RULEMAKING ISSUE
NOTATION VOTE

March 29, 2005 SECY-05-0052

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: PROPOSED RULEMAKING FOR "RISK-INFORMED CHANGES TO LOSS-OF-COOLANT ACCIDENT TECHNICAL REQUIREMENTS"

PURPOSE:

To obtain Commission approval to publish the proposed rule for public comment.

SUMMARY:

The staff has prepared a proposed rulemaking to add a new section to 10 CFR Part 50 providing an alternative, risk-informed set of requirements for emergency core cooling systems. These requirements could be voluntarily adopted by current light-water reactor licensees. This paper summarizes the development of the proposed rule and the contents of this rulemaking package.

The staff recommends that the Commission approve publication of the proposed rule in the *Federal Register* for public comment.

BACKGROUND:

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

CONTACT: Richard Dudley, NRR/DRIP
301-415-1116

(68 FR 54123, September 16, 2003). Another topic that the Nuclear Regulatory Commission (NRC) decided to examine was the requirements for large-break loss of coolant accidents (LOCAs). A number of possible changes were considered. These included changes to General Design Criterion (GDC) 35 and changes to § 50.46 acceptance criteria, evaluation models, and functional reliability requirements. The NRC also proposed to refine previous estimates of LOCA frequency for various sizes of LOCAs to more accurately reflect the current state of knowledge of the mechanisms and likelihood of primary coolant system rupture.

Industry interest in a redefined LOCA was shown by the Nuclear Energy Institute's (NEI's) filing of Petition for Rulemaking (PRM 50-75) in February 2002. Notice of the petition was published in the *Federal Register* for comment on April 8, 2002 (67 FR 16654). The petition requested that the NRC amend § 50.46 and Appendices A and K to allow — as an option to the double-ended rupture of the largest pipe in the reactor system — the maximum LOCA break size to be "up to and including an alternate maximum break size that is approved by the Director of the Office of Nuclear Reactor Regulation." The NRC received 17 sets of comments. Most were from the power reactor industry in favor of the petition. A few other stakeholders were concerned about potential impacts on defense-in-depth or safety margins if significant changes were made to reactor designs based upon use of a smaller break size. The NRC staff considered 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 as a result of redefining the large-break LOCA. These include lengthening diesel generator start times, optimizing containment spray system setpoints, increasing power, improving fuel management, eliminating potentially required actions for postulated sump blockage issues, and changing setpoints, the required number of accumulators, equipment sequencing, or valve stroke times.

The Commission's March 31, 2003, Staff Requirements Memorandum (SRM) on SECY-02-0057, "Update to SECY-01-0133, 'Fourth Status Report on Study of Risk-Informed Changes to the Technical Requirements of 10 CFR Part 50 (Option 3) and Recommendations on Risk-Informed Changes to 10 CFR 50.46 (ECCS Acceptance Criteria)'" approved most of the staff recommendations on 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. After holding several public meetings to discuss the direction of the proposed rule, the NRC staff requested additional guidance from the Commission in SECY-04-0037, "Issues Related to Proposed Rulemaking to Risk-Inform Requirements Related to Large Break Loss-of-Coolant Accident (LOCA) Break Size and Plans for Rulemaking on LOCA with Coincident Loss-of-Offsite Power" dated March 3, 2004. The Commission provided direction in an SRM dated July 1, 2004. The Commission stated that the staff should determine an appropriate risk-informed alternative break size and that breaks larger than this size should be removed from the design basis event category. The proposed rule should be structured to allow operational as well as design changes and should include requirements for licensees to maintain the capability to mitigate the full spectrum of LOCAs up to the double-ended guillotine break of the largest reactor coolant system pipe. To maintain the core in a coolable geometry, the Commission stated that a high-level criterion in the rule should include the requirement for the licensee to provide effective mitigation capabilities, including effective severe accident mitigation strategies directed at break sizes larger than the alternative maximum break size permitted by the rule. The Commission also stated that the mitigation capabilities for beyond-design-basis events should be controlled by NRC requirements commensurate with the safety significance of these capabilities. Finally, the Commission stated that LOCA frequencies should be periodically reevaluated and if increases in frequency required 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 Boiling Water Reactor Owners Group pilot exemption request before proceeding with a separate rulemaking on that topic.

DISCUSSION:

Based on the above Commission guidance, the staff has prepared a proposed rule which contains alternative emergency core cooling system (ECCS) evaluation requirements. These alternative requirements would be codified in a new regulation, § 50.46a, and could be used in lieu of the requirements in the current § 50.46. The rule could be adopted by current nuclear power reactor licensees.[1]

Proposed Rule

The proposed rule would divide the current spectrum of LOCA break sizes into two regions. The division between the two regions is determined by a “transition break size” (TBS). The first region includes small breaks up to and including the TBS. The second region includes breaks larger than the TBS up to and including the double-ended guillotine break (DEGB) of the largest reactor coolant system pipe. The term, “break,” in the TBS does not mean a double-ended guillotine break; rather it refers to an equivalent opening in the reactor coolant system boundary.

The staff determined that an appropriate TBS would be the cross-sectional area of the largest pipe attached to the reactor coolant system. Thus, the TBS will vary from plant to plant depending on the specific piping system design. For pressurized water reactors (PWRs), the largest attached pipe will be the pressurizer surge line whose diameter varies from about 8 inches to 14 inches. For boiling water reactors (BWRs), the area of the TBS break is the cross-sectional flow area of the larger of either the feedwater or the residual heat removal piping inside primary containment. The BWR TBS corresponds to a pipe diameter of approximately 20 inches.

Pipe breaks in the smaller break size region are considered much more likely than pipe breaks in the larger break size region. Consequently, each region will be subject to ECCS requirements commensurate with the relative likelihood of breaks in that region. LOCAs in the smaller break size region will continue to be “design basis accidents” and will continue to be analyzed by current methods, assumptions, and criteria. In the design basis accident region, licensees must perform analyses under current ECCS requirements to determine the limiting size and location for breaks up to and including the TBS.

Pipe breaks larger than the TBS, because of their lower likelihood, can be analyzed by the more realistic and less stringent analysis methods established in the new § 50.46a. Although LOCAs

[1]The rule would not apply to future design approvals or standard design certifications or to any plants whose construction permits are issued after the effective date of the final rule.

for break sizes larger than the transition break will become “beyond-design-basis accidents,” the proposed rule includes requirements ensuring that licensees maintain the ability to mitigate all LOCAs up to and including the double-ended guillotine break of the largest reactor coolant system pipe. Although these breaks must be mitigated, the methods and initial and boundary conditions used for the mitigation analysis may be more realistic. The analysis results must show that the core remains amenable to cooling. Licensees would be allowed to take credit for reliable nonsafety-related systems without assuming other independent failures. The specific metrics for demonstrating "coolable core geometry" are not necessarily limited to a peak cladding temperature of 2200 degrees F and less than 17 percent local cladding oxidation, as required for breaks smaller than the TBS. Licensees could use other metrics and acceptance criteria for demonstrating coolable core geometry if an adequate technical basis is provided to support the licensee’s proposal.

Licensees who perform LOCA analyses using the risk-informed alternative requirements may find that their plant designs are no longer limited by certain parameters from previous large-break analyses. The new analyses could enable licensees to propose a wide range of design or operational changes. The intent of the proposed rule is that licensees use the revised § 50.46a to optimize safety system design and setpoints, and that overall implementation will result in a net reduction in risk to public health and safety. Nevertheless, the proposed rule would require that any increases in core damage frequency (CDF) and large early release frequency (LERF) are themselves small and that plant baseline risk remains relatively small.

To allow licensees to optimize their safety systems for the more likely (smaller) breaks, licensees would be permitted to make changes in containment systems as long as structural and leak tight integrity is maintained for the realistically calculated pressures and temperatures resulting from LOCAs larger than the TBS. In addition, as part of the defense-in-depth evaluation, licensees would be required to show that a reasonable balance is provided between accident prevention and mitigation. This evaluation would include an assessment of the impact of proposed changes on the frequency of late containment failure. This assessment would allow licensees (and the NRC) to identify proposed plant changes that have no effect on CDF or LERF, but are nonetheless risk significant because of the magnitude of the increase in likelihood of late containment failure.

The rule would not require assumption of LOOP or a limiting single failure of the ECCS for the analyses performed to show that the acceptance criteria are met for breaks larger than the TBS. Thus, it is possible that a licensee may be crediting that the full complement of ECCS is available. To ensure that the facility will continue to comply with the acceptance criteria under any at-power operating configurations allowed by the license, the staff proposes to include in § 50.46a(f)(7), requirements 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.

The rule would establish an “inconsequential risk” threshold for allowing licensees to implement certain plant changes made possible by the alternative ECCS requirements in § 50.46a without specific prior NRC review and approval. After initial NRC review and approval of a licensee’s license amendment request and the associated risk analysis and evaluation methodology, licensees could make subsequent plant changes meeting the inconsequential risk criterion without further NRC review or approval.[2] The proposed § 50.46a would state that the provisions of § 50.59 are not applicable to inconsequential risk changes under § 50.46a. Other plant changes which comply with the requirements in § 50.59, and which could have been made under existing § 50.46 (i.e., do not require use of the alternative ECCS requirements in § 50.46a), may continue to be made under § 50.59.

Under the provisions of § 50.46a, facility or operational changes (including necessary changes to the facility's license or technical specifications) having risk impacts greater than the inconsequential risk threshold would be reviewed and approved by the NRC via the license amendment process in §§ 50.90, 50.91 and 50.92.

The potential impacts of plant changes on facility security would be evaluated as part of the license amendment review process. The proposed rule does not contain specific requirements for licensees to evaluate the safety-security interface for proposed changes. The NRC staff is currently developing options regarding the interaction between safety and security considerations with respect to facility changes. The staff is examining the merits of a more global approach to establishing regulatory requirements for the safety-security interface, such as potentially amending § 50.59 and similar parts of the regulations, rather than establishing requirements in individual rule changes associated with more narrowly focused aspects of the regulations, such as changes to § 50.46.

The NRC will periodically evaluate LOCA frequency information. If estimated LOCA frequencies significantly increase so that the conservatism used in selecting the TBS is unacceptably reduced, the NRC will undertake rulemaking (or issue orders, if appropriate) to change the TBS. In that case, § 50.46a provides that the backfit rule (§ 50.109) would not apply, consistent with Commission direction. As a result of changing the TBS, some licensees may be required to modify their facilities in order to restore compliance with the § 50.46a requirements. In these cases, the proposed rule also provides that the backfit rule (§ 50.109) would not apply.

The NRC staff also proposes several conforming changes to the GDC in Appendix A to 10 CFR Part 50, to allow the single failure and LOOP assumptions to be eliminated during analysis of breaks larger than the TBS without creating inconsistencies between the GDC and the requirements in § 50.46a.

Regulatory Analysis

By revising the ECCS requirements for breaks larger than the TBS, the proposed rule would facilitate a large variety of possible design changes at various facilities. The cost-beneficial nature of these design changes would be heavily dependent on plant-specific design parameters and individual licensee business strategies. Thus, when preparing the regulatory analysis, the NRC staff had difficulty estimating generic costs and benefits (including safety benefits) that could result from the rule. The cost-beneficial nature of other plant changes, such as lengthening emergency diesel start times and increasing power generation, are more easily estimated. Accordingly, the NRC regulatory analysis estimates the net positive benefit of plant changes to lengthen emergency diesel start times and to increase power. The NRC staff and

---

[2]Provided, of course, that the plant change did not involve a change to the license or technical specifications.

the nuclear industry are now performing additional analyses of selected design changes that are anticipated to increase plant safety. One safety enhancement plant change that is being analyzed is modifying the containment spray system actuation settings to minimize risk by more effectively mitigating the more likely small break LOCAs. The results of these studies will also be addressed by the NRC in the final regulatory analysis.

Contents of the Proposed Rulemaking Package

This rulemaking package includes the *Federal Register* notice for the proposed rule (Attachment 1). The notice includes the proposed rule language and statement of considerations. The regulatory analysis is provided in Attachment 2. The rule also amends information collection requirements that must be submitted to the Office of Management and Budget no later than the date the proposed rule is forwarded to the *Federal Register* for publication. The staff has prepared its supporting statement for this rulemaking, which will be finalized upon Commission approval to publish the proposed rule.

Regulatory Guidance

The NRC staff is working to complete a regulatory guide to facilitate implementation of the final rule. The guide is expected to be completed at the same time as the final rule. The industry, via the Nuclear Energy Institute, has proposed to develop implementation guidance which, if found acceptable by the NRC staff, could be endorsed in the regulatory guide as an acceptable way to implement the § 50.46a rule.

RESOURCES:

The resources needed to complete the proposed rulemaking (1.0 FTE in FY 2005; 0.5 FTE in FY 2006) and guidance (1.5 FTE in FY 2005; 0.5 FTE in FY 2006) are included in the current FY 2005 and FY 2006 budgets. Plant-specific implementation will be achieved through individual licensing actions. Inspection of licensee implementation will be performed through the normal inspection process.

RECOMMENDATIONS:

That the Commission:

1. *Approve* the notice of proposed rulemaking for publication (Attachment 1).

2. *Certify* that this rule, if promulgated, will not have a negative economic impact on a substantial number of small entities in order to satisfy the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).3.

   Note:

   1. The proposed rule will be published in the *Federal Register* with a 75-day public comment period.

2. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the basis for it, as required by the Regulatory Flexibility Act.

3. Copies of the *Federal Register* Notice of proposed rulemaking will be distributed to all affected Commission licensees. The notice will be sent to other interested parties upon request. Copies of the documents are also available in the NRC's Agencywide Document Access and Management System (ADAMS), the Public Document Room and on the NRC rulemaking web site.

4. A public announcement will be issued.

5. The appropriate Congressional committees will be informed.

6. The supporting statement concerning changes in information collection requirements will be sent to the Office of Management and Budget.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper.

The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections.

The staff met with the Advisory Committee on Reactor Safeguards concerning the rulemaking approach and implementation guidance on a number of occasions, most recently on March 3, 2005. In a letter dated March 14, 2005, the Committee supported the staff's proposal to issue the proposed rule for public comment.

The Committee to Review Generic Requirements has deferred its review of the rule until the final rule stage.

/RA/

Luis A. Reyes
Executive Director
for Operations

Attachments: 1. *Federal Register* Notice
2. Regulatory Analysis

[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 75 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

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

D. Changes to the facility, technical specifications, or procedures

1. NRC approval of specific changes to a facility, technical specifications, or procedures

a. Criteria for approval of changes

i. LOCA mitigation capability

ii. Changes in break frequency or uncertainty

iii. Aggregation of plant changes when evaluating changes in risk

iv. Cumulative increases in core damage frequency and large early release frequency

v. Defense-in-depth

vi. Safety margins

vii. Incorporating RG 1.174 criteria in rule

b. Process for NRC review and approval of requested changes

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

a. Criteria for making changes without NRC review and approval

i. Acceptance criteria in § 50.46a(d)(2) and (f)(2) are met

ii. Change would not otherwise require reporting under paragraph (h)(1)

iii. Inconsequential increases in LERF and CDF

b. Process for NRC review and approval of licensee change process

3. Preliminary guidance for risk metric acceptance criteria

4. Minimum requirements for PRA and risk assessments

a. PRA requirements

b. Risk assessments other than PRA

5. Monitoring and feedback

6. Operational requirements

E. Reporting requirements

1. ECCS analysis of record and reporting requirements

2. Plant design change and risk assessment reporting requirements

3. Inconsequential change reporting requirement

F. Plant change safety and security review process

G. Documentation, change control, and restriction of reactor operation requirements

1. Documentation 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. <u>Deterministic Approach</u>

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.

---

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

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 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. <u>Probabilistic Approach</u>

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 §§ 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, and 44, and Appendix K.

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 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

---

[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)

[3]Different TBSs for pressurized water reactors and boiling water reactors are being established due to the differences in design between these two types of reactors.

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 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 criteria for evaluating design changes. These criteria will be consistent with the criteria for risk-informed license amendments contained in RG 1.174. These criteria ensure both the acceptability of the changes from a risk perspective and the maintenance of sufficient defense-in-depth. The risk evaluation criteria are described in Section III.D of this supplementary information.

The rule would also require that proposed changes to a facility, technical specifications[4], or operating procedures[5] made possible by 10 CFR 50.46a be reviewed and approved by the NRC via the routine process for risk-informed license amendments,[6] except for changes that result in inconsequential changes in risk[7]. Potential impacts of the plant changes on facility security would be evaluated as part of the license amendment review process. The safety and security review process for plant changes is discussed in Section III.F of this supplementary information.

The NRC will periodically evaluate LOCA frequency information. If estimated LOCA frequencies significantly increase, the NRC will undertake rulemaking (or issue orders, if appropriate) to change the TBS. In such a case, the backfit rule (10 CFR 50.109) would not apply. If previous plant changes are invalidated because of a change in the TBS, licensees would have to 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. <u>Determination of the Transition Break Size</u>

---

[4]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.

[5]Only changes to operating procedures that affect the design of the facility as described in the Final Safety Analysis Report (FSAR) require NRC review and approval.

[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]Changes that are not enabled by § 50.46a, which meet the criteria of 10 CFR 50.59 may continue to be made by licensees without prior NRC approval.

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). A baseline TBS was established using these pipe break frequencies as a point of departure. The TBS was then adjusted to account for other significant contributing factors that were not explicitly addressed in the expert elicitation process. In brief, the following process was used by the NRC in establishing the TBS.

(1) Break sizes for each reactor type (PWR and BWR) were selected that corresponded to a break frequency of 1.0E-05 per reactor year from the expert elicitation results.

(2) The NRC 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, and

(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 (WASH-1400 and NUREG-1150) were based primarily on non-nuclear industry operating experience. A more recent study (NUREG/CR-5750) was based on a significant amount of nuclear operating experience, but 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.

There are now over 3,000 reactor years of operating experience and a much better understanding of the types of piping systems and sizes that are more likely to fail. In addition, there is more extensive knowledge of degradation mechanisms that cause failures in piping systems. To apply this operating experience and knowledge to risk-informing ECCS requirements, the NRC formed a group of experts with 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. 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 1E-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 5 inches to 7 inches equivalent diameter, and for BWRs, from approximately 10 inches to 18 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 1E-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. There are other important considerations in estimating overall frequencies, in addition to the degradation-related frequency estimates, including:

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 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 in size 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 break frequencies vary from plant to plant because of site seismicity and design considerations and are affected by the amount of 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. The following conclusions have been obtained from these studies. Piping and other passive RCS components generally exhibit high seismic capacities and are, therefore, not significant risk contributors. However, these studies did not explicitly consider the effect of degraded component performance on the risk contributions.

