[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150-AH29

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

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) proposes to amend its regulations to permit current power reactor licensees to implement a voluntary, 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 requesting changes in plant design and procedures based upon the results of the new analyses of ECCS performance during LOCAs.

DATES: Submit comments by [insert date 90 days after publication in the *Federal Register.*] Submit comments specific to the information collections aspects of this proposed rule by [insert date 30 days after publication in the *Federal Register.*] 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 on the proposed rule by any one of the following methods. Please include the following number, RIN 3150-AH29, in the subject line of your comments. Comments on rulemakings 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.

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

E-mail comments to: SECY@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. You may also submit comments via the NRC's rulemaking web site at http://ruleforum.llnl.gov. Address questions about our rulemaking website to Carol Gallagher (301) 415-5905; email cag@nrc.gov. Comments can also be submitted via the Federal eRulemaking Portal http://www.regulations.gov.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays. (Telephone (301) 415-1966).

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

You may submit comments on the information collections by the methods indicated in the Paperwork Reduction Act Statement.

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. Selected documents, including comments, may be viewed and downloaded electronically via the NRC rulemaking web site at http://ruleforum.llnl.gov.

Publicly available documents created or received at the NRC after November 1, 1999, 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 email to pdr@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Richard Dudley, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001; telephone (301) 415-1116; e-mail: rfd@nrc.gov,

SUPPLEMENTARY INFORMATION:

Table of Contents

3. Adjustments to address failure mechanisms not considered by the expert elicitation

a. LOCAs caused by failure of active components, such as stuck-open valves and blown out seals or gaskets.

b. Seismically-induced LOCAs, both with and without material degradation.

c. LOCAs caused by dropped heavy loads.

4. Consideration of connected auxiliary piping

5. Considerations of break location and flow characteristic

6. Effects of future plant modifications on TBS

7. Future adjustments to TBS

C. Alternative ECCS analysis requirements and acceptance criteria

1. Acceptable methodologies and analysis assumptions

2. Acceptance criteria

3. Plant operational requirements related to ECCS analyses

4. Restrictions on reactor operation

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

1. Requirements for the Risk-Informed Integrated Safety Performance (RISP) assessment process

a. Risk acceptance criteria for plant changes under 10 CFR 50.90

b. Risk acceptance criteria for plant changes under 10 CFR 50.59

c. Cumulative risk acceptance criteria

d. Defense-in-depth

e. Safety margins

f. Performance measuring programs

2. Requirements for risk assessments

a. Probabilistic Risk Assessment (PRA) requirements

b. Requirements for risk assessments other than PRA

3. Operational requirements

a. Maintain ECCS model(s) and/or analysis method(s)

b. Do not place the plant in unanalyzed at-power operating configurations

c. Evaluate all facility changes using the RISP assessment process

d. Implement adequate performance-measurement programs

e. Periodically re-evaluate and update risk assessments

E. Reporting requirements

1. ECCS analysis of record and reporting requirements

2. Risk assessment reporting requirements

3. Minimal risk plant change reporting requirement

F. Documentation requirements

G. Submittal and review of applications under § 50.46a

1. Initial application for implementing alternative § 50.46a requirements

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

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.

In stakeholder interactions, one candidate area identified for possible revision was emergency core cooling system (ECCS) requirements in response to postulated loss-of-coolant accidents (LOCAs). The NRC considers that large break LOCAs to be very rare events. Requiring reactors to conservatively withstand such events focuses attention and resources on extremely unlikely events. This could have a detrimental effect on mitigating accidents initiated by other more likely events. Nevertheless, because of the interrelationships between design features and regulatory requirements, making changes to technical requirements of certain parts of the regulations on ECCS performance has the potential to affect many other aspects of plant design and operation. The NRC has evaluated various aspects of its requirements for ECCS and LOCAs in light of the very low estimated frequency of the large LOCA initiating event.

A. Deterministic Approach

The NRC has established a set of regulatory requirements for commercial nuclear reactors to ensure that a reactor facility does not impose an undue risk to the health and safety of the public, thereby providing reasonable assurance of adequate protection to public health and safety. The current body of NRC regulations and their implementation are largely based on a “deterministic” approach.

This deterministic approach establishes requirements for engineering margin and quality assurance in design, manufacture, and construction. In addition, it assumes that adverse conditions can exist (e.g., equipment failures and human errors) and establishes a specific set of design basis events (DBEs) for which specified acceptance criteria must be satisfied. Each DBE encompasses a spectrum of similar but less severe accidents. The deterministic approach then requires that the licensed facility include safety systems capable of preventing and/or mitigating the consequences of those DBEs to protect public health and safety. While the requirements are stated in deterministic terms, the approach contains implied elements of probability (qualitative risk considerations), from the selection of accidents to be analyzed to the system level requirements for emergency core cooling (e.g., safety train redundancy and protection against single failure). Structures, systems or components (SSC) necessary to defend against the DBEs were defined as “safety-related,” and these SSCs were the subject of many regulatory requirements designed to ensure that they were of high quality, high reliability, and had the capability to perform during postulated design basis conditions.

Defense-in-depth is an element of the NRC's safety philosophy that employs successive measures, and often layers of measures, to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility. Defense-in-depth is used by the NRC to provide redundancy through the use of a multiple-barrier approach against fission product releases. The defense-in-depth philosophy ensures that safety will not be wholly dependent on any single element of the design, construction, maintenance, or operation of a nuclear facility. The net effect of incorporating defense-in-depth into reactor design, construction, maintenance and operation is that the facility or system in question tends to be less susceptible to, as well as more tolerant of failures and external challenges.

The LOCA is one of the design basis accidents established under the deterministic approach. If coolant is lost from the reactor coolant system and the event cannot be terminated (isolated) or the coolant is not restored by normally operating systems, it is considered an "accident" and then subject to mitigation and consideration of potential consequences. If the amount of coolant in the reactor is insufficient to provide cooling of the reactor fuel, the fuel would be damaged, resulting in loss of fuel integrity and release of radiation.

B. History of Requirements and Design for LOCAs

When the first commercial reactors were being licensed, design-basis LOCAs were assumed to have the potential of leading to substantial fuel melting. Therefore, emphasis was placed on containment capability, low containment leak rate, heat transfer out of the containment to prevent unacceptable pressure buildup, and containment atmospheric cleanup systems. The earliest commercial reactor containments were designed to confine the fluid release from a double-ended guillotine break (DEGB) of the largest pipe in the reactor coolant system (RCS). These early designs had long-term core cooling capability, but before 1966, high-capacity emergency makeup systems were not required.

During the review of applications for construction permits for large power reactors in 1966, evaluations of the possibility of containment basemat melt-through made it apparent to the Atomic Energy Commission (AEC) and the Advisory Committee on Reactor Safeguards (ACRS) that a containment might not survive a core meltdown accident. An ECCS task force was appointed to study the problem. In 1967, the task force concluded that a more reliable, high-capacity ECCS was needed to ensure that larger plants could safely cope with a major LOCA. The General Design Criteria (GDC) in Appendix A to 10 CFR Part 50, which were being

developed at the time, included requirements to this effect. The ECCS was to be designed to accommodate pipe breaks up to and including a DEGB of the largest pipe in the RCS.

In 1971, General Design Criterion 35 was finalized (36 FR 3256; February 20. 1971, as corrected, 36 FR 12733; July 7, 1971). GDC 35 states:

> *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, 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.

On January 4, 1974, (39 FR 1002) the Commission adopted 10 CFR 50.46, Acceptance Criteria for Emergency Core Cooling for Light Water Cooled Nuclear Power Reactors. Appendix K to 10 CFR 50 was promulgated with 10 CFR 50.46 to specify required and acceptable features of ECCS evaluation models. Appendix K included assumptions regarding initial and boundary conditions, acceptable models, and imposed conditions for the analysis. In developing Appendix K, conservative assumptions and models were imposed to cover areas where data were lacking or uncertainties were large or unquantifiable.

Later in 1974, the Commission began an effort to quantify the conservatism in the § 50.46 rule and Appendix K to 10 CFR Part 50. From 1974 until the mid-1980's, the AEC, and

subsequently the NRC, as well as the regulated industry; embarked on an extensive research program to quantify the conservative safety margins. In 1988, as a result of these research programs, 10 CFR 50.46 was revised to permit the use of realistic (or best-estimate) analyses in lieu of the more conservative Appendix K calculations, provided that uncertainties in the best-estimate calculations are quantified (53 FR 36004; September 16, 1988). Regulatory Guide 1.157 presents acceptable procedures and methods for realistic ECCS evaluation models.

The ECCS cooling performance must be calculated for a number of LOCA sizes (up to and including a double-ended rupture[1] of the largest pipe in the RCS), locations and other properties sufficient to provide assurance that the most severe postulated LOCAs are calculated, using one of the following two types of acceptable evaluation models:

(1) An ECCS model with the required and acceptable features of 10 CFR Part 50, Appendix K, or

(2) A best-estimate ECCS evaluation model which realistically represents the behavior of the reactor system during a LOCA, and includes an assessment of uncertainties which demonstrates that there is a high level of probability that the above acceptance criteria are not exceeded.

The requirements of 10 CFR 50.46 are in addition to any other requirements applicable to ECCS set forth in Part 50, and implement the general requirements for ECCS cooling performance design set forth in GDC 35. Thus, in order to mitigate LOCAs, an ECCS is required to be included in the design of light water reactors. The ECCS is currently required to be designed to mitigate a LOCA from breaks in RCS pipes up to and including a break

[1]In this document, the terms “rupture” and “break” are used interchangeably with no intended difference in meaning.

equivalent in size to a DEGB of the largest diameter RCS pipe. The ECCS is required to have sufficient redundancy that it can successfully perform its function with or without the availability of offsite power and with the occurrence of an additional single active failure.

GDC 35 requires that the ECCS be capable of providing sufficient core cooling during a LOCA even when a single failure is assumed. Standard Review Plan 6.3 interprets this as requiring the ECCS to perform its function during the short-term injection mode in the event of the failure of a single active component and to perform its long-term recirculation function in the event of a single active or passive failure.

All power reactors operating in the United States have multiple trains of ECCS capable of mitigating the full spectrum of LOCAs. Redundant divisions of electrical power and trains of cooling water are also available in pressurized-water reactors (PWRs) and boiling water reactors (BWRs) to support ECCS operation and together, provide the redundancy necessary to meet the single failure criterion.

C. Probabilistic Approach

A probabilistic approach to regulation enhances and extends the traditional deterministic approach by allowing consideration of a broader set of potential challenges to safety, providing a logical means for prioritizing these challenges based on safety significance, and allowing consideration of a broader set of resources to defend against these challenges. In contrast to the deterministic approach, PRAs address a very wide range of credible initiating events and assess the event frequency. Mitigating system reliability is then assessed, including the potential for common cause failures. The probabilistic treatment considers the possibility of multiple failures, not just the single failure requirements used in the deterministic approach. The probabilistic approach to regulation is therefore considered an extension and enhancement

of traditional regulation that considers risk (i.e. product of probability and consequences) in a more coherent and complete manner.

D. Commission Policy on Risk-Informed Regulation

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.

In addition to quantitative risk estimates, the defense-in-depth philosophy is invoked in risk-informed decision-making as a strategy to ensure public safety because both unquantified and unquantifiable uncertainties exist in engineering analyses (both deterministic analyses and risk assessments). The primary need with respect to defense-in-depth in a risk-informed regulatory system is guidance to determine which measures are appropriate and how good these should be to provide sufficient defense-in-depth.

Risk insights can clarify the elements of defense-in-depth by quantifying their benefit to the extent practicable. Although the uncertainties associated with the importance of some elements of defense-in-depth may be substantial, the quantification of the resulting safety enhancement can aid in determining how best to achieve defense-in-depth. Decisions on the

adequacy of, or the necessity for, elements of defense should reflect risk insights gained through identification of the individual performance of each defense system in relation to overall performance.

To implement the Commission Policy Statement, the NRC developed guidance on the use of risk information for reactor license amendments and issued Regulatory Guide (RG) 1.174, "An Approach for Using Probabilistic Risk Assessments in Risk-Informed Decisions on Plant Specific Changes to the Licensing Basis," (ADAMS 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 experience with the process and applications grew, the Commission 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 10 CFR 50.44 (68 FR 54123; September 16, 2003). The NRC also decided to examine the requirements for large break LOCAs. A number of possible changes were considered, including changes to GDC 35 and changes to § 50.46 acceptance criteria, evaluation models, and functional reliability requirements. The NRC also proposed to refine previous estimates of LOCA frequency for various sizes of LOCAs to more accurately reflect the current state of knowledge with respect to the mechanisms and likelihood of primary coolant system rupture.

Industry interest in a redefined LOCA was shown by filing of a Petition for Rulemaking (PRM 50-75) by the Nuclear Energy Institute (NEI) in February 2002 (ADAMS No. ML020630082). Notice of that petition was published in the *Federal Register* for comment on April 8, 2002 (67 FR16654). The petition requested the NRC to amend §50.46 and Appendices A and K to allow an option [to the double-ended rupture of the largest pipe in the RCS] for the maximum LOCA break size as "up to and including an alternate maximum break size that is approved by the Director of the Office of Nuclear Reactor Regulation." Seventeen sets of comments were received, mostly from the power reactor industry in favor of granting the petition. A few stakeholders were concerned about potential impacts on defense-in-depth or safety margins if significant changes were made to reactor designs based upon use of a smaller break size. The Commission is addressing the technical issues raised by the petitioner and stakeholders in this proposed rulemaking.

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 design optimization, fuel management improvements, elimination of potentially required actions for postulated sump blockage issues, power uprates, and changes to the required number of accumulators, diesel start times, sequencing of equipment, and valve stroke times; among others. In later written comments provided after an August 17, 2004, public meeting, the Westinghouse Owners Group concluded that the redefinition of the large break LOCA should have a substantial safety benefit (September 16, 2004; ADAMS No. ML042680079). NEI submitted comments (September 17, 2004; ADAMS No. ML042680080) which included a discussion of six possible plant changes made possible by such a rule. NEI stated its expectation that all six changes would most likely result in a safety benefit. The submittal from the Boiling Water Reactors Owners' Group (BWROG) (September 10, 2004; ADAMS No. ML 042680077) did not specifically address potential safety benefits from redefining the large break LOCA. The BWROG stated that certain design changes (recovering some operating margin, reducing blowdown loads, reducing use of snubbers, etc.) could be made possible by the redefinition.

The Commission 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

significant differences between stated Commission and industry interests. The original concept for Option 3 in SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR Part 50 - 'Domestic Licensing of Production and Utilization Facilities'," (ML992870048) was to make risk-informed changes to technical requirements in all of Part 50. The March 2003 SRM, as it related to LOCA redefinition, preserved design basis functional requirements (i.e., retaining installed structures, systems and components), but allowed relaxation in more operational aspects, such as sequencing of emergency diesel generator loads. The Commission supported a rule that allowed for operational flexibility, but did not support risk-informed removal of installed safety systems and components. Stakeholders expressed varying expectations about how broadly LOCA redefinition should be applied and the extent of changes to equipment that might result, based upon their understanding of the intended purpose of the Option 3 initiative.

