SUPPORTING STATEMENT FOR PROPOSED RULE
10 CFR PART 50

"RISK-INFORMED CHANGES TO LOSS-OF-COOLANT
ACCIDENT TECHNICAL REQUIREMENTS"

(OMB CLEARANCE NO. 3150-0011)

DESCRIPTION OF THE INFORMATION COLLECTION

Existing regulations in 10 CFR Part 50 specify reporting and recordkeeping requirements associated with emergency core cooling systems (ECCS) used in a nuclear power plant. The subject rulemaking would revise certain provisions of these regulations as they pertain to ECCS evaluation requirements for loss-of-coolant accidents (LOCAs), meaning those analyses, programs, reporting requirements, and other activities intended to demonstrate that ECCS can perform their intended LOCA safety functions when needed. The rulemaking provides, in a new Section 50.46a, a voluntary set of alternative acceptance criteria under which a licensee may apply risk-informed mitigation measures for low probability LOCAs that are larger than the transition break size (TBS). The rule is intended to provide more flexibility to licensees in the application of requirements for design-basis LOCAs by replacing some of the prescriptive programmatic requirements with more general performance requirements. In addition, requirements are being included to specify the process for obtaining NRC approval for implementing the alternative requirements and for licensee preparation of required information against established criteria. The rule provisions would modify certain recordkeeping and reporting requirements only for those licensees who choose to implement the alternative requirements. The rule provisions may be used by current holders of operating licenses issued under Part 50 by the effective date of the rule, to holders of operating licenses issued after the effective date of the rule whose design is demonstrated in accordance with § 50.46a(c)(2) to be similar to the design of reactors licensed before, and to each holder of an operating license whose design approval or design certification under Part 52 is demonstrated in accordance with § 50.46a(c)(2) to be similar to the design of reactors licensed before. A licensee choosing to use the provisions of Section 50.46a would be required to submit a license amendment request with the required information, using the existing processes in Section 50.34, Section 50.90, or Part 52.

The exact number of facilities affected is uncertain because the information collection is associated with a voluntary alternative requirement. Information received from the regulated community indicated that although PWRs saw potential benefit from the rule, boiling water reactors (BWRs) did not see much benefit in it above the costs BWRs would incur. The staff also did not expect BWRs to be likely to take advantage of the rule as much as pressurized water reactors (PWRs). Accordingly, this supporting statement and the Regulatory Analysis accompanying the proposed rule assume that roughly 25 percent of PWRs, or 18 in total, will use the rule to seek certain changes in their facilities, but no BWRs will. NRC has determined that, although the rule would be available to new Part 52 reactors, none of the current or expected applicants are expected to take advantage of the rule;

therefore, this supporting statement and the Regulatory Analysis assume that the potential construction of new PWRs will not affect the potential burdens or benefits of the rule.

The initial burden of using the rule means that licensees would need to expect a significant savings to justify the investment. Although changes that can be made under the rule, such as power uprates, definitely can provide an economic incentive for use of the rule, financial analysis indicates that other changes prominently identified as potential benefits, such as the relaxation of emergency diesel generator (EDG) start times, offer only a marginal business case even for many PWRs. The Regulatory Analysis and this supporting statement assume that licensees will seek to piggy-back § 50.46a EDG amendment requests and § 50.46a uprate amendment requests with a common ECCS re-analysis to achieve some efficiencies.

This supporting statement and the Regulatory Analysis accompanying the proposed rule anticipate that licensees will take advantage of the § 50.46a(f)(1) provision that would enable them to make changes that are inconsequential to safety without NRC review and approval. As noted above, roughly 25 percent of PWRs are expected to use the § 50.46a rule to secure changes following NRC review and approval, while the BWRs are not expected to use the rule. These expectations will be re-assessed based on comments received on the proposed rule and any changes incorporated into the final rule based on those comments. Therefore, licensees are expected to use § 50.46a(f)(1) as currently drafted.