The NRC has recently conducted a preliminary scoping study to evaluate the risk contribution associated with seismic loading on undegraded and degraded passive system failures. This study examined operating experience, seismic probabilistic risk assessment (PRA) insights, and models developed to compare the failure probabilities of undegraded and degraded passive system components. The operating experience review considered passive component failures that have occurred as a result of strong motion earthquakes in nuclear and fossil power plants as well as other industrial facilities. This review concluded that there were no catastrophic failures of large pipes resulting from earthquakes between 0.2g and 0.5g peak ground acceleration in power plants. Models were developed as part of this research to compare the failure probabilities between undegraded and degraded piping components. The risk increase is directly related to the magnitude of the degradation. Based on the results of this study, the risk associated with seismic loading for non-degraded piping with diameter larger than the TBS is expected to be inconsequential. This NRC study has not yet been published.

Nevertheless, degradation can increase the risk associated with passive system failure for piping with diameters larger than the TBS. Therefore, licensees choosing to enact this voluntary rule will be requested to demonstrate that sufficient inspection plans exist for all RCS piping to ensure that in the event of a very large earthquake (1) pipe degradation does not exist that could significantly increase the frequency of a break larger than the TBS, or (2) pipe degradation is appropriately analyzed to preclude significant increases in the frequency of a break larger than the TBS. Specific guidance for making these determinations will be provided by the NRC in the regulatory guide pertaining to this rule.

c. Dropped heavy loads.

During power operation, personnel entry into the containment is typically infrequent and of short duration. The lifting of heavy loads that have the potential to damage safety-related equipment is typically performed while the plant is shutdown. During refueling evolutions when the majority of heavy loads are lifted, the primary system may be open, which further reduces the risk due to 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 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 1E-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.

The proposed 10 CFR 50.46a would require that proposed plant modifications not significantly increase the pipe break LOCA frequency estimates used as the basis for the TBS. This would generally include changes that significantly affect the basis for estimates generated during the expert elicitation. 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 using evaluation models and analysis methods reviewed and approved by NRC. These analyses must demonstrate that the cooling performance conforms to the acceptance criteria set forth in the rule. For breaks at or below the TBS, § 50.46a(c)(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(c)(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, 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(c)(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, and the level of NRC staff review would be less rigorous. This concept is reflected in the differences between paragraphs (c)(1) and (c)(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 (c)(2) of § 50.46a indicates that only the most important phenomena must be addressed by the analysis method, and that the model must reasonably, rather than realistically, describe the behavior of the RCS during the LOCA such that there is a reasonable, rather than high, level of probability that the criteria would not be exceeded. 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, and instead may submit an analysis method for review and approval by the NRC. Modifications have been made to paragraph 5 of Appendix K, Part II, to reflect the reduced documentation requirements for these analysis methods. A licensee may opt to use a presently approved best-estimate methodology for breaks larger than the TBS. Such an evaluation model would exceed the requirements for analysis methods, but would likely yield margin to the acceptance criteria. Also, these models have already been approved for use at most plants for some break sizes.

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(c)(1) of the proposed rule retains the high level of probability as the statistical acceptance criterion for breaks at or below the TBS, but § 50.46a(c)(2) relaxes the criterion to a reasonable level of probability (i.e., less than 95 percent) for breaks larger than the TBS. The NRC is preparing a regulatory guide which would provide more detailed guidance about meeting the criterion for a “reasonable” level of probability.

Reducing the required probability level of meeting the acceptance criteria for the break sizes larger than the TBS has an effect similar to allowing higher acceptance criteria at a high probability level. It is a matter of keeping a consistent set of criteria but using different levels for probability of achieving the criteria. For example, a 70 percent probability value of peak cladding temperature (PCT) indicates that the probability of the hot pin in the core exceeding the calculated PCT is 30 percent — this does not imply that 30 percent of the fuel pins in the core would exceed the calculated PCT. The number of fuel pins that probabilistically might exceed the criterion is not specifically predicted by LOCA analyses because the regulation requires only that the calculated PCT (which is the PCT of the hot pin) be compared to the acceptance criterion. Only a very small fraction of the fuel rods run at the conditions of the hot pin. The temperature of the bulk of the fuel pins would depend on the core peaking factors and would be much lower than the hot pin PCT.

Section 50.46a(c)(1) and (c)(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. However, as discussed in Section III.D.7, “Operational

Requirements," § 50.46a(f)(7) would prohibit operation in any plant operating configuration for which maintenance of coolable geometry and long-term cooling for all LOCAs (including beyond design-basis LOCAs) have not been demonstrated. A licensee may analyze planned operating configurations or may opt to 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(d)(1) 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(d)(2) 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 proposed metrics and acceptance criteria must be reviewed and approved by the NRC before being used. In absence of data or other valid justification provided by the licensee, the NRC will 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. 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.

D. Changes to the Facility, Technical Specifications, or Procedures

Licensees that adopt 10 CFR 50.46a would be able to make changes to a facility, technical specifications, or plant procedures that take into account more realistic requirements for LOCA break sizes larger than the TBS. These changes could include some that previously would have been prohibited under 10 CFR 50.46. Section 50.46a(f) of the proposed rule would address the procedures and criteria for determining whether such changes are acceptable. Under proposed § 50.46a(f)(1), a licensee seeking to make a risk-informed plant change would submit an application that would be reviewed and approved by the NRC prior to the licensee making the proposed change. However, under proposed § 50.46a(f)(6), a licensee would have the option of requesting the authority to make subsequent changes without prior NRC review and approval, but only if the changes constitute an "inconsequential increase" in risk (and, of course, do not otherwise involve a license amendment). Under this option, the licensee would initially submit for NRC review the licensee's proposed plant change process and criteria for determining that proposed changes constitute an inconsequential increase in risk. Regardless of whether the NRC reviews a specific change under proposed § 50.46a(f)(1) and (f)(2), or the licensee implements a change under the NRC-approved process under § 50.46a(f)(6), the licensee's PRA and/or risk assessment methodologies must meet the requirements in proposed § 50.46a(f)(3) and (f)(4), respectively. Once a licensee implements a change under § 50.46a(f), the licensee would be required to comply with the monitoring and feedback requirements in § 50.46a(f)(5). The remainder of this section will discuss each of these requirements.

1. NRC approval of specific changes to a facility, technical specifications, or procedures.

a. Criteria for approval of changes

Proposed 50.46a(f)(2) sets forth the six criteria that the NRC would utilize in assessing licensee-proposed changes to a facility, technical specifications or plant procedures, which are based upon the analyses of ECCS cooling performance permitted under this section. In general, the criteria were selected to ensure that the plant continues to provide defense-in-depth and mitigation capabilities, consistent with the Commission's determination that the frequency of occurrence of LOCAs larger than the TBS is acceptably low. Each of the six criteria are discussed below.

i. LOCA mitigation capability

To ensure that the most limiting LOCA can be mitigated, Section 50.46a(f)(2)(i) of the proposed rule would require that the NRC find that the facility is able to mitigate LOCAs for pipe 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. Breaks in the range from the TBS to the DEGB must be analyzed based on both break size and location. The combination of break size and location is to ensure that the break resulting in the most limiting thermal hydraulic conditions has been determined. Results are known to vary for breaks such as slot-type breaks depending on where the break is assumed to occur; the top, side or bottom of the pipe. Similarly, break locations along the length of the piping from the reactor vessel to the steam generator will affect the thermal hydraulic response. The determination of the worst break size and location is based on the calculated peak cladding temperature and maximum local oxidation for varying combinations of break size and location.

The Commission adopted this criterion to ensure that mitigation capability continues to be provided for LOCAs larger than the TBS up to the double-ended rupture of the largest pipe in the RCS. Although the Commission believes that the probability of a LOCA larger than the TBS is low, the Commission believes that, given the uncertainty associated with the frequency of such breaks, it is prudent to continue requiring mitigation capability for such LOCAs, albeit not at the current high likelihood of success.

The proposed rule provides that this criterion is satisfied only if two conditions are met. First, § 50.46a(f)(2)(i)(A) would require that the analysis performed under § 50.46a(c)(2) demonstrate that the acceptance criteria in § 50.46a(d)(2) are met under all power operating conditions (i.e., all modes of operation when the reactor is critical). This condition would ensure that the ECCS acceptance criteria in § 50.46a(d)(2) applicable to LOCA break sizes larger than the TBS continue to be met after the licensee-initiated changes to the facility, technical specifications, and procedures are implemented. Second, § 50.46a(f)(2)(i)(B) would require that for LOCAs larger than the TBS, the integrity of the reactor containment structure is maintained using realistically calculated pressure and temperature. This condition is intended to ensure that containment structural and leak-tight integrity are not adversely affected by any licensee-initiated change under this section. The Commission believes that it is acceptable to use realistically calculated pressures and temperatures - as opposed to the much more conservative analysis techniques currently used in deterministic analyses of containment integrity - because of the low probability of occurrence of such ruptures. However, a licensee may choose to use - and in such cases the NRC will accept - existing conservative analytical techniques.

ii. Changes in break frequency or uncertainty

Section 50.46a(f)(2)(ii) would require licensees to show that the frequency of occurrence of pipe breaks larger than the TBS, or the uncertainty of the frequency of such breaks, is not significantly increased. The Commission is proposing this criterion to ensure that the underlying bases for this rulemaking, *viz*., the frequency of occurrence of pipe ruptures larger than the TBS, are not significantly increased by design or operational changes proposed by a licensee. Although § 50.46a(j) provides that a licensee must make necessary changes to its facility, technical specifications, or procedures as the result of any increase in the TBS delineated in § 50.46a, the additional margin included in selection of the TBS should tend to reduce the need for additional rulemaking changing the TBS. Accordingly, the Commission is proposing that a limitation be included in § 50.46a(f)(2)(ii) to ensure that licensees would not propose changes that significantly increase the frequency of occurrence of LOCAs larger than the TBS or the uncertainty of the frequency of occurrence of such breaks.

This paragraph contains two conditions that must be met in order to provide the necessary assurance that frequencies of LOCAs larger than the TBS are not significantly increased. First, proposed § 50.46a(f)(2)(ii)(A) requires the NRC to find that the proposed licensee changes do not introduce new RCS pressure boundary degradation mechanisms. Second, proposed § 50.46a(f)(2)(ii)(B) requires the NRC to find that the proposed licensee changes do not reduce the likelihood of detecting RCS boundary degradation. These conditions ensure that licensee-initiated changes do not cause degradation to be larger than that assumed in the expert elicitation process which was part of the basis for establishing the TBS.

The Commission also considered whether additional, or augmented, inservice inspection (ISI) requirements (i.e., beyond those required by § 50.55a(g)) should be imposed on licensees that would voluntarily adopt proposed § 50.46a to ensure that the probability of failure of piping larger than the TBS would be maintained acceptably small. In estimating LOCA frequencies, the expert elicitation process used to help define the TBS assumed that the current, or risk-informed, ISI requirements would continue to be conducted. The expert elicitation panel concluded that the frequency of breaks in RCS piping larger than the TBS is very low using current, or risk-informed, ISI requirements. The Commission has concluded that this pipe break frequency is acceptably low, considering that breaks in this region are still required to be mitigated so that coolable core geometry is maintained. Therefore, it is unnecessary to impose additional, or augmented, ISI requirements on licensees that would voluntarily adopt proposed § 50.46a. However, as discussed in Section III.B.3 of this document, licensees will be expected to demonstrate that inspection plans are sufficient to ensure that pipe degradation does not exist such that a seismic event would fail RCS piping larger than the diameter of the TBS.

iii. Aggregation of plant changes when evaluating changes in risk

Licensees often make changes to the facility, technical specifications, and procedures. Some changes that the licensees would make after adopting this rule would not have been permitted without the new § 50.46a (related or enabled changes). Other changes would be unrelated insofar as the basis of the changes and NRC approval, when necessary, will rely on regulations, guidelines, or facility priorities that do not depend on the new TBS. Unrelated changes will indirectly influence the change in risk of the § 50.46a related changes insofar as they change the risk profile of the facility. If unrelated changes are combined with related changes in determining the § 50.46a change in risk estimates (bundling), the result will normally be different than if the unrelated changes are considered as part of the baseline risk associated with the current design and operation of the facility. If bundling is permitted, a licensee could more easily offset increased risk from § 50.46a enabled changes by risk reductions attributable to unrelated changes, or take advantage of risk reductions achieved by implementation of § 50.46a enabled changes to more easily offset risk increases attributable to unrelated changes.

Accordingly, the Commission considered whether the change in risk estimates used by the licensee to demonstrate compliance with § 50.46a(f)(2)(iv) must only include the risk impact of changes related to this rule or, alternatively, may also include the impact of unrelated changes. Combining, or bundling of unrelated changes would be consistent with RG 1.174, which permits the risk impact of unrelated changes to be combined into a single aggregate change in risk estimate that is compared to the relevant RG 1.174 risk guidelines. However, RG 1.174 provides additional guidelines to be applied when evaluating the acceptability of submittals that bundle related and unrelated facility changes.

The Commission believes that allowing bundling of unrelated changes into the § 50.46a change in risk estimates will encourage licensees to use risk-informed methods to take advantage of opportunities to reduce risk, and not just eliminate requirements that a licensee deems as undesirable. Therefore, proposed § 50.46a would allow changes unrelated to § 50.46a to be combined with changes enabled by § 50.46a in the calculation of the change in risk that is compared with the acceptance criteria in § 50.46a(f)(2)(iv).

However, in some situations, bundling could mask the creation of significant risk outliers. To ensure that risk outliers are not created, the appropriate guidelines in RG 1.174 to prevent such undesirable outcomes are included in the proposed rule. Accordingly, proposed § 50.46a (f)(2)(iii) would require that if a licensee uses bundling, the Commission must then find that: (1) the risk from significant accident sequences is not significantly increased, (2) the frequencies of the lower ranked contributors are not increased so that they become significant contributors to risk; and (3) no new sequences are created that become significant contributors to risk.

It is possible that a licensee might propose to bundle changes required to bring the facility into compliance with NRC regulations. Permitting these changes (which should reduce overall risk) to be bundled with § 50.46a changes would provide a licensee with an inappropriate benefit from previous non-compliance, and does not further the use of risk analysis to enhance safety. Accordingly, § 50.46a(f)(2)(iii) stipulates that none of the facility, technical specification and procedure changes bundled into the estimate used to demonstrate that the criteria in § 50.46a(f)(2)(iv) are met are changes that were or are necessary to address non-compliance with NRC regulations.

The Commission requests public comments on the acceptability of combining § 50.46a related and unrelated changes to meet § 50.46a risk acceptance criteria. In particular, the Commission seeks comment on whether § 50.46a(f)(2)(iv) should allow unrelated changes to be bundled, or whether the rule should limit the consideration of risk impacts to only those changes related to the proposed rule. The Commission also requests comments on whether changes unrelated to § 50.46a proposed by a licensee that meet the proposed high-level criteria for preventing creation of risk outliers should be included in determining the § 50.46a change in risk estimate regardless of whether they are risk decreases or increases. If bundling should be allowed, are the proposed high-level criteria for preventing creation of risk outliers adequate or should additional high-level criteria be imposed on what can and cannot be bundled, and if so, what specific high-level criteria should be utilized and incorporated into the final rule?

Section 50.46a(f)(1)(v) permits bundling of *proposed* plant changes (i.e., changes to the facility, technical specifications and procedures), and would not allow a licensee to bundle changes that have already been implemented or to take credit for (other than in the baseline risk estimate) the risk impacts of existing plant features. This provision was intended to ensure that on an overall basis, § 50.46a will tend to create safety improvements. Allowing a licensee to take repeated credit for past changes and existing plant features would be inconsistent with the Commission's intent in this rulemaking. However, the Commission requests public comment on whether there are circumstances that would favor bundling of changes that have already been implemented or the risk impacts of existing plant features when calculating the § 50.46a change in risk estimates, in order to facilitate or enable safety improvements.

iv. Cumulative increases in core damage frequency and large early release frequency

Proposed § 50.46a(f)(2)(iv) would require that the total increases in core damage frequency (CDF) and large early release frequency (LERF) due to facility, technical specification, and procedure changes that have been and are proposed to be implemented under this section are themselves small, and the plant baseline risk remains relatively small. The NRC is preparing a regulatory guide containing guidance for determining when these criteria will be met, consistent with the guidelines in RG 1.174. The regulatory guide will be issued with the final rule. Preliminary guidance is provided in Section III.D.3 of this supplementary information.

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 inservice testing, 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., ISI programs and inservice testing 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.

The Commission is proposing to require that the cumulative risk from all changes be tracked. It is important to track the cumulative change in risk from § 50.46a changes 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. Under the proposed rule, a licensee might choose to implement a series of changes over time. A licensee could inappropriately partition a change into a number of smaller changes so that any individual change is kept below the proposed rule's risk acceptance criteria, even though the changes, considered cumulatively, could result in a significant increase in risk. For example, a licensee might extend a test interval in steps chosen such that the increase in risk for each step is just below the proposed rule’s acceptance criteria even though the total increase would exceed them. Requiring that the cumulative 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 the changes, as they are implemented over time, would not constitute more than a small increase in risk. Comparing the risk increase from each change to the acceptance criteria independently of all previous changes would render the RG 1.174 risk acceptance guidelines inadequate to monitor and control increases in risk from a series of plant changes implemented over time.

The proposed rule’s requirement for cumulative risk tracking is consistent with RG 1.174, the application-specific RG’s, and current staff practice. Inclusion of this requirement in the rule, which is a necessary element for ensuring adequate protection to public health and safety, is required to ensure that such tracking is performed by all licensees under § 50.46a. Consequently, the NRC believes that the requirement for tracking the cumulative increases and comparing this to the acceptance criteria is necessary for this rulemaking.

The Commission requests public comments on whether there is an alternative to tracking the cumulative risk increases that is sufficient to provide reasonable assurance of protection to public health and safety and common defense and security.

v. Defense-in-depth

Section 50.46a(f)(2)(v) would require that a proposed change provide an “appropriate level of defense-in-depth.” 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. In RG 1.174, the NRC developed seven attributes 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 seven 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 criteria 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)(2)(v)(A) through (C) would incorporate three of the higher level defense-in-depth criteria that the Commission believes are generally applicable to all proposed risk informed changes. They are:

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

(2) Preservation of 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, in part, 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. The proposed rule would enable 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 requirement is included in the proposed rule.

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.