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 DEGB of the largest RCS pipe. The Commission stated that the mitigation capabilities for beyond design-basis events should be controlled by

NRC requirements commensurate with the safety significance of these capabilities. The Commission also stated that LOCA frequencies should be periodically reevaluated and should increases in frequency require licensees to restore the facility to its original design basis or make other compensating changes, the backfit rule (10 CFR 50.109) would not apply. Regarding the current requirement to assume a loss-of-offsite power (LOOP) coincident with all LOCAs, the Commission accepted the NRC staff recommendation to first evaluate the BWROG pilot exemption request before proceeding with a separate rulemaking on that topic.

III. Proposed Action

The Commission proposes to establish an alternative set of risk-informed requirements with which licensees may voluntarily choose to comply in lieu of meeting the current emergency core cooling system requirements in 10 CFR 50.46. Using the alternative ECCS requirements will provide some licensees with opportunities to change other aspects of facility design. The overall structure of the risk-informed alternative is described below. The initial focus for this rulemaking is on operating plants. The Commission does not now have enough information to develop generic ECCS evaluation requirements appropriate to the potentially wide variations in designs for new nuclear power reactors. Promulgation of a similar rule applicable to future plants may be undertaken separately, at a later time, as the Commission's understanding of advanced reactor designs increases.[2] The potential rule changes discussed in this document would, at this time, only apply to nuclear power reactors which currently hold operating licenses. Proposed changes would consist of a new § 50.46a and conforming changes to existing

[2]The Commission notes that it is undertaking an effort to develop a technology-neutral licensing framework applicable to future advanced reactor designs. See 70 FR 5228 (February 1, 2005)

§§ 50.34, 50.46, 50.46a (to be redesignated as § 50.46b), 50.109, 10 CFR Part 50, Appendix A, General Design Criteria 17, 35, 38, 41, 44, and 50.

A. Overview of Rule Framework

The proposed rule 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).[3] 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" in the term, "TBS", does not mean a double-ended offset break. Rather, it relates to an equivalent opening in the reactor coolant boundary. Details on selection of the risk-informed LOCA TBS are presented in Section III.B of this supplementary information.

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 methods, assumptions and criteria currently used for LOCA analysis; accidents in the larger break size region will be analyzed by less stringent methods based on their lower likelihood. Although LOCAs for break sizes larger than the transition break will become "beyond design-basis accidents," the NRC would promulgate regulations ensuring that licensees maintain the ability to mitigate all LOCAs up to and including the DEGB of the largest RCS pipe. Design information for systems and components addressing the capability to mitigate LOCAs in the larger than TBS region would still be part of a plant's "design basis," as that term is defined in § 50.2, even though that equipment would be

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

used to mitigate a beyond design-basis accident. Since they would be mitigated to prevent core damage, LOCAs in the larger than TBS region would not be considered “severe accidents,” which are addressed by voluntary industry guidelines. The ECCS requirements for both regions are discussed in detail in Section III.C of this supplementary information.

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 required accident analyses. Potential design changes include optimization of containment spray designs, modifying core peaking factors, optimizing 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 since a licensee could optimize its systems to better mitigate the more likely LOCAs. The risk-informed § 50.46a option would establish risk acceptance criteria for evaluating *all* design changes, including those that are made possible by the revised ECCS requirements. These acceptance criteria would be consistent with the criteria for risk-informed license amendments contained in RG 1.174. These criteria would ensure both the acceptability of the changes from a risk perspective and the maintenance of sufficient defense-in-depth. They are discussed in detail in Section III.D of this supplementary information.

The rule would require that *all* future changes[4] to a facility, technical specifications[5], or operating procedures made by licensees who adopt 10 CFR 50.46a be evaluated by a risk-informed integrated safety performance (RISP) assessment process which has been reviewed and approved by the NRC via the routine process for license amendments.[6] The RISP assessment process would ensure that all plant changes involved acceptable changes in risk and were 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 would be allowed to make certain facility changes without NRC review if they met § 50.59[7] 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 the criterion that risk increases cannot exceed a "small" threshold. Potential impacts of the plant changes on facility security would be evaluated as part of the license amendment review

---

[4]The scope of changes subject to the change criteria in paragraph (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.

[5]The Commission notes that under the Atomic Energy Act of 1954, as amended, technical specifications are part of the license. Therefore, plant-specific technical specifications must be changed by a license amendment.

[6]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.

[7]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.

process. The safety and security review process for plant changes is discussed further in Section III.G.2 of this supplementary information.

The NRC would periodically evaluate LOCA frequency information. If estimated LOCA frequencies significantly increase, 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 (see Sections III.B.6 and III.H of this supplementary information). The backfit rule (10 CFR 50.109) also would not apply in these cases.

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 RCSs (SECY-04-0060, “Loss-of-Coolant Accident Break Frequencies for the Option III Risk-Informed Reevaluation of 10 CFR 50.46, Appendix K to 10 CFR Part 50, and General Design Criteria (GDC) 35;" April 13, 2004; ML040860129). This 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 by unisolable primary system side failures related to material degradation.

A baseline TBS was established using these pipe break frequencies as a starting point. This baseline TBS was then adjusted to account for other significant contributing factors that

were not explicitly addressed in the expert elicitation process. The following three-step process was used by the NRC in establishing the TBS.

(1) Break sizes for each reactor type (i.e., PWR and BWR) were selected that corresponded to a break frequency of once per 100,000 reactor-years (i.e., 1.0E-5 per reactor-year) from the expert elicitation results.

(2) The NRC then considered uncertainty in the elicitation process, other potential mechanisms that could cause pipe failure that were not explicitly considered in the expert elicitation process, and the higher susceptibility to rupture/failure of specific piping in the RCS.

(3) The NRC adjusted the TBS upwards to account for these factors.

The remainder of this section discusses this process and the bases for the NRC's decision in greater detail.

1. Historical estimates of LOCA frequencies.

Previous studies documented in WASH-1400 ("Reactor Safety Study – An Assessment of Accident Risks in U.S. Commercial Nuclear Power Plants," October 1975), NUREG-1150 ("Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants," December 1990), and NUREG/CR-5750 ("Rates of Initiating Events at U.S. Nuclear Power Plants: 1987-1995," February 1999) developed pipe break frequencies as a function of break size. The earliest studies (i.e., WASH-1400 and NUREG-1150) were based primarily on non-nuclear industry operating experience. A more recent study (i.e., NUREG/CR-5750) was based on a significant amount of nuclear operating experience; however, it only considered the LOCA frequencies associated with precursor leak events and did not separately evaluate the effects of known degradation mechanisms. These previous studies did not comprehensively evaluate the contribution to LOCA frequency for non-piping components other than steam generator tube

ruptures. They also did not address all current passive system degradation concerns and did not discriminate among breaks having effective diameters larger than 6 inches. Because of these limitations, these earlier studies were not sufficient to develop a TBS for use within 10 CFR 50.46a.

With over 3,000 reactor-years of operating experience, there is now a much better understanding of the failure frequencies for the various types of piping systems and sizes that are found in light water reactors. In addition, there is a more extensive knowledge of degradation mechanisms that could cause failures in these piping systems. To apply this operating experience and knowledge to risk-informing ECCS requirements, the NRC formed a group of experts with extensive knowledge of plant design, operation, and material performance to develop LOCA frequency estimates using an expert opinion elicitation process.

2. Expert opinion elicitation process.

In establishing pipe break frequencies as a function of break size, the NRC used an expert opinion elicitation process with a panel of 12 experts as documented in SECY-04-0060, “Loss-of-Coolant Accident Break Frequencies for the Option III Risk-Informed Reevaluation of 10 CFR 50.46, Appendix K to 10 CFR Part 50, and General Design Criteria (GDC) 35,” (April 13, 2004, ML040860129) and NUREG-1829, "Estimating Loss-of-Coolant Accident (LOCA) Frequencies Through the Elicitation Process, Draft Report for Comment," (June 30, 2005; ML052010464). The LOCA frequency contributions from pipe breaks in the reactor coolant pressure boundary as well as non-piping passive failures were considered in this study. Non-piping passive failure contributions were evaluated in reactor coolant pressure boundary components including the pressurizer, reactor vessel, steam generator, pumps, and valves, as appropriate, for BWR and PWR plant types. LOCA frequencies under normal operational

loading and transients expected over a 60 year reactor operating life were developed separately for PWR and BWR plant types, which comprise all the nuclear plants in the U.S. These frequencies represent generic values applicable to the currently operating U.S. commercial nuclear reactor fleet, based on an important assumption implicit in the elicitation, which is that all U.S. nuclear plant construction and operation is in accordance with applicable codes and standards. In addition, plant operation, inspection, and maintenance were generally assumed to occur within the expected parameters allowable by the regulations and technical specifications.

The uncertainty associated with each expert's generic frequency estimates was also estimated. This uncertainty was associated with each expert's confidence in their generic estimates and frequency differences stemming from broad plant-specific factors, but did not consider factors specific to any individual plants. Thus, the uncertainty bounds of the expert elicitation do not represent LOCA frequency estimates for individual plants that deviate from the generic values. Variability among the various experts' results was also examined. A number of sensitivity analyses were conducted to examine the robustness of the LOCA frequency estimates to assumptions made during the analysis of the experts' responses.

The LOCA frequency estimates developed using this process are consistent with operating experience for small breaks and precursor leaks and exhibit trends that are expected based on an understanding of passive system failure processes. This is important because it is expected from the results that the most significant LOCA frequency contribution occurs from degradation-induced precursors such as cracking and wall thinning. The LOCA frequency estimates are also comparable to prior LOCA frequency estimates.

There is significant uncertainty associated with the final LOCA frequency estimates caused by both individual expert opinion uncertainty and variability among the experts' opinions. The estimates also depend on certain assumptions used to process the experts' input. In addition, the effect of licensees' safety culture can significantly influence the cause, detection, and mitigation of degradation of safety components.

As a starting point, the NRC selected break sizes associated with a mean frequency of 10^{-5} per reactor-year using both geometric and arithmetic aggregations of individual expert opinion. For PWRs, this corresponds to a range of values from approximately 4 inches to 7 inches equivalent diameter, and for BWRs, from approximately 6 inches to 14 inches equivalent diameter. To address the uncertainty in the expert opinion elicitation estimates, the staff selected a pipe break frequency having approximately a 95th percentile probability of 10^{-5} per reactor-year which resulted in a range of values from approximately 6 inches to 10 inches equivalent diameter for PWRs and from approximately 13 inches to 20 inches equivalent diameter for BWRs. However, this does not account for all failure mechanisms. In addition, the results of an expert opinion elicitation do not have the same weight as actual failure data. Therefore, choosing the 95th percentile values gathered from the expert opinion elicitation leaves additional margin for uncertainty than would be necessary if the mean frequency had been calculated from actual failure data.

3. Adjustments to address failure mechanisms not considered by the expert elicitation.

The expert elicitation process was chartered to consider only LOCAs that could result from material degradation-related failures of passive components under normal operational conditions. There are also LOCAs resulting from failures of active components and other LOCAs resulting from low probability events (such as earthquakes of magnitude larger than the

safe shutdown earthquake, etc.) that contribute to the determination of pipe break frequencies. These LOCAs have a strong dependency on plant-specific factors. The NRC has evaluated the applicability of both LOCAs caused by failures of active components and those that could result from low probability events, as discussed below.

The NRC approach for the selection of the TBS is to use the frequency estimates of various degradation-related pipe breaks as a starting reference point. The frequencies for degradation-related breaks represent generic information, broadly applicable for indicating the trend of the frequency as the break size increases. In addition to the degradation-related frequency estimates, there are other important considerations in estimating overall LOCA frequencies. These include LOCAs caused by failures of active components; seismically-induced LOCAs (both with and without pipe degradation), and LOCAs caused by dropped heavy loads. Each is discussed below.

a. LOCAs caused by failure of active components, such as stuck-open valves and blown out seals or gaskets.

LOCAs caused by failure of these active components have a greater frequency of occurrence than LOCAs resulting from the failure of passive components. LOCAs resulting from the failure of active components are considered small-break (SB) LOCAs, when considering components which could fail open or blow out (e.g., safety valves, pump seals). Active 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, since the valves are back-seated in the open configuration. Based on these considerations, active LOCAs are relatively small in size and are bounded by the selected TBS.

b. Seismically-induced LOCAs, both with and without material degradation.

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.

The NRC is conducting a study to evaluate the seismic performance of undegraded and degraded passive system components. This effort is examining operating experience, seismic probabilistic risk assessment (PRA) insights, and models to evaluate the failure likelihood of undegraded and degraded piping. The operating experience review is considering 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. When completed, the results of this study could indicate that licensees choosing to implement this voluntary rule must perform a site-specific seismic assessment. The purpose of the assessment would be to demonstrate that RCS piping, assuming degradation that would not be precluded by implementing a licensee's inspection and repair programs, will withstand earthquakes such that the seismic contribution to the overall frequency of pipe breaks larger than the TBS is insignificant. If needed, this assessment would

be required to be submitted as a part of a licensee’s application for approval to implement the § 50.46a alternative ECCS requirements. Specific guidance for making these determinations would be provided by the NRC in the regulatory guide pertaining to this rule.

Plant-specific assessments could be needed because the seismically-induced break frequencies (direct and indirect) are governed by site hazard estimates, plant-specific configurations, and individual plant design. The NRC's generic analysis, by its very nature, cannot reasonably encompass all potential plant-to-plant variations. For some plants, a plant-specific assessment could be a relatively simple evaluation to show that the likelihood of breaks larger than the TBS is sufficiently low because of a low seismic hazard and consequently very low stresses. For other plants, an assessment might involve performing more detailed plant-specific calculations to better estimate seismic stresses and other parameters, or developing augmented plant-specific in-service inspection programs for very strict control of pipe degradation. These programs would be designed to detect and repair piping flaws that could increase the likelihood of seismically-induced pipe breaks with cumulative area larger than the TBS. Other approaches, including more detailed studies, generically or for group of plants with similar characteristics from the perspective of this issue, could also be undertaken.

The NRC is continuing work to assess the likelihood of seismically-induced pipe breaks larger than the TBS. These analyses are generic in nature and make use of a combination of insights from deterministic and probabilistic considerations. To facilitate public comment on the technical aspects of this issue, an NRC report outlining the details and results of the NRC's approach will be posted in December 2005 on the NRC rulemaking web site at http://ruleforum.llnl.gov. Stakeholders should periodically check the NRC rulemaking web site for this information. (See Section III.J.2 of this supplementary information.)

Since a plant-specific seismic assessment requirement might be included in the final rule, the NRC is requesting specific public comments on potential options and approaches to address this issue. (See Section III.J.3 of this supplementary information.)

c. LOCAs caused by dropped heavy loads.

Another consideration in selecting the TBS is the possibility of dropping heavy loads and causing 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, which further reduces 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. Therefore, based on this information, the contribution of heavy load drops on LOCA frequency is not considered to be significant. Finally, the resolution of GSI-186 (NUREG-0933; ML04250049) resulted in recommendations which are expected to further reduce the overall risk due to heavy load drops in the future.

4. Consideration of connected auxiliary piping.

Other considerations in selecting the TBS were 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 reactor-year ranged from values of approximately 13 inches to 20 inches equivalent diameter. The information gathered from the expert opinion 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. In looking at BWR designs, it was determined that typical residual heat removal piping connected to the recirculation loop piping and feedwater piping is about 20 to 24 inches in diameter. It was also recognized that the sizes of attached pipes vary somewhat among plants. Accordingly, the NRC chose a TBS for BWRs based on the larger of either the feedwater or the residual heat removal (RHR) piping inside primary containment. Selecting these pipes results in a TBS equivalent diameter of about 20 inches. 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.