A. JUSTIFICATION

1. Need for the Collection of Information

Section 50.34(a)(4) and (b)(4) require preliminary and final analysis and evaluation of ECCS cooling performance and the need for high point vents following postulated LOCAs to be performed either in accordance with the requirements of § 50.46 or, as amended, with the proposed requirements of § 50.46a for licensees who choose to conduct a re-analysis. This information is needed to ensure that the reactor operates within the limits required to protect public health and safety. The burden for licensees choosing to do a reanalysis is included in the burden estimate for § 50.46a(e).

Section 50.46(a)(1) contains acceptance criteria for ECCS analyses, including a requirement for sufficient supporting justification and, through reference to Appendix K, required documentation. The proposed amendments to this section would allow power reactor licensees to voluntarily comply with the alternative requirements of Section 50.46a. The burden of complying with alternative criteria for ECCS systems is included in the burden estimate for § 50.46a(e).

Section 50.46a(c)(1) would specify that a licensee choosing to implement Section 50.46a must submit a license amendment application under § 50.90 that includes:

(i) A written evaluation demonstrating applicability of the results in NUREG-1829 and NUREG-1903 to the licensee’s facility, provided, however,

that if the facility differs significantly from the facilities analyzed in NUREG-1903, the application must contain a plant-specific analysis demonstrating that the risk of seismically-induced LOCAs larger than the TBS is comparable to or less than the seismically–induced LOCA risk reported in NUREG-1903.

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

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

(iv) A licensee who wishes to make design changes enabled by this section without prior NRC review and approval must submit for NRC approval a process for evaluating the acceptability of such changes, including:

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

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

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

The estimated burden for license amendments under § 50.90 is included in Section 1 of the Part 50 OMB clearance. The burden for the technical contents of the license amendment application is described herein.

Section 50.46a(c)(2) would require an applicant for a construction permit, operating license, design approval, design certification, manufacturing license, or combined license to submit an analysis demonstrating that the proposed reactor design is similar to the designs of reactors licensed before the effective date of the rule. The analysis must also include a recommendation for an appropriate TBS and a justification that the recommended TBS is consistent with the technical basis for this section. For the purposes of this analysis, it is assumed that this requirement would not increase the information collection burden associated with this rule because NRC does not expect any applicants to seek to use the proposed rule during the analysis period.

Section 50.46a(d)(1)-(3) would require a licensee whose application under paragraph (c) is approved by the NRC to comply with the following operating requirements: (1) the licensee shall maintain ECCS model(s) and/or analysis method(s) meeting the acceptance requirements in paragraphs (e)(1) and (e)(2); (2) the licensee shall have leak detection systems available at the facility; the

licensee shall implement actions as necessary to ensure that adverse safety consequences do not result from primary pressure boundary leakage from piping and components larger than the transition break size; and (3) the licensee shall evaluate any change to the facility using a risk-informed evaluation demonstrating that the acceptance criteria in paragraph (f) of this section are met, in addition to meeting other applicable NRC requirements.

The (d)(1) burden for maintaining ECCS models and/or analysis methods is already included in the burden for Part 50. The requirement in (d)(2) contains no information collection, reporting, or recordkeeping requirements. The (d)(3) burden for evaluating any changes to the facility, technical specifications, or procedures is included in the burden for paragraph (f).

Section 50.46a(d)(4) would require the licensee that received approval to implement changes to periodically re-evaluate and update its risk assessments to address changes to the plant, operational practices, equipment performance, plant operational experience, the PRA model, and revisions in analysis methods, model scope, data, and modeling assumptions. Such re-evaluations and updates must be conducted no less than once every two refueling outages (i.e., about once every three years) and must continue to meet the requirements of paragraphs (f)(4) and (f)(5). Based upon the risk assessments, the licensee shall take appropriate action to ensure that the acceptance criteria in paragraphs (f)(1) or (f)(2), as applicable, are met.

Section 50.46a(d)(5) would require that, for LOCAs larger than the TBS, operation in a plant configuration not demonstrated to meet the acceptance criteria in paragraph (e)(4) shall not exceed a total of 14 days in any 12 month period. This requirement contains no information collection, reporting, or recordkeeping requirement.

