allowed time period for operation in an unanalyzed condition to fourteen days in any twelve month period to ensure that mitigation capability is maintained except for occasional brief periods long enough to perform online maintenance of mitigation structures, systems and components.

G. Reporting Requirements

1. ECCS Analysis Reporting Requirements

Section 50.46a(g)(1) 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 and explanation of 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)(2) would set forth reporting requirements with respect to the PRA maintenance and upgrading that would be required by § 50.46a(d)(4). When updating and upgrading the PRA, § 50.46a(g)(2) would require the licensee to report changes to the NRC within 60 days if the acceptance criteria in §§ 50.46a(f)(2)(ii) or (f)(2)(iii) (for new reactors) are exceeded. This provision would also require 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 would ensure 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)(3) would require 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.

H. Documentation Requirements

Section 50.46a(h) of the revised proposed rule would require 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 would be 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 also required under Part II of Appendix K to Part 50 to document the bases of evaluation models used to perform ECCS calculations. Licensees would also be required to 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 fourteen days in any twelve month period limit in paragraph (d)(5) of this section. This documentation could be reviewed during NRC inspections and/or audits to ensure that the risk criteria in § 50.46a(f) would be satisfied.

I. 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 as specified in §§ 50.46a(c)(1)(i) through (v). This includes information related to the applicability to the facility of the NUREG–1829 and NUREG–1903 results; information identifying the ECCS analysis methods to be used; information describing the licensee's risk-informed evaluation process; information describing the licensee's proposed process for making risk-informed changes without prior NRC approval (if the licensee is seeking approval of such a process); and information describing non safety equipment to be credited for compliance with the ECCS acceptance criteria in § 50.46a(e). 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 for compliance with the alternative § 50.46a requirements, there is no purpose served by also requiring licensees to perform a § 50.59 evaluation, because § 50.59 is a process to determine the need for prior NRC approval of a change to a facility or its procedures as described in the FSAR. After the § 50.46a evaluation models and initial ECCS LOCA analyses are established by approval of the license amendment implementing § 50.46a, subsequent changes to ECCS analyses would 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) is significant.

The initial application may request one or more facility changes. The initial application may also include 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 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)(iv). Otherwise, this information would not need to be submitted in the initial application.

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 would invalidate the applicability to the facility of the generic NUREG–1829 and NUREG–1903 reports.

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 requirements for plant physical security. The NRC would 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 do so at any time by submitting the information described in paragraph (c)(1)(iv).

J. Applicability to New Reactor Designs

As previously discussed under NRC Topic 1, the NRC has evaluated public comments and agrees with commenters who stated that there are no technical reasons which prevent the revised proposed § 50.46a regulations from being applied to new light water reactor designs that are similar in nature (with respect to design and expected LOCA pipe break frequency) to current operating reactors.

1. Similarity of New Reactor Designs to Existing Reactor Designs

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 revised proposed rule has been modified to apply to new LWR reactor 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 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 transition break size (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 would 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 generic results in NUREG–1829 and NUREG–1903.

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 proposed rule. 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.

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. Therefore, the TBS defined in the proposed rule for currently operating reactors could potentially be applicable to some new reactor designs.

In addition, after obtaining an operating or combined license for a plant with a currently-approved standard design, a licensee could adopt § 50.46a if the design is demonstrated to be similar to the designs of plants licensed before the effective date of the rule (by evaluating the criteria above) and the TBS proposed by the licensee is found acceptable by the NRC.

2. NRC Request for Public Comments on the Use of Large Release Frequency (LRF) as the Risk Acceptance Criteria Metric for New Reactors

Regulatory Guide 1.174, ''An Approach for Using Probabilistic Risk Assessment in Risk Informed Decisions on Plant Specific Changes to the Licensing Basis,'' was originally issued in July 1998. This RG provides guidance for a multitude of risk-informed applications and improves consistency in regulatory decisions in areas where the results of risk analyses are used to help justify regulatory action. The guide is the foundation for many other risk-informed programs (*e.g.,* inservice testing, inservice inspection of piping) at the agency.