The NRC believes these definitions of the TBS provide necessary conservatism to address uncertainties in estimation of break frequencies. In addition, these TBS values are

within the range supported by the expert opinion elicitation estimates when considering the uncertainty inherent in processing the degradation-related frequency estimates. Furthermore, the NRC expects that these values will provide regulatory stability such that future LOCA frequency reevaluations are less likely to result in a requirement that licensees undo plant modifications made as a result of implementing 10 CFR 50.46a.

5. Considerations of break location and flow characteristic.

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 in size. The cold legs (including the intermediate legs) operate at slightly cooler temperatures and any degradation mechanism that might appear 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 which would be smaller in size than the surge lines. 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 circumferential break) plus the frequency of a partial break of that size in an equal or larger size pipe (a 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 in the hot and cold legs which would be equivalent to the frequency of a complete surge line break. From this, it was 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 enough specific detailed information to adequately quantify any specific differences in the frequencies compared to a complete surge line break. Because a smaller size partial break TBS criterion in either the hot or cold legs could not be established, it was determined that the required TBS partial breaks in the hot and cold legs should remain equivalent in size to the internal cross sectional area of the surge line.

There is no significant difference in piping or service conditions in BWRs compared to the PWR hot and cold leg differences described above, where a difference in the rates of degradation could be identified. Thus, a smaller size partial break TBS criterion also could not be established for BWRs.

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 estimates are based on knowledge of physical pressure retaining component behavior and are not premised on breaks being either single-ended or double-ended. This is a feature of the response of the particular system configuration to the occurrence of the break, i.e., whether reactor coolant can feed either end 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 in accordance with 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. While this is true, the

dominant effect in terms of core cooling is loss of the fluid exiting from the hot leg side of the break, with much less effect due to fluid 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 based on the larger of the RHR or main feedwater lines would bound breaks of the smaller lines in the reactor recirculation and feedwater piping where a complete break would result in a double-ended discharge flow. Therefore, the NRC has determined that the assumption of a single-ended characteristic of the TBS break reasonably represents the effect of RCS breaks. This conclusion is not inconsistent with the expert opinion elicitation estimates of break frequencies.

6. Effects of future plant modifications on TBS.

For the proposed 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 power uprate allowances may change plant performance and relevant operating characteristics to a degree that they might impact future LOCA frequencies. In applications for power uprates that use or intend to use § 50.46a, the NRC will expect licensees to explain why uprate conditions (e.g., increased flow-induced vibrations and increased potential for flow-assisted corrosion in the reactor coolant pressure boundary piping) do not significantly increase break frequencies.

7. Future adjustments to TBS.

The initial 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 mechanisms, the NRC will assess whether the TBS (as defined in the rule) 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 precursors that might be indicative of an increase in pipe break frequencies in plants operating under power uprate conditions to establish whether the TBS would need to be adjusted.

C. Alternative ECCS Analysis Requirements and Acceptance Criteria

The 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 must be performed by acceptable methods 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) of the proposed rule specifies requirements identical to the existing ECCS analysis requirements set forth in § 50.46. However, commensurate with the lower probability of breaks larger than the TBS, § 50.46a(e)(2) of the proposed rule specifies more realistic requirements associated with the rigor and conservatism of the analyses and associated acceptance criteria for breaks larger than the TBS. LOCA analyses for break sizes equal to or smaller than the TBS should 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) should also be applied to all locations in the RCS to find the limiting break size and location. This analytical approach is consistent with current 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. 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 would be retained in § 50.46a(e)(1) of the proposed rule for breaks at or below the TBS.

The NRC expects that the level of conservatism of an analysis method used for breaks larger than the TBS would be less than for breaks at or below the TBS. This concept is reflected in the differences between paragraphs (e)(1) and (e)(2) of § 50.46a, which respectively describe ECCS evaluation requirements for breaks at or below the TBS and breaks larger than the TBS. As noted above, for breaks at or below the TBS, all current requirements, including use of an ECCS evaluation model as defined in the rule, are retained. For larger breaks, paragraph (e)(2) of § 50.46a indicates that only the most important phenomena must be addressed by the analysis method, and that the model must reasonably describe the behavior of the RCS during the LOCA. The term "analysis method" is used for the larger than TBS break sizes to indicate that these methods need not be the same as the ECCS evaluation models required for breaks at or below the TBS. To analyze breaks larger than the TBS, a

licensee need not use an NRC currently approved evaluation model, plant-specific or generic. A licensee may use a presently approved best-estimate methodology for breaks larger than the TBS. Such an evaluation model would exceed the requirements for analysis methods, and would likely yield margin to the acceptance criteria. Also, these approved models are available for use at most plants for some break sizes.

Licensees would not be required to submit detailed analysis method documentation for LOCAs larger than the TBS. Section 50.46a would not require prior NRC approval of these analysis methods. Licensees would only be required to describe the analysis methods used. Analyses using methods unfamiliar to the NRC or of questionable accuracy would be reviewed by NRC via the inspection process.

As currently required under § 50.46, the analysis must demonstrate with a high level of probability that the acceptance criteria will not be exceeded for breaks at or below the TBS. What constitutes a high level of probability is not delineated in the rule. 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 proposed rule retains the high level of probability as the statistical acceptance criterion for breaks at or below the TBS. Because of the much lower frequency of pipe breaks larger than the TBS, proposed § 50.46a(e)(2) relaxes the criterion to "reasonably" describe the system behavior for breaks larger than the TBS. The NRC is preparing a regulatory guide which would provide more detailed guidance about meeting this criterion.

Paragraphs 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 will be used for each break size region. Consistent with current § 50.46 requirements, breaks at or below the TBS will be

analyzed 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, credit may be taken for operation of any and all equipment supported by availability data, along with the use of nominal operating conditions rather than technical specifications 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 are not required. These more realistic requirements are appropriate because breaks larger than the TBS are very unlikely. Thus, less margin is needed in the analysis of breaks in this region.

As discussed further in Section III.C.3, “Plant operational requirements related to ECCS analyses,” § 50.46a(d)(2) would prohibit plant operation in any at-power operating configuration for which maintenance of coolable geometry and long-term cooling for LOCAs larger than the TBS has not been demonstrated. A licensee could analyze planned operating configurations or justify that a particular configuration is bounded by failures assumed in other analyses to limit the number of calculations necessary to support plant operation when equipment is out of service or equipment performance is degraded. The NRC will provide further guidance on analysis methods and assumptions in the regulatory guide issued with the final rule.

2. Acceptance criteria.

ECCS acceptance criteria in proposed § 50.46a(e)(3) for breaks at or below the TBS are 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:

i. PCT less than 2200EF;

ii. Maximum local cladding oxidation (MLO) less than 17 percent;

iii. Maximum hydrogen production -- core wide cladding oxidation (CWO)

less than 1 percent;

iv. Maintenance of coolable geometry; and

v. Maintenance of long-term cooling.

The first two criteria are established to ensure that the clad retains adequate ductility as it is quenched from the elevated temperatures anticipated during a LOCA. Loss of ductility would potentially result in fragmentation of the fuel and loss of a coolable geometry. Clad temperatures in the range of 2200EF result in rapid decreases in cladding ductility and ductility is reduced when oxidation levels reach 17 percent. The calculated maximum local cladding oxidation must account for the pre-existing oxidation accumulated during burnup and that generated during the LOCA. In addition, oxidation on the inside of the clad surface must also be considered once the clad is calculated to have ruptured. For the majority of current plants, operation is limited by the PCT criterion, as total oxidation levels typically calculated do not exceed approximately 10 percent for most plants. However, as the break size definition for a design basis accident decreases, cladding oxidation can become limiting. Small breaks result in extended periods of time at moderate temperatures, in the range of 1800EF, which can produce oxidation levels as great or greater than short time spans at higher temperatures. The limit on hydrogen production is important for small breaks for the same reason -- long periods at moderate temperatures can cause greater clad oxidation and hydrogen production. Only hydrogen calculated to be produced during the LOCA is compared to the CWO limit. The CWO limit was not removed from the breaks at or below the TBS because the requirements of 10 CFR 50.44, “Combustible Gas Control for Nuclear Power Reactors,” ensure combustible gas control for beyond design basis accidents only and thus can rely on non-safety systems and less rigorous analysis techniques to demonstrate compliance.

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

i. Maintenance of coolable geometry, and

ii. Maintenance of long-term cooling.

The proposed rule would afford 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 2200EF and 17 percent for the limits on PCT and MLO, respectively, as metrics and quantitative acceptance criteria for meeting the proposed rule's acceptance criteria. Other less conservative criteria would be acceptable if properly justified by licensees. In addition, the requirements of 10 CFR 50.44 specify that all containments have the capability for ensuring a mixed atmosphere, thus reducing the potential for hydrogen combustion in the event of a beyond design-basis LOCA. The rule requires that BWRs with Mark III containments and all PWRs with ice condenser containments must have the capability for controlling combustible gas generated from a metal-water reaction involving 75 percent of the fuel cladding surrounding the active fuel region, and BWRs with Mark I and II containments must have inerted containments. Analyses performed to support the § 50.44 rulemaking (68 FR 54141; September 16, 2003) demonstrated that PWRs with large dry containments do not require additional measures to control combustible gas generated from a metal-water reaction involving 75 percent of the fuel cladding surrounding the active fuel region. This bounds the level of oxidation expected in the event of a LOCA larger than the TBS.

3. Plant operational requirements related to ECCS analyses.

The proposed rule would require that a facility be able to mitigate LOCA break sizes larger than the TBS up to and including a double-ended rupture of the largest pipe in the RCS at the limiting location. The licensee must demonstrate this mitigative ability, in part, using evaluation models or analysis methods under § 50.46a(e)(2) to demonstrate compliance with the acceptance criteria in § 50.46a(e)(4). For LOCAs larger than the TBS, licensees must demonstrate compliance with the acceptance criteria in § 50.46a(e)(4) under all at-power operating conditions (i.e., all modes of operation when the reactor is critical). This demonstration is required at-power because LOCAs are most likely to challenge the ECCS acceptance criteria during power operation. These analyses will identify ECCS components and trains (including sufficiently reliable non-safety related systems) that are required to operate to mitigate LOCA break sizes larger than the TBS.

The proposed rule would not require assuming a loss-of-offsite power or a limiting single failure of the ECCS for LOCA analyses performed for breaks larger than the TBS. Thus, it is possible that a licensee's analyses would credit that the full complement of ECCS was available. To ensure that the facility will continue to comply with the acceptance criteria for LOCAs larger than the TBS under any at-power operating configuration allowed by the license, the Commission would require both that the acceptance criteria not be exceeded during any at-power condition that has been analyzed, and that the plant not be placed in any unanalyzed condition.

One circumstance where the ability to comply with the acceptance criteria might be called into question would be if an ECCS train or component was removed from service (such as for maintenance) while the plant is in operation. For this time period, the assumed set of mitigation systems would not be available to respond should a beyond TBS LOCA occur, and the acceptance criteria might not be satisfied. Thus, the licensee would either have to

demonstrate that under such conditions the acceptance criteria would not be exceeded, or not place the facility in that configuration. To satisfy this requirement a licensee might prepare analyses showing acceptable results with expected complements of equipment that might be taken out of service or could propose suitable Technical Specifications as part of its application for the facility change that would restrict plant operation to acceptable conditions.

Accordingly, in § 50.46a(d)(2) of the proposed rule, the Commission would require that the facility may not operate in any at-power configuration of operable ECCS components where the ECCS cooling performance for LOCAs larger than the TBS has not been demonstrated to meet the acceptance criteria in § 50.46a(e)(4). The evaluation must be calculated in accordance with § 50.46a(e)(2). Bounding analyses may be performed to reduce the number of model calculations.

4. Restrictions on reactor operation.

Proposed § 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 § 50.46a(e)(1) through (e)(4) of this section. 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 § 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 such issues are settled. This

requirement would be included in the proposed rule for consistency with the current ECCS regulations, since it is comparable to existing § 50.46(a)(2).

D. <u>Risk-Informed Changes to the Facility, Technical Specifications, or Procedures</u>

The Commission proposes that licensees who adopt § 50.46a would use an integrated, risk-informed change process to demonstrate the acceptability of *all* future facility changes, both with and without NRC approval, made under § 50.90 or § 50.59, respectively. This risk-informed integrated safety performance assessment, or RISP assessment, would be required to demonstrate that (1) increases in plant risk (if any) meet appropriate risk acceptance criteria, (2) defense-in-depth is maintained, (3) adequate safety margins are maintained, and (4) adequate performance-measurement programs are implemented.

The Commission considered adopting two sets of change control criteria: one for changes enabled by the new rule,[8] and one for all other changes. The Commission rejected this option because it may be difficult to distinguish between facility changes enabled by § 50.46a and changes that are permitted by the current ECCS requirements in § 50.46.

1. Requirements for the Risk-Informed Integrated Safety Performance (RISP) assessment process.

A licensee who wishes to implement § 50.46a requirements would submit a license amendment request under § 50.90 and receive prior NRC approval to implement the alternative requirements. As discussed in Section III.C.1 of this supplementary information, the proposed

---

[8]As discussed in Section III.A of this supplementary information, licensees approved to implement § 50.46a would be able to make facility changes which would not have been permitted without the revised ECCS analyses allowed by the rule. These are considered to be § 50.46a enabled changes. Other changes that licensees could make after adopting this rule could be unrelated to the new § 50.46a, insofar as the basis of the changes and NRC approval, when necessary, would rely on requirements or analyses that do not depend on the new ECCS analyses and acceptance criteria.

rule would require a description of the method(s) and the results of the analyses to demonstrate compliance with the § 50.46a ECCS acceptance criteria and a description of the RISP assessment process to be used in evaluating whether proposed changes to the facility, technical specifications, or procedures meet the requirements in 50.46a(f). In particular, § 50.46a(c)(1)(ii)(A) would require a description of the licensee's PRA model and risk assessment methods, and § 50.46a(c)(1)(ii)(B) would require a description of the methods and decisionmaking process for evaluating compliance with the risk criteria, defense-in-depth criteria, safety margin criteria, and performance measurement criteria in § 50.46a(f). The information required to be submitted in the application would form the basis for the NRC's determination of whether the licensee's process will ensure that the requirements of § 50.46a(f)(1) are met for future changes made according to the § 50.59 requirements.

The Commission could approve a licensee's application to implement 10 CFR 50.46a if the criteria in § 50.46a(c)(2) were met. Section 50.46a(c)(2) would require that:

1. The licensee's ECCS analyses and results demonstrate compliance with the ECCS acceptance criteria,

2. The RISP assessment process assures that all facility changes meet the risk assessment requirements of § 50.46a(f), and

3. The RISP assessment process ensures that changes not requiring prior NRC review and approval are evaluated and comply with § 50.59.

Compliance with the ECCS acceptance criteria is necessary to ensure that licensed facilities are able to adequately mitigate LOCAs of varying sizes and locations. 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 RISP assessments is required to ensure that

facility changes result in acceptable changes in risk, adequate defense-in-depth and safety margins are maintained, and acceptable performance-measurement programs are implemented. The § 50.46a(f) requirements are discussed individually below.