Four of the RG 1.174 principles related 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.

vi. Safety margins

Proposed 50.46a(f)(2)(vi) 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 made under this section 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.

vii. Incorporating RG 1.174 criteria in rule

In several public meetings during the development of the proposed rule, NEI representatives expressed the view that it was unnecessary to include requirements in the proposed rule that were based on the risk evaluation process and acceptance criteria described in RG 1.174. The proposed rule would incorporate high-level criteria derived from the guidance in RG 1.174 as regulatory requirements. The Commission specifically requests additional public comments on this topic.

b. Process for NRC review and approval of requested changes

Proposed 50.46a(f)(1) would require a licensee who wishes to make a change to its facility, technical specifications, or procedures based upon the analyses of ECCS performance permitted under § 50.46a, to submit an application for a license amendment to allow such a change. The application would be required to address six areas, which will be evaluated by the NRC when determining whether the acceptance criteria in proposed § 50.46a are met. In addition, potential impacts of the changes on facility security will be evaluated as part of the application review, to ensure that the proposed change does not significantly reduce the "built-in capability" of the plant to resist security threats. More detail about the security evaluation is provided in Section III.F of this supplementary information.

The Commission believes that all changes to a plant, its technical specifications, or its procedures which are based upon the analyses of ECCS performance permitted under § 50.46a – with the exception of those changes permitted under § 50.46a(f)(6) – must be reviewed and approved by the NRC for two reasons. First, a wide range of changes could be implemented under § 50.46a(f)(2), which, if improperly implemented by licensees, could result in significant adverse impacts on public health and safety or common defense and security. NRC review and approval would provide verification that a licensee has properly evaluated its proposed change against the acceptance criteria in § 50.46a. Second, changes involving technical specifications must receive NRC review and approval in the form of a license amendment, as required by the Atomic Energy Act of 1954, as amended. Accordingly, the Commission is proposing to require NRC review and approval of all changes initiated under § 50.46a(f)(2).

Proposed § 50.46a(f)(1)(i) through (vi) would set forth the specific types of information that must be included in the application. This information must be submitted in the application for several reasons. The information specified in proposed § 50.46a(f)(1)(i) describing the proposed changes and how they will affect the licensing basis of the plant is needed by the NRC to understand the nature and scope of the proposed change so that, among other things, the NRC can also consider any physical security impacts. The information specified in proposed § 50.46a(f)(1)(ii) discusses the technical adequacy of modeling and assessment methods and demonstrates that the criteria in § 50.46a(f)(2) are met. The information in proposed § 50.46a(f)(1)(iii) on the adequacy of measures taken to ensure that processes for evaluating internal and external events are adequate for estimating CDF and LERF is needed to help determine whether the criteria in § 50.46a(f)(2)(iv) are met. The information in proposed § 50.46a(f)(1)(iv) is necessary to determine that the PRA and risk methodologies utilized in support of the licensee's application are acceptable and meet the requirements in proposed § 50.46a(f)(3) and (f)(4), as applicable. Section 50.46a(f)(1)(v) states that if a licensee wishes to include consideration of changes other than those specifically now permitted by § 50.46a, the licensee is to submit information about those changes so that NRC can evaluate them as part of its review of the application. The information in proposed § 50.46a(f)(1)(vi) describing all the previous § 50.46a changes is needed by the NRC to be able to determine whether, for a combined change, the acceptance criteria in § 50.46a(f)(2) have been satisfied when evaluating the cumulative effect of all changes that have been implemented under this section. (See Section III.D.1.a.iii of this document for additional discussion about combined or bundled changes). The Commission believes that the information required to be submitted by proposed § 50.46a(f)(1) is necessary and sufficient to allow the NRC to properly review and determine the acceptability of the application.

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

As a general matter, the licensee must obtain NRC review and approval (through a license amendment application) for any changes to the facility, technical specifications, or procedures that may be implemented under this section. However, the Commission believes that there is a subset of plant and procedure changes made possible by § 50.46a involving inconsequential changes in risk which also have no significant impact upon defense-in-depth capabilities. Prior NRC review and approval of these changes on an individual basis would be unnecessary *if* the NRC has previously concluded that the licensee has an adequate technical process for appropriately identifying this subset of changes. In the Commission's view, plant changes which involve inconsequential changes in risk and have no significant impact upon defense-in-depth (and do not involve a change to the license), by definition, do not result in significant issues involving public health and safety or common defense and security. Expending licensee resources to prepare an application for approval of plant changes involving trivial changes in risk, and NRC resources to review and approve such applications, is not an efficient use of resources. Rather, the Commission believes that if it reviews and approves in advance the licensee's processes (including the adequacy of the licensee's PRA and other risk assessment methods) and criteria for identifying changes which are both inconsequential from a risk standpoint and do not significantly affect defense-in-depth or plant physical security, then there is no need to review and approve each of the changes individually. Further, the Commission believes that these inconsequential changes are unlikely to impact the built-in capability of the facility to resist security threats. Accordingly, the Commission has proposed in § 50.46a(f)(6) an alternative allowing a licensee to obtain "pre-approval" of a process for identifying inconsequential plant and procedure changes made possible under § 50.46a[8].

The proposed § 50.46a(f)(6) would state that a licensee may make changes based upon the provisions of this section without prior review and approval if the stated requirements in paragraph (f)(6) are met. The proposed rule would also state that the provisions of § 50.59 are not applicable. As noted, these provisions apply only to changes that are enabled by § 50.46a and not to other changes that a licensee already has the authority to make using § 50.59. The intention of this specific provision is that a licensee would apply the inconsequential criteria (which include consideration of impacts on risk and defense-in-depth) to determine whether changes using § 50.46a require prior NRC approval. The provision for nonapplicability of § 50.59 serves both to limit duplication of review efforts and to include consideration of inconsequential in the decisionmaking process. As further discussed in Section III. E of this document, the recordkeeping and reporting requirements for inconsequential changes are similar to those for § 50.59, so the primary distinction is with respect to review criteria.

a. Criteria for making changes without NRC review and approval

[8]Other facility changes which are not made possible (enabled) by the alternative ECCS requirements in § 50.46a and which meet the provisions of § 50.59 may continue to be made without prior NRC approval under § 50.59.

Proposed § 50.46a(f)(6)(ii) would establish three criteria to be used by the NRC in evaluating the acceptability of a licensee's proposed process and criteria for identifying inconsequential changes that may be made without NRC review and approval. Each of these criteria are discussed below.

i. Acceptance criteria in § 50.46a(d)(2) and (f)(2) are met

Proposed § 50.46a(f)(6)(ii)(A) would require that the licensee's process and acceptance criteria ensure that the § 50.46a(d)(2) criteria for ECCS performance, and the overall plant and procedure change criteria in § 50.46a(f)(2) are satisfied. Proposed § 50.46a(d)(2) is referenced because the Commission wishes to ensure that ECCS mitigation capability for pipe ruptures larger than the TBS would continue to be provided and would not be adversely affected. The overall criteria in § 50.46a(f)(2) are referenced primarily to ensure that the licensee-proposed change does not have any significant impact upon defense-in-depth. Appropriate consideration of defense-in-depth (e.g. independence of barriers, system redundancy) will also provide assurance that the proposed change does not reduce the "built-in capability" of the plant to resist security threats. The Commission also finds additional benefit in referencing all the § 50.46a(f)(2) criteria because it believes that a screening of the licensee-proposed change against the § 50.46a(f)(2) criteria provides additional verification and assurance that the change will not have a significant adverse effect on public health and safety or common defense and security.

ii. Change would not otherwise require reporting under paragraph (h)(1)

Proposed § 50.46a(f)(6)(ii)(B) would allow a licensee to make a change without NRC review and approval unless the change would otherwise require reporting under § 50.46a(h)(1). Under this paragraph, a licensee must report changes to its ECCS evaluation models if certain thresholds are exceeded. In the Commission's view, changes that would meet this reporting requirement are of sufficient significance they should not be allowed as inconsequential changes. Furthermore, as with the provision in § 50.46a(f)(6)(ii)(A) referencing the acceptance criteria in § 50.46a(f)(2), this paragraph would provide additional verification and assurance that a licensee-proposed change will not have a significant adverse effect on public health and safety or common defense and security.

iii. Inconsequential increases in CDF and LERF

Proposed § 50.46a(f)(6)(ii)(C) would preclude a licensee change without NRC review and approval unless the change, considered individually, constitutes an "inconsequential increase" in CDF and LERF. In the Commission's view, an "inconsequential increase" is one that, even if taken with all other inconsequential increases, would not be considered significant. The NRC is preparing a regulatory guide with guidance for determining "inconsequential changes" to CDF and LERF.

b. Process for NRC review and approval of licensee change process

The proposed rule would require NRC review and approval of a licensee's process for making plant and procedure changes without NRC approval. Although the acceptance criteria that the licensee must meet before making a change under this paragraph are established in the rule, the NRC has concluded that it must have a high level of assurance that the licensee's overall evaluation process (including the technical adequacy of the risk assessment) will correctly determine if the acceptance criteria in § 50.46a(f)(6)(ii) are met.

Proposed § 50.46a(f)(6)(i) would set forth the information that must be provided in the application for approval of the licensee's methods and decisionmaking process. In particular, § 50.46a(f)(6)(i)(A) would require a description of the licensee's PRA model and risk assessment methods, and § 50.46a(f)(6)(i)(B) would require a description of the methods and decisionmaking process for evaluating compliance with the acceptance criteria in (d)(2) and (f)(2). Thus, the information required to be submitted in the application will form the basis for the NRC's determination of whether the licensee's process will ensure that the requirements of § 50.46a(f)(6)(ii)(A) through (D) are met.

3. Preliminary guidance for risk metric acceptance criteria.

As discussed in RG 1.174, whether a change in risk is small depends on a plant's current CDF and LERF. For plants with total 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 total baseline CDF greater than 10^{-4} per year, small CDF increases are those of up to 10^{-6} per year. For plants with total 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 total baseline LERF greater than 10^{-5} per year, small LERF increases are considered to be up to 10^{-7} per year. The Commission proposes to use these quantitative guidelines as the basis for determining whether a risk increase is both itself small and that the plant baseline risk remains relatively small. The cumulative change in risk from all changes that have been and are proposed to be implemented under this section will be compared with the applicable criteria.

An "inconsequential" increase is one which, when considered qualitatively by itself or in combination with all other inconsequential increases, would never become significant. Logically, it is less than the small increase in CDF, and was chosen as an increase of less than 10^{-7} per year for CDF and an increase in LERF less than 10^{-8} per year. These values are an order of magnitude less than the small criterion for plants with elevated total CDF or LERF. Although ten such changes could cause the combination of inconsequential increases to exceed the small criteria for an elevated CDF or LERF facility, the Commission believes that most of these changes will have a much smaller (and, in some cases, an unmeasurable) increase in risk. Whenever a licensee proposes to make a change under § 50.46a(f)(1), the total cumulative risk including all the individually inconsequential risk increases must be considered. If a licensee implements an unexpectedly large number of inconsequential changes, the periodic reporting requirements in § 50.46a(h)(3) will provide adequate notice to ensure that the NRC is aware of potentially significant changes (or any collective impact), so that the NRC may undertake additional oversight actions it deems necessary and appropriate.

4. Minimum requirements for PRA and other 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. In addition, other rule provisions, e.g., § 50.46a(h)(3), require ongoing consideration of risk. Inasmuch as PRA methodologies are generally recognized as the best current approach for conducting risk assessment suitable for making decisions in areas of potential safety significance, § 50.46a(f)(3) 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)(4) 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.[9] 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. PRA requirements

Proposed § 50.46a(f)(3)(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)(3)(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. 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 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.

---

[9] 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.

Proposed § 50.46a(f)(3)(ii) would require that the PRA calculates CDF and LERF inasmuch as this proposed rule would require that these measures be compared against thresholds established in this proposed rule.

Proposed § 50.46a(f)(3)(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)(3)(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 decisionmaker 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. 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)(4) 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 “realistically conservative” results. Realistically conservative results are as realistic as practicable yet conservative enough to preserve adequate safety margins despite uncertainties in the assumptions or possible scenarios. 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. The Commission believes that a “realistically conservative” risk assessment is desirable for two reasons. First, use of realistic methods provides the best insight into the relevant phenomenology, thereby providing the best decisionmaking. Second, selecting assumptions at the conservative end of the credible spectrum for phenomena that are not well understood or are characterized by large uncertainties ensures that uncertainties are appropriately considered and that there is adequate confidence that unacceptable consequences due to these uncertainties are minimized.

5. Monitoring and feedback.

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. 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 licensee-initiated risk-informed changes to a plant’s licensing basis. Monitoring and feedback are necessary to ensure that the engineering evaluation conducted to examine the impact of the proposed change(s) continues to reflect the actual design and operation of the plant and that the decisions based on the evaluation remain valid. 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 risk assessments and affect the acceptability of a previously acceptable change is collected and incorporated into the risk assessments. Accordingly, the Commission has determined that the proposed rule should include appropriate monitoring and feedback requirements.

Proposed § 50.46a(f)(5) would set forth the proposed rule's requirements governing monitoring and feedback.[10] This paragraph would mandate that a licensee under § 50.46a must, following the initial implementation of a change to its facility, technical specifications, or procedures, periodically reevaluate and update the assessment (the PRA and/or associated non-quantitative risk assessments) required under § 50.46a(f)(3) and (f)(4). In particular, § 50.46a(f)(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. This is necessary because unrelated changes accomplished under the proposed rule, can affect the risk impacts previously determined for changes under the proposed rule. 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 to reflect these changes unrelated to § 50.46a, so that the licensee (and the NRC) will have an accurate understanding of risk at its facility, and that changes previously implemented under

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

§ 50.46a(f) continue to be acceptable from a safety and risk standpoint (i.e., the changes continue to meet the relevant acceptance criteria in either § 50.46a(f)(2) or (f)(6)).

The updated risk assessments must continue to meet the minimum quality requirements in § 50.46a(f)(3) and (f)(4) 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 decisionmaking 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 § 50.46a. 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., 10 CFR 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(f)(5) would require the licensee to take "appropriate action" to ensure that all changes accomplished under § 50.46a continue to meet the relevant acceptance criteria in § 50.46a(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)(2). 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)(2) acceptance criteria, and is consistent with the concept of performance-based regulation.

Finally, the proposed rule specifies 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.

6. Operational requirements.

The Commission would require in § 50.46a that a facility be able to mitigate LOCA break sizes larger than the TBS size 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(c)(2) to demonstrate compliance with the acceptance criteria in § 50.46a(d)(2) 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 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 (d)(2) are met for breaks larger than TBS. Thus, it is possible that a licensee may be crediting that the full complement of ECCS is available. 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. 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(f)(7) of the proposed rule, the Commission would require that the facility may 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 (d) will be met. The evaluation must be calculated in accordance with § 50.46a(c). Bounding analyses may be performed to reduce the number of model calculations.

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, 10 CFR 50.46(a)(3)(ii) would also require 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 temperature calculation, 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 breaks equal to or smaller than the TBS (consistent with the existing requirements in § 50.46), § 50.46a(h)(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. Proposed § 50.46a would have a requirement that licensees also 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.

For breaks larger than the TBS, § 50.46a(h)(1)(ii) would define a significant change as one which results in a calculated peak temperature differing by more than 300EF from the peak temperature from the last analysis method or is an accumulation of changes and errors such that the sum of the absolute magnitudes of the respective temperature changes is greater than 300EF. This threshold for prompt reporting was determined by engineering judgement and is not a safety limit. The 300EF value was considered large enough to provide licensees with flexibility for input and analysis method changes for these lower frequency breaks, while still ensuring that NRC would retain oversight of the use of the approved analysis methods if large errors or other changes should occur, consistent with the performance standard of reasonable probability that the acceptance criteria are not exceeded. For any changes or errors where PCT or oxidation exceeds the approved regulatory limit, licensees would be required to take immediate action to come back into compliance.

2. Plant design change and risk assessment reporting requirements.

Proposed § 50.46a(h)(2) sets forth reporting requirements with respect to the PRA reevaluation and updating required by § 50.46a(f)(5). When reevaluating and updating the PRA (and associated risk assessments), § 50.46a(h)(2) would require the licensee to compare the revised baseline CDF and LERF to those calculated under the last PRA model, and to report to the NRC if there is an increase of 20 percent or more. The reporting requirement is intended to ensure that the NRC is given early notification of relatively large changes in CDF or LERF. The Commission selected 20 percent as the threshold for CDF or LERF changes because it wants to establish a threshold for reporting that avoids trivial changes in the relevant calculated risk measures, but provides for early awareness of potentially significant changes in the PRA or in the plant risk profile. A 20 percent change was viewed as a prudent threshold for licensee notification of the NRC. It should be emphasized that the Commission does not regard the 20 percent criterion as a safety threshold.

The change 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.

Proposed § 50.46a(h)(2) would also require the licensee, as part of the periodic PRA reevaluation and reporting process, to determine the cumulative change in both CDF and LERF using the updated PRA model (and associated risk assessments), and compare it with the revised cumulative change of CDF and LERF calculated under the last PRA model. If the cumulative change in CDF caused by § 50.46a changes increases by 1 x 10^{-6} per year or more, or if the cumulative change in LERF caused by § 50.46a changes increases by 1 x 10^{-7} per year or more, the licensee would be required to report the change to the NRC. As with the reporting of increases in baseline risk, the Commission believes that increases in the cumulative changes in CDF and LERF should also be reported to ensure that the NRC is aware of potentially significant cumulative changes, so that if necessary, the NRC may undertake additional oversight activities.

The Commission proposed these reporting levels 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. The thresholds on the increase in cumulative risk are equivalent to 10 percent of the relevant maximum allowable limit under the § 50.46a(f)(2) acceptance criteria. The Commission deems this to be a reasonable point for initiating licensee reporting to the NRC. Again, these thresholds are intended for reporting, and should not be viewed as having any safety significance *per se*. As with the change in baseline risk, any changes exceeding the relevant threshold must be reported to the NRC within 60 days of completion of the PRA update, and must include a description of the PRA changes, as well as an explanation of the reasons for the increase in CDF and/or LERF. In addition, this paragraph would require that the licensee report include a schedule for implementation of any corrective actions required under § 50.46a(f)(5) for failure to comply with the acceptance criteria in § 50.46a(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. Inconsequential change reporting requirement.

In § 50.46a(h)(3) the Commission is proposing to require periodic reports by licensees who make "inconsequential" changes pursuant to § 50.46a(f)(6). 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 inconsequential changes which would provide for NRC awareness of inconsequential changes that, taken together, may result in a significant increase in risk. An alternative would be to require that the cumulative risk increases from inconsequential changes be tracked separately from the cumulative risk increase from all changes, and be compared to another quantitative criteria. 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 such changes remains inconsequential. The Commission notes that other reporting requirements (FSAR updates, ECCS model changes or PRA update results exceeding specified thresholds) exist. If reporting of inconsequential changes is required, should reporting be required every 24 months, every two refueling cycles (like the PRA updating), or on a different frequency?