Regulatory Guide 1.174 describes five key principles of the risk-informed, integrated decision making process. In Principle 4—When proposed changes result in an increase in core damage frequency or risk, the increases should be small and consistent with the intent of the Commission's Safety Goal Policy Statement—the regulatory guide presents quantitative guidelines for acceptably small increases in CDF and LERF, as depicted in Figures 3 and 4 of the guide. The magnitude of acceptably small increases varies stepwise with the baseline CDF and LERF. A small increase up to 10^{-5} per reactor year for CDF and 10^{-6} per reactor year for LERF are normally acceptable until the baseline risk increases to reference values of approximately 10^{-4} per reactor year and 10^{-5} per reactor year for CDF and LERF respectively. Plants with baseline CDF and LERF which exceed the reference values, or with baseline risks that are not known with precision, would normally be limited to very small risk increases of up to 10^{-6} per reactor year and 10^{-7} per reactor year for CDF and LERF, respectively. Before RG 1.174 was issued, the Commission's SRM dated June 26, 1990, prepared in response to SECY–90–016, ''Evolutionary Light Water Reactor Certification Issues and their Relationships to Current Regulatory Requirements,'' established a goal for large release frequency (LRF) of less than 10^{-6} per reactor year for new reactor design certification and licensing. These goals are discussed further in Standard Review Plan (NUREG–0800) Chapter 19, and RG 1.206 ''Combined License Applications for Nuclear Power Plants'' Section C.I.19.

In light of this difference in the risk metrics used for currently operating reactors (LERF) and new reactors (LRF), the NRC is seeking 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?

The NRC has previously sought stakeholder input on the issue of risk metrics for new light-water reactors. A memorandum dated February 12, 2009, from R. W. Borchardt, Executive Director for Operations, to the Commissioners, ''Alternative Risk Metrics for New Light-Water Reactor Risk-Informed Applications'' (Adams Accession No. ML090160008), provides a discussion of the issues. The white paper attached to that memorandum presents a full discussion of the issues and options for applying or modifying the current set of reactor risk metrics to new reactors. The paper discusses the issues posed by the lower risk estimates of new reactors in risk-informed applications, including changes to the licensing basis and the reactor oversight process, and describes the advantages and disadvantages of each option.

On February 18, 2009, the NRC held a public meeting with stakeholders on the topic of risk metrics for new light-water reactors (see meeting summary; Adams Accession No. ML090570356). Additionally, both the NRC and industry representatives provided a briefing on the topic at the April 3, 2009, meeting of the ACRS.

As discussed in these documents, the NRC is considering several options regarding risk metrics for new reactor risk-informed applications. The options include applying the existing operating reactor acceptance guidelines to new reactors, using new guidelines and thresholds for new reactors, or postponing any significant change to the process and evaluating new reactors on a case-by-case basis for an indeterminate period. As described in the NEI paper, ''Risk Metrics for Operating New Reactors'' (ML090900674; March 27, 2009), NEI has expressed its preference for applying the existing operating reactor acceptance guidelines to new reactors (which is referred to as Option 1 in the NRC white paper).

As part of the public comment process for this revised proposed rule, public stakeholders are invited to comment on the use of any of the alternative risk metric approaches for determining compliance with the risk acceptance criteria in § 50.46a.

VI. Specific Topics Indentified for Public Comment

The NRC seeks specific public comments on three topics. These issues were discussed previously in this document, but are summarized again here to assist commenters.

1. Although the revised proposed rule would permit licensees to make plant changes that result in very small risk increases, the NRC is requesting 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 final rule require that the net effect of plant changes made under § 50.46a be risk neutral or risk beneficial? The NRC requests stakeholders to provide comments on the use of risk acceptance criteria that would not allow a cumulative increase in risk for plant changes made under § 50.46a. (*See* Section V.E.4.b of this document.)

2. Because of the difference in the risk acceptance criteria metrics used for currently operating reactors (LERF) and new reactors (LRF), the NRC is seeking 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? (*See* Section V.J of this document.)