Sections § 50.46a(f)(1)(ii) and (f)(2)(ii) would describe the risk acceptance criteria that the RISP assessment must demonstrate are met. Paragraph (f)(3) would describe the requirements on the defense-in-depth and safety margin evaluations, and on the performance measurement programs. Paragraphs (f)(4) and (f)(5) would describe the requirements on the PRA or non-PRA risk assessment models and methodologies used to determine the impact of the changes on risk.

A RISP assessment process would include quantitative and qualitative risk analysis tools, a framework for evaluating defense-in-depth implications of changes, a framework for evaluating safety margins, and performance-measurement programs that monitor the facility and provide feedback of information for timely corrective actions. These attributes have been identified by the Commission as a necessary set of evaluation tools to ensure that changes to the facility do not endanger the public health and safety.

a. Risk acceptance criteria for plant changes under 10 CFR 50.90

Section 50.46a(f)(2)(ii) would require that the RISP demonstrate, for changes made under § 50.90, that the total increases in core damage frequency (CDF) and large early release frequency (LERF) are small and that the overall plant risk remains small. CDF and LERF are surrogates for early and latent health effects, which are used in the NRC's Safety Goals (Safety Goals for the Operation of Nuclear Power Plants; Policy Statement, 51 FR 30028; August 4, 1986). The NRC has used CDF and LERF in making regulatory decisions for over 20 years. Most recently, 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.

Application-specific regulatory guides have been developed on risk-informed IST, ISI, graded quality assurance, and technical specifications. Since the adoption of RG 1.174, the Commission has had eight 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, the Commission believes 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.

Paragraph 50.46a(f)(2)(ii) would require the total increases in CDF and LERF to be small, and the overall plant risk to remain small.[9] As discussed in RG 1.174, whether a change in risk is small depends on a plant's overall risk as measured by the current CDF and LERF. For plants with an overall baseline CDF of 10^{-4} per year or less, small CDF increases are considered to be up to 10^{-5} per year. For plants with an overall baseline CDF greater than 10^{-4} per year, small CDF increases are those of up to 10^{-6} per year. For plants with an overall baseline LERF of 10^{-5} per year or less, small LERF increases are considered to be up to 10^{-6} per year, and for plants with an overall baseline LERF greater than 10^{-5} per year, small LERF increases are considered to be up to 10^{-7} per year. Since 1997, the Commission has applied

[9]Section 2.2.4 in RG 1.174 clarifies that the acceptance criteria for changes to CDF and LERF are to be compared with the results of a full-scope risk assessment including internal events, external events, full power, low power, and shutdown. All references to CDF and LERF refer to estimates that include the risk from internal events, external events, full power, low power, and shutdown. Therefore the CDF and LERF estimates to be used in § 50.46a evaluations are directly comparable to the acceptance guidelines on CDF and LERF in RG 1.174.

these quantitative guidelines to individual plant changes and to sequences of plant changes implemented over time. The Commission has found these guidelines and these 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 the public health and safety from those that might. The Commission proposes to use these quantitative guidelines as the basis for determining whether the total increase in CDF and LERF are small and that the overall plant risk remains small.

The Commission requests specific public comments on the acceptability of applying the change in risk acceptance guidelines from 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? (See Section III.J.13 of this supplementary information.)

b. Risk acceptance criteria for plant changes under 10 CFR 50.59

After the adoption of § 50.46a by a licensee and the approval of the proposed RISP assessment program by the NRC, a risk assessment would be required for all changes to the facility, technical specifications, and procedures that a licensee proposes to make.
Section 50.46a(f)(1)(ii) of the proposed rule would require that the RISP demonstrate, for changes made under § 50.59, that any increases in the estimated risk are "minimal" compared to the overall[10] plant risk profile. In the Commission's view, plant changes which individually and taken together involve minimal changes in risk and have no significant impact upon defense-in-depth or safety margins (and do not involve a change to the license), do not result in significant issues involving public health and safety or common defense and security. For such changes, a qualitative assessment instead of a quantitative estimate of the change in risk may

[10]As with plant changes made under § 50.90, "overall" plant risk includes the risk from internal events, external events, full power, low power, and shutdown.

be sufficient to demonstrate that the proposed change meets the minimal increase in risk criteria.

For plant changes for which it is possible to quantitatively estimate the resulting change in plant risk, existing guidance in RG 1.174 for NRC review of risk-informed changes does not address a threshold for changes that result in risk increases that might be small enough (i.e., minimal) that the proposed plant change does not warrant review by the NRC. Section 50.59, however, contains guidance on determining when non risk-informed plant changes do not warrant review by the NRC. Consequently, the Commission proposes to develop the new criteria proposed in § 50.46a(f)(1)(ii) to be consistent with “minimal” as it is described in supplementary information published with the December 2001 amendment to 10 CFR 50.59 (66 FR 64738).

The Commission believes that if a change in risk is so small that it cannot be reasonably concluded that the risk has actually changed (i.e., there is no clear trend toward increasing the risk), the change need not be considered an increase in risk. If defense-in-depth, safety margins, and performance measurement program criteria are also met, such changes would always have a “minimal” increase in risk. However, the Commission believes that the appropriate threshold for "minimal" should provide more flexibility than afforded by the description above.

In the December 2001 amendment to § 50.59, the Commission also stated that “minimal” as used in § 50.59 is intended to limit the amount of increase in probability or consequences of accidents such that it remains substantially less than a ‘‘significant increase’’ as referred to in § 50.92. Therefore the Commission proposes that the “minimal” in § 50.46a(f)(1)(ii) should limit the amount of increase in risk such that it remains less than the “small” increase permitted in § 50.46a(f)(2)(ii).

As discussed below, RG 1.174 guidelines state that, if the overall CDF is greater than 10^{-4} per year, an increase in CDF greater than 10^{-6} per year is not small. Similarly, if the overall LERF is greater than 10^{-5} per year, an increase in LERF greater than 10^{-7} per year is not small. Conversely, increases in CDF less than 10^{-6} per year and increases in LERF 10^{-7} per year are always small. The Commission proposes to define "minimal" as 10 percent of the risk increases that would be small for *any* licensee. An alternative, consistent with RG 1.174, would be to define minimal as 10 percent of small, and allow small to vary from plant to plant according to the overall plant specific CDF and LERF. For example, minimal could be defined as an increase in CDF less than 10^{-6} per year if the overall CDF is less than 10^{-4} per year, or less that 10^{-7}per year otherwise. However, if correction of a PRA error or new information caused the overall CDF to rise from below to above 10^{-4} per year, the acceptance criteria for minimal would drop from 10^{-6} per year to 10^{-7} per year from one moment to the next. Existing §§ 50.59 and 50.92 provide acceptance criteria that are applicable to all the plants and that do not change with time. Therefore, the Commission believes that, when quantified, a "minimal" risk increase would be an increase in CDF less than 10^{-7} per year and an increase in LERF less than 10^{-8} per year. This permits a single risk level to be applied to all plants and limits the likelihood of the acceptable risk level changing as the plant overall risk changes.

Paragraph 50.46a(f)(ii) would also require that the increase in risk from each change is minimal compared to the overall plant-specific risk profile. For licensed facilities which have very low overall risk estimates, the proposed criteria of 10^{-7} per year and 10^{-8} per year for CDF and LERF, respectively, may permit increases that are significantly large compared to the overall plant risk profile. Permitting a licensee to make changes without NRC review that are not minimal compared to the overall plant risk is contrary to the intent of the proposed rule. Therefore, the Commission proposes that, when quantified, a "minimal" increase in CDF and

LERF must also be an increase of less than 1 percent of the overall plant-specific risk. The Commission expects that the fixed risk threshold on “minimal” changes discussed above (i.e., less than 10^{-7} per year and 10^{-8} per year increase in CDF and LERF respectively) will be applicable to most, if not all, plants.

For the reasons discussed above, the Commission proposes that a risk increase, when evaluated quantitatively, would be considered to be "minimal compared to the overall plant risk profile" if it meets both of the following criteria:

(1) The increase in CDF less than 10^{-7} per year and an increase in LERF less than 10^{-8} per year, and

(2) The increases in CDF and LERF are increases of less than 1 percent of the overall plant-specific risk.

c. Cumulative risk acceptance criteria

To satisfy the Commission’s proposed requirement in § 50.46a(f)(2)(ii) that the total increases in CDF and LERF are small and overall plant risk remains small, the total risk from all changes since the adoption of § 50.46a must be tracked. It is important to track the total change in risk from changes to the facility, technical specifications, and procedures to ensure that these changes, when taken in total as they are implemented over time, do not contribute more than a small increase in risk. A licensee may always choose to implement a series of changes over time. If tracking the total increase in CDF and LERF criteria were not implemented, a number of smaller changes where every individual change is kept below the proposed rule’s risk acceptance criteria could, considered cumulatively, result in a significant increase in risk. The proposed rule’s requirement for risk tracking is consistent with RG 1.174, the application-specific RG’s, and current staff practice. Tracking the total risk increase caused by implementing related changes over time and comparison of the total against the RG 1.174

criteria has been used for risk-informed in-service testing (IST), in-service inspection (ISI), and integrated leak rate interval extension and is included as part of the § 50.69 risk assessment process. However, tracking the total risk increase caused by sequential risk-informed extensions of technical specification allowed outage times is not required under RG 1.177 guidance for risk-informed technical specification changes. Instead, approved changes must include provisions to control the potential total risk increase by a configuration risk management program that prevents unacceptable risk increases that could be caused by overlapping the extended allowed outage times permitted by the changes.

This rule would require that the cumulative risk increase from all changes be evaluated against the “small” criteria. Requiring that the total change in risk from a series of changes be compared to the § 50.46a acceptance criteria instead of allowing the risk to be partitioned and individually compared to the acceptance criteria will ensure that the total risk increase of all changes, as they are implemented over time, would not constitute more than a small increase in risk. Current staff practice, consistent with RG 1.174, is to compare the cumulative risk increase from all related changes, and only related changes, to the acceptance guidelines. Regulatory Guide 1.174 also provides additional acceptance guidelines that must be met before permitting unrelated plant changes that might decrease risk to be combined (bundled) together with a group of related changes in a change in risk estimate. Defining and tracking related and bundled changes and separating out the cumulative impact on risk of these changes from all other changes is a complex process. The proposed rule would simplify this process by combining the cumulative increase of all plant changes after adoption of the new rule consistent with the Commission decision that all changes be evaluated using the RISP assessment process. Under this proposal, there is no need to differentiate between related and unrelated

changes, and the total cumulative change in risk is directly related to the change in the overall CDF and LERF over time.

The Commission believes that including this requirement in the proposed rule is required to ensure that risk tracking is performed by all licensees and is a necessary element for ensuring that changes which would be permitted by the revised ECCS analyses allowed under § 50.46a do not result in a greater change in risk than intended by the Commission. Comparing the risk increase from each change to the acceptance criteria independently of all previous changes would render the use of the “small” criteria inadequate to monitor and control increases in risk from a series of plant changes implemented over time. Defining and tracking the cumulative risk impact of “related” changes is complex and impracticable. Furthermore, licensees who approach the acceptance criteria on risk increases may chose to implement other plant changes that reduce risk in order to take advantage of further changes that might otherwise increase risk above the criteria. Comparing the total risk increase to the risk increase criteria will support the Commission 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.

The Commission requests specific public comments on whether there is an alternative to tracking the cumulative risk increase that is sufficient to provide reasonable assurance of protection to public health and safety and common defense and security. (See Section III.J.12 of this supplementary information.)

The Commission also requests specific public comments on the acceptability of combining § 50.46a related and unrelated changes to meet the risk acceptance criteria. (See Section III.J.11 of this supplementary information.)

Section 50.46a(f)(2)(ii) requires tracking of all proposed plant changes (i.e., changes to the facility, technical specifications, and procedures), but would not require a licensee to include risk increases caused by previous risk-informed changes that were implemented before § 50.46a was adopted. Conversely, licensees who adopt § 50.46a, will be required to include every risk increase caused by every facility, technical specification, or procedure change. Consequently, licensees who adopt § 50.46a before implementing other risk-informed applications, will effectively have a smaller risk increase "available" compared to licensees that have already incorporated some risk-informed changes into their overall plant risk before adopting § 50.46a. The Commission does not consider this a safety issue but requests specific public comment on whether this potential inconsistency should be addressed and, if so, how? (See Section III.J.14 of this supplementary information.)

d. Defense-in-depth

Section 50.46a(f)(3)(i) would require that the RISP assessment 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 assured in all risk-informed regulatory activities. Upon implementation of § 50.46a, all changes to the facility, technical specifications, and procedures will become risk-informed regulatory activities.

In RG 1.174, the NRC developed seven elements that should be utilized in evaluating the level of defense-in-depth provided for nuclear power plants in making risk-informed

changes to the licensing basis. Since the adoption of RG 1.174 in 1997, the Commission has had eight years of experience in applying its guidance to a variety of applications, as discussed above. On the basis of this experience, the Commission believes that these elements have generally been effective in either identifying licensee-proposed changes with unacceptable reductions in defense-in-depth, or precluding submission of licensee-initiated changes with unacceptable reductions in defense-in-depth. Accordingly, proposed § 50.46a(f)(3)(i)(A) through (C) would incorporate three of the higher level defense-in-depth elements as criteria that the Commission believes are generally applicable to all proposed risk informed changes. They are:

(1) Preserving a reasonable balance among prevention of core damage, prevention of containment failure (early and late), and consequence mitigation;

(2) Preserving system redundancy, independence, and diversity commensurate with the expected frequency and consequences of challenges to structures, systems and components, and uncertainties; and

(3) Ensuring that the independence of barriers is not degraded.

Criterion 1 is intended to assure that licensees do not unduly rely upon prevention for accident sequences. Demonstration of reasonable balance requires that any increase in the probability of containment failure (early and late) does not significantly increase the frequency of a significant fission product release. Licensees must also retain a level of mitigation to ensure that mitigation capabilities are maintained for accident sequences that lead to relatively late containment failure and result in late radiological releases to the public. Plant changes, and in particular some changes enabled by the new § 50.46a, include a wide variety of containment related changes, including some that may affect the frequency of late containment

failure without affecting either CDF or LERF. Thus, this criterion explicitly includes consideration of the impact of a proposed change on late containment failure.

The second criterion, which addresses redundancy, independence, and diversity, refers to design principles that the Commission has historically employed and that are proven concepts for maintaining safety in the nuclear and other industries.

The third criterion, which requires that independence of barriers is not degraded, is a fundamental aspect of defense-in-depth. As with the second criterion, independence of barriers has long been used to successfully ensure public health and safety.

The proposed rule states that demonstrating that a change satisfies the above three criteria provides assurance, in part, that defense-in-depth is maintained. The four remaining RG 1.174 elements of defense-in-depth relate to over-reliance on programmatic activities, defenses against common cause failures, defenses against human errors, and compliance with the intent of the GDC in Appendix A to 10 CFR Part 50 are not included in the proposed rule. These criteria are relatively specific and their applicability depends on the specific change under consideration. Each of these remaining elements should be evaluated for applicability to each change and, if applicable, the licensee should include these effects in their integrated decision for the proposed change.

e. Safety margins

Proposed § 50.46a(f)(3)(ii) would require that adequate safety margins are retained to account for uncertainties. These uncertainties include phenomenology, modeling, and how the plant was constructed or is operated. The Commission’s concern is that plant changes could inappropriately reduce safety margins, resulting in an unacceptable increase in risk or challenge to plant SSCs. This paragraph 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.

f. Performance measuring programs

Proposed § 50.46a(f)(3)(iii) would require that adequate performance measurement programs and feedback strategies are implemented to ensure that the RISP assessment continues to reflect actual plant design and operation. The RISP assessment includes the risk assessment, maintenance of defense-in-depth, and adequate 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 RISP assessment that the change satisfied all the change criteria.