F. Plant Change Safety and Security Review Process

The proposed rule would require that changes to the facility, technical specifications, or operating procedures be reviewed and approved by the NRC as risk-informed applications in accordance with the existing license amendment process. The NRC would review the requested change to ensure that it complies with NRC regulations and that public health and safety and the common defense and security are protected. Potential impacts of the proposed changes on facility security would be evaluated as part of the process for performing license amendment reviews. The application would be reviewed to ensure that the proposed 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.

G. Documentation, Change Control, and Restriction of Reactor Operation Requirements

1. Documentation requirements.

The proposed rule contains several documentation requirements. Proposed § 50.46a(g)(2) contains documentation requirements for changes made to a facility and/or operating procedures. Licensees would be required to document the bases of information provided in applications for requesting plant changes or making inconsequential risk changes under § 50.46a and the basis for concluding that the acceptance criteria in § 50.46a are satisfied. Licensees would also be required under Part II of Appendix K to this part to document the bases of evaluation models or analysis methods used to perform ECCS calculations. The information would be used by the NRC to ensure public health and safety by determining whether the evaluation models or analysis methods (including any computer codes) used by licensees adequately demonstrate ECCS performance and that the acceptance criteria in § 50.46a are satisfied.

2. Change control process for ECCS analysis.

Section 50.46a(g)(1) would also specify that when a licensee first decides to comply with the optional § 50.46a requirements, that first change to the ECCS analysis must be submitted for NRC review and approval and the ECCS evaluation change need not be reviewed under the provisions of 10 CFR 50.59. As discussed in Section III.C of this document, the proposed rule would require that the evaluation models and analysis methods be reviewed and approved by NRC, so that NRC can determine if they are technically adequate to demonstrate that the acceptance criteria would be satisfied. Because the proposed rule already requires NRC review and approval, there is no purpose served by also requiring a § 50.59 evaluation, which is a process intended to determine if prior NRC approval of a change to a facility or its procedures as described in the FSAR is necessary. Once the new § 50.46a analysis (and methods) have been initially approved for use, subsequent changes can 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 such as the provisions in § 50.46a(h) that reporting is required if the cumulation of changes (whether from correction of errors or changes) is significant.

3. Restriction of reactor operation.

Proposed § 50.46a(e) 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(c) 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(d), 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, since it is comparable to existing § 50.46(a)(2).

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 the previous facility changes or by making other changes to compensate for the increased risk. In these cases, the backfit rule (10 CFR 50.109) would also not apply (see further discussion in section XV).

I. Changes to General Design Criteria

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 considered to 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 requirements for LOCAs larger than the TBS do not require the assumption of a single failure, which is required by each of these GDC. Also, GDC 35, on emergency core cooling systems, requires the assumption of a loss of offsite power in addition to a single failure. 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 requirement for assuming a single failure (and, for GDC 35, the requirement for assuming a loss of offsite power) 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 loss of offsite power.

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 that 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.

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. The NRC believes the last of these factors, that is, “the conservatism of the calculational model and input parameters,” and the terminology “sufficient margin” in the introductory sentence to GDC 50 are worded generally enough to allow for less margin and conservatism for breaks larger than the TBS than would typically be applied to design basis LOCAs. Therefore, there is no need to modify GDC 50 to allow a licensee to use a more realistic analyses of the pressure and temperature conditions following LOCAs involving pipe breaks larger than the TBS.

The containment requirements in § 50.46a(f)(2)(i)(B) for beyond design-basis LOCAs, i.e., breaks larger than the TBS, allow the use of realistic calculations to determine resultant pressures and temperatures. This could result in smaller margins between actual and design basis containment pressures and temperatures. The requirements in § 50.46a(f)(2)(i)(B) will also allow less margin to be included in the assessment of the containment structural capability for these larger that TBS LOCA events which are now considered beyond design-basis accidents. This is consistent with the proposed treatment of beyond design-basis LOCAs in the assessments of ECCS capability, component cooling water system capability, and containment systems capability. The use of a realistic calculational model and input parameters would be acceptable for breaks larger than the TBS because LOCAs involving pipe breaks larger than the TBS are judged to be of very low probability and therefore should not be considered design basis accidents.

For plant modifications made 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)(iv) and the defense-in-depth acceptance criterion in § 50.46a(f)(2)(v)(A). 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 single failure) is still required to provide defense-in-depth for these low probability initiating events.

Proposed § 50.46a(f)(2)(i)(B) would require licensees to maintain the “structural and leak tight integrity of the reactor containment structure.” 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.

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. The NRC has also added language to clarify the requirements for reporting PRA changes that cause increases of 20 percent or more in facility risk.

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*, and GDC 44, *Cooling water systems.*

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 process to the NRC for approval. After NRC approval is granted, licensees can make certain plant changes that do not exceed an "inconsequential risk" threshold without further NRC review or approval. Licensee changes enabled by § 50.46a that also satisfy the requirements for inconsequential changes would not be required to be evaluated under the deterministic criteria contained in 10 CFR 50.59.

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 PRA and change evaluation process, licensees are free to make plant operational changes that satisfy the inconsequential change criteria. Any operational changes that do not qualify as inconsequential 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 50.46 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. Specifically, Appendix K, Part II and the rule language have been modified to reflect the less rigorous documentation and review requirements for evaluation models for breaks larger than the TBS, respectively. 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 (1) the expert elicitation process for estimating pipe break frequency, and (2) the § 50.46a requirement that plant changes cannot significantly increase the possibility of pipe breaks larger than the TBS. 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 document. 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 drafting the proposed rule, the NRC has clarified the requirement for not significantly increasing the frequency of occurrence (or uncertainty of the frequency of occurrence) of pipe breaks larger than the TBS by specifying two subcriteria: (1) new RCS (RCS) pressure boundary degradation mechanisms are not introduced, nor is the likelihood or effect of known degradation mechanisms significantly increased, and (2) the likelihood of detecting RCS boundary degradation is not reduced. Licensees would be allowed to increase power as long as they can demonstrate that these criteria (and all other applicable requirements) continue to be met. In reviewing applications for power uprates, the NRC will determine whether the information provided by the licensee is adequate to ensure that these subcriteria are satisfied. In the longer term, the NRC will 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 the same as existing definitions used in §50.46. They are replicated here for completeness. 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(f)(7) to specify conditions to 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 define the ECCS evaluation requirements for two LOCA break size regions. Paragraph (c)(1) would specify methods for evaluating ECCS cooling performance at or below the TBS. These breaks may be analyzed by the methods presently used for LOCA analysis (§ 50.46). Paragraph (c)(2) would specify methods for evaluating ECCS cooling performance above the TBS. ECCS cooling performance for LOCAs involving breaks larger than the TBS may be analyzed by realistic methods.

Paragraph (d) would define the ECCS acceptance criteria for the two LOCA break size regions. Paragraph (d)(1) would provide ECCS acceptance criteria for LOCAs up to and including the TBS. The criteria specified are equivalent to the current requirements in § 50.46 (e.g., 2200EF PCT and 17 percent fuel cladding oxidation). Paragraph (d)(2) would provide ECCS acceptance criteria for LOCAs larger than the TBS. These acceptance criteria are based on coolable geometry and long term cooling and are less prescriptive than the criteria presently used for LOCA analysis.

Paragraph (e) 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. Paragraph (f)(1) would require that except for inconsequential changes, the licensee must submit a license amendment request. Paragraphs (f)(1)(i) through (f)(1)(vi) would describe the information the application must contain. Paragraph (f)(2) would provide acceptance criteria for facility, technical specification and procedure changes. Paragraph (f)(2)(i) would require that the facility can mitigate LOCAs at any location and of any size ranging from the TBS up to and including the DEGB of the largest RCS pipe and that the structural and leak tight integrity of the reactor containment be maintained for realistically calculated temperatures and pressures resulting from all LOCAs larger than the TBS. Paragraphs (f)(2)(ii) through (f)(2)(vi) would require that the frequency of pipe breaks larger than the TBS is not significantly increased, none of the changes analyzed are necessary to address non-compliance with NRC regulations, any quantitative risk increases are small, and appropriate defense-in-depth and adequate safety margins are retained. Once the cumulative risk increase criteria are met, no further risk increases would be acceptable. If a licensee wished to implement additional changes that may cause the cumulative risk increase to exceed the acceptance criteria, the licensee could propose to also implement unrelated changes that would decrease the cumulative risk below the criteria. Paragraphs (f)(1)(v), (f)(1)(vi), and (f)(2)(iii) would provide additional requirements for such combined changes.

Paragraph (f)(3) would provide acceptance criteria for the PRA used to evaluate the change. Paragraphs (f)(3)(i) through (f)(3)(iv) would require that the PRA used has sufficient scope and technical adequacy. Paragraph (f)(4) would provide acceptance criteria for non-PRA risk assessments used to evaluate the change. Paragraph (f)(5) would provide acceptance criteria for the monitoring and feedback program. The criteria would require that risk assessments be reevaluated and updated no less often than every two refueling outages. Paragraph (f)(6) would specify a process by which licensees may make inconsequential changes without prior NRC review and approval of the change. Descriptions of the submittal and approval process and the associated acceptance criteria would be included. The scope, level of detail, and technical acceptability of the licensee's process would be commensurate with the types of changes the licensee intends to make without prior review and approval. The increases in CDF and LERF for facility and procedure changes that are proposed to be implemented under paragraph (f)(6) would be evaluated for each change. Because the risk increase from each change must be inconsequential, bundling is not possible when estimating the change in risk under paragraph (f)(6).

Paragraph (f)(7) would prohibit a licensee from operating its facility in any at-power operating configuration for which the ECCS acceptance criteria have not been shown by analysis to be satisfied.

Paragraph (g) would provide documentation and change control requirements. Paragraph (g)(1) would require that after the first § 50.46a ECCS analysis is approved by the NRC, the licensee's FSAR must be revised. Subsequent ECCS analysis changes could then be made under the provisions of this section and 10 CFR 50.59. Paragraph (g)(2) would require that the bases for meeting the acceptance criteria for all changes made under § 50.46a be documented and that the changes are reflected in updates to the licensee's FSAR.

Paragraph (h) would provide the requirements for making reports to the NRC. Paragraph (h)(1) would contain reporting requirements for errors or changes to ECCS analyses. Errors or changes that exceed the criteria specified would be reported and corrective actions to restore compliance would be taken as needed. Paragraph (h)(2) would contain reporting requirements for errors or changes to PRA analyses. Errors or changes that exceed the specified criteria must be reported and corrective actions to return to compliance must be taken as needed. Paragraph (h)(3) would contain reporting requirements for inconsequential changes.

Paragraph (i) would be reserved for future use.

Paragraph (j) 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 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 criteria contained in Appendix A would be modified to remove the requirement to assume a single failure 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 under §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*. In the specific case of GDC 17, the revision would be limited to the onsite electric power supplies and distribution system; for the others there are no such limitations. GDC 35 would also be modified to remove the requirement to assume that offsite power is unavailable for pipe breaks 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		ML 042680077
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	X	ML050480169

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[11] 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.

---

[11]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: New

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: When licensees decide to implement the requirements of this rule. This rule is voluntary.

Who will be required or asked to report: Licensees who are authorized to operate a nuclear power reactor.

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: **315,541** hours total, including **286,856** hours for reporting (an average of **7,898** hours per respondent) + **28,685** hours recordkeeping (an average of **789.8** 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 requesting 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, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0146), 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 Mr. Richard Dudley at rfd@nrc.gov or comment by telephone at (301) 415-1116.

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. This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The current requirements were approved by the Office of Management and Budget (OMB) approval number 3150-0011.

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.5 - Monitoring and feedback, § 50.46a(f)(5) would require that a PRA used to demonstrate compliance with the relevant criteria in § 50.46a(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 in § 50.46a(f)(2) 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 (f)(5) are not considered backfitting, § 50.46a(f)(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(f)(5) is appropriate.

Section 50.46a(j) 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(j) 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(j) 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:

<u>§ 50.34 Contents of application; technical information.</u>

(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 § 50.46(b) for facilities for which construction permits may be issued after [EFFECTIVE DATE OF RULE], and design approvals and standard design certifications under part 52 of this chapter 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 50.46(b) for facilities for which construction permits may be issued after [EFFECTIVE DATE OF RULE], and design approvals and standard design certifications under part 52 of this chapter issued after [EFFECTIVE DATE OF RULE].

* * * * *

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

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

(a) Each boiling or pressurized light-water nuclear power reactor fueled with uranium oxide pellets within cylindrical zircalloy or ZIRLO cladding must be provided with an emergency core cooling system (ECCS). 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, and a new § 50.46a is added to read as follows:

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

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

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

(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.

(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 paragraph (d) of this section, with cooling performance calculated in accordance with an acceptable evaluation model or analysis method under paragraph (c) 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) 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 paragraph (d) of this section. The evaluation models and analysis methods 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 and analysis methods.

(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 (d)(1) 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 (d)(1) of this section, there is a high level of probability that the criteria would not be exceeded.

(2) *ECCS evaluation for LOCAs involving breaks larger than the TBS.* ECCS cooling performance for LOCAs involving breaks larger than the TBS must be calculated and must

demonstrate that the acceptance criteria in paragraph (d)(2) of this section are satisfied. The evaluation model or 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, locations, and other properties sufficient to provide assurance that the most severe postulated LOCAs larger than the TBS up to the double-ended rupture of the largest pipe in the reactor coolant system are analyzed. Sufficient supporting justification must be provided 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. These calculations may take credit for the availability of offsite power and do not require the assumption of a single failure. Comparisons to applicable experimental data must be made. When the calculated ECCS cooling performance is compared to the criteria set forth in paragraph (d)(2) of this section, there must be a reasonable level of probability that the criteria would not be exceeded.

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

(1) *Acceptance criteria for LOCAs involving breaks at or below the TBS.*

(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.

(2) *Acceptance criteria for LOCAs involving breaks larger than the TBS.*

(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.

(e) *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 (c) of this section.

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

(1) *Submission and approval process*. A licensee may request to make changes to its facility, technical specifications and procedures based upon the analyses of ECCS performance permitted under this section, by submitting an application for a license amendment, provided, however, that changes to the facility and procedures may be made without submitting an application or obtaining NRC review and approval if the requirements of paragraph (f)(6) of this section are met. The application must contain the following information:

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

(ii) A discussion demonstrating that the criteria in paragraph (f)(2) of this section have been met, including a discussion of the technical adequacy of all modeling and assessment methodologies used;

(iii) A description of the measures taken to assure that the quality and level of detail of the systematic processes that evaluate the plant for internal and external events during normal operation, low power, and shutdown meet the requirements of paragraphs (f)(3) and (f)(4) of this section;

(iv) A description of all initiating events and the plant operating modes, an assessment of how each of these events and modes may be affected by the proposed changes, and the bases for this assessment including the manner in which the events and modes are addressed in the risk estimates in paragraphs (f)(3) and (f)(4) of this section;

(v) A description of any proposed change not otherwise permitted under this section that the licensee proposes to combine in the evaluation used to demonstrate that the criteria in paragraph (f)(2) of this section have been met, and a discussion of how each proposed change will affect the licensing basis; and

(vi) If any changes are proposed to be combined pursuant to paragraph (f)(1)(v) of this section, a description of all previous changes that have been implemented under this section and the change in risk estimate for each individual change.

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

(i) The facility is able to mitigate a LOCA at the limiting location(s) involving breaks larger than the TBS up to and including a double-ended rupture of the largest pipe in the reactor coolant system, such that:

(A) The analysis performed under paragraph (c)(2) of this section has demonstrated that the acceptance criteria in paragraph (d)(2) of this section are met under all at power operating configurations; and

(B) The structural and leak tight integrity of the reactor containment structure, including access openings, penetrations, and its internal compartments, is maintained for the realistically calculated pressure and temperature conditions resulting from any loss of coolant accident larger than the TBS.

(ii) The frequency of occurrence of pipe breaks larger than the TBS at the facility, or the uncertainty in the frequency of occurrence of such pipe breaks, is not significantly increased, by assuring that:

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

(B) The likelihood of detecting RCS boundary degradation is not reduced.

(iii) For combined changes pursuant to paragraph (f)(1)(v) of this section:

(A) None of the facility, technical specification and procedure changes included in the evaluation used to demonstrate that the criteria in this paragraph are met were or are necessary to address non-compliance with NRC regulations;

(B) The risk from significant accident sequences is not significantly increased;

(C) The frequencies of the lower ranked contributors are not increased so that they become significant contributors to risk; and

(D) No new sequences are created that become significant contributors to risk.

(iv) The total increases in core damage frequency (CDF) and large early release frequency (LERF) due to facility, technical specification and procedure changes that have been and are proposed to be implemented under this section are themselves small, and the plant baseline risk remains relatively small.

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

(A) Reasonable balance is provided among prevention of core damage, containment failure (early and late), and consequence mitigation, in part by showing that any increase in the probability of containment failure (early and late) does not significantly increase the frequency of a significant fission product release;

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

(C) Independence of barriers is not degraded.

(vi) Adequate safety margins are retained to account for uncertainties.

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

(i) Address initiating events from sources both internal and external to the plant and for all modes of operation, including low power and shutdown modes, that 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.

(4) *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 to demonstrate compliance with paragraph (f)(2) of this section, a licensee shall justify that the methods used produce realistically conservative results.

(5) *Monitoring and Feedback*. Upon implementation of a change to the facility, technical specifications, or procedure under this section, the licensee shall periodically re-evaluate and update its risk assessments required under paragraphs (f)(3) and (f)(4) of this section to address subsequent changes to the plant, operational practices, equipment performance, plant operational experience, changes in the PRA model, 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)(3) and (f)(4) of this section. Based upon the risk assessments, the licensee shall take appropriate action to ensure that all changes accomplished under this section continue to meet the acceptance criteria in paragraph (f)(2) of this section. 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.

(6) *Facility and procedures changes not requiring NRC review and approval*. A licensee may make changes to its facility and procedures based upon the analysis of ECCS performance permitted under this section without prior NRC review and approval and, provided the requirements below are met, the provisions of § 50.59 are not applicable.

(i) *Submission and approval process*. A licensee who wishes to make changes to its facility and procedures without prior NRC review and approval must submit an application under § 50.90 to request NRC approval of a process for evaluating the acceptability of such changes. The application must contain the following information:

(A) A description of the licensee's PRA model and risk assessment methods demonstrating compliance with paragraphs (f)(3) and (f)(4) of this section; and

(B) A description of the methods and decisionmaking process for evaluating compliance with the risk criteria and defense-in-depth criteria in paragraph (f)(2) of this section.