3. In § 50.46a(e)(4)(i) of the revised proposed rule the NRC proposes 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 (2200 °F PCT and 17 percent MLO). However, the NRC acknowledges 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 is requesting stakeholder comments on whether the final § 50.46a rule should retain the coolable geometry criterion for beyond-TBS breaks. Retaining coolable geometry would give licensees the option to demonstrate alternative coolable geometry metrics or use the current metric (2200 °F PCT and 17 percent MLO). If the NRC removed the coolable geometry criterion, the beyond-TBS acceptance criteria would be the same as the acceptance criteria for TBS and smaller breaks (2200 °F PCT and 17 percent MLO). The NRC will evaluate stakeholder comments on this question before deciding which beyond-TBS acceptance criteria to include in the final rule. (*See* Section V.D.2 of this document.)

VII. 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 (ML020630082). Notice of that petition was published in the **Federal Register** 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

RCS, a maximum LOCA break size of ''up to and including an alternate maximum break size that is approved by the Director of the Office of Nuclear Reactor Regulation.'' Seventeen sets of comments were received, mostly from the power reactor industry in favor of granting the petition. A few stakeholders were concerned about potential impacts on defense-in-depth or safety margins if significant changes were made to reactor designs based upon use of a smaller break size. The NRC considered the public comments, evaluated the petition, and published a notice in the **Federal Register** resolving the petition and closing the PRM–50–75 docket. (*See* 73 FR 66000; November 6, 2008.) The NRC concluded that the issue raised by the petitioner should be considered in the rulemaking process. Documents related to the resolution of PRM–50–75 are available at *http://www.regulations.gov* under docket ID: NRC–2002–0018. The NRC is addressing the issues raised by the petitioner and stakeholders in this rulemaking.

VIII. Section-by-Section Analysis of Changes

A. Section 50.34—Contents of Application; Technical Information

Paragraph (a)(4)(i) of this section would specify that § 50.46a contains alternative ECCS requirements that licensees could 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 could 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) would specify 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 would specify that applicants for operating licenses for facilities which may be issued before the effective date of the rule could choose to apply the § 50.46a alternative ECCS requirements in the final analysis and evaluation of the design. This section also states that applicants for operating licenses for facilities which may be issued after the effective date of the rule could 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) would specify 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 would specify that emergency core cooling systems of BWRs and PWRs licensed before the effective date of the rule must be designed under § 50.46 or § 50.46a. Paragraph (a) would also specify that emergency core cooling systems of BWRs and PWRs licensed after the effective date of the rule could 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.

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

Paragraph (a) of this section would provide 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:

(1) *Changes enabled by this section,* which means changes to the facility, technical specifications, or procedures that comply with § 50.46a but do not comply with § 50.46;

(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

(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) would provide the applicability and scope of the requirements of this section. Proposed § 50.46a would apply to currently licensed light-water nuclear power reactors (licensed before the effective date of the rule). Proposed § 50.46a would also apply to LWRs licensed after the effective date of the rule which have been demonstrated to be similar to the designs of LWR facilities licensed before the effective date of the rule. Its requirements would be in addition to any other requirements applicable to ECCS set forth in 10 CFR 50, with the exception of § 50.46.

Paragraph (c)(1) would specify the contents of initial licensee applications for implementing the alternative ECCS requirements in § 50.46a. Paragraph (c)(1)(i) would require that an application contain a written evaluation demonstrating applicability of the results in NUREG–1829 and NUREG–1903 to the licensee's facility. However, if the facility differs significantly from the facilities analyzed in NUREG–1903, the application must contain a plant specific analysis demonstrating that the risk of seismically-induced LOCAs larger than the TBS is comparable to or less than the seismically-induced LOCA risk associated with the NUREG–1903 results. Paragraph (c)(1)(ii) would require 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) would require a description of the risk-informed evaluation process used to determine whether proposed changes to the facility meet the requirements for risk-informed evaluations in paragraph (f). Paragraph (c)(1)(iv) would require licensees who wish to make changes enabled by § 50.46a without prior NRC approval to submit a description of the risk-informed evaluation process and the PRA or non-PRA risk-assessment methods to be used to determine the acceptability of such changes. The licensee's process must be capable of demonstrating that all of the acceptance criteria in paragraph (f) will be met for each change. Paragraph (c)(1)(v) would require licensees 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)(2) states that applicants for a construction permit, operating license, design approval, design certification, manufacturing license, or combined license seeking to implement the requirements of this section shall, in addition to the information that would be required by paragraph (c)(1) of this section, submit an analysis demonstrating why the proposed reactor design is similar to the designs of currently operating reactors.