The section requires that the monitoring programs be designed to detect degradation of SSCs before plant safety is compromised. Permitting degradation to advance until plant safety could be compromised would be inconsistent with the Commission's regulatory responsibility of protecting public safety. The associated strategies should ensure that relevant observations of the monitoring program are fed back into the RISP assessment and result in timely corrective actions as appropriate. Consistent with all risk informed activities, the monitoring, feedback, and corrective action programs should target resources and emphasis on SSCs at a level commensurate with their safety significance.

The Commission expects that licensee will integrate the performance measuring programs required by this section with existing programs for monitoring equipment performance and other operating experience on their site and throughout industry. In particular, monitoring that is performed in conformance with the Maintenance Rule (§ 50.65) could be used when the monitoring performed under the maintenance rule is sufficient to meet the requirements in § 50.46a(f)(3)(iii). Licensees who have implemented previous risk-informed regulatory actions

have normally also been required to implement risk-informed monitoring and feedback programs, particularly in the area of risk assessment; for example, licensees who adopt § 50.69 will need to develop relatively extensive risk-informed monitoring and feedback programs. These should be integrated into the proposed paragraph (f)(3)(iii) performance measuring programs to the extent practicable.

2. Requirements for risk assessments.

The proposed rule is based upon the regulatory premise that the acceptability of licensee-initiated changes should be judged in a risk-informed manner. Thus, risk assessment plays a key role in the regulatory structure of the proposed rule. Various provisions of proposed § 50.46a require the licensee to submit risk information for the purpose of demonstrating that one or more of the criteria in the rule have been met. 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 proposed rule requires 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 Commission recognizes that non-quantitative PRA assessment methodologies and approaches could also be used to complement or supplement the quantitative aspects of a PRA, especially where performance of a quantitative PRA methodology of the level needed to support a particular decision is not technically 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 be utilized.

Because risk information forms a key role in the agency's decisionmaking under this proposed rule, the Commission has determined that it would be prudent to establish in this rule

minimum requirements for PRAs and nonquantitative risk assessments to be used in implementing the rule.[11] Establishment of minimum requirements for PRAs and other risk assessments would provide assurance that the numerical and qualitative insights produced by the risk assessments are adequate to support decisions in areas of potential safety significance.

a. Probabilistic Risk Assessment (PRA) requirements

Proposed § 50.46a(f)(4)(i) through (iv) would set forth the four general attributes of an acceptable PRA for the purposes of this proposed 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. Plant risk is a function of initiating events from both internal and external sources. In addition, plant risk can vary significantly depending upon the plant's operating mode. Studies ("Proposed Staff Plan for Low Power and Shutdown Risk Analysis Research to Support Risk-informed Regulatory Decision Making", SECY-00-0007, January 12, 2000) have shown that relatively high levels of risk can occur during low power and shutdown modes. Failure to consider sources of risk from internal and external events, or from operating modes that the plant may be placed in, 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 must be considered by the PRA, in order to ensure that the

[11]These requirements are only intended to be used in conjunction with the proposed rule, and are not intended to be established as generic requirements applicable to other regulatory applications at this time. Although these requirements are drawn from RG 1.174, the Commission has not yet determined whether the requirements should be adopted by rule for generic use outside of § 50.46a.

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.

Proposed § 50.46a(f)(4)(ii) would require that the PRA calculates CDF and LERF inasmuch as this proposed rule would require that these measures be compared against acceptance criteria established in this proposed rule.

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

Finally, § 50.46a(f)(4)(iv) 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 total CDF and LERF, and changes in total CDF and LERF adequately reflect the proposed change. The 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.

b. Requirements for risk assessments other than PRA

Risk assessment need not always be performed using PRA. The proposed 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 Commission believes that minimum quality requirements for PRAs and risk assessments used by a licensee in implementing the rule must be established in the rule. Accordingly, § 50.46a(f)(5) of the proposed rule would establish the minimum requirement for risk assessment methodologies other than PRA. This paragraph would require that the licensee demonstrate that any non-PRA risk assessment methods used in demonstrating compliance with one or more requirements of the proposed rule produce realistic results. The Commission believes that this requirement would provide flexibility to licensees to use the non-PRA risk methodology (or combination of different methodologies) which produces results that are sufficient upon which to base decisions that the various acceptance criteria in the proposed rule have been met.

3. Operational requirements.

The Commission proposes five specific operational requirements that would apply to licensees who are approved to implement § 50.46a. These requirements are set forth in § 50.46a(d) and would remain in effect until such time as the licensee permanently ceases operations by submitting the decommissioning certifications required under § 50.82(a). They are:

(1) maintain ECCS model(s) and/or analysis method(s) meeting the acceptance requirements of the rule,

(2) do not exceed ECCS acceptance criteria under any allowed at-power operating configuration and do not place the plant in any at-power operating configuration not analyzed and shown to meet ECCS acceptance criteria,

(3) evaluate *all* changes to the facility, technical specifications, or procedures as described in the FSAR, using the NRC-approved RISP assessment process to demonstrate

that the risk, defense-in-depth, safety margin and performance-measurement criteria are satisfied,

(4) implement adequate performance-measurement programs to ensure that the RISP assessment process reflects actual plant design and operation, and

(5) periodically re-evaluate and update the risk assessments required under § 50.46a(f) to address changes to the plant, operational practices, equipment performance, plant operational experience, and PRA model, and revisions in analysis methods, model scope, data, and modeling assumptions.

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

a. Maintain ECCS model(s) and/or analysis method(s)

Section 50.46a(d)(1) and (d)(2) would require the licensee to maintain the ECCS models and/or methods that are used to demonstrate ECCS performance meets Section 50.46a(e). As stated above, the RISP assessment process must be used for *all* changes made under § 50.59 or § 50.90. For changes made under § 50.90, the licensee would submit information demonstrating that the ECCS acceptance criteria in Section 50.46a(e)(3) and (e)(4) are met for the change. For changes made under § 50.46a(f)(1), the licensee would need to assure that any impact of the change upon the ECCS performance meets the requirements of § 50.59. Therefore, the proposed rule would require the ECCS models and/or analysis methods to be maintained that meet the requirements of § 50.46a(e)(1) and (e)(2), to ensure that the acceptance criteria in § 50.46a(e)(3) and (e)(4) continue to be met for the plant.

b. Do not place the plant in unanalyzed at-power operating configurations

The Commission would require in § 50.46a(d)(2) that a facility be provided with an ECCS designed so that its calculated cooling performance conforms to the criteria in

§ 50.46a(e)(4) for LOCAs involving breaks larger than the TBS, up to and including a double-ended rupture of the largest pipe in the RCS. For LOCAs involving breaks larger than the TBS, the analyses performed will identify ECCS components and trains (including sufficiently reliable non-safety related systems) that are assumed to function in order to demonstrate compliance with the acceptance criteria in paragraph 50.46a(e)(4). The proposed rule would not require assumption of loss-of-offsite power or a limiting single failure of the ECCS for the analyses performed to show acceptance criteria in (e)(4) are met for breaks larger than TBS. Thus, it is possible that a licensee's analysis may take credit for the availability of the full complement of ECCS. To ensure that the facility will continue to comply with the acceptance criteria under any at-power operating configurations (allowed by the license), the Commission will require both that the acceptance criteria not be exceeded during any at-power condition that has been analyzed, and further that the plant not be placed in any unanalyzed condition.

One circumstance where the ability to comply with the acceptance criteria might be called into question would be if an ECCS train or component was removed from service (such as for maintenance) while the plant is in operation, where this would result in the available ECCS trains or components being less than that assumed in the licensee's analysis for LOCAs involving breaks larger than the TBS. For this time period, the assumed set of mitigation systems would not be available to respond should a LOCA occur, and the acceptance criteria might not be satisfied. Thus, the licensee would either have to be able to demonstrate that under such conditions the acceptance criteria would not be exceeded, or not place the facility in that configuration. To satisfy this requirement a licensee might prepare analyses showing acceptable results with expected complements of equipment that might be taken out of service

or could propose suitable technical specifications as part of its application for the facility change that would restrict plant operation to acceptable conditions.

Accordingly, in § 50.46a(d)(2) of the proposed rule, the Commission would require that the facility not operate in any at-power configuration where the ECCS cooling performance available from operable ECCS components has not been evaluated and found to be sufficient to assure that the acceptance criteria in paragraph (e)(4) will be met. The evaluation must be calculated in accordance with § 50.46a(e)(2). Bounding analyses may be performed to reduce the number of model calculations.

c. Evaluate all facility changes using the RISP assessment process

Section 50.46a(d)(3) would require that, for licensees that use § 50.46a, the integrated, risk-informed change process should be used for *all* changes made under § 50.59 or § 50.90. For changes made under § 50.90, the licensee would submit the information required in § 50.46a(f)(2), which would include information from the RISP assessment performed for the change. The NRC would review the change as described above. For changes made under § 50.46a(f)(1), which must also meet the requirements of § 50.59, the licensee would be required to evaluate the change using the NRC-approved RISP assessment process and demonstrate that the acceptance criteria in § 50.46a(f) are met.

d. Implement adequate performance-measurement programs

The Commission acknowledged the importance of monitoring and feedback in risk-informed decisionmaking in RG 1.174, which identified these as one of the five key principles of risk-informed changes to a plant's licensing basis. These programs are important to ensure that (1) the RISP assessment conducted to examine the impact of proposed change(s) continues to reflect the actual design and operation of the plant and (2) no adverse safety degradation occurs as a result of facility, technical specification or procedure changes implemented after a

licensee adopts 10 CFR 50.46a as the licensing basis for its facility. NRC experience with RG 1.174 has confirmed that monitoring and feedback are necessary to provide confidence that new information that could change the results of the assessment of proposed changes or affect the acceptability of a previously acceptable change is collected and incorporated into the assessments. Accordingly, the Commission proposes that licensees be required to implement appropriate monitoring and feedback programs. Paragraph (d)(4) would require the licensee to implement performance monitoring programs capable of meeting the acceptance criteria for such programs as described in paragraph (f)(3)(iii).

Section 50.46a(f)(3)(iii)(A) through (C) would require that the performance-measurement programs be designed to detect degradation in SSCs, monitor the SSCs at a level commensurate with their safety significance, and provide feedback of information to allow timely corrective actions to be implemented before plant safety is compromised. When successfully implemented, these programs would ensure that the RISP assessment continues to reflect the risk, defense-in-depth and safety margin attributes during the evaluation of proposed changes, and will ensure that the conclusions that have been drawn from the evaluation about previous changes remain valid.

e. Periodically re-evaluate and update risk assessments

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. Proposed § 50.46a(d)(5) would set forth the proposed rule's requirements governing the periodic re-evaluation and updating of licensee's risk assessments.[12] This paragraph would mandate that a licensee must, following implementation

[12]Reporting requirements relevant to the PRA updating required by this paragraph are set forth in § 50.46a(g)(2) of the proposed rule.

of a change to its facility, technical specifications, or procedures after adopting § 50.46a, periodically reevaluate and update the risk assessments (both PRA and non-PRA) required under § 50.46a(f)(1) and (f)(2). In particular, § 50.46a(d)(5) specifies that the reevaluation and updating must address changes in the risk assessments; revisions in analysis methods, model scope, and modeling assumptions; and changes to the plant, operational practices, equipment performance, and operational data. In addition, the risk assessments may be updated to address, among other things, known errors or limitations in the model, or new information. Accordingly, it is necessary that the risk assessments be updated so that the licensee (and the NRC) will have an accurate understanding of risk at its facility, and that changes implemented since the licencee adopted § 50.46a continue to be acceptable from a safety and risk standpoint (i.e., the facility design and operation continue to be consistent with the assumptions of the risk assessments used to meet the acceptance criteria in § 50.46a(f)(1) or (f)(2)).

The updated risk assessments must continue to meet the minimum quality requirements in § 50.46a(f)(4) and (f)(5) in order to ensure that the updated risk assessments provide the requisite level of quality deemed by the Commission to be the minimum necessary to support reasoned decision making under the proposed rule.

The proposed rule would specify that the reevaluation and updating be conducted "periodically," but no less often than once every two refueling outages. The Commission 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 Commission's preliminary determination in this regard is based upon the stringent acceptance criteria governing changes initiated 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, e.g., §§ 50.46a(f)(1) and 50.59. The updating period specified in the proposed rule is also comparable to other NRC requirements governing updating and reporting of safety information, e.g, §§ 50.59, 50.71(e), as well as the current ASME consensus standard on PRA quality.

With respect to feedback, § 50.46a(d)(5) would require the licensee to take “appropriate action“ to ensure that all facility design and operation continue to be consistent with the risk assessment assumptions used to meet the acceptance criteria in § 50.46a(f)(1) or (f)(2). Such actions may include (but are not limited to) improvements or corrections to the risk analyses to demonstrate compliance, implementation of changes to offset adverse changes in risk or defense in depth, or reversal of changes previously made under the provisions of § 50.46a(f). The Commission believes that this requirement would provide appropriate flexibility to 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.

Finally, § 50.46a(d)(5) would specify that the reevaluation and updating of the risk assessments, and any changes to the facility, technical specifications, or procedures necessary as a result of this periodic reevaluation and updating, shall not be deemed backfitting. The Commission regards the reevaluation and updating to be an inherent part of the regulatory concept of the proposed rule. Hence, this activity, and any licensee action necessary to ensure the continued validity of the associated risk assessments are understood to be part of the regulatory process under this rulemaking, and licensees who voluntarily choose to implement § 50.46a understand that the regulatory process involves such updating, reevaluation, and possible need for making changes to its facility, technical specifications, or procedures.

E. Reporting Requirements

1. ECCS analysis of record and reporting requirements.

Reporting requirements for the proposed § 50.46a would be patterned after the existing reporting requirements in § 50.46. Existing 10 CFR 50.46(a)(1) requires that a licensee demonstrate that its ECCS is adequate to meet the acceptance criteria using an approved evaluation model. The results obtained with the evaluation model are often referred to as the "analysis of record" (AOR). This AOR is documented in the licensee's FSAR and is also used to establish core operating limits for each cycle according to the licensee's approved reload methodology. Because changes (such as changes to the moderator temperature coefficient and peaking factors) are made to the plant on a cycle specific basis, deviations from the AOR PCT are permitted. Existing requirements in 10 CFR 50.46(a)(3)(i) specify that the licensee estimate the deviation in PCT from such changes (or error corrections). The amount of deviation is calculated by summing the absolute value of each of the individual changes. The licensee's estimate must be accurate but is typically not evaluated by running the accordingly revised evaluation model. Deviations greater than 50EF are deemed "significant." The purpose of the 50EF restriction is to ensure that the evaluation model accurately reflects the plant conditions, the methodology used by the licensee is that reviewed and approved by the NRC, and the changes made to the plant or operation of the plant do not appreciably change the ECCS response.