(ii) *Acceptance criteria*. The NRC may approve a licensee's process for making changes to its facility and procedures without prior NRC review and approval, and a licensee may make such changes following such NRC approval if the process ensures that:

(A) The acceptance criteria in paragraphs (d)(2) and (f)(2) of this section are met;

(B) A change is not made if licensee reporting under paragraph (h)(1) of this section would be required; and

(C) The increases in CDF and LERF due to each facility and procedure change that is proposed to be implemented under paragraph (f)(6) of this section are inconsequential.

(7) *Operational requirements*. The acceptance criteria in paragraph (d) of this section must not be exceeded under any allowed at-power operating configurations analyzed under paragraph (c) of this section, and the plant may not be placed in any at power operating configuration not addressed under paragraph (c) of this section.

(g) *Documentation and change control.*

(1) *ECCS analysis change*. The first change to the ECCS analysis performed in conformance with this section must be reflected in the ECCS analysis required by § 50.34(b) of this chapter, but need not include a supporting § 50.59 evaluation of the change. Thereafter, any changes to the ECCS analysis, as described in the FSAR, may be made if the requirements of this section and § 50.59 continue to be met.

(2) *Facility and procedures change*. The licensee shall document the bases for its application under paragraph (f)(1) or (f)(6) of this section, and the bases demonstrating compliance with the acceptance criteria in paragraph (f)(2) and (f)(6) of this section. Upon

either the approval of the change under paragraph (f)(2) of this section or licensee implementation of the change under paragraph (f)(6) of this section, the licensee shall update the final safety analysis report in accordance with § 50.71(e).

(h) *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 or method that affects the temperature calculation, 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 paragraph (d) 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 calculated peak fuel cladding temperature different by more than 300°F from the temperature calculated for the limiting transient using the last acceptable analysis method, or is a cumulation of changes and errors such that the sum of the absolute magnitudes of the respective temperature changes is greater than 300°F.

(2) As part of the PRA update under paragraph (f)(5) of this section, the licensee shall compare the revised values of baseline CDF and LERF to those calculated under the last PRA model required by paragraph (f)(5) of this section; determine the cumulative changes in CDF and LERF for changes in the facility, technical specifications and procedures implemented under this section using the updated PRA model; and compare the revised values to the CDF and LERF values calculated under the previous PRA model required by paragraph (f)(5) of this section. If the baseline CDF or LERF increases by 20 percent or more, the cumulative change in CDF increases by $1x10^{-6}$ per year or more, or the cumulative change in LERF increases by $1x10^{-7}$ per year or more, the licensee shall report the change to the NRC. The report must be filed with the NRC no more than 60 days after completing the PRA update and 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 (f)(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 inconsequential changes made under paragraph (f)(6) of this section since the last report.

(i) [RESERVED]

(j) *Changes to TBS; changes to the facility, technical specifications and procedures.* 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 paragraph (c) of this section and reconfirm compliance with the acceptance criteria in paragraph (d) of this section. If the licensee cannot demonstrate compliance with the acceptance criteria, then the licensee shall change its facility, technical specifications or procedures so that the acceptance criteria are met. The evaluation required by this paragraph, and any necessary changes to the facility, technical specifications or procedures as the result of this evaluation, must not be deemed to be backfitting under any provision of this chapter.

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

§ 50.109 Backfitting.

*   *   *   *   *

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

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

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

*   *   *   *   *

6. In Appendix A to 10 CFR Part 50, under the heading, "CRITERIA," Criterion 17, 35, 38, 41, 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 loss of coolant accidents involving pipe breaks larger than the transition break size under § 50.46a, where a single failure need not be assumed for plants under § 50.46a.

*   *   *   *   *

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 loss of coolant accidents involving pipe breaks larger than the transition break size under § 50.46a, where a single failure need not be assumed for plants under § 50.46a.

* * * * *

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 loss of coolant accidents involving pipe breaks larger than the transition break size under § 50.46a, where a single failure need not be assumed for plants under § 50.46a.

* * * * *

7. In 10 CFR Part 50, Appendix K, paragraph 5 of Section II is revised to read as follows:

APPENDIX K TO PART 50 - ECCS EVALUATION MODELS

* * * * *

II. REQUIRED DOCUMENTATION

* * * * *

5. General Standards for Acceptability - Elements of evaluation models and analysis methods reviewed will include technical adequacy of the calculational methods. For models covered by § 50.46(a)(1)(ii), the review of technical adequacy will include compliance with

required features of section I of this appendix K; and for models covered by § 50.46(a)(1)(i), assurance of a high level of probability that the performance criteria of § 50.46(b) would not be exceeded. For models covered by § 50.46a(c)(1), the review will include either compliance with the required features of section I of this appendix K, or assurance of a high level of probability that the performance criteria of § 50.46a(d)(1) would not be exceeded. For analysis methods covered by § 50.46a(c)(2), the review will include whether there is a reasonable demonstration that the criteria of § 50.46a(d)(2) would not be exceeded.

*   *   *   *   *

Dated at Rockville, Maryland, this ___th day of ____, 2005.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission

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

TABLE OF CONTENTS

EXECUTIVE SUMMARY

The NRC is proposing an alternative set of risk-informed requirements that licensees may voluntarily choose in lieu of the current requirements for analyzing the performance of emergency core cooling systems (ECCS) in 10 CFR 50.46. The alternative requirements will enable some licensees to change aspects of facility design and procedures. This major, complex rulemaking culminates years of study and analysis on the topic of risk-informing technical requirements in Part 50.

This regulatory analysis assesses the potential values and impacts of the proposed rule. Because the proposed rule is voluntary, it is difficult to project whether and how different types of licensees may use it. Moreover, the proposed rule contains new procedures and requirements whose costs cannot be precisely benchmarked. Therefore, the regulatory analysis follows a conservative approach throughout and addresses uncertainty by analyzing three scenarios representing different degrees to which licensees may employ the rule. Based on input from the BWR Owners' Group and the Westinghouse Owners Group, the analysis quantifies values and impacts only for pressurized water reactors (PWRs) and analyzes the potential use of the rule only for power uprates and relaxation of emergency diesel generator (EDG) start times.

The NRC expects that the rule will achieve safety benefits by allowing plant changes such as optimization of safety system design and set points for the more likely (smaller) pipe breaks. Because the cost-beneficial nature of this voluntary rule is highly dependent on individual plant design features and licensee business strategies, its benefits are difficult to quantify on a generic basis. In addition to safety improvements, the rule would allow other plant changes, such as power uprates, as long as the acceptance criteria are met. The increased ability to uprate power should make this an attractive rule for PWRs despite the regulatory costs, which exceed required capital costs at lower uprate levels (at 7.5 percent uprates, capital costs exceed regulatory costs). The NRC also will incur substantial review and research costs, the majority of which can be recovered from licensees.

The regulatory analysis considered two types of benefits. The higher benefit came from increased power generation due to power uprating that will displace some of the high cost oil and gas generation and lead to significant cost savings. The expected monetary benefits related to EDGs were much smaller but still significant. Although this analysis did not attempt to quantify the benefits of increasing safety, achievement of safety benefits would add to the net benefit of the rule.

Integrating the values and impacts reveals a proposed rule with a positive net present value (NPV). The NPV ranges from $697 million to $5.9 billion (7 percent discount rate) and $1.5 billion to $12.9 billion (3 percent discount rate). This is a cost-beneficial rule, as measured by the data and assumptions documented in the regulatory analysis.

1. STATEMENT OF THE PROBLEM AND NRC OBJECTIVES

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.

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 acknowledges that large break LOCAs are considered 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.

NRC's regulations and their implementation are largely based on a "deterministic approach," which 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). Those 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 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.

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.

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 uncertainty 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.

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 Assessment In Risk-Informed Decisions On

Plant-Specific Changes to the Licensing Basis." 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 only 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 the above 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.

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 themselves. 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 General Design Criteria (GDC) 35 and changes to §50.46 acceptance criteria, evaluation models, and functional reliability requirements. The NRC also proposed to refine previous estimates of LOCA frequency for various sizes of LOCAs to more accurately reflect the current state of knowledge with respect to the mechanisms and likelihood of primary coolant system rupture.

Industry interest in a redefined LOCA was shown by filing of a Petition for Rulemaking (PRM 50-75) by the Nuclear Energy Institute (NEI) in February 2002. Notice of that petition was published in the *Federal Register* for comment on April 8, 2002 (67 FR16654). The petition requested the NRC to amend §50.46 and Appendices A and K to allow an option [to the double-ended rupture of the largest pipe in the reactor system] for the maximum LOCA break size as "up to and including an alternate maximum break size that is approved by the Director of the Office of Nuclear Reactor Regulation." Seventeen sets of comments were received, mostly from the power reactor industry in favor of granting the petition. A few stakeholders were concerned about potential impacts on defense-in-depth or safety margins if significant changes were made to reactor designs based upon use of a smaller break size. 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 (WOG) concluded that the redefinition of the large break LOCA should have a substantial safety benefit. The Nuclear Energy Institute (NEI) submitted comments 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 Commission staff requirements memorandum (SRM) of March 31, 2003, 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),'"approved most of the staff recommendations related to possible changes to LOCA requirements and also directed the NRC staff to prepare a proposed rule that would provide a risk-informed alternative maximum break size. The NRC 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 Option 3 concept in SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR Part 50 - 'Domestic Licensing of Production and Utilization Facilities,'"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 EDG 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). The Commission provided direction in an SRM dated July 1, 2004. The Commission stated that the staff should determine an appropriate risk-informed alternative break size and that breaks larger than this size should be removed from the DBE category. The Commission indicated that the proposed rule should be structured to allow operational as well as design changes and should include requirements for licensees to maintain capability to mitigate the full spectrum of LOCAs up to the double-ended guillotine break of the largest reactor coolant system pipe. The Commission stated that the mitigation capabilities for beyond DBEs 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 Boiling Water Reactor Owners Group pilot exemption request before proceeding with a separate rulemaking on that topic.

2. ANALYSIS OF ALTERNATIVE REGULATORY STRATEGY

The Commission is considering an alternative set of risk-informed requirements with which licensees may voluntarily chose to comply in lieu of meeting the current emergency core cooling system requirements in 10 CFR 50.46. Using the alternative ECCS requirements will provide some licensees with opportunities to change aspects of facility design and operations. The overall structure of the risk-informed alternative is described below.

This rulemaking will apply to 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.

The proposed rule will establish risk-informed LOCA break sizes[1] (smaller than the double-ended guillotine break (DEGB) of the largest reactor coolant system pipe) to divide the current spectrum of LOCA break sizes into two regions, which are delineated by a "transition" break size (TBS). The first region includes small size breaks up to and including the TBS. The second region includes breaks larger than the TBS up to and including the DEGB of largest reactor coolant system pipe.

Pipe breaks in the smaller break size region are considered more likely than pipe breaks in the larger break size region. Consequently, each region will be subject to different ECCS requirements, commensurate with the relative likelihood of the breaks in each region. LOCAs in the smaller break size region will continue to be analyzed by current methods, assumptions, and criteria.

Based on their lower likelihood, accidents in the larger break size region will be analyzed by less stringent methods. Although LOCAs for break sizes larger than the TBS will become "beyond design-basis accidents," the NRC will include requirements ensuring that licensees maintain the ability to mitigate all LOCAs up to and including the DEGB of the largest reactor coolant system pipe.

Licensees who perform the new LOCA analyses using the risk-informed alternative requirements may find that their plant designs are no longer limited by certain parameters associated with previous DEGB analyses. Reducing the DEGB limitations could enable licensees to propose a wide scope of design or operational changes. Potential design changes include optimization of containment spray designs, increasing power, modifying core peaking factors, optimizing setpoints on accumulation or removing some from service, eliminating fast starting of one or more EDGs, etc. Some of these design and operational changes could increase plant safety, since a licensee could optimize its systems to mitigate the more likely LOCAs. The risk-informed § 50.46a option will establish criteria for evaluating design changes. The criteria will

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

be consistent with the criteria for risk-informed license amendments contained in RG 1.174. These criteria ensure both the acceptability of the changes from a risk perspective and the maintenance of sufficient defense-in-depth.

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

The NRC periodically will evaluate LOCA frequency information. If estimated LOCA frequencies significantly increase, the NRC will undertake rulemaking (or issue orders, if appropriate) to change the TBS. In that case, the backfit rule (10 CFR 50.109) would not apply. As the result of changing the TBS, some licensees might be required to take appropriate action to modify their facilities in order to restore compliance with 50.46a requirements. In these cases, the backfit rule (10 CFR 50.109) would not apply.

BACKFIT CONSIDERATION

The NRC has determined that the backfit rule (10 CFR 50.109) does not apply to this proposed regulation and that a backfit analysis is not required for this proposed regulation because the proposed rule does not involve any provisions that would impose backfits as defined in 10 CFR 50.109(a)(1). This proposed rule would amend the NRC's regulations by establishing an alternate requirement that licensees may voluntarily adopt.

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

3. ESTIMATION AND EVALUATION OF VALUES AND IMPACTS

3.0 Overview

This section describes the analysis conducted to identify and evaluate the benefits (values) and costs (impacts) of the proposed rule. Section 3.1 identifies the attributes that the proposed rulemaking is expected to affect. Section 3.2 describes the baseline used to analyze the benefits and costs associated with changes to the affected attributes. Section 3.3 presents the impacts of the proposed rule, while Section 3.4 presents the benefits.

3.1 Identification of Affected Attributes

This section identifies the factors that affect the public and private sectors as a result of the proposed rulemaking. These factors are classified as "attributes" using the list of potential attributes provided in Chapter 5 of the NRC's "Regulatory Analysis Technical Evaluation Handbook."[3] Each attribute listed in Chapter 5 was evaluated, and the basis for selecting those attributes expected to be affected by the potential action is presented in the balance of this section.

- *Industry Implementation*. The proposed regulatory action will require licensees to prepare and submit ECCS re-analyses for small break LOCA (SBLOCA) and large break (LBLOCA), risk-based plant change packages, and license amendment applications to support changes to design, operations, and technical specifications.

- *Industry Operation*. Licensees will need to update their PRAs periodically, submit reports, and perform annual monitoring of approved changes. In addition, licensees may need to implement corrective actions as necessary to ensure compliance with all applicable regulatory requirements. Licensees are expected to incur significant operational benefits from the opportunities provided by the rule, both in cost savings as well as revenue enhancements.

- *NRC Implementation*.[4] In order to implement the regulatory action, the NRC will review ECCS re-analysis and plant modification information submitted by licensees and conduct the license amendment process. NRC also will develop one or more RGs for the final rule.

- *NRC Operation*. The proposed action would require NRC inspections of facility changes, review of PRA updates, evaluation of LOCA frequency information, and additional research on the adequacy of the break sizes.

---

[3] NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook: Final Report," U.S. Nuclear Regulatory Commission, Office of Nuclear Regulatory Research, January 1997.

[4] Consistent with direction in Section 5.7.9 of the NRC's " Regulatory Analysis Technical Evaluation Handbook," this analysis does not include the predecisional costs of analyzing and promulgating the proposed requirements.

- *Regulatory Efficiency*. The proposed action would enhance regulatory efficiency by reducing attention on very-low probability accident scenarios and replacing exemption requests with a well-defined regulatory process.

- *Improvements in Knowledge*. The proposed rule will require licensees to use acceptable PRAs or other risk assessment techniques and update them periodically.

- *Other Considerations*. The proposed rule could affect public confidence in the NRC. Although NRC believes that meeting the generic acceptance criteria will maintain an adequate level of safety, the public may perceive the new rule's flexibility as providing less assurance of safety. Consequently, the public may perceive NRC to be unnecessarily relaxing safety standards.

The proposed rulemaking is not expected to affect the following attributes:

- *Environmental Considerations*
- *General Public*
- *Public Health (Routine)*
- *Public Health (Accidental)*
- *Other Government*
- *Occupational Health (Accidental)*
- *Occupational Health (Routine)*
- *Offsite Property*
- *Onsite Property*
- *Improvements in Knowledge*
- *Antitrust Considerations*
- *Safeguards and Security Considerations*

Industry implementation/operation and NRC implementation/operation are evaluated quantitatively. Quantitative analysis requires a baseline characterization of factors such as the number of licensees anticipated to take advantage of the rule, the cost to prepare and review a 50.46a request, and the economic benefits of uprates and delayed EDG start-times.

3.2 Baseline for Analysis

This regulatory analysis estimates the incremental benefits and costs of the proposed rulemaking relative to a baseline, which is how the world would be if the proposed regulation were not imposed.

The proposed regulation is applicable to both pressurized water reactors (PWRs) and boiling water reactors (BWRs). However, NRC expects that PWRs will be the primary beneficiaries. The NRC expects that most PWRs may be able to uprate power, depending upon plant-specific equipment capabilities, such as steam generator capacity, and also may be able to extend EDG start times. The WOG has identified LBLOCA Redefinition as the highest priority regulatory issue facing the industry since 2000 and reiterated that position in its response to the questions raised at the August 17, 2004, public meeting. Although the WOG did not survey its membership to determine how many would take advantage of LB LOCA redefinition, it expected that most PWRs (greater than75 percent) will ultimately perform one or more applications, such as power uprates and relaxation of EDG start times. BWRs, which tend not to be LOCA-limited, may not be able to uprate power but may be able to relax technical specifications and reduce analysis as well as operations and maintenance costs. The BWR Owners' Group, in comments submitted in response to the questions raised at the August 17, 2004, meeting, identified no potential values at the proposed TBS and added that it was extremely difficult to evaluate the cost-benefit of the proposed rule, independent of any value that could be gained, due to uncertainties about the true costs of adopting the proposed rule. Accordingly, this regulatory analysis focuses solely on PWRs.

The baseline used in this analysis assumes that all 69 PWR licensees will seek and obtain license renewals. This is consistent with NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Rev. 3, which states that, "… estimates for a license renewal term should be made if the analyst judges that the results of the regulatory analysis could be significantly affected by the inclusion of such a renewal term."

Section 3.3 presents the estimated incremental costs and Section 3.4 presents the estimated incremental benefits associated with the proposed rule relative to this baseline. The benefits of the rule include any desirable changes in affected attributes while the costs include any undesirable changes in affected attributes.