Paragraph (c)(3) specifies the acceptance criteria for approval of applications to comply with § 50.46a. Paragraph (c)(3)(i) would require the evaluation submitted under paragraph (c)(1)(i) to demonstrate that the NUREG–1829 results are applicable to the facility, and the risk of seismically-induced LOCAs larger than the TBS is comparable to or less than the seismically-induced LOCA risk associated with the NUREG–1903 results. Paragraph (c)(3)(ii) would require 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) would require that the risk-informed evaluation process the licensee proposes to use for making changes enabled by this section be adequate for determining whether the acceptance criteria in paragraph (f) of this section have been met. Paragraph (c)(3)(iv) would require that all non safety equipment credited for demonstrating compliance with the ECCS acceptance criteria is identified and listed as such in plant Technical Specifications. Paragraph (c)(3)(v) would require 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 the applicant's proposed TBS is consistent with the technical basis for Section 50.46a.

Paragraph (d) specifies the requirements with which licensees would be required to comply during facility operation after implementing § 50.46a.

Paragraph (d)(1) would require 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) would require that the licensee maintain leak detection equipment available at the facility and identify, monitor, and quantify leakage to reduce the likelihood of a LOCA larger than the TBS.

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

Paragraph (d)(4), would require licensees to maintain and upgrade its PRA analyses no less often than once every 2 refueling outages. 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 would be required to continue to meet the quality requirements in §§ 50.46a(f)(4) and (f)(5). Licensees would be required to take action to ensure that facility design and operation continue to be 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 would not be deemed backfitting.

Paragraph (d)(5) would require 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) would not exceed a total of fourteen days in any 12 month period.

Paragraph (d)(6) would require licensees to perform an evaluation to determine the effect of all planned facility changes and would prohibit licensees from implementing 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 generic results in NUREG–1829 and NUREG–1903.

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

Paragraph (e)(1) would specify 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) would specify 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 more realistic analysis inputs and 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) would provide ECCS acceptance criteria for LOCAs smaller than or equal to the TBS. The criteria specified would be the same as the current requirements in § 50.46(b).

Paragraph (e)(4) would provide ECCS acceptance criteria for LOCAs larger than the TBS. These acceptance criteria would be 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) would provide that the Director of the Office of Nuclear Reactor Regulation may impose restrictions on reactor operation if ECCS requirements are not met. This paragraph would be added to be consistent with existing § 50.46 which also contains this requirement.

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

Paragraph (f)(1) would specify that licensees may make changes without NRC approval if:

(i) The changes are permitted under § 50.59;

(ii) A risk-informed evaluation process has been submitted by the licensee and reviewed and approved by the NRC under § 50.46a(c)(1)(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) would state that for plant changes not permitted under paragraph (f)(1), licensees must submit an application for a license amendment under § 50.90. The application must contain:

(i) The information required under § 50.90;

(ii) For reactors licensed before the effective date of the rule, 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 that the risk-informed change criteria in paragraph (f)(3) are met;

(iii) For all applicants other than those holding operating licenses issued before the effective date of the rule, information from the risk-informed evaluation demonstrating that the total increases in core damage frequency and large release frequency are very small, the overall risk remains small, and the criteria in paragraph (f)(3) of this section are met;

(iv) An evaluation of the cumulative effect of previous changes that have increased risk but have met the acceptance criteria. If more than one plant change is combined, including plant changes not enabled by § 50.46a, 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;

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

(vi) 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 generic seismic 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) that support the technical basis for § 50.46a.

Paragraph (f)(3) would specify requirements for all plant changes. Paragraph (f)(3)(i) would require that defense-in-depth is maintained. Paragraph (f)(3)(ii) would require that adequate safety margins are maintained. Paragraph (f)(3)(iii) would require that adequate performance-measurement programs will be implemented. Paragraph (f)(3)(iii) provides criteria on the specific attributes required to meet the performance measurement requirements.

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 revised proposed rule would identify specific technical requirements for the risk-informed assessment.

(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) would require 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) would provide the requirements for making reports to the NRC.