Section 50.46a(d)(6) would require the licensee to evaluate all proposed changes to the facility before such changes are implemented to ensure that the change does not invalidate the evaluation performed pursuant to paragraph (c)(1)(i) demonstrating the applicability to the licensee's facility of the generic studies performed in NUREG-1829, "Estimating Loss-of-Coolant Accident (LOCA) Frequencies through the Elicitation Process," March 2008, and NUREG-1903, "Seismic Considerations for the Transition Break Size," February 2008, that support the technical basis for this section. Although creating no reporting burden, this section would impose an information collection and recordkeeping burden.

Section 50.46a(e) would establish alternative criteria for ECCS performance evaluation models and requires that the models for LOCAs at or below the TBS receive NRC approval and meet the criteria in (e)(3). This section also includes, through reference to Appendix K, required documentation for evaluation models for LOCAs at or below the TBS. The paragraph requires that analysis methods for all LOCAs must be maintained, available for inspection, and include the analytical approaches, equations, approximations, and assumptions. Whereas the evaluation model requirements for all LOCAs are the same under § 50.46, the requirements differ for LOCAs under § 50.46a.

Sections 50.46a(e)(1) and (3) would describe ECCS evaluation requirements and acceptance criteria for LOCAs at or below the TBS and require sufficient calculations for a number of postulated LOCAs at or below the TBS to ensure that the analytical technique is realistic. Licensees using § 50.46a must meet either the ECCS evaluation model requirements under Section I to Appendix K or requirements identical to § 50.46(a) with respect to LOCAs at or below the TBS, found in paragraph (e)(3).

Sections 50.46a(e)(2) and (4) would impose less stringent ECCS evaluation model requirements and acceptance criteria on LOCAs above the TBS. For LOCAs involving breaks larger than the TBS, paragraph (e)(2) of the proposed rule would establish new ECCS evaluation requirements that cover the same basic program elements as for LOCAs at or below the TBS, but that are more realistic and less stringent. For LOCAs above the TBS, the analysis method need not meet the technical requirements of Section I to Appendix K or the detailed requirements of paragraph (e)(1) for LOCAs at or below the TBS; rather, the analysis method must address the "most important phenomena" in analyzing the course of the accident. For LOCAs above the TBS, sufficient supporting justification must be available to show that the analytical technique "reasonably describes" the behavior of the reactor system, rather than the paragraph (e)(1) requirement for LOCAs at or below the TBS that sufficient supporting justification be available to show that the model "realistically describes" that behavior. Proposed paragraph (e)(2) does not contain the requirement applicable to LOCAs at or below the TBS that uncertainties "be identified and assessed." Finally, paragraph (e)(2) requires that the acceptance criteria of paragraph (e)(4) be satisfied. Because the proposed requirements for LOCAs above the TBS provide more flexibility to the licensee, they may result in some reduction in level of detail from existing requirements; however, because there is no experience with this process, such an assumption may not be realistic.

Therefore, although the § 50.46a(e) information collection may be somewhat reduced for LOCAs above the TBS, the total ECCS evaluation burden under § 50.46a likely will not decrease compared to current § 50.46 because, instead of performing one more stringent analysis for all types of breaks, a licensee must perform separate ECCS analyses for LOCAs at or below and LOCAs above the TBS. Therefore, under § 50.46a there will be two sets of ECCS analyses (i.e., the stringent one for LOCAs at or below the TBS and the less stringent one for LOCAs above the TBS) as opposed to one set under § 50.46.

While specific records for LOCAs analyses above the TBS are not identified for retention in § 50.46a, licensees are expected to retain all documentation (as required by Part II of Appendix K, as amended) for LOCAs above the TBS so that they could show how they comply with this requirement if inspected.

Section 50.46a(f) would require a licensee who wishes to make changes to its facility, procedures, or technical specifications enabled by the § 50.46a rule to

perform a risk-informed evaluation. Although the proposed rule does not define a "risk-informed evaluation" itself, various provisions throughout the rule address the risk-informed evaluation process (i.e., paragraphs (c)(1)(iii), (c)(3)(iii), (d)(3) & (d)(4)) and information from the risk-informed evaluation (i.e., paragraphs (f)(1)(ii), (f)(2)(ii), (f)(3)(iii), (f)(3)(iv)). There is a one-time burden for licensees to prepare and submit a risk-informed evaluation for proposed changes to its facility, technical specifications, and procedures. It is expected that two § 50.46a risk-informed evaluations will be received from each of 18 PWRs after the rule becomes effective. Conceivably, the two evaluations could be consolidated, but this would have no impact on the estimated burdens because the two risk-informed assessments are expected to address different facility changes (e.g., power uprates and relaxation of EDG start times, respectively).