The NRC believes that many PWRs will seek power uprates to generate additional electricity. Since 1977, NRC staff have approved 59 power uprate license amendments for PWRs. These license amendment applications have been filed by 54 of the 69 PWRs (78 percent). Therefore, five PWRs have received power uprate license amendments twice:

- H.B. Robinson (4.5 percent and 1.7 percent)
- Comanche Peak 2 (1 percent and .4 percent)
- Kewaunee (1.4 percent and 6 percent)
- Palo Verde 2 (2 percent and 2.9 percent)
- Salem 1 (2 percent and 1.4 percent)

Power uprates by PWRs have ranged from 0.4 to 7.5 percent. The most frequently requested power uprate level among the 59 approved uprates is 1.4 percent, which occurred 16 times. The average power uprate level granted to PWRs is 3.1 percent, while the median power uprate level is 2 percent.

Fifteen PWRs (representing approximately 22 percent of all PWRs) have yet to receive power uprate license amendments:

- Arkansas Nuclear 1
- Catawba 1
- Catawba 2
- Davis-Besse
- Diablo Canyon 2
- McGuire 2
- Millstone 3
- Oconee 1
- Oconee 2
- Oconee 3

- Ginna
- McGuire 1
- Seabrook 1
- Prairie Island 1
- Prairie Island 2

As of October 2004, NRC staff are reviewing six power uprate license amendments for PWRs. Due to the uncertainty associated with these pending uprates, NRC excluded them from the baseline used for this regulatory analysis:

- Waterford (8 percent)
- Indian Point 2 (3.26 percent)
- Seabrook (5.2 percent)
- Indian Point 3 (4.85 percent)
- Palo Verde 1 (2.94 percent)
- Palo Verde 3 (2.94 percent)

In this regulatory analysis, the values and impacts associated with future power uprates are calculated based on three scenarios that could result from the rule change. The power uprate scenarios were developed by the NRC staff based on the history discussed above (e.g., 78 percent of PWRs have received uprates ranging from 4 to 7.5 percent, with an average of 3.1 percent and median of 2 percent), ongoing research and analysis, and other expertise available in published literature. The scenarios are defined in Exhibit 1.

Exhibit 1
SUMMARY OF POWER UPRATE SCENARIOS

Scenario	Degree of Power Uprate	Degree of Participation	Participating Plants
1	1%	100%	69
2	3%	90%	62
3	10%	75%	52

Scenario 1 is based on the regulatory analysis related to the revision of Appendix K, 10 CFR Part 50.[5] In the Appendix K analysis, NRC assumed that all nuclear power reactors would be able to achieve a power uprate of 1 percent. NRC staff believes that this scenario is a realistic lower bound for the rule change currently under consideration.

[5] U.S. Nuclear Regulatory Commission, "Regulatory Analysis for Revision of 10 CFR Part 50, Appendix K." September 23, 1999.

The assumptions for Scenario 2 are based on statements made by an industry representative regarding the § 50.46 rule change.[6] In an interview, an NEI staff member predicts "power uprates on the order of 3 percent."[7] NRC believes it is quite plausible that 90 percent of PWRs will be able to achieve a 3 percent uprate.[8]

Scenario 3 serves as an upper bound for the anticipated power uprates in this regulatory analysis. Although NRC staff believes that the rule change will result in power uprates of up to 10 percent, it is not known how many reactors will actually be able to accomplish that level of power uprate. Although power uprates greater than 10 percent also may be feasible, Scenario 3 is considered a realistic upper bound for the uprate values and impacts NRC expects to result from this rule change.

This analysis also assumes that licensees applying for a license amendment to uprate power will simultaneously seek reductions to their EDG start times. However, licensees are not expected to incur the costs of § 50.46a solely to secure the benefits of relaxed EDG start times. Therefore, the rates of PWR's seeking relaxed EDG start times were assumed to be identical to the three scenarios enumerated above (e.g. 100 percent, 90 percent, 75 percent).

Appendix A further describes the methodology and data used to analyze quantitatively the benefits associated with the proposed rule.

3.3 Analysis of the Impacts

3.3.1 Impacts to Licensees

Unit Regulatory Costs. The PWRs will incur implementation costs associated with pursuing power uprates and relaxed start times for EDGs through § 50.46a. To achieve the benefits associated with this rule change, a PWR must submit a § 50.46a package and license amendment request to NRC. To ensure that safety is not compromised, NRC requires documentation from the licensee to support the risk-informed changes. As a result, the licensee is subject to costs associated with providing these supporting analyses. NRC staff assume that these costs will begin to accrue to industry following the promulgation of the final rule in June 2005 (estimated) and will continue through 2006.

(a) Initially, to take advantage of the rule, a licensee must conduct ECCS re-evaluations separately for SBLOCAs and for LBLOCAs that meet applicable requirements and acceptance criteria. The NRC estimates that this process will require 2,500 hours of

---

[6] Knapik, M. "Industry, Seeing Huge Benefits, Presses for Redefining Large-Break LOCA." *Inside NRC*. January 15, 2001.

[7] Ibid.

[8] See note 2 above. On the other hand, the WOG, in its comments in response to the questions raised in the August 17, 2004 public meeting, stated that, depending on how the revised rule is written, only up to 25 percent of PWRs would use the new 50.46a rule to achieve a 2.5 percent power uprate.

industry staff/consultant time.[9] At an average labor rate of $157 per hour (2004$), the NRC estimates that this activity will cost $392,500 (i.e., 2,500 hours x $157 per hour) over a four month period for each submission.

(b) Based on the re-analysis of ECCS performance, a licensee may request to make changes to its facility, procedures, and technical specifications, by submitting an application for a license amendment. There are four basic steps that must be completed prior to conducting the licensing process. The first of four steps is a description of the proposed plant modifications and changes in current licensing basis (CLB) including a description of the SSCs, rules and regulations, operating procedures, and plant activities that will be affected by the change. This includes a justification of how the proposed change relates to the new rule. The NRC estimates this process will take 700 person-hours of industry staff time. Using an average labor rate of $157 per hour, the NRC estimates industry will incur costs of $109,900 (i.e., 700 hours x $157 per hour) over a three month period for each submission.

(c) The next step is a comprehensive engineering analysis to determine if the plant can safely sustain the proposed changes. Analysis of safety margins, defense-in-depth, equipment reliability, core damage frequency (CDF), large early release frequency (LERF), and a PRA[10] of LBLOCA frequencies (or other type of risk assessment) must be performed under the assumption that the proposed plant changes have been implemented. The NRC expects that this process will require 1900 person-hours of industry staff time and 600 hours of contractor support time. Using an average labor rate of $157 per hour both for industry and its contractors, the NRC estimates the cost of this engineering analysis to be $392,500 (i.e., (1,900 hours + 600 hours) x $157 per hour). For this analysis, it is assumed these costs will be incurred over an eight month period.

(d) In order to ensure equipment and SSCs continue functioning properly if changes to a plant have been made, and to retain proper documentation of all plant changes and the effects of those changes, a licensee must create and maintain a comprehensive continuous monitoring program. The NRC estimates that design and planning of a monitoring program specifically for plant alterations and documentation in line with the new rule will require 850 person-hours of staff time. Likewise, the NRC estimates that a licensee will incur an additional annual monitoring burden of 1150 person-hours of staff time to oversee changes related to the new risk-informed rule. The NRC estimates this additional monitoring burden

---

[9] *Final OMB Supporting Statement for Acceptance Criteria for Emergency Core Cooling Systems (ECCS): 10 CFR 50.46 and Appendix K (Section 7).*

[10] The licensee will need to address PRA quality issues. At a minimum, licensees will need to have a PRA that reflects the current plant configuration, is sufficiently complete for the intended application, meets a quality standard (RG 1.200), and is up-to-date. Depending on the state of the licensee's PRA, this activity could involve a significant commitment in resources. NRC notes that many licensees have already made investments in development of a PRA and having the PRA peer-reviewed for use in various applications, such as implementation of Section 50.65(a)(4) and new 50.69. Some licensees who choose to implement this risk-informed alternative already may have incurred many of these costs and would be interested in additional opportunities for using the PRA.

will cost a licensee $180,550 annually (i.e., 1150 hours x $157 per hour) after a one-time cost of $133,450 (i.e., 850 hours x $157 per hour) to design the monitoring plan over a three month period.

(e) To alter its licensing basis, a licensee must draft a comprehensive proposal documenting and articulating all the requirements outlined above and submit this to NRC for approval. The NRC anticipates a licensee will require 540 person-hours of staff time to synthesize the necessary components of the proposal.[11] Using an average labor rate of $157 per hour, the NRC estimates this step will cost a licensee $84,780 (i.e., 540 hours x $157 per hour) and will take approximately 3 months.

(f) The rule will require that proposed facility changes be reviewed and approved by the NRC as risk-informed applications in accordance with the existing license amendment process, including any needed changes to the facility's technical specifications. Potential impacts of the changes on facility security will be evaluated as part of the process for performing license amendment reviews. In addition, the application will be reviewed to ensure that any changes to onsite physical protection systems and security organizations needed to maintain high assurance that activities involving nuclear material are not inimical to the common defense and security and do not constitute an unreasonable risk to the public health and safety are identified. Alternatively, a justification of why changes are not needed must be provided. NRC has previously estimated a licensee burden of 384 hours for a license amendment under §§ 50.59, 50.90, or 50.91. At an average labor rate of $157 per hour, the NRC estimates that this licensing process will cost a licensee $60,288 (i.e., $157 per hour x 384 hours).

(g) To implement § 50.46a, licensees will incur impacts that result from the need to periodically (every other refueling outage) reevaluate and update risk assessments to reflect subsequent changes to the plant, operational practices, equipment performance, changes in the model, and other factors. NRC believes that licensees have already developed much of this infrastructure in order to comply with the PRA quality guidance being implemented in support of the maintenance rule. NRC estimates that the update will require 200 licensee person-hours and 200 contractor hours every three years. At an average labor rate of $157 per hour, each update will cost a licensee $62,800 (i.e., 400 hours x $157/hour).

Total upfront plant-specific implementation would cost $1,173,418 per application, as depicted in Exhibit 2. For comparison purposes, in its September 16, 2004, submission, WOG estimated an implementation cost between $700K and $1 million per unit, plus up to $500,000 per licensee for new thermal-hydraulic analyses for breaks larger than the TBS.

---

[11] NRC estimated 530-550 hours per submittal for risk-informed alternative ISI and IST programs, in *Final OMB Supporting Statement for an Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Current Licensing Basis* (Section 33).

Exhibit 2
SUMMARY OF 50.46a UNIT COSTS TO LICENSEES
(2004$)

Activity	Burden	Estimated Cost
ECCS Re-Analysis	2,500 hours	$ 392,500
Describe Proposed Change	700 hours	$ 109,900
Engineering Analyses	2,500 hours	$ 392,500
Develop Monitoring Plan	850 hours	$ 133,450
Synthesize Proposal	540 hours	$ 84,780
License Amendment Process	384 hours	$ 60,288
	Upfront Implementation Total	$1,173,418
PRA Updates	400 hours/@3 years	$62,800/@3 years
Implement Monitoring	1150 hours/year	$180,500/year

Capital Costs. Licensees will incur capital costs associated with the plant modifications needed to uprate PWRs; however, relaxation of EDG start times requires no significant additional capital. Following NRC's approval for license modification, PWRs will require upgrades in order to achieve the power uprate. These upgrades can range from minor to major plant modifications. For the purposes of the regulatory analysis, NRC staff assume that license amendment approvals will be spread over a three-year period, reflecting the assumption that NRC staff approve one-third of all power uprate requests per year. Therefore, upfront capital costs will accrue to licensees in 2007, 2008, and 2009.

In general, the larger the power uprate, the greater the capital investment necessary to achieve the higher power level. As a result, NRC assumes that the power uprates from Scenarios 1 and 2 associated with this rule change will require capital costs that range from $183 per kilowatt to $409 per kilowatt (2004$).[12] This range of costs is typical of a stretch power uprate. NRC estimates that Scenario 1 will add nearly 600,000 kW to nuclear electricity generation by 2010, while Scenario 2 will add nearly 1.6 million kW. Scenario 3 assumes that 75 percent of the PWRs will achieve a higher power uprate (10 percent); generally, power uprates at this level require higher capital costs. Therefore, NRC has assigned larger unit capital cost estimates (in 2004$) to Scenario 3 ($445/kW to $734/kW).[13] NRC estimates that Scenario 3 will add nearly 4.5 million kW to baseline nuclear electricity generation by 2010. For the purposes of this regulatory analysis, NRC staff chose the upper bound of each unit cost range to estimate total capital costs associated with power uprates. Exhibit 3 contains the estimated capital costs associated with power uprates for all licensees according to the three scenarios, calculated by multiplying the unit cost per kilowatt by the total number of kilowatts added.

---

[12] Renwick, B. "Nuclear Station Performance Fuels Industry Renaissance." *Power*. July/August, 2001.

[13] Renwick, B. "Nuclear Station Performance Fuels Industry Renaissance." *Power*. July/August, 2001.

Exhibit 3
TOTAL UPFRONT INDUSTRY CAPITAL COSTS OF POWER UPRATES
(millions 2004$)

		Expected Years of Implementation	Estimated Cost All Licensees
Capital Costs	Scenario 1	2007 - 2008 - 2009	$243/kW
	Scenario 2	2007 - 2008 - 2009	$654/kW
	Scenario 3	2007 - 2008 - 2009	$3,264/kW

Accordingly, Exhibit 4 contains the net present value of total capital costs for the three power uprate scenarios discussed in the regulatory analysis. The net present value is calculated using both a 3 percent and 7 percent discount rate.

Exhibit 4
NPV OF INDUSTRY CAPITAL COSTS OF POWER UPRATES
(millions 2004$)

		Estimated NPV 3 % discount rate 7 % discount rate
Capital Costs All Licensees	Scenario 1	$215 $185
	Scenario 2	$582 $500
	Scenario 3	$2,900 $2,500

Relaxation of EDG Start Times. The regulatory analysis considers scenarios described in Section 3.2, where 75 percent to 100 percent of PWRs apply for power uprates while simultaneously seeking relaxation of EDG start times. This assumption differs from the WOG expectation that (depending on how the revised rule is written) a greater portion (50 percent) of PWRs will seek changes in EDG start times than will seek power uprates. Given the initial costs of applying for § 50.46a, this analysis assumes that a licensee would seek both power uprate and EDG benefits in the absence of other constraints. EDG benefits alone are not likely to be worth the costs to licensees, based on commercial discount rates.

In this regulatory analysis, the values and impacts associated with EDG start time relaxation are therefore calculated using three plausible scenarios that could result from the rule change, defined as follows:

Exhibit 5
SUMMARY OF EDG START TIME RELAXATION SCENARIOS FOR PWRS

Scenario	Degree of Participation
1	100%
2	90%
3	75%

Each EDG scenario corresponds to the power uprate scenario described in 3.2. PWRs not applying for power uprates are assumed in this analysis to also not apply for relaxation of EDG start times.

The PWRs will incur costs associated with pursuing the EDG start-time relaxations. For the purposes of this regulatory analysis, the industry's costs include:

- Implementation costs associated with preparing EDG start-time relaxation requests; and

- Operating costs associated with monitoring changes related to EDG start-time relaxations.

There are no significant capital costs associated with plant modifications related to relaxation of EDG start-time requirements.

To achieve the benefits associated with EDG start-time changes resulting from this rule, a PWR must submit a § 50.46a package and license amendment request to NRC. To ensure that safety is not compromised, NRC requires documentation from the licensee to support the EDG start-time relaxation. As a result, the licensee is subject to costs associated with providing these supporting analyses. By piggy-backing on the § 50.46a package for power uprates, each licensee can use the same ECCS re-analysis, avoiding incurring a cost of $392,500. However, the other elements of the application listed in sections 3.3.1(b)-3.3.1(f) must be tailored to this set of changes, and the regulatory analysis does not assume any "learning curve" cost avoidance because the applications occur concurrently. The total cost per licensee for requesting relaxation of EDG start times comes to $780,900 (2004$). This impact is expected to accrue to licensees through 2006, assuming the rule change is effective in June 2005.

The three scenarios result in estimated implementation costs shown in Exhibit 6.

Exhibit 6
SUMMARY OF UPFRONT IMPLEMENTATION COSTS FOR EDG START TIME RELAXATION REQUESTS (2004$)

Category		Expected Year of Implementation	Estimated Cost
License Amendment Request Costs	Scenario 1	2006	$53,882,100
	Scenario 2	2006	$48,415,800
	Scenario 3	2006	$40,606,800

Summary. NRC assumes that licensees must conduct all the activities, with the exception of the ECCS Re-analysis, twice to account for power uprates and EDG start time relaxation applications. NRC believes this is a conservative approach to estimating the impacts on the industry. Exhibits 7 and 8 display the total net present value, discounted at 3 percent and 7 percent respectively, of the total industry burden for all activities required to implement the new rule and benefit from both power uprates and EDG start time relaxation.

Exhibit 7
NPV SUMMARY OF IMPACTS TO INDUSTRY @ 3 Discount Rate (millions 2004$)

Activity	Scenario 1	Scenario 2	Scenario 3
ECCS Re-analysis	$26.30	$23.63	$19.82
Proposed Modifications	$14.72	$13.24	$11.10
Engineering Analysis	$51.06	$45.88	$38.48
Implementation & Monitoring Plan	$17.34	$15.58	$13.06
Synthesize Proposal	$11.02	$9.90	$8.30
License Amendment	$7.84	$7.04	$5.90
Uprate Capital Costs	$215	$582	$2,900
Subtotal (Upfront costs)	**$343**	**$697**	**$2,997**
Monitoring Program	$616.90	$554.28	$464.28
PRA Reassessments	$64.80	$58.22	$48.84
Total	***$1,025***	***$1,310***	***$3,510***

Exhibit 8
NPV SUMMARY OF IMPACTS TO INDUSTRY @ 7% Discount Rate
(millions 2004$)

Activity	Scenario 1	Scenario 2	Scenario 3
ECCS Re-analysis	$25.30	$22.74	$19.07
Proposed Modifications	$14.18	$12.74	$10.68
Engineering Analysis	$47.30	$42.52	$35.66
Implementation & Monitoring Plan	$16.08	$14.46	$12.12
Synthesize Proposal	$10.20	$9.18	$7.70
License Amendment	$7.26	$6.52	$5.48
Uprate Capital Costs	$185	$500	$2,500
Subtotal (Upfront costs)	**$306**	**$609**	**$2,591**
Monitoring Program	$320.58	$288.06	$241.52
PRA Reassessments	$32.04	$28.78	$24.14
Total	***$659***	***$926***	***$2,857***

3.3.2 Impacts to NRC

In implementing the regulatory action, the NRC expects to incur costs from performing regulatory review and research activities.