Paragraph (g)(1) would require reporting of all errors or changes to ECCS analyses at least annually as specified in § 50.4. For significant changes or errors, licensees would be required to 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), for LOCAs involving pipe breaks equal to or smaller than the TBS, significant changes would be defined as a change in peak cladding temperature of greater than 50 °F. Under paragraph (g)(1)(ii), for LOCAs involving pipe breaks larger than the TBS, a significant change would be defined as one resulting in a significant reduction in the capability to meet the ECCS acceptance criteria in § 50.46a(e)(4).

Paragraph (g)(2) would set forth reporting requirements with respect to the PRA maintenance and upgrading that would be required by § 50.46a(d)(4). When maintaining and upgrading the PRA, § 50.46a(g)(2) would require the licensee to report changes to the NRC within 60 days if the acceptance criteria in §§ 50.46a(f)(2)(ii) or (f)(2)(iii) (for new reactors) are exceeded. This provision would also require 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)(3) would contain reporting requirements for plant changes made under § 50.46a(f)(1) involving minimal risk. A short description of these changes would be reported every 24 months.

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

Paragraphs (i) through (l) would be reserved for future use.

Paragraph (m) would provide that changes made by the NRC to the TBS and all changes required to return a facility to compliance with the acceptance criteria after a change in the TBS are not deemed to be backfitting under 10 CFR 50.109.

E. Section 50.109—Backfitting

This section would be 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. Appendix A to Part 50—General Design Criteria for Nuclear Power Plants

Five of the general design criteria contained in Appendix A would be 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,* would also be 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. Section 52.47—Contents of Applications; Technical Information

Paragraph (a)(4) of this section would be 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) would to specify 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) would specify 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 52.79—Contents of Applications; Technical Information in Final Safety Analysis Report

In this section paragraph (a)(5) would be 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) would specify 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) would specify 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.

I. Section 52.137—Contents of Applications; Technical Information

Paragraph (a)(4) of this section would be 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) would specify 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) would specify 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.

J. Section 52.157—Contents of Applications; Technical Information in Final Safety Analysis Report

Paragraph (f)(1) of this section would be 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) would specify 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) would specify 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.

IX. Criminal Penalties

For the purposes of Section 223 of the Atomic Energy Act (AEA), as amended, the NRC is issuing the proposed 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 would 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.

X. 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; September 3, 1997), this rule is classified as compatibility ''NRC.'' 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 AEA or the provisions of Title 10 of the Code of Federal Regulations, and 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, but does not confer regulatory authority on the State.

XI. Availability of Documents

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), O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee.

Publicly available documents are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, (301) 415–4737 or by e-mail to *pdr@nrc.gov.* The NRC is making the documents identified below available to interested persons through one or more of the following methods as indicated.

Public Document Room (PDR). The NRC Public Document Room is located at Public File Area O–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

Federal eRulemaking 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.*

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

Document	PDR	Web	Err (Adams)
Initial Proposed Rule (70 FR 67598)	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
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
Regulatory Analysis	X	X	ML091050748

XII. 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 requests comments on the proposed rule specifically with respect to the clarity and reflectiveness of the language used. Comments should be sent to the address listed under the **ADDRESSES** caption of the preamble.

XIII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 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 proposed rule, the NRC proposes to use 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. The Government standards would allow the use of voluntary consensus standards, but would not require their use. The NRC does not believe that these other 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. The NRC will consider using a voluntary consensus standard if an appropriate standard is identified. If a voluntary consensus standard is identified for consideration, the submittal should explain how the voluntary consensus standard is comparable and why it should be used instead of the proposed Government-unique standard.

XIV. 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, if adopted, would 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. If adopted, the proposed rule would establish 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 proposed 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 would still be required but with less redundancy and margin for the larger, low probability breaks. Increases in risk, if any, would be 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 proposed action would not significantly increase the probability or consequences of an accident, when considered in a risk-informed manner. No changes would 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 would be made to non-radiological plant effluents and there would be no changes in activities that would adversely affect the environment. Therefore, there are no significant non-radiological impacts associated with the proposed action.

The primary alternative would be 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 proposed rule that could increase plant safety, increase operational flexibility, or decrease costs. The no action alternative would also maintain existing regulatory burdens for which there could be little or no safety, risk, or environmental benefits.