Existing 10 CFR 50.46(a)(3)(ii) requires the licensee to submit an annual report of these estimated deviations to the NRC. When they are "significant," the licensee is required to contact the NRC within 30 days to schedule a re-analysis or get approval for other actions that may be needed to show compliance with § 50.46 requirements. In establishing the schedule, the NRC will consider the safety significance of the deviation and the proximity of the AOR PCT to the acceptance criterion of 2200EF. To ensure safety, existing 10 CFR 50.46(a)(3)(ii) also

requires the licensee to algebraically sum the estimated individual changes in PCT to ensure that the estimated PCT does not exceed 2200EF. If this algebraic sum exceeds 2200EF, or if the changes cause the licensee to not comply with any other acceptance criteria specified in 10 CFR 50.46(b), the licensee must take immediate action to comply with 10 CFR 50.46 and report the event per 10 CFR 50.55(e), 50.72, and 50.73.

When 10 CFR 50.46 was first promulgated, the regulations focused primarily on large break LOCAs (LBLOCAs). Cladding oxidation is a function of both temperature and time at temperature. In LBLOCAs, because of the short period of time at high temperature, oxidation can be treated as a simple function of temperature and is not expected to change if the calculated PCT does not change (as long as the time period at high temperature does not change either). Therefore, the PCT reporting requirement alone was adequate to control changes to ECCS analyses.

However, under the proposed § 50.46a, ECCS capability would be focused on the more likely small break LOCAs where the fuel is subject to high temperatures for longer periods of time. Because time at temperature is just as important as temperature in determining oxidation, cladding oxidation is expected to be the controlling factor in many instances, not PCT. Thus, the Commission proposes to include an additional reporting requirement in § 50.46a. Licensees would report model changes or errors whenever the change in the calculated oxidation or the sum of the absolute values of the changes equals or exceeds 0.4 percent oxidation. This would make the proposed § 50.46a oxidation reporting requirement the same, on a percentage basis, as the existing PCT change reporting requirement.

Under the proposed § 50.46a, for each change to or error discovered in an ECCS evaluation model or analysis method that affects the calculated temperature or level of oxidation, the licensee would be required to report the change or error and its estimated effect

on the limiting ECCS analysis to the Commission at least annually. If the change or error is significant, the licensee would provide this report within 30 days and include with the report a proposed schedule for providing a re-analysis or taking other action to show compliance with § 50.46a requirements. For any changes or errors where calculated results exceeded the approved regulatory limit, licensees would be required to take immediate action to come back into compliance with the acceptance criteria.

For breaks equal to or smaller than the TBS (consistent with the existing requirements in § 50.46), § 50.46a(g)(1)(i) would define a significant change as one in which the change in calculated peak fuel temperature differs by more than 50EF from the peak fuel temperature calculated by the last model or is an accumulation of changes and errors such that the sum of the absolute magnitudes of the respective temperature changes is greater than 50EF. For oxidation, proposed § 50.46a(g)(1)(i) would define a significant change as when the change in the calculated oxidation, or the sum of the absolute values of the changes in calculated oxidation equals or exceeds 0.4 percent oxidation. For breaks larger than the TBS, § 50.46a(g)(1)(ii) would define a significant change as one which results in a significant reduction in the capability to meet the ECCS acceptance criteria in § 50.46a(e)(4). Guidance for determining what would be considered a significant reduction will be provided in the associated regulatory guide.

2. Risk assessment reporting requirements.

Proposed § 50.46a(g)(2) sets forth reporting requirements with respect to the PRA reevaluation and updating required by § 50.46a(d)(5). When reevaluating and updating the PRA and non-PRA risk assessments, § 50.46a(g)(2) would require the licensee to report changes to the NRC if they result in a significant reduction in the capability to meet the requirements of § 50.46a(f). Changes would be reported to the NRC within 60 days of

completion of the PRA update, and would include a description of the PRA changes, as well as an explanation of the reasons for the increase in CDF and/or LERF. The 60 day period is twice the time allowed for reporting of “significant” errors and changes to an evaluation model under the current § 50.46. This period ensures sufficient time for the licensee to complete its evaluation and explanation of the significance of such 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 Commission proposed this reporting level to establish a threshold that avoids trivial changes in the relevant calculated risk measures, but provides for NRC awareness of changes that may warrant further oversight. In addition, this paragraph would require that the licensee report include a schedule for implementation of any corrective actions required under § 50.46a(d)(5) for failure to comply with the acceptance criteria in § 50.46a(f)(1) or (f)(2). The Commission 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.

3. Minimal risk plant change reporting requirement.

In § 50.46a(g)(3) the Commission is proposing to require periodic reports by licensees who make “minimal” risk plant changes pursuant to § 50.46a(f)(1). This process is comparable in many respects to the § 50.59 process that requires similar reports. The NRC would rely on these reports to identify unexpected numbers of minimal risk changes which would provide for NRC awareness of changes that, taken together, may result in a significant increase in risk.

An alternative would be to require that the cumulative risk increases from minimal risk changes be tracked separately from the cumulative risk increase from all changes, and be compared to another quantitative criterion. In Section III.J.11 of this supplementary information, the Commission seeks public comment about whether there are less burdensome or more

effective ways of ensuring that the cumulative impact of an unbounded number of minimal risk changes remains minimal. The Commission notes that other reporting requirements (FSAR updates, ECCS model changes or PRA update results) exist. If reporting of minimal risk changes is required, should reporting be required every 24 months, every two refueling cycles (like the PRA updating), or on a different frequency?

F. Documentation Requirements

The proposed rule contains several documentation requirements. Proposed § 50.46a(h) contains documentation requirements for changes made to a facility and/or operating procedures. When making plant changes under § 50.46a(f), licensees would be required to document the bases for concluding that the acceptance criteria in § 50.46a(f)(1) or (f)(2) and (f)(3) are satisfied. Licensees would also be required under Part II of Appendix K to this part to document the bases of evaluation models used to perform ECCS calculations for break sizes at or below the TBS. For ECCS analysis methods used for breaks larger than the TBS, licensees would be required under § 50.46a(e)(2) to maintain sufficient supporting justification, including the methodology used, to demonstrate that the analytical technique reasonably describes the behavior of the reactor system during LOCAs of varying size from the TBS up to the double-ended rupture of the largest reactor coolant pipe. This information would be reviewed during NRC inspections and/or audits to ensure that the risk criteria in § 50.46a(f) are satisfied and to determine whether the analysis methods (including computer codes) used by licensees adequately demonstrate ECCS performance such that the ECCS acceptance criteria in § 50.46a(e) are met.

G. Submittal and Review of Applications under § 50.46a

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

When a licensee first decides to comply with the optional § 50.46a requirements, that licensee must submit an application under 10 CFR 50.90 for NRC review and approval of a license amendment request. The initial application must contain the information required by § 50.46a(c)(1)(i). This includes information required by § 50.46a(e)(1) sufficient to allow the NRC to approve the licensee's evaluation models[13] for design-basis accident LOCAs equal to or smaller than the TBS and a discussion of the method used for analyzing LOCAs larger than the TBS. Analysis methods for LOCAs larger than the TBS would be required to meet the criteria specified in § 50.46a(e)(4), but the proposed rule would not require prior NRC review and approval of these methods.

Licensees must also submit the results of the ECCS analyses performed for LOCAs up to and including the TBS and LOCAs larger than the TBS showing compliance with the acceptance criteria in § 50.46a(e)(3) and (e)(4). A licensee's initial change from its existing ECCS analysis need not be reviewed by the licensee under the provisions of 10 CFR 50.59. Because the proposed rule would require 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, since § 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. Once the new § 50.46a evaluation models and initial ECCS LOCA analyses have been approved for use, subsequent changes 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 other requirements in § 50.46a(h) for reporting when changes to

[13]If a licensee wishes to continue to use an already approved evaluation model meeting the requirements of Appendix K to 10 CFR Part 50, the licensee should specify the approved model that will be utilized.

evaluation models and analysis methods (whether from correction of errors or changes) is significant.

Proposed § 50.46a(c)(1)(ii) would require the initial application to also contain a description of the RISP assessment process. The RISP assessment process would contain a description of the licensee's PRA and non-PRA risk assessment methods and a description of the methods and decisionmaking process used to show that proposed facility changes comply with the defense-in-depth, safety margins, and performance measurement criteria in proposed § 50.46a(f)(3). The RISP assessment process must also ensure that all future licensee changes to the facility, technical specifications, and procedures as described in the FSAR be evaluated by a RISP assessment which demonstrates that the acceptance criteria in § 50.46a(f) are met and requires that changes made pursuant to § 50.46a(f)(1) are also evaluated under § 50.59.

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

After NRC approval of a licensee's initial license amendment application addressing ECCS analyses and RISP assessment processes, licensees may submit individual license amendment applications for plant changes which may not be made under § 50.59 or § 50.46a(f)(1). These individual license amendment applications must contain:

a. the information required by § 50.90,

b. information from the RISP assessment 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, and

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

After review of 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.

H. Potential Revisions Based on LOCA Frequency Reevaluations

The NRC plans to periodically evaluate LOCA frequency information. Selection of the TBS was based on several factors including the generic frequency estimates provided by the expert elicitation process. The NRC recognizes that due to unforeseen factors (operating experience, identified degradation or other plant changes), our estimation of LOCA frequencies could change in the future. Although the margins in the TBS as defined in the proposed rule are intended to preclude plant changes as a result of minor changes in break frequency estimates, the NRC believes it is important to include provisions in the rule so that if LOCA frequencies significantly increase, appropriate actions would be taken to protect public health and safety. If an increase in LOCA frequency were sufficient to invalidate the basis for selecting the TBS defined in the proposed rule, the NRC would undertake rulemaking (or issue orders to specific licensees, if appropriate) to change the TBS. In such a case, the backfit rule (10 CFR 50.109) would not apply. Likewise, if future reevaluations of LOCA frequency invalidate the bases for facility changes implemented by a licensee, that licensee would be required to take appropriate action to reduce facility risk to acceptable levels; either by reversing previous facility changes or by making other changes to compensate for the

increased risk. In these cases, the backfit rule (10 CFR 50.109) would also not apply (see further discussion in section XV).

I. <u>Changes to General Design Criteria</u>

In several instances, the proposed § 50.46a rule is not consistent with some of the GDC for nuclear power plants contained in 10 CFR Part 50, Appendix A. To eliminate inconsistencies between the deterministic GDC and the risk-informed § 50.46a, the NRC reviewed all of the GDC and is proposing revisions to 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*. These GDC contain design requirements related to LOCAs, and the definition of LOCA in 10 CFR Part 50 includes breaks larger than the TBS up to and including the DEGB of the largest RCS pipe. Under proposed § 50.46a, breaks larger than the TBS would be beyond design-basis accidents. As a consequence, these GDC would be modified to allow certain LOCA-related § 50.46a requirements for pipe breaks larger than the TBS to differ from the design-basis accident requirements in the GDC. These exceptions are needed because § 50.46a analysis requirements for LOCAs larger than the TBS would not require the assumption of a LOOP and a single failure, which are required by each of these GDC. The likelihood of these large LOCAs is judged to be low enough that the additional mitigation capability currently afforded by the redundancy requirements in these GDC is not necessary. The modifications made to each of the above GDC removes the requirements for assuming a single failure and a LOOP in the assessment of the ECCS capability to perform its intended safety function for beyond design-basis loss of coolant accidents involving pipe breaks larger than the TBS. However, assessment of the ECCS capability for LOCAs involving pipe breaks up to and including the

TBS is unchanged from current requirements and must still assume both a single failure and LOOP.

The NRC also reviewed GDC 50, *Containment design basis*. GDC 50 specifies, in part, that the reactor containment structure shall be designed to accommodate, with sufficient margin, the calculated pressure and temperature from any LOCA. It also lists several factors that should be considered when determining the available margin. The NRC has determined that these factors should also be considered when determining the available margin for accommodating LOCAs larger than the TBS. Under § 50.46a, however, LOCAs larger than the TBS are not design-basis accidents since they are highly unlikely. Nevertheless, reactor containment designs should continue to consider beyond TBS LOCAs, but the methods used to calculate containment temperatures and pressures need not be as conservative as they are for design-basis accidents. Thus, the NRC proposes to modify GDC 50 to specify that under § 50.46a, leak tight containment capability should maintained for "realistically" calculated temperatures and pressures for LOCAs larger than the TBS.

Should licensees make plant modifications under § 50.46a resulting in containment pressures and temperatures that exceed the current design values by a small amount, the NRC will evaluate the acceptability of revised containment structural integrity criteria. Criteria will be provided in a regulatory guide for containment structural integrity that could be used with § 50.46a. However, the acceptability of containment pressures and temperatures exceeding current values will also be evaluated for conformance with the LERF acceptance criteria specified in § 50.46a(f)(2) and the defense-in-depth acceptance criteria in § 50.46a(f)(3). The basis for allowing revision to containment structural integrity criteria is that LOCAs involving pipe breaks larger than the TBS are judged to be of very low probability and are no longer considered to be design basis accidents. The likelihood of LOCAs involving pipe breaks larger

than the TBS is judged to be low enough that the large margins currently required in design basis accident assessments are not necessary. However, a realistic assessment of containment structural capability for LOCAs involving pipe breaks larger than the TBS (without consideration of a loss-of-offsite-power and a single failure) is still required to provide defense-in-depth for these low probability initiating events.

The inherent physical robustness of current reactor containments contributes significantly to the "built-in capability" of the plant to resist security threats. The Commission expects licensees not to make design modifications to the containment under § 50.46a that would reduce its structural capability (based on realistically calculated containment pressures and temperatures for breaks larger than the TBS) to a level that would compromise plant security.

The NRC considered modifying GDC 4, *Environmental and dynamic effects design bases*, based on the TBS as defined in proposed § 50.46a. However, the NRC decided to leave this GDC unchanged for the following reasons. GDC 4, as currently written, contains a provision whereby licensees can exclude designing for dynamic effects associated with piping ruptures from their plants' design bases based on the probability of piping ruptures being extremely low. This provision of the GDC has historically been implemented by the NRC's review and approval of a leak-before-break (LBB) analysis (reference Standard Review Plan Section 3.6.3). Approval of LBB technology for PWRs only was based, in part, on fracture mechanics and the absence of any active degradation mechanisms. This mechanistic rationale for not having to address dynamic effects (i.e., defined and controlled loadings) is still necessary to ensure that piping will not tear unexpectedly, including piping larger than the TBS. Absent an approved LBB analysis for piping larger than the TBS (for plants implementing § 50.46a), PWR licensees would still need to consider dynamic effects because asymmetric

blowdown loads could cause fuel rods to bow which could in turn impede control rod insertion. In addition, excluding dynamic effects from consideration for breaks larger than the TBS would permit removal of pipe whip restraints and jet impingement barriers at BWRs. Without pipe whip restraints and jet impingement barriers, a double-ended rupture of the largest pipe in the RCS could result in loss of more than one train of ECCS and could challenge the integrity of the containment. Finally, the dynamic loads associated with a double-ended rupture of the largest pipe in the RCS must be considered to preclude subcompartment pressurization and structural failure of reinforced concrete walls inside the containment that could affect multiple trains in multiple systems. In sum, licensees that voluntarily adopt § 50.46a must continue to comply with GDC 4 and evaluate the dynamic and environmental effects of pipe breaks larger than the TBS, unless a leak-before-break analysis has been approved by the NRC in accordance with GDC 4. Analyses addressing GDC 4, including dynamic effects, approved leak-before-break, and environmental effects, will continue to be part of the design basis of the plant.