(a) Activities involved in processing applications under § 50.46a include review of the ECCS re-analyses; proposed plant modifications (e.g., for power uprates and relaxation of EDG start times) and their anticipated effects on SSC's, safety margins, and defense-in-depth measures; licensee plans for monitoring plant operations and equipment, and changes in CDF and LERF; and the scientific validity of the PRA performed by the licensee which encompasses the proposed plant changes. The NRC estimates that the staff burden for reviewing applications for changes to the licensing basis will depend on the size of the requested power uprate.[14,15] Therefore, NRC has calculated three distinct review burdens for the three power uprate scenarios (1 percent, 3 percent, 10 percent) enumerated above. NRC estimates 30 percent more time to review applications for changes to a licensing basis under the new § 50.46a rule than to review applications solely for power uprates, due to a larger work load associated with reviewing the risk-informing and PRA information. The NRC review burden calculations are presented in Exhibit 9 below. An estimated average labor rate of $88 per hour was assigned for NRC staff time.

[14] *Final OMB Supporting Statement for PRA in Risk Informed Decisions on Plant-Specific Changes to the Current Licensing Basis* (Sections 33, 3150-0011).

[15] U.S. Nuclear Regulatory Commission, "Status Report on Power Uprates," *SECY-04-0104*, June 24, 2004.

Exhibit 9
NRC REVIEW BURDEN FOR § 50.46a APPLICATIONS
(2004$)

Power Uprate Type	Review Burden	Impacts
Measurement Uncertainty Recapture (1%)	1,248 hours	$109,800
Stretch (3%)	2,340 hours	$205,900
Extended Power (10%)	5,070 hours	$446,200

Source: U.S. Nuclear Regulatory Commission, *SECY-04-0104: Status Report on Power Uprates*. June 24, 2004, and NRC calculations.

(b) Should the NRC decide to endorse a proposal for changes to the licensing basis, NRC must thoroughly document the decision and rationale for approval. The NRC has estimated this process will take 200 person-hours per application. Using an average NRC labor rate of $88 per hour, the cost to NRC is estimated to be $17,600 per license approved. NRC assumes this work burden will be accomplished in four month's time.

In 2001, NRC approved 22 power uprate requests, while in 2002 the agency approved 18 such license amendments.[16] NRC staff have indicated that, apart from review of the ECCS re-evaluation and risk-based change submissions, the power uprates resulting from this rule change will not require extensive NRC review.[17] Therefore, it is reasonable to assume that NRC will review a comparable number of license amendment applications as was accomplished per year between 2001-2002. Therefore, in terms of Scenarios 1 and 2, it is reasonable to assume that NRC reviews will be completed within a similar time period. With regard to Scenario 3, NRC assumes a longer review time since 10 percent power uprates are considered "extended power" and therefore require more time to review.

This analysis assumes that these review costs will accrue to the NRC in 2007, 2008, and 2009. Exhibit 10 presents the annual costs associated with license amendment reviews under the three scenarios outlined above.

---

[16] U.S. Nuclear Regulatory Commission. "Fact Sheet: Power Uprates for Nuclear Plants." Washington, D.C. March 2004.

[17] Based on a phone conversation conducted with NRC staff July 30, 2004.

Exhibit 10
TOTAL ANNUAL NRC REVIEW BURDEN FOR § 50.46a UPRATE APPLICATIONS (2004$)

Scenario	Years	Number of CLB Requests	Review Burden	Licensing Process
1	2007-2009	23	$2,526,000	$405,000
2	2007-2009	20.7	$4,263,000	$364,000
3	2007-2009	17.3	$7,719,000	$304,000

(c) NRC will develop one or more RGs for this rule. The exact number of RGs to be developed has not been defined and will depend on the specifics of the final rule. This analyses assumes that 1,000 hours of NRC staff time and 2,000 hours of NRC contractor time will be required.[18] At an average labor rate of $88 per hour for NRC staff and $157 per hour for NRC contractors, the cost for the regulatory guide(s) would be $402,000, which would be incurred in 2005.

(d) NRC must undertake the responsibility of reviewing risk reassessments from industry. NRC estimates that each risk reassessment review takes 200 person-hours of staff time. Using an NRC labor rate of $88 per hour, the NRC burden for reviewing each risk reassessment is $17,600 (i.e., 200 person-hours x $88 per hour). NRC anticipates reviewing licensee risk reassessments approximately every 3 years.

(e) The Commission has directed the staff to conduct a rigorous re-estimation of LOCA frequency distributions every 10 years and review for new types of failures every 5 years. Staff is to conduct a practical reconciliation of LOCA frequency distributions by the (1) expert use of service-data, (2) probabilistic fracture mechanics (PFM), and (3) expert elicitation to converge the results. Research will be carried out to determine the accuracy of the previous frequency estimates and to determine if a new TBS should be set. This effort will be repeated every ten years. The NRC estimates this process will require 6,000 person-hours of NRC staff time and 12,000 person-hours of NRC contractor support time.[19] Using the average labor rates of $88 per hour for NRC staff and $157 per hour for its contractors, the costs for each 10 year review are estimated to be $2,412,000 in 2004 dollars.

---

[18] The Probabilistic Safety Assessment Branch of the Division of Systems Safety & Analysis estimated, in August 2004, required resources of 600 staff hours to revise existing regulatory documents pertaining to crediting containment accident pressure in determining net positive suction head of ECCS and containment heat removal pumps.

[19] NRC issued a three-year, $2.3 million, sole-source contract RS-RES-02-074 to Battelle Memorial Institute Columbus Operations to provide "Technical Development of Loss-of-Coolant Frequency Distributions," including PFM code, estimated LOCA frequency distributions, and management of expert elicitation process. This contract was preceded by a four-year contract NRC-04-98-039 for approximately $600K which ran from 1998-2002.

(f) NRC also will incur implementation costs associated with the review and approval of the EDG start-time relaxation requests. Activities involved in processing EDG applications under § 50.46a include review of the ECCS re-analyses; proposed plant modifications and their anticipated effects on SSC's, safety margins, and defense-in-depth measures; licensee plans for monitoring plant operations and equipment, changes in CDF, LERF, and late release frequency; and the scientific validity of the PRA performed by the licensee which encompasses the proposed plant changes. The NRC estimates that 2,000 person-hours of NRC staff time and 1,000 person-hours of contractor time will be required to perform each review. Using an estimated average labor rate of $88 per hour for NRC staff time and $157 per hour for NRC contractor support time, the total cost for each NRC review is anticipated to be $333,000 [(2,000 person-hours x $88 per hour) + (1,000 person-hours x $157 per hour)]. Since the EDG package will be submitted together with the power uprate application, NRC will not need to review the ECCS re-analyses, which NRC estimates to be about 25 percent of the total review burden, thus avoiding $83,250 (i.e., .25 x $333,000), for a net cost of 2,400 hours and $249,750, as summarized in Exhibit 11 below.

Exhibit 11
TOTAL ANNUAL NRC REVIEW BURDEN FOR PIGGY-BACKED EDG START TIME RELAXATION APPLICATIONS (2004$)

Scenario	Years	Number of Requests	Costs to NRC
1	2007 - 2009	23	$5,744,000
2	2007 - 2009	20.7	$5,170,000
3	2007 - 2009	17.3	$4,321,000

Exhibits 12 and 13 display the net present value, discounted at 3 percent and 7 percent respectively, of the total NRC impacts for all activities required to implement the new rule and review industry requests for changes to licensing basis given the three scenarios. The Review Submissions, Process License Amendments, and Review of PRA Updates lines of these exhibits reflect the total net present value of the costs associated with both the uprate and EDG applications.

Exhibit 12
NPV Summary of Impacts to NRC @ 3% Discount Rate
(2004$)

Activity	Scenario 1	Scenario 2	Scenario 3
Prepare Reg. Guide(s)	$ 390,000	$390,000	$390,000
Review Submissions	$22,050,535	$25,148,981	$32,099,946
Process License Amendments	$2,158,000	$1,942,000	$1,624,000
Review PRA Updates	$18,160,000	$16,318,000	$13,686,000
Research LOCA Frequencies	$4,586,000	$4,586,000	$4,586,000
Total	***$47,344,535***	***$48,384,981***	***$52,385,946***

Exhibit 13
NPV Summary of Impacts to NRC @ 7% Discount Rate
(2004$)

Activity	Scenario 1	Scenario 2	Scenario 3
Prepare Reg. Guide(s)	$376,000	$376,000	$376,000
Review Submissions	$18,956,851	$21,621,166	$27,595,762
Process License Amendments	$1,856,000	$1,670,000	$1,396,000
Review PRA Updates	$8,980,000	$8,068,000	$6,766,000
Research LOCA Frequencies	$2,036,000	$2,036,000	$2,036,000
Total	***$32,204,851***	***$33,771,166***	***$38,169,762***

3.4 Analysis of the Benefits

This section analyzes the different quantifiable benefits associated with the proposed rule and estimates the present value of these benefits using 3 and 7 percent discount rates. Benefits are calculated separately for the three uprate scenarios discussed above and the corresponding increased generation over a "business-as-usual" baseline.

- Section 3.4.1 analyzes *Power Uprate Benefits*. Because electricity generated from nuclear units is cheaper than electricity generated from fossil fuels, increased nuclear generation due to uprates can lead to significant monetary benefits. *Power Uprate Benefits* are valued on the assumption that this increased nuclear generation would displace some of the more expensive generation capacity from other sources at the margin. Because nuclear generation costs less than fossil fuel generation on a per unit basis, significant cost savings for the industry and society can result. This valuation method is defined as the *Generation Cost Savings* method in this study.

- Section 3.4.2 estimates the value of *EDG Benefits* by assessing how relaxed requirements for EDGs can lead to cost savings, not just from reduced labor cost and materials needed for maintenance tear downs, but also from the replacement power saved due to shortened outages.

The following sections provide details on the methods, data, and assumptions used to quantify these benefits associated with the proposed rule change.[20] Summary tables providing the discounted benefits under the different scenarios are presented at the end of Section 3.4.

3.4.1 Power Uprate Benefits

Increased generation from existing **PWR units can lead to significant quantifiable benefits**. **Because nuclear generation is cheaper than the other primary generating type -- fossil fuel -- increased nuclear generation from uprates can lead to significant monetary benefits**.

NRC's method of valuing increased nuclear generation is to compare its cost to the more expensive generation costs from other sources, assuming that the former displace the latter and lead to *Generation Cost Savings*. On a per unit basis, nuclear generation costs less than most other types of fossil generation, especially oil and gas generation. Oil and gas units have the highest variable cost of generation due to their high fuel cost. Because they have the highest cost, NRC assumed that, *at the margin*, the increased generation from nuclear units would replace the most expensive oil and gas units and lead to significant cost savings for the industry and society.

[20] In addition to these quantified benefits, industry representatives mentioned other potential benefits expected as a consequence of this proposed rulemaking (i.e., optimization of containment spray setpoints, fuel management improvements; elimination of potentially required actions for postulated sump blockage issues; changes to required number of accumulators, sequencing of equipment, and valve stroke times; among others).

The benefits depend not only on the cost and performance characteristics of nuclear power generation, but also on the characteristics of other sectors of the power industry, particularly oil and gas units (since the calculation depends on the ability of increased nuclear generation to displace oil and gas generation). Moreover, because of the extended time period for this analysis, the study uses projected data that take into account well-defined assumptions about the power industry. The data used for the projected cost and performance characteristics of the electricity generation industry are taken from the Integrated Planning Model (IPM). IPM is a multi-regional, dynamic, deterministic, linear programming model of the electric power sector used extensively by the Federal Energy Regulatory Commission (FERC) and the U.S. Environmental Protection Agency (EPA) to analyze policy and regulatory issues and to consider the costs and benefits of alternate proposals. Details on IPM's forecast capabilities and reasons why NRC choose to use IPM data for this analysis are discussed in Appendix A.

The data used for fossil and nuclear generation costs come from IPM projections for the Base Case scenario where results are reported for 2005, 2010, 2015, and 2020.[21] Specific years were chosen for reporting purposes in the Exhibit below. This analysis assumes that the first year PWRs start benefitting from the LOCA rule is 2008, and therefore reports results for that year using 2005 data from IPM. For reasons discussed elsewhere in this report, NRC also assumed an annual phase-in rate such that the full impact of the rule is felt in 2010 (see Section 3.3.2 where the phase-in rate is discussed). Moreover, since one of the "Run Years" in IPM is 2010, NRC chose 2010 as the next reporting year where the full benefits from the rule materialize. The next three reporting years (2015, 2020, and 2030) are chosen to be consistent with IPM Run Years, because of the extended time horizon considered in this analysis.

NRC's preferred approach to value the benefit of increased PWR generation is to assume that this increase will replace an equivalent amount of electricity generated by units that are most expensive to operate *at the margin*.[22] Comparison of generation cost data from IPM Base Case results indicate that in terms of fuel and non-fuel variable O&M (VOM) costs, the most expensive units at the margin are the existing oil and gas units. In this method, NRC considered only the fuel and non-fuel VOM costs of competing sources of electricity to determine which units are more expensive than nuclear units, because these two cost components are functions of the generation level. Exhibit 14 below provides the projected costs for these types of units.

[21] For details about the assumptions used in IPM Base Case scenario, see Appendix A.

[22] NRC employed this method in the Regulatory Analysis for the Revision of Appendix K of 10 CFR Part 50 (1999).

Exhibit 14
GENERATION COST SAVINGS ASSUMPTIONS
(2004$/MWh)

Assumptions	**2008**	**2010**	**2015**	**2020**	**2030**
Coal Generation Cost	15.58	15.03	14.56	13.99	13.99
Oil/Gas Generation Cost	29.30	30.42	30.29	29.51	29.51
Nuclear Generation Cost	6.86	6.94	6.88	6.87	6.87
Cost Savings per MWh[1]	**22.44**	**23.48**	**23.41**	**22.64**	**22.64**

[1] Cost Savings are calculated as the difference between the generation costs of oil/gas units and nuclear units. Generation cost data for the coal units are presented for illustrative purposes only.
Sources: IPM Base Case results and NRC calculations.

According to IPM's Base Case forecasts, generation cost from oil/gas units is expected to hover around the $29-$30/MWh mark between 2008 and 2030. Generation cost from nuclear units in the same time period is projected to be a little less than $7/MWh. The difference in the per MWh generation cost is thus $22.44/MWh in 2008, which indicates the per unit cost saving if a MWh of oil and gas generation is replaced by additional nuclear generation. Similar calculations were performed to obtain the per unit generation cost savings for the other years in the Exhibit above. Given the increased generation expected from PWRs because of this rule, NRC then calculated the total generation cost savings by multiplying this per unit cost savings times the incremental generation expected from PWRs for each of the three scenarios.

3.4.2 Relaxation of EDG Start Time Benefits

NRC believes that the proposed rule change will allow PWRs to eliminate fast starts of EDGs. This will yield two categories of benefits to the plants.

First, PWRs will benefit from the reduced cost and time needed for EDG maintenance tear downs. Specifically, reactors will experience cost savings related to materials and labor used to conduct tear downs. For each uprate scenario, NRC assumed 80 percent of the plants will save $173,000 per year and the remaining 20 percent will save $266,000 per year in reduced costs for maintenance tear downs (in 2000$). The $173,000 per year figure is based on a savings of 26 percent in baseline tear down costs of $500,000 per EDG every 18 months; the latter figures were provided by WOG in 2000, and NRC adjusted the numbers to reflect a per year value, as plants typically have 2 EDGs. The $266,000 figure also originates with WOG estimates that, if EDG tear downs had been outsourced, the reduction in scope of the tear down could result in $200,000 savings per EDG by allowing the work to be performed in-house. NRC adjusted the $200,000 savings figure to reflect 2 EDGs per plant and an annual basis. Based on input from the vendor community and NRC staff, and to be conservative, the regulatory analysis assumes most PWRs will be able to attain the smaller savings amount, as opposed to the larger amount.[23]

Second, EDG tear downs typically occur during scheduled reactor outages necessary for refueling and other maintenance. Such refueling outages occur, on average, every 18 months and last, on average, 35 days. This rule is expected to reduce the duration of such outages by reducing the duration of the tear downs. In 2000, the WOG stated that if the EDG tear down was done during a refueling outage and was on the critical path, the tear down scope reduction could reduce the critical path duration by 3.5 days. To be conservative, NRC assumed, for each uprate scenario, only 10 percent of the plants experiencing EDG benefits will save 3.5 days of avoided replacement power costs (out of the average duration of 35 days) in addition to the savings above.

Since the replacement power cost savings in this section arise only during outages, NRC first determined the number of PWRs having such outages every year, based on their last scheduled outage data[24] and assuming these outages occur every 18 months for each plant. Then, because the number of units affected under the three uprate scenarios are different, NRC estimated the corresponding number of units that can save on replacement power costs due to reduced outage duration, assuming all PWRs are equally likely to benefit. For example, since 75 percent of the plants are affected under uprate scenario 3, and since only 10 percent of these units may save on replacement power, NRC assumed 7.5 percent of the operating units save on replacement power (=75%*10%). Moreover, since 3.5 days of savings out of an 35-day outage duration translate to a 10 percent savings for these plants, the overall savings is estimated to be 0.75 percent of the total replacement power needs for all PWRs (=10%*7.5%).

To estimate how much replacement power is needed during these scheduled outages every year, and consequently, how much money can be saved, NRC used the projected annual generation under the baseline and assumed an average outage duration of 35 days per outage per plant. However, since the number of operating plants decrease rapidly over time (once licenses expire), NRC weighted the total generation lost by the proportion of operating plants having scheduled outages for each year. Combining these calculations, NRC estimated the total MWh of replacement power that can be saved annually by relaxing EDG start times.

To estimate the value of the replacement power saved, NRC then multiplied the MWh of replacement power saved calculated above, by the difference between the wholesale price of electricity (in $/MWh) and the average variable cost of nuclear generation consisting of the fuel, and non-fuel VOM costs (in $/MWh). This difference represents the per MWh savings for a plant from not having to purchase replacement power during outages, and multiplying this per

---

[23] It is possible that the BWRs also benefit from the reduced cost and time needed for EDG maintenance tear downs. However, the analysis presented above does not attempt to quantify the benefits to BWRs from this rule.

[24] Scheduled outage data were obtained from the NRC Daily Report Files, available at www.nrc.gov/reading-rm/doc-collections/event-status/reactor-status.

unit savings by the MWh of replacement power saved gives the total cost savings due to a 3.5-day reduction in scheduled outages.

Finally, the total benefit is calculated by summing up the cost savings from reduced tear down labor and materials and the cost savings from reduced replacement power needs for each scenario for each year. Results are presented using 3 and 7 percent discount rates.