The determination of this environmental assessment is that there will be no significant offsite impact to the public from this action. However, public stakeholders should note that the NRC is seeking public participation on this assessment. Comments on any aspect of the environmental assessment may be submitted to the NRC as indicated under the **ADDRESSES** heading of this document.

The NRC has sent a copy of the environmental assessment and this proposed rule to every State Liaison Officer and requested their comments on the environmental assessment.

XV. Paperwork Reduction Act Statement

This proposed rule amends information collection requirements contained in 10 CFR part 50 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*). These information collection requirements have been submitted to the Office of Management and Budget (OMB) for approval. Existing requirements were approved by the Office of Management and Budget, control number 3150–0011.

Type of submission: Revision.

The title of the information collection: 10 CFR part 50—Domestic Licensing of Production and Utilization Facilities.

The form number if applicable: Not applicable.

How often the collection is required: Annually.

Who will be required or asked to report: Licensees authorized to operate a nuclear power reactor or applicants for standard design certifications, combined licenses, standard design approvals or manufacturing licenses who have been approved to implement the risk-informed alternative requirements in 10 CFR 50.46a for analyzing the performance of emergency core cooling systems during loss-of-coolant accidents.

An estimate of the number of annual responses: 12.

The estimated number of annual respondents: 6.

An estimate of the total number of hours needed annually to complete the requirement or request: 53,388 hours total, including 48,000 hours for reporting (an average of 8,000 hours per respondent) + 5,388 hours recordkeeping (an average of 898 hours per recordkeeper).

Abstract: The Nuclear Regulatory Commission (NRC) proposes to amend its regulations to permit applicants for and/or holders of power reactor operating licenses, standard design certifications, combined licenses, standard design approvals or manufacturing licenses 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). In addition, the proposed rule would establish procedures and criteria for making changes in plant design and procedures based upon the results of the new analyses of ECCS performance during LOCAs. A licensee or applicant choosing to use the provisions of Section 50.46a would be required to submit a license amendment request with the required information, using the existing processes in Section 50.34 and Section 50.90.

The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collections contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

A copy of the OMB clearance package may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O–1 F21, Rockville, MD 20852. The OMB clearance package and rule are available at the NRC worldwide Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/index.html* for 60 days after the signature date of this notice.

Send comments on any aspect of these proposed information collections, including suggestions for reducing the burden and on the above issues, by September 9, 2009 to the Records and FOIA/Privacy Services Branch (T–5 F53), 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. Comments on the proposed information collection may also be submitted via the Federal eRulemaking Portal *http://www.regulations.gov,* docket # NRC–2004–0006. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date. You may also e-mail comments to *Christine_J._Kymn@omb.eop.gov* or comment by telephone at (202) 395–4638.

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.

XVI. Regulatory Analysis

The NRC has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC. The NRC requests public comment on the draft regulatory analysis. Availability of the regulatory analysis is provided in Section X of this document. Comments on the draft analysis may be submitted to the NRC as indicated under the **ADDRESSES** heading of this document.

XVII. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the NRC certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. This proposed rule affects only the licensing and operation of 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).

XVIII. Backfit Analysis

The NRC has determined that the proposed rule generally does not constitute backfitting as defined in the backfit rule, 10 CFR 50.109(a)(1), and that three provisions of the proposed rule effectively excluding certain 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.

The NRC has determined that the proposed 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 proposed rule.

As discussed in Section V.B 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. A proposed amendment to the backfit rule, § 50.109(b)(2), would provide that future changes to the TBS would not be subject to the backfit rule. The NRC has determined that there is no statutory bar to the adoption of such a provision. The NRC also believes that the proposed exclusion of such rulemakings from the backfit rule is appropriate. The NRC intends to revise the TBS in § 50.46a rarely and only if necessary based upon public health and safety and/or common defense and security considerations. The NRC also does not regard the proposed 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 proposed 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. In addition, this revised proposed rulemaking as applied to licensees who have not yet transferred to § 50.46a would not constitute backfitting for those licensees, inasmuch as the backfit rule does not protect a future applicant who has no reasonable expectation that requirements will remain static. The policies underlying the backfit rule apply only to licensees who have already received regulatory approval. Accordingly, the NRC concludes that the proposed 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 V.E of this document, § 50.46a(d)(4) would require 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 such a 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) would provide that such a re-evaluation, updating, and changes are not deemed to be backfitting. 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) would provide 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 to be considered 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, and that the proposed provision represents a justified departure from the principles underlying the backfit rule. First, 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. Second, the licensee has substantial flexibility under the proposed rule 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 revised proposed rule 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.