As stated in GDC 4, “dynamic effects associated with postulated pipe ruptures in nuclear power units may be excluded from the design basis when analyses reviewed and approved by the Commission demonstrate that the probability of fluid system piping ruptures is extremely low under conditions consistent with the design basis for the piping.” Without such an approved analysis, licensees would be required to address the dynamic effects (including the effects of missiles, pipe whipping, and discharging fluids) in their piping system design and analysis. The Commission has not historically required licensees to consider such dynamic effects in performing the ECCS analysis required by § 50.46, containment analysis required by GDC 16 and GDC 50, and probabilistic risk assessments (PRAs). Dynamic effects have been excluded from these analyses because of certain design features (e.g., pipe whip restraints, jet impingement barriers, ECCS train separation) or because of the extremely low likelihood of a

double-ended rupture of the largest pipe in the RCS (*i.e*. leak-before-break analysis). This NRC staff position will be maintained for licensees that voluntarily adopt § 50.46a. However, licensees who voluntarily adopt § 50.46a need to consider environmental and dynamic effects in these analyses where non-safety related equipment is credited for mitigating breaks larger than the TBS.

J. Specific Topics Identified for Public Comment

The NRC seeks specific public comments on numerous questions and issues. All specific topics for comment are identified in this section, but some have been discussed elsewhere in this supplementary information.

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

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. In December 2005, stakeholders should periodically check the NRC rulemaking web site for this information. 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. (See Section III.B.3 of this supplementary information.)

3. Depending on the outcome of an ongoing NRC study (see Section III.B.3 of this supplementary information), 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 precluded 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.

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.

5. The 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, 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 Commission solicits specific public comments on

whether to revise existing §§ 50.59 and 50.90 to accommodate the requirements for making plant changes under § 50.46a.

6. The proposed § 50.46a 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. § 50.65 maintenance rule and § 50.69 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.

7. The proposed § 50.46a rule 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.

8. Given the Commission's intent (See SRM for SECY-04-0037) that plant changes made possible by this 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 Commission seeks examples on either side of this threshold (plant changes allowed vs. changes prohibited), and additionally any examples of changes made possible by § 50.46a that could *enhance* plant security and defense against radiological sabotage or attack. (See Section III.G.2 of this supplementary information.) The Commission also solicits comments on whether the § 50.46a rule should explicitly include a requirement to maintain plant security when making 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 plant changes under §§ 50.59 and 50.90. Any examples of plant changes that involve Safeguards Information should be marked and submitted using the appropriate procedures.

9. Given the potential impact to the licensee (since 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 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?

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?

11. The proposed § 50.46a rule would impose no limitations on "bundling" of different facility changes together in a single application. Changes which would increase plant risk substantially or create risk outliers could be grouped with other plant 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?

12. Is there an alternative to tracking the cumulative risk increases associated with plant 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? (See Section III.D.1 of this supplementary information.)

13. The Commission requests 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? (See Section III.D.1.c of this supplementary information.)

14. After approval to implement § 50.46a, the proposed rule would require tracking risk associated with all proposed plant changes but would not require a licensee to include risk increases caused by previous risk-informed changes that were implemented before § 50.46a was adopted. Licensees who adopt § 50.46a before implementing other risk-informed applications will have a smaller risk increase “available” compared to licensees who have already incorporated some risk-informed changes into their overall plant risk before adopting § 50.46a. The Commission does not consider this a safety issue but requests specific public comments on whether this potential inconsistency should be addressed and, if so, how? (See Section III.D.1 of this supplementary information.)

15. The 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?   (See Section III.E.3 of this supplementary information.)

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

IV. Public Meeting During Development of Proposed Rule

The NRC first prepared a “conceptual basis” document and draft rule language indicating the rulemaking approach that was being considered. This conceptual basis was made public on the NRC website on August 2, 2004 (69 FR 46110). The NRC then held a public meeting on August 17, 2004, to inform stakeholders of the rule concept and early draft rule language and to solicit industry stakeholder information about possible plant design changes made possible by the draft rule and their associated costs and benefits. Comments received from stakeholders during the August public meeting are discussed below.

Industry stakeholders asked the NRC to clarify the rule requirements in several areas to allow them to assess the potential costs and benefits of the proposed rule. The NRC has clarified the proposed rule by describing in more detail how the single failure criterion would be applied to ECCS analysis and to other required analyses for pipe breaks larger than the TBS.

Industry stakeholders stated that several GDC other than GDC 35 on ECCS would need to be modified to be consistent with the alternative ECCS requirements in 10 CFR 50.46a. The NRC agrees with this comment and has proposed additional changes to GDC 17, *Electrical*

power systems, GDC 38, *Containment heat removal*, GDC 41, *Containment atmosphere cleanup*, GDC 44, *Cooling water systems* and GDC 50, *Containment design basis.*

Industry stakeholders asked the NRC (1) to define a threshold for § 50.46a plant changes below which license amendments would not be required, and (2) if the NRC could review and approve a licensee's PRA and process and then allow licensees to make plant changes without further NRC review. The NRC has added language in the proposed rule which allows a licensee to submit a PRA and a plant change evaluation (RISP assessment) process to the NRC for approval. After NRC approval is granted, licensees can make certain plant changes that do not exceed a "minimal risk" threshold without further NRC review or approval.

Industry stakeholders asked the NRC to address how § 50.46a could be used to increase plant operational flexibility without changing facility design. The NRC intends for licensees to make plant operational changes under § 50.46a using the same processes used to make facility design changes. As noted above, after NRC approval of a licensee's RISP assessment process, licensees are free to make plant operational changes that satisfy the minimal risk change criteria. Any operational changes that do not qualify as minimal risk changes or involve changes to the technical specifications or the license must be submitted to the NRC for review and approval as license amendments.

Industry stakeholders asked if the NRC could reduce the ECCS analytical burden associated with § 50.46a by reducing the number of required analyses or eliminating the need for or reducing the extent of required NRC reviews. The NRC has reviewed the analytical requirements incumbent upon licensees who adopt the 10 CFR 50.46a alternative requirements. In this case, the NRC modified its analysis requirements to be less prescriptive, affording licensees flexibility in demonstrating that the ECCS can successfully mitigate LOCAs up to and including the double-ended rupture of the largest pipe in the RCS. Analysis,

documentation and code review requirements are reduced commensurate with the lower likelihood of the larger breaks. Submittal of detailed documentation of licensees' analysis methods used for breaks larger than the TBS is not required, nor is formal NRC approval of analysis methods. The NRC will explicitly define its expectations in the regulatory guide before the final rule is promulgated.

Industry stakeholders asked the NRC to explain its position on the effects of increasing plant power levels on the expert elicitation process for estimating pipe break frequency. The expert elicitation process did not consider potential increases in power. Nevertheless, in determining the TBS, the NRC increased the break size resulting from the expert elicitation process to account for several types of known uncertainties while still maintaining margin for unanticipated uncertainties. These uncertainties are discussed in Section III.B of this supplementary information. While the NRC believes that the proposed rule adequately accounts for modest increases in power, significant power uprates may change plant performance and relevant operating characteristics (e.g., temperature, environment, flow rate, etc.) to a degree which could significantly impact LOCA frequencies. For example, higher temperatures could increase the likelihood of stress corrosion cracking and higher flow rates could increase flow-induced vibration which might accelerate the growth of any pre-existing cracks in the piping. In reviewing applications for power uprates for licensees who comply with § 50.46a, the NRC would determine whether the information provided by the licensee is adequate to ensure that frequencies of LOCAs larger than the TBS are not significantly affected and that adequate performance monitoring programs were implemented under § 50.46a(f)(3)(iii). These performance measurement programs would be required to monitor SSCs commensurate with their safety significance, detect degradation of SSCs before plant safety was compromised, and provide feedback to ensure timely corrective actions. In the

longer term, the NRC would continue to assess the precursors that might indicate an increase in pipe break frequencies in plants operating under power uprate conditions to establish whether the TBS would need to be adjusted.

V. Section-by-Section Analysis of Substantive Changes

A. Section 50.34 - Contents of application; technical information

Paragraph (a)(4) of this section would clarify that § 50.46a is applicable to reactors whose construction permits were issued before the effective date of the rule and that preliminary safety analysis reports (PSARs) for facilities whose construction permits are issued after the effective date of this rule and design approvals and design certifications issued after the effective date of this rule are not allowed to use § 50.46a.

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

This section would be modified to allow the optional use of a new § 50.46a containing alternative, risk-informed requirements for emergency core cooling systems for reactors whose operating licenses were issued before the effective date of the rule change.

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

Paragraph (a) would provide definitions for terms used in other parts of this section. Two of the definitions, loss-of-coolant accidents and evaluation model, are based on the existing definitions used in § 50.46 but have been modified to indicate that pipe breaks larger than the TBS are beyond design-basis accidents. The two new definitions are: (1) transition break size, 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; and (2) operating

configuration, which is used in § 50.46a(d)(2) to specify plant equipment availability conditions that must be analyzed for conformance with acceptance criteria.

Paragraph (b) would provide the applicability and scope of the requirements of this section. Proposed § 50.46a would apply only to the current fleet of licensed light-water nuclear power reactors (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) would specify the contents of and acceptance criteria for initial licensee applications for implementing the alternative ECCS requirements in § 50.46a.
Paragraph (c)(1)(i) requires that an application contain specific information about the ECCS models and analysis methods to be used by a licensee. Paragraph (c)(1)(ii) requires a description of the RISP assessment process, including (A) a description of the PRA model and other risk assessment methods demonstrating compliance with the risk assessment quality requirements in § 50.46a (f)(4) & (f)(5) and (B) a description of the methods and decisionmaking process to be used to show compliance with the risk, defense in depth, safety margins and performance measurement criteria specified in § 50.46a(f)(1), (f)(2) and (f)(3).
Paragraph (c)(2) would specify that the acceptance criteria that must be met by a licensee before the NRC may approve an application to comply with § 50.46a. Paragraph (c)(2)(i) would specify the ECCS acceptance criteria; paragraph (c)(2)(ii) would require that the RISP assessment processes meets the requirements in § 50.46a(f); and paragraph (c)(2)(iii) would require that the RISP process ensures that plant changes made without NRC review pursuant to § 50.46a(f)(1) are also permitted under § 50.59.

Paragraph (d) would specify the requirements with which licensees approved by the NRC to utilize § 50.46a must comply throughout the operating lifetime of the facility. In

paragraph (d)(1), licensees would be required to maintain ECCS evaluation models and analysis methods meeting the requirements in § 50.46a(e)(1) & (e)(2). In paragraph (d)(2), licensees would be required to control plant operation to ensure that for LOCAs larger than the TBS, the ECCS acceptance criteria in § 50.46a(e)(4) would not be exceeded under any allowed at-power operating configuration. In paragraph (d)(3), licensees would be required to ensure that changes to the facility, technical specifications, or procedures are evaluated by an NRC-approved RISP which demonstrates that acceptance criteria in § 50.46a(f) are met. In paragraph (d)(4), licensees would be required to implement a performance-measurement program meeting the requirements in § 50.46a(f)(3)(iii) so that the RISP assessment process reflects actual plant design and operation. In paragraph (d)(5), licensees would be required to update risk assessments to address plant changes and conditions no less often than once every 2 refueling outages. 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 (f)(1) or (f)(2). Any necessary changes to facility caused by updating risk assessments would not be deemed backfitting.

Paragraph (e) would provide the ECCS evaluation requirements and acceptance criteria for the two LOCA break size regions. Paragraph (e)(1) would specify methods for evaluating ECCS cooling performance for breaks at or below the TBS. These requirements are the same as the current requirements for LOCA analyses in existing § 50.46. Paragraph (e)(2) would specify methods for evaluating ECCS cooling performance for breaks larger than the TBS. ECCS cooling performance for LOCA breaks larger than the TBS may be analyzed by realistic methods. Paragraph (e)(3) would provide ECCS acceptance criteria for LOCAs up to and including the TBS. The criteria specified would be equivalent to the current requirements in

§ 50.46 (e.g., 2200EF PCT and 17 percent fuel cladding oxidation). Paragraph (e)(4) would provide ECCS acceptance criteria for LOCAs larger than the TBS. These acceptance criteria would be based on coolable geometry and long term cooling 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 and (ii) a RISP assessment has been performed which demonstrates that any possible increases in risk are minimal and that the criteria in paragraph (f)(3) are met.

Paragraph (f)(2) would state that for plant changes not permitted under paragraph (f)(1), licensees must submit an application for a license amendment containing: (i) the information required by § 50.90; (ii) information from the RISP assessment demonstrating that any increases in CDF and LERF are small, overall plant risk is small, and that the criteria in paragraph (f)(3) are met; and (iii) information demonstrating that the ECCS acceptance criteria in § 50.46a(e)(3) and (e)(4) are met.

Paragraph (f)(3) would specify requirements for all plant changes. Paragraph (f)(3)(i) would require that defense-in-depth is maintained, in part, by assuring that: (A) reasonable balance is provided among prevention of core damage, containment failure (early and late), and consequence mitigation; (B) system redundancy, independence, and diversity is commensurate with expected frequency of accidents, consequences of those accidents, and uncertainties; and

(C) independence of barriers is not degraded. Paragraph (f)(3)(ii) would require that (ii) adequate safety margins are maintained. Paragraph (f)(3)(iii) would require that adequate performance-measurement programs will be implemented that: (A) detect degradation before plant safety is compromised, (B) provide feedback of information and timely corrective actions, and (C) monitor SSCs commensurate with their safety significance.

Paragraph (f)(4) would provide the quality and scope requirements for risk assessments using PRA. Paragraph (f)(4)(i) would require that the PRA address internal and external events and all plant operating modes that would affect a regulatory decision. Paragraph (f)(4)(ii) would require that the PRA calculate both CDF and LERF. Paragraph (f)(4)(iii) would require that the PRA reasonably represent the current plant configuration and operating practices. Paragraph (f)(4)(iv) would require the PRA to have sufficient technical adequacy and level of detail to be confident that calculated CDF and LERF reflects the actual plant risk.

Paragraph (f)(5) would require licensees using risk assessment methods other than PRA to justify that the methods used produce realistic results.

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 or a change in calculated cladding oxidation that equals or exceeds 0.4 percent oxidation. 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 contain reporting requirements for errors or changes to PRA analyses. Errors or changes that result in a significant reduction in the capability to meet the requirements in § 50.46a(f) would be reported within 60 days of completing a PRA update. 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. For all plant changes made under § 50.46a(f), licensees would be required to document the bases for meeting the acceptance criteria in § 50.46a(f)(1) or (f)(2) and (f)(3). These plant changes would also be required to be reflected in updates to the licensee's FSAR.

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 the plant to compliance with the acceptance criteria after a change in the TBS are not deemed to be backfitting under 10 CFR 50.109.

D. Section 50.46a - Acceptance criteria for reactor coolant system venting systems

This section would be redesignated as § 50.46b.

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 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 maintained for "realistically" calculated temperatures and pressures for LOCAs larger than the TBS.