According to NRC staff, over the past 10 years, the NRC has become increasingly open to relaxing the testing requirements for fast starts. This has included changing from fast-start tests on a monthly basis to monthly tests using a slow start procedure and one fully loaded test every six months that mimics an emergency situation calling for a fast-start. Additionally, the NRC is allowing pre-lube and pre-warm systems during all surveillance start tests, and has relaxed the 3-day servicing to be conducted while the plant is on-line. On-line servicing has significantly reduced the replacement power issue associated with major tear down events. Unfortunately, data were not available regarding the extent to which PWRs have been able to take advantage of these policies.

3.4.3 Results of Benefits Analyses

In sum, Exhibits 15, 16, and 17 below present benefit results for Scenarios 1, 2, and 3, respectively, using 3 and 7 percent discount rates.

Exhibit 15
PRESENT VALUE OF MONETIZED BENEFITS UNDER UPRATE SCENARIO 1[a]
(2004$ in Millions)

Discount Rates	Increased Nuclear Energy Benefits	Relaxation of EDG Benefits	Total
3 percent	2,148	429	2,577
7 percent	1,151	237	1,388

[a] Uprate Scenario 1 assumes a 1% uprate for all PWRs.
Totals may not add due to rounding.

Exhibit 16
PRESENT VALUE OF MONETIZED BENEFITS UNDER UPRATE SCENARIO 2[a]
(2004$ in Millions)

Discount Rates	Increased Nuclear Energy Benefits	Relaxation of EDG Benefits	Total
3 percent	5,801	386	6,187
7 percent	3,108	213	3,321

[a] Uprate Scenario 2 assumes a 3% uprate for 90% of PWRs
Totals may not add due to rounding.

Exhibit 17
PRESENT VALUE OF MONETIZED BENEFITS UNDER UPRATE SCENARIO 3[a]
(2004$ in Millions)

Discount Rates	Increased Nuclear Energy Benefits	Relaxation of EDG Benefits	Total
3 percent	16,113	321	16,434
7 percent	8,633	178	8,811

[a] Uprate Scenario 3 assumes a 10% uprate for 75% of PWRs
Totals may not add due to rounding.

4. VALUE-IMPACT RESULTS

This section integrates the principal costs and benefits associated with the proposed rule-making to add provisions to 10 CFR Part 50.46 to enable licensees to use a risk-informed alternative maximum LOCA break size to support risk-informed changes in a reactor's design and operations.

4.1 Principal Benefits Assessed

The following benefits were quantified as part of this regulatory analysis:

Power Uprate Benefits. These benefits accrue from the increased nuclear generation facilitated by the proposed rulemaking. Because nuclear power is cheaper to generate than power from non-nuclear sources, the proposed rulemaking will result in cost savings.

Relaxed EDG Start-Time Benefits. These benefits result from savings in the cost of EDG tear downs as well as some additional savings due to reduced outages and replacement power needs resulting from less time required for EDG tear downs.

4.2 Principal Costs Assessed

The following costs were quantified as part of this regulatory analysis:

Industry Costs. The burden of these costs will fall on nuclear power licensees and may be further classified as:

- *Initial Licensing Costs*: These up-front costs include the emergency core cooling system re-analysis, engineering analysis, design of annual monitoring program, definition of proposed change, license amendment, and submission of license modification proposal.

- *Capital Costs*: These are the costs of plant upgrades that will be necessary to achieve the projected uprate levels. *(**Note:** This analysis computed both a low-end and a high-end estimate of capital costs. Only the high-end values are displayed and utilized in the value-impact analysis)*.

- *Recurring Monitoring/Licensing Costs:* These include an annual monitoring program and a recurring three-yearly probabilistic risk reassessment update.

NRC Costs. The burden of these costs initially would fall on the NRC and may be further classified as:

- *Initial Regulatory Costs:* These up-front costs include the NRC review of submissions, management of the license amendment process, and the development of regulatory guides.

C *Deferred/Recurring Regulatory Costs:* These include the cost of a recurring 10-year TBS review and a recurring three-yearly probabilistic risk reassessment review.

4.3 Key Assumptions

Scenarios Assessed. Three different scenarios reflecting potential industry responses to the rule-making were assessed as part of this analysis. These scenarios were described earlier in Section 3.3.3; a summary table is repeated here for ready reference.

Exhibit 18
SUMMARY OF POWER UPRATE AND EDG SCENARIOS

Scenario	Degree of Power Uprate	Degree of Participation
1	1%	100%
2	3%	90%
3	10%	75%

The regulatory analysis assumes that PWRs which apply for power uprates simultaneously apply for released EDG start times. PWRs which do not apply for power uprates are assumed to not apply for relaxed EDG start times.

Energy Demand. An assumption inherent in this analysis is that the increased nuclear generation will be "absorbed" in the market. Under the three scenarios for this rule, the highest overall increase in PWR generation is 7.5 percent under Scenario 3, which, assuming PWRs comprise about two-thirds of all nuclear generation, and nuclear generation is approximately 20 percent of total generation, implies an overall increase of about 1 percent of electricity generation due to this rule (20%*66%*7.5% = 0.99%). Given the Energy Information Agency's assumption of about a 1.8 percent annual growth rate in electricity demand in the reference case,[25] and that this added nuclear capacity is from current nuclear plants operating more efficiently, coupled with the fact that nuclear plants generally have lower marginal cost of generation than fossil units, NRC expects this added generation to be absorbed fairly easily in the market without any significant price impact. In other words, the absorption assumption appears quite reasonable.

Base-Year for Present Value Estimates. All present value estimates are for the year 2004.

Base-Year for Real Dollar Values. All discounted costs and benefits are reported in 2004 dollars.

Inflation Indices. Cost estimates were updated to 2004 dollars using inflation indices obtained from the GDP inflation calculator at http://www.jsc.nasa.gov/bu2/inflateGDP.html.

[25] See Energy Information Agency, *Annual Energy Outlook 2004* - Table A8 - "Electricity Supply, Disposition, Prices, and Emissions".

<u>Discount Rates</u>. NRC Guidelines Section 4.3.3 states that, based on OMB guidance, both 3 and 7 percent real discount rates are to be used in preparing regulatory analyses. Accordingly, real discount rates of 3 percent per year and 7 percent per year have been applied in this analysis.

4.4 Net Present Value Estimates of the Proposed Rule

Exhibits 19-20 display net present value estimates of the proposed rule for 3 and 7 percent discount rates, as specified, for each of the three scenarios defined earlier. All values presented below are in millions of 2004 dollars, rounded to the nearest million. Values in parentheses represent costs.

Exhibit 19 presents the net present value in the year 2004 (in millions of 2004 dollars) of the proposed rule at a <u>7 percent per year</u> discount rate.

Exhibit 19

Net Present Value in 2004 in millions of 2004$

Annual Discount Rate = 7%

Quantitative Attributes		Present Value Estimates (2004$)		
		Scenario 1	**Scenario 2**	**Scenario 3**
Power Uprating Benefits		$1,151	$3,108	$8,633
EDG Benefits		$237	$213	$178
Licensee Costs	Capital Costs	($185)	($500)	($2,493)
	Initial Licensing Costs	($120)	($108)	($91)
	Recurring Monitoring/PRA Costs	($353)	($317)	($266)
NRC Costs	Initial Regulatory Costs	($21)	($24)	($29)
	Deferred/Recurring Regulatory Costs	($11)	($10)	($9)
Overall Net Present Value		$697	$2,362	$5,923

Note: Totals are subject to round-off error

Exhibit 20 presents the net present value in the year 2004 (in millions of 2004 dollars) of the proposed rule at a <u>3 percent per year</u> discount rate.

Exhibit 20
Net Present Value in 2004 in millions of 2004$
Annual Discount Rate = 3%

Quantitative Attributes		Present Value Estimates (2004$)		
		Scenario 1	**Scenario 2**	**Scenario 3**
Power Uprating Benefits		$2,148	$5,801	$16,113
EDG Benefits		$429	$386	$321
Licensee Costs	Capital Costs	($215)	($582)	($2,900)
	Initial Licensing Costs	($128)	($115)	($97)
	Recurring Monitoring/PRA Costs	($682)	($613)	($514)
NRC Costs	Initial Regulatory Costs	($25)	($28)	($34)
	Deferred/Recurring Regulatory Costs	($23)	($21)	($18)
Overall Net Present Value		$1,504	$4,829	$12,871

Note: Totals are subject to round-off error

4.5 Significant Results in the Present Value Analysis

The principal results from the present value analysis are as follows:

- The net present value of the proposed rule is positive, regardless of discount rate or scenario.
- The low-bound NPV (at 7 percent discount rate and scenario 1) is estimated at $697 million.
- The high-bound NPV (at 3 percent discount rate and scenario 3) is estimated at $12,871 million.
- For any given discount rate, NPV in Scenario 3 is greater than NPV in Scenario 2 and is greater than NPV in Scenario 1. In other words, the economic value to society increases as more plants undertake greater uprates facilitated by the rule.
- Using a discount rate of 3 percent instead of a discount rate of 7 percent approximately doubles NPV estimates, for any given scenario.

5. DECISION RATIONALE

Based on the available information, it is the NRC's judgment that the values described above substantially outweigh the identified impacts. However, because the proposed rule is voluntary, NRC does not know how many or which licensees will seek to use it nor how those licensees will value the potential benefits of the rule.

6. IMPLEMENTATION SCHEDULE

The proposed rule will be issued for public comment. Following review of public comments and incorporation of any changes to the proposed rule, it will be issued in its final form and should be made effective 60 days following issuance.

Tentative Schedule:

C	Proposed Rule Issued for Public Comment	January 2005
C	End of Public Comment Period	April 2005
C	Final Rule Issued	July 2005

Given the NRC's expectations that implementation guidance will be issued in conjunction with the final rule or shortly thereafter, the NRC expects that the final rule can be made effective immediately upon publication (or within a reasonably short period of time such as 60 days) in the Federal Register.

7. REFERENCES

BWR Owners' Group, "Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements, Cost Benefit Information Requested at August 17, 2004 Public Meeting," BWROG-04023, September 10, 2004.

Knapik, M. "Industry, Seeing Huge Benefits, Presses for Redefining Large-Break LOCA." *Inside NRC*, January 15, 2001.

Renwick, B. "Nuclear Station Performance Fuels Industry Renaissance." *Power*. July/August, 2001.

U.S. Department of Energy, Energy Information Agency, *Annual Energy Outlook 2004*.

U.S. Nuclear Regulatory Commission, "Fact Sheet: Power Uprates for Nuclear Plants." Washington, D.C. March 2004.

U.S. Nuclear Regulatory Commission, *Final OMB Supporting Statement for Acceptance Criteria for Emergency Core Cooling Systems (ECCS): 10 CFR 50.46 and Appendix K (Section 7)*.

U.S. Nuclear Regulatory Commission, *Final OMB Supporting Statement for an Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Current Licensing Basis* (Section 33).

U.S. Nuclear Regulatory Commission, Office of Nuclear Regulatory Research, NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook: Final Report," January 1997.

U.S. Nuclear Regulatory Commission, "Regulatory Analysis for Revision of 10 CFR Part 50, Appendix K." September 23, 1999.

U.S. Nuclear Regulatory Commission, "Status Report on Power Uprates," *SECY-04-0104*, June 24, 2004.

Westinghouse Owners Group, "Comments on Cost and Benefit of NRC's Conceptual Rule Change for Redefining the Large Break Loss of Coolant Accident Design Basis Break Size in 10 CFR 50.46," WOG-04-470, September 16, 2004.

APPENDIX A
BENEFITS VALUATION METHODS

This Appendix provides further details on the methodology used to determine the baseline power generation for all 69 pressurized water reactors (PWRs) and the steps involved in calculating the increased generation due to the three scenarios. It also provides further details on the Integrated Planning Model (IPM) used for analyzing the cost and performance characteristics of the power sector, including projected emissions.

A.1 Convert Uprates Into Increased Base Power Generation

The first step in quantifying the benefits of uprates is to estimate the generation increases as a result of expected uprates. To do that, this study first defines a baseline generation from all PWRs based on historical data and then Energy Information Administration's (EIA) projections for capacity factors. Next, to convert the uprate scenarios to increased generation, an "Overall Increase" parameter is calculated for the different scenarios. Since two out of three uprate scenarios provide a "Degree of Participation" less than 100 percent, and identifying which PWRs would actually benefit under each scenario is beyond the scope of this study, NRC calculated an "Overall Increase" parameter that combined the Degrees of Uprate and Participation into one composite number as a convenience for the analysis. (See Exhibit A-1). That is, under Scenario 3, instead of estimating the impact of 75 percent of the PWRs increasing their generation by 10 percent, this study estimated the benefit of 100 percent of the PWRs increasing their generation by 7.5 percent (i.e., 75%*10% = 7.5%). This assumes that all PWRs are equally likely to apply for and benefit from the marginal uprates.

Exhibit A-1
Uprate Scenarios

Scenarios	Degree of Uprate	Degree of Participation	Overall Increase
1	1%	All	1%
2	3%	90%	2.7%
3	10%	75%	7.5%

A.2 Determination of Baseline Generation

The baseline generation for all PWRs is calculated using the following steps:

1. Using actual summer 2002 capacity (latest available) and the corresponding capacity factors for all 69 PWRs from EIA, this study first calculated their actual generation in 2002.

2. To calculate the baseline generation beyond 2002, NRC assumed all PWR units will apply for and receive a 20-year license extension (some plants already have received license extensions). This yielded a total time period for the analysis that extended up to 2054, when the last PWR unit (Watts Bar 1) reaches the end of its extended license period.

3. Also, using projections from EIA's *Annual Energy Outlook* (AEO) 2004, NRC assumed an average capacity factor of 90 percent between 2002 and 2010 and 91 percent for the period after 2010 until the end of a plant's license. Note that EIA provided capacity factor projections until 2025, and NRC used the same capacity factors for the period beyond that due to the lack of any other data sources.

4. For those plants that already have implemented an uprate (54 PWRs), NRC incorporated the increased capacity in estimating the baseline generation. However, for those that plan to apply for an uprate but have not done so yet, NRC excluded the planned uprates from the baseline. There are six such units that have pending uprate applications with NRC.[1]

Exhibit A-2 below presents the baseline generation for all PWRs for 2002 and NRC's projections based on the discussion above.[2] For brevity, results are presented for selected years only.

Exhibit A-2
PWR GENERATION IN BASELINE AND UNDER UPRATING SCENARIOS

Assumption	**2002**	**2008**	**2010**	**2020**	**2030**	**2050**
Avg. Capacity Factor (%)	90	90	90	91	91	91
Generation ('000 GWh)						
Baseline	520	520	520	524	515	18
Scenario 1	--	521	525	529	520	18.2
Scenario 2	--	524	534	538	528	18.5
Scenario 3	--	533	559	564	553	19.4

Sources: EIA Survey Form 906 (for 2002 generation data), AEO 2004 projections, and NRC calculations.

The increased generation in the baseline from 2020 is due to the increased capacity factor assumption (91 percent versus 90 percent), based on EIA's projections. The significant drop in PWR generation for 2050 is driven by units shutting down as their licenses expire. In fact, 2050 generation shown in the Exhibit above is from two out of the 69 units - Comanche Peak 2 and Watts Bar 1, with all the others having reached the end of their license renewal periods.

---

[1] See NRC website www.nrc.gov/reactors/operating/licensing/power-uprates/approved-applications.html for data on uprates.

[2] To verify the baseline calculations for 2002, NRC cross-checked the total generation estimated in Exhibit A-2 with other industry data. Given that the nuclear industry generates about 20 percent of total electricity and PWRs make up about two-thirds of all nuclear units (the other one-third being BWRs), the expected generation from PWRs is about 13 percent of total annual generation (20%*67%). Since EIA estimated total electricity generation in 2002 was about 3,831 million MWh, the baseline estimate of 520 million MWh from PWRs in 2002 equates to approximately 13.6 percent of the total generation.

A.3 Increased Generation Due to the 3 Uprating Scenarios

The next step in this analysis was to calculate the increased generation over the baseline expected from the three uprate scenarios. Using the same capacity factor assumptions outlined above for the lifetime of the plants, NRC calculated the incremental generation from the PWRs under the three uprate scenarios defined above. Exhibit A-2 above summarizes these results. Again, for brevity, results are presented for selected years only.

Similar temporal patterns are observed in the generation increases due to uprates. Moreover, generation increases across uprate scenarios are directly proportional to the overall increase assumptions shown in Exhibit A-1 above. Thus Scenario 1 produces the smallest incremental generation and Scenario 3 the largest, because of the similar patterns in the overall increase parameter above.

A.4 Integrated Planning Model

Most of the benefit calculations in this regulatory analysis are driven by the characteristics of the electric power industry in general, and the nuclear industry in particular. The data used for the projected cost and performance characteristics of the electricity generation industry are taken from the Integrated Planning Model (IPM). IPM is a multi-regional, dynamic, deterministic, linear programming model of the electric power sector used extensively by the Federal Energy Regulatory Commission (FERC) and the U.S. Environmental Protection Agency (EPA) to analyze policy and regulatory issues and to consider the costs and benefits of alternate proposals.[3] IPM can provide forecasts of least-cost capacity expansion, electricity dispatch, and emission control strategies for meeting various energy demand and environmental (both single- and multi-pollutant), transmission, dispatch, and reliability constraints. IPM is one of the best known simulation models used to project the behavior of the power industry and has been extensively peer-reviewed. NRC used results from this model in this regulatory analysis because they are easy to understand, readily available in the public domain, and perhaps more importantly, used extensively by EPA to estimate impacts for potential regulations that would have effects similar to the ones analyzed in this study (i.e., reduced emissions from fossil-fueled power plants).

Much of the IPM data used in this analysis have been taken from results for the EPA "Base Case assumptions." The Base Case assumes the current state-of-the-world is true going forward and projects industry characteristics and behavior until 2020.[4] Because Base Case projections are used only until 2020 and because the time period in this analysis extends until 2054, NRC assumed that IPM projections for 2020 would be constant until 2054 when the last of the PWRs

[3] More information on IPM is available at EPA's website at www.epa.gov/airmarket/epa-ipm/.

[4] The full set of constraints used in the Base Case simulation and detailed results can be accessed at the EPA website www.epa.gov/airmarkets/epa-ipm/results2003.html. IPM also projects for 2026, but because this is the last year in the model's time horizon, IPM recommends not using those data for significant uncertainty.

shuts down.[5] This is similar to the assumption for the EIA projections that also end in the same time horizon. Given the large uncertainties expected in any projections beyond 2020, this is the least speculative approach when dealing with an extended analysis period.

[5] This is the recommended approach when using IPM data, because 2026, being the last year in IPM's horizon, may produce estimates that are less reliable than the other years.