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. 553; the NRC is proposing to adopt 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 § 50.34, 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 operating licenses were issued after December 28, 1974, but before [EFFECTIVE DATE OF RULE], and for facilities for which construction permits may be issued after [EFFECTIVE DATE OF RULE] and are demonstrated under § 50.46a(c)(2) to have designs that are similar to the designs of reactors licensed before [EFFECTIVE DATE OF RULE].

(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 [EFFECTIVE DATE OF RULE] and are not demonstrated under § 50.46a(c)(2) to have designs that are similar to the designs of reactors licensed before [EFFECTIVE DATE OF RULE].

* * * * *

(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 were issued after December 28, 1974, but before [EFFECTIVE DATE OF RULE], and for facilities whose operating licenses are issued after [EFFECTIVE DATE OF RULE] and are demonstrated under § 50.46a(c)(2) to have designs that are similar to the designs of reactors licensed before [EFFECTIVE DATE OF RULE].

(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 are issued after [EFFECTIVE DATE OF RULE] and are not demonstrated under § 50.46a(c)(2) to have designs that are similar to the designs of reactors licensed before [EFFECTIVE DATE OF RULE].

* * * * *

3. 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 [EFFECTIVE DATE OF RULE]; 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 [EFFECTIVE DATE OF RULE] and are demonstrated under § 50.46a(c)(2) to have designs that are similar to the designs of reactors licensed before [EFFECTIVE DATE OF RULE]; and for design approvals and design certifications under part 52 of this chapter issued after [EFFECTIVE DATE OF RULE] that are demonstrated under § 50.46a(c)(2) to have designs that are similar to the designs of reactors licensed before [EFFECTIVE DATE OF RULE]. 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 [EFFECTIVE DATE OF RULE] and are not demonstrated under § 50.46a(c)(2) to have designs that are similar to the designs of reactors licensed before [EFFECTIVE DATE OF RULE]; 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 [EFFECTIVE DATE OF RULE].

(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.

* * * * *

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

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

(a) *Definitions.* 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 [EFFECTIVE DATE OF RULE] 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 larger of the feedwater line inside containment or the residual heat removal line inside containment for a boiling water reactor. For reactors licensed after [EFFECTIVE DATE OF RULE], 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 [EFFECTIVE DATE OF RULE]; 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 [EFFECTIVE DATE OF RULE] and whose design is demonstrated under § 50.46a(c)(2) to be similar to the designs of reactors licensed before [EFFECTIVE DATE OF RULE]; 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 [EFFECTIVE DATE OF RULE]. 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 licensee of a facility seeking to implement this section shall submit an application for a license amendment under § 50.90 that contains 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 licensee's facility. As part of this evaluation, the application must contain a plant specific analysis demonstrating that the risk of seismically-induced LOCAs larger than the TBS is comparable to or less than the seismically-induced LOCA risk associated with the NUREG–1903 results.

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

(iii) A description of the risk-informed evaluation process used in evaluating whether proposed changes to the facility meet the requirements in paragraph (f) of this section.

(iv) A licensee 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 licensee's PRA model and non-PRA risk assessment methods to be used for demonstrating compliance with paragraphs (f)(4) and (f)(5) of this section.

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

(2) An applicant for a construction permit, operating license, design approval, design certification, manufacturing license, or combined license seeking to implement the requirements of this section shall, in addition to the information 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 [EFFECTIVE DATE OF RULE] 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 that the NUREG–1829 results are applicable to the facility, and the risk of seismically-induced LOCAs larger than the TBS is comparable to or less than the seismically-induced LOCA risk associated with the NUREG–1903 results;

(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 the licensee proposes to use for making changes enabled by this section is adequate for determining whether the acceptance criteria in paragraph (f) of this section have been met; and

(iv) 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.