VI. Criminal Penalties

For the purposes of Section 223 of the Atomic Energy Act (AEA), as amended, the Commission is issuing the proposed rule to amend § 50.46, add § 50.46a and redesignate existing § 50.46a and § 50.46b 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.

VII. 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.

VIII. Availability of Documents

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 11555 Rockville Pike, Rockville, Maryland.

Rulemaking Website (Web). The NRC's interactive rulemaking Website is located at http://ruleforum.llnl.gov. These documents may be viewed and downloaded electronically via this Website.

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

Document	PDR	Web	PERR
Conceptual basis and draft rule	X	X	ML042160503
WOG comment letter	X		ML042680079
NEI comment letter	X		ML042680080
BWROG comment letter	X		ML042680077
SRM of March 31, 2003	X	X	ML030910476
SECY-02-0057	X	X	ML020660607
SECY-98-300	X	X	ML992870048
SECY-04-0037	X	X	ML040490133
SRM of July 1, 2004	X	X	ML041830412
RG 1.174	X	X	ML023240437
Petition for Rulemaking 50-75	X	X	ML020630082
SECY-04-0060	X	X	ML040860129
NUREG-0933	X	X	ML042540049
Regulatory Analysis	X		ML052870368
SECY-05-0052	X	X	ML050480155
SRM of July 29, 2005	X	X	ML052100416
NUREG 1829	X	X	ML052010464

IX. Plain Language

The Presidential memorandum dated June 1, 1998, entitled "Plain Language in Government Writing" directed that the Government's writing be in plain language. This memorandum was published on June 10, 1998 (63 FR 31883). The NRC 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.

X. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or is otherwise impractical. In this proposed rule, the NRC proposes to use the following Government-unique standard: 10 CFR 50.46a. The Commission notes the development of voluntary consensus standards on PRAs, such as an ASME 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 Commission 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.

XI. Finding of No Significant Environmental Impact: Environmental Assessment

The Commission 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 Commission'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. Using the alternative ECCS requirements[14] will provide some licensees with opportunities to change other aspects of plant design to increase safety, increase operational flexibility or decrease costs. Accordingly, licensee actions taken under the proposed rule could either decrease the probability of an accident or slightly increase the probability of an accident. 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 small enough that adequate assurance of public health and safety is maintained. When considered together, the net effect of the licensee actions is expected to have a negligible 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 of quantities of radiological effluents that may be released offsite, and there is no significant increase in public radiation exposure since 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.

---

[14]The alternative requirements are less stringent in the area of large break LOCAs. The NRC believes that large break LOCAs are very rare events; hence requiring reactors to conservatively withstand such events focuses attention and resources on extremely unlikely events and could have a detrimental effect on mitigating accidents initiated by other more likely events.

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. The no action alternative would also continue existing regulatory burdens for which there may be little or no safety, risk, or environmental benefit.

The determination of this environmental assessment is that there will be no significant offsite impact to the public from this action. However, the general public 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.

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.

XII. Paperwork Reduction Act Statement

This proposed rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). This rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

Type of submission, new or revision: Revision

The title of the information collection: 10 CFR Part 50, "Risk-Informed Changes to Loss-Of-Coolant Accident Technical Requirements"

The form number if applicable: Not applicable.

How often the collection is required: One-time submission of a risk assessment of ECCS performance, submission of PRAs and corrective actions on occasion, ongoing recordkeeping.

Who will be required or asked to report: Licensees authorized to operate a nuclear power reactor that choose to implement the risk-informed alternative for analyzing the performance of emergency core cooling systems during loss-of-coolant accidents.

An estimate of the number of annual responses: **46**

The estimated number of annual respondents: **23**

An estimate of the total number of hours needed annually to complete the requirement or request: **324,208** hours total, including **268,640** hours for reporting (an average of **11,680** hours per respondent) + **55,568** hours recordkeeping (an average of **2,416** hours per recordkeeper).

Abstract: The Nuclear Regulatory Commission (NRC) proposes to amend its regulations to permit current power reactor licensees to implement a voluntary, 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.

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 1F21, 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 and are also available at the rule forum site, http://ruleforum.llnl.gov.

Send comments on any aspect of these proposed information collections, including suggestions for reducing the burden and on the above issues, by (**INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER**) to the Records and FOIA/Privacy Services Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS@NRC.GOV and to the Desk Officer, John A. Asalone, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0011), Office of Management and Budget, Washington, DC 20503. 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 your comments to

John A. Asalone@omb.eop.gov or comment by telephone at (202) 395-4650.

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.

XIII. Regulatory Analysis

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

XIV. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission 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).

XV. Backfit Analysis

The NRC has determined that the proposed rulemaking 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(f)(5), and § 50.46a(j), are appropriate. The bases for each of these determinations follows.

The NRC has determined that the proposed rulemaking 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 III. H, "Potential Revisions Based on LOCA Frequency Reevaluations," the Commission 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 Commission has determined that there is no statutory bar to the adoption of such a provision. The Commission also believes that the proposed exclusion of such rulemakings from the Backfit Rule is appropriate. The Commission 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 Commission also does not regard the proposed exclusion as allowing the Commission 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 Commission has also adopted guidelines governing treatment of individual requirements in a regulatory analysis (69 FR 29187; May 21, 2004). The Commission believes that a regulatory analysis performed in accordance with these guidelines will be effective in identifying unjustified regulatory proposals. In addition, such 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 Commission 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 III.D.3.e, § 50.46a(d)(5) 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 re-evaluation and updating of the PRA and any necessary changes to a facility and its procedures under paragraph (d)(5) are not considered backfitting, § 50.46a(d)(5) would provide that such re-evaluation, updating, and changes are not deemed to be backfitting. The Commission 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: (i) the unrecovered cost of the first change; and (ii) 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 such incremental increases in risk does not appear to be an appropriate regulatory approach. Accordingly, the Commission concludes that the backfitting exclusion in § 50.46a(d)(5) 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 such 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 Commission 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 Commission'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. In this sense, the performance-based approach of the proposed rule lends substantial flexibility to the licensee and may tend to reduce the burden associated with changes in the TBS. Accordingly, the Commission 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.

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 Part 50.

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).

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5841). Section 50.10 also issued under secs. 101, 185, 68 Stat. 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332).
Sections 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a and Appendix Q also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.C. 5844). Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80 - 50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

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

§ 50.34 Contents of application; technical information.

(a) * * *

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

50.46a, and 50.46b for facilities for which a license to operate may be issued after December 28, 1974, but before [EFFECTIVE DATE OF RULE]. The analyses must be performed in accordance with the requirements of §§ 50.46 and 50.46b for facilities for which construction permits may be issued after [EFFECTIVE DATE OF RULE], and design approvals and standard design certifications under part 52 of this chapter issued after [EFFECTIVE DATE OF RULE].

* * * * *

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

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

(a) Each boiling or pressurized light-water nuclear power reactor fueled with uranium oxide pellets within cylindrical zircalloy or ZIRLO cladding must be provided with an emergency core cooling system (ECCS). Reactors whose operating licenses were issued before [EFFECTIVE DATE OF RULE] must be designed in accordance with the requirements of either this section or § 50.46a. Reactors whose construction permits were issued prior to, but have not received operating licenses as of [EFFECTIVE DATE OF RULE], and those reactors whose construction permits are issued after [EFFECTIVE DATE OF RULE] must be designed in accordance with this section.

(1)(i) The ECCS system must be designed so that its calculated cooling performance following postulated 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.

5. 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) *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.

(2) *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 considered design-basis accidents. LOCAs involving breaks larger than the TBS are considered beyond design-basis accidents.

(3) *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.

(4) *Transition break size (TBS)* is a break of area equal to the cross-sectional flow area of the inside diameter of specified piping for a specific reactor. The specified piping for a pressurized water reactor is the largest piping attached to the reactor coolant system. The specified piping for a boiling water reactor is the larger of the feedwater line inside containment or the residual heat removal line inside containment.

(b) *Applicability and scope.*

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

(2) The requirements of this section are in addition to any other requirements applicable to ECCS set forth in this part, with the exception of § 50.46. The criteria set forth in 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 voluntarily choosing to implement this section shall submit an application for a license amendment under § 50.90 that contains the following information:

(i) A description of the method(s) for demonstrating compliance with the ECCS criteria in paragraph (e) of this section;

(ii) A description of the risk-informed integrated safety performance (RISP) assessment process to be used in evaluating whether proposed changes to the facility, technical specifications, or procedures meet the requirements in paragraph (f) of this section; including:

(A) a description of the licensee's PRA model and non-PRA risk assessment methods demonstrating compliance with paragraphs (f)(4) and (f)(5) of this section, and

(B) a description of the methods and decisionmaking process for evaluating compliance with the risk criteria, defense-in-depth criteria, safety margin criteria, and performance measurement criteria.

(2) *Acceptance criteria.* The Commission may approve an application to use this section if:

(i) 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);

(ii) The RISP assessment process (including any PRA model and other risk assessment methods) meets the requirements in paragraph (f) of this section; and

(iii) The RISP assessment process ensures that changes made pursuant to paragraph (f)(1) are permitted under § 50.59.

(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 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 acceptance requirements in paragraphs (e)(1) and (e)(2) of this section,

(2) For LOCAs larger than the TBS, the acceptance criteria in paragraph (e)(4) shall not be exceeded under any allowed at-power operating configurations analyzed under paragraph (e), and the plant may not be placed in any at-power operating configuration not addressed under paragraph (e) of this section.

(3) The licensee shall evaluate any change to the facility as described in the FSAR, technical specifications, or procedures using the NRC-approved RISP assessment process and shall demonstrate that the acceptance criteria in paragraph (f) of this section are met.

(4) The licensee shall implement adequate performance-measurement programs to ensure that the RISP assessment process reflects actual plant design and operation. These programs must meet the criteria in paragraph (f)(3)(iii) of this section.

(5) The licensee shall periodically re-evaluate and update its risk assessments required under paragraph (c)(1)(ii) of this section to address changes to the plant, operational practices, equipment performance, plant operational experience, and PRA model, and revisions in analysis methods, model scope, data, and modeling assumptions. The re-evaluation and updating must be completed in a timely manner, but no less often than once every two refueling outages. The updated risk assessments must continue to meet the requirements in paragraphs (f)(4) and (f)(5) of this section. Based upon the risk assessments, the licensee shall take appropriate action to ensure that facility design and operation continue to be consistent with the risk assessment assumptions used to meet the acceptance criteria in paragraphs (f)(1) or (f)(2) of this section, as applicable. The re-evaluation and updating required by this section, and any necessary changes to the facility, technical specifications and procedures as a result of this re-evaluation and updating, shall not be deemed to be backfitting under any provision of this chapter.

(e) *ECCS Performance.* Each nuclear power reactor subject to this section must be provided with an ECCS that must be designed so that its ECCS calculated cooling performance following postulated LOCAs conforms to the criteria set forth in this section. The evaluation models for LOCAs involving breaks at or below the TBS must meet the criteria in this paragraph, and must be approved for use by the NRC. Appendix K, Part II, 10 CFR Part 50, sets forth the documentation requirements for evaluation models for LOCAs involving breaks at or below the TBS. The analysis methods for LOCAs involving breaks larger than the TBS must be maintained, available for inspection, and include the analytical approaches, equations, approximations and assumptions.

(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 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 and must demonstrate that the acceptance criteria in paragraph (e)(4) of this section are satisfied. The analysis method must address the most important phenomena in analyzing the course of the accident. 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. Sufficient supporting justification, including the methodology used, must be available to show that the analytical technique reasonably describes the behavior of the reactor system during a LOCA from the TBS up to the double-ended rupture of the largest reactor coolant system pipe. Comparisons to applicable experimental data must be made. 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 equipment may be assumed if supported by plant-specific data or 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 shall perform a RISP assessment.

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

(i) The change is permitted under § 50.59, and

(ii) The RISP assessment 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.

(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) Information from the RISP assessment demonstrating that the total increases in core damage frequency and large early release frequency are small and the overall risk remains small, and the criteria in paragraph (f)(3) of this section are met; and

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

(3) All changes to a facility or procedures or to the technical specifications must meet the following criteria:

(i) Defense in depth is maintained, in part, by assuring that:

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

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

(C) Independence of barriers is not degraded;

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

(iii) Adequate performance-measurement programs are implemented to ensure the RISP assessment continues to reflect actual plant design and operation. These programs shall be designed to:

(A) Detect degradation of the system, structure or component before plant safety is compromised,

(B) Provide feedback of information and timely corrective actions, and

(C) Monitor systems, structures or components at a level commensurate with their safety significance.

(4) *Requirements for risk assessment - PRA.* To the extent that a PRA is used in the RISP assessment, the PRA must:

(i) Address initiating events from sources both internal and external to the plant and for all modes of operation, including low power and shutdown modes, that would affect the regulatory decision in a substantial manner;

(ii) Calculate CDF and LERF;

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

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

(5) *Requirements for risk assessment other than PRA.* To the extent that risk assessment methods other than PRAs are used to develop quantitative or qualitative estimates of changes to CDF and LERF in the RISP assessment, a licensee shall justify that the methods used produce realistic results.

(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 a change in the calculated oxidation, or the sum of the absolute value of the changes in calculated oxidation, equals or exceeds 0.4 percent oxidation; 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 update under paragraph (d)(5) of this section, the licensee shall report the change to the NRC if the change results in a significant reduction in the capability to meet the requirements in paragraph (f) of this section. The report must be filed with the NRC no more than 60 days after completing the PRA update and must include a description of the relevant PRA updates performed by the licensee, an explanation of the changes in the PRA modeling, plant design, or plant operation that led to the increase(s) in CDF or LERF after completing the PRA update, a description of any corrective actions required under paragraph (d)(5) of this section, and a schedule for implementation.

(3) Every 24 months, the licensee shall submit, as specified in § 50.4, a short description of all changes involving minimal changes in risk made under paragraph (f)(1) of this section since the last report.

(h) *Documentation of changes to facility, technical specification, and procedures*. When making changes under paragraph (f) of this section, the licensee shall document the bases for demonstrating compliance with the acceptance criteria in paragraphs (f)(1) or (f)(2) and (f)(3) of this section. Upon the approval of the change under paragraph (f)(2) of this section or licensee

implementation of the change under paragraph (f)(1) of this section, the licensee shall update the final safety analysis report in accordance with § 50.71(e).

(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.

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

§ 50.109 Backfitting.

* * * * *

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

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

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

* * * * *

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

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

* * * * *

CRITERIA

* * * * *

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

The onsite electric power supplies, including the batteries, and the onsite electrical distribution system, shall have sufficient independence, redundancy and testability to perform their safety functions assuming a single failure, except for loss of coolant accidents involving pipe breaks larger than the transition break size under § 50.46a, where a single failure of the onsite power supplies and electrical distribution system need not be assumed for plants under § 50.46a.

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 accidents, a single failure need not be assumed and the unavailability of offsite power need not be assumed for onsite electric power system operation.

*   *   *   *   *

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, where a single failure and the unavailability of offsite power need not 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, where a single failure and the unavailability of offsite power need not 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, where a single failure and the unavailability of offsite power need not 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.

*   *   *   *   *

Dated at Rockville, Maryland, this 28th day of October, 2005.

For the Nuclear Regulatory Commission.

/RA/

Annette L. Vietti-Cook,
Secretary of the Commission.