(v) For all applicants other than those holding operating licenses issued before [EFFECTIVE DATE OF RULE], the proposed reactor design is similar to the designs of reactors licensed before [EFFECTIVE DATE OF RULE] and the applicant's proposed TBS is consistent with the technical basis of this section.

(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) A change enabled by 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 two refueling outages. 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 paragraphs (f)(2) or (f)(3) 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 LOCAs 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 total of fourteen days in any 12 month period.

(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 generic results in NUREG–1829 and NUREG–1903.

(e) *ECCS Performance.* Each nuclear power reactor subject to this section must be provided with an ECCS that must be designed so that its calculated cooling performance following postulated 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. Realistic initial conditions and 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 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 licensee who wishes to make changes to the facility or procedures or to the technical specifications enabled by this rule shall perform a risk-informed evaluation.

(1) The licensee may make such changes without prior NRC approval if:

(i) The change is permitted under § 50.59,

(ii) The risk informed evaluation process described in paragraph (c)(1)(iii) of this section demonstrates that any increases in the estimated risk are minimal compared to the overall plant risk profile, 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 licensee's facility.

(2) For implementing changes which are not permitted under paragraph (f)(1) of this section, the licensee must submit an application for license amendment under § 50.90. The application must contain:

(i) The information required under § 50.90;

(ii) For applicants whose operating licenses were issued before [EFFECTIVE DATE OF RULE], 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) For applicants whose operating licenses were not issued before [EFFECTIVE DATE OF RULE], information from the risk-informed evaluation demonstrating that the total increases in core damage frequency and large release frequency are very small and the overall risk remains small, and the criteria in paragraph (f)(3) of this section are met;

(iv) 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; and

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

(vi) 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 generic 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'') that support the technical basis for this section.

(3) All changes enabled by this rule must meet the following criteria:

(i) Adequate defense in depth is maintained;

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

(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.

(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) 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. 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:

(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.

(2) 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 paragraphs (f)(1) or (f)(2) 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.

(3) Every 24 months, the licensee shall submit, as specified in § 50.4, 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).

(h) *Documentation.* Following implementation of the § 50.46a requirements, the licensee 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 applicable to a licensee's nuclear power plant, each licensee subject to this section shall 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, must not be deemed to be backfitting under any provision of this chapter.

5. 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.

* * * * *

6. 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 § 50.46a, where a single failure of the onsite power supplies and electrical distribution system need not be assumed for plants under § 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 § 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 § 50.46a. For those pipe breaks only, neither a single failure nor the unavailability of offsite power need be assumed.

* * * * *

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 § 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 § 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 § 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 licensees voluntarily choosing to comply with § 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

7. 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 (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. 594 (2005), secs. 147 and 149 of the Atomic Energy Act.

8. 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 [EFFECTIVE DATE OF RULE] and demonstrated under § 50.46a(c)(2) of this chapter to be similar to reactor designs licensed before [EFFECTIVE DATE OF RULE], 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 [EFFECTIVE DATE OF RULE].

* * * * *

9. 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 [EFFECTIVE DATE OF RULE] and demonstrated under § 50.46a(c)(2) of this chapter to be similar to reactor designs licensed before [EFFECTIVE DATE OF RULE], 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 [EFFECTIVE DATE OF RULE] and not demonstrated under § 50.46a(c)(2) of this chapter to be similar to reactor designs licensed before [EFFECTIVE DATE OF RULE].

*   *   *   *   *

10. 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 [EFFECTIVE DATE OF RULE] and demonstrated under § 50.46a(c)(2) of this chapter to be similar to reactor designs licensed before [EFFECTIVE DATE OF RULE], 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 [EFFECTIVE DATE OF RULE].

*   *   *   *   *

11. 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 [EFFECTIVE DATE OF RULE] and demonstrated under § 50.46a(c)(2) to be similar to reactor designs licensed before [EFFECTIVE DATE OF RULE], 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 [EFFECTIVE DATE OF RULE] and not demonstrated under § 50.46a(c)(2) of this chapter to be similar to reactor designs licensed before [EFFECTIVE DATE OF RULE].

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Dated at Rockville, Maryland, this 6th day of July 2009.

For the Nuclear Regulatory Commission.

Bruce S. Mallett,

Acting Executive Director for Operations.

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