While specific records are not identified for retention in § 50.46a(f), licensees are expected to retain all documentation so that they could show how they comply with this requirement if inspected.

Section 50.46a(f)(1) would establish a process and criteria whereby a licensee may make changes to its facility, technical specifications, or procedures based upon the § 50.46a(c) analysis of ECCS performance without prior NRC review and approval. The change must be permitted under § 50.59 – which does not allow changes to technical specifications incorporated in the license – and the risk-informed evaluation must demonstrate that any increases in the estimated risk are minimal compared to the overall plant risk profile and that the criteria in paragraph (f)(3) are met.

To comply with Section 50.59, licensees must maintain records of changes, including a written evaluation of the bases for the determination that the change does not require a license amendment. Per § 50.59(d)(3), records of changes in procedures must be maintained for a period of 5 years. Section 50.59(d)(2) requires licensees to submit, as specified in § 50.4, a report containing a brief description of any changes, including a summary of the evaluation of each; the report must be submitted at intervals not to exceed 24 months.

The burden associated with § 50.59 license amendments is included in Section 17 of the Part 50 OMB clearance (3150-0011).

Section 50.46a(f)(2) would provide a process and criteria for implementing changes not permitted under paragraph (f)(1). Instead, the licensee must submit an application for license amendment under § 50.90. The application must contain: (i) the information required under § 50.90; (ii) for reactors licensed before the effective date of the rule, information from the risk-informed evaluation demonstrating that the total increases in core damage frequency and large early release frequency are very small, the overall risk remains small, and the criteria in paragraph (f)(3) are met; (iii) for all applicants other than those holding operator licenses issued before the effective date of the rule, information from the risk-informed evaluation demonstrating that the total increases in core damage frequency and large release frequency are very small, the overall risk remains small, and the criteria in paragraph (f)(3) of this section are met; (iv) an evaluation of the cumulative effect of previous changes that have increased risk but have met the acceptance criteria.

If more than one plant change is combined, including plant changes not enabled by this section, into a group for the purposes of evaluating acceptable risk increases, the evaluation of each individual change shall be performed along with the evaluation of combined changes; and (v) information demonstrating that the acceptance criteria in paragraphs (e)(3) and (e)(4) are met.

The burden associated with § 50.90 license amendments is included in Section 1 of the Part 50 OMB Clearance.

Section 50.46a(f)(3). All changes enabled by the rule would be required to meet the following criteria:

> (i) Defense in depth is maintained, in part, by assuring that reasonable balance is provided among prevention of core damage, containment failure (early and late), and consequence mitigation; system redundancy, independence, and diversity are provided commensurate with the expected frequency of postulated accidents, the consequences of those accidents, and uncertainties; and independence of barriers is not degraded;
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> (ii) Adequate safety margins are retained to account for uncertainties; and
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> (iii) Adequate performance-measurement programs are implemented to ensure the risk-informed evaluation continues to reflect actual plant design and operation. These programs shall be designed to detect degradation of the system, structure or component before plant safety is compromised, provide feedback of information and timely corrective actions, and monitor systems, structures or components at a level commensurate with their safety significance.

Section 50.46a(f)(4) would lay out specific technical requirements to the extent that a probabilistic risk assessment (PRA) is used in the risk-informed assessment, although paragraph (f) does not require use of PRA in assessing risks associated with the proposed changes. 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) reasonably represent the current configuration and operating practices at the plant; (iii) have sufficient technical adequacy (including consideration of uncertainty) and level of detail to provide confidence that the total risk estimate and the change in total risk estimate adequately reflect the plant and the effect of the proposed change on risk; and (iv) be determined, through peer review, to meet industry standards for PRA quality that have been endorsed by NRC.

Section 50.46a(f)(5) would require that to the extent that risk assessment methods other than PRA are used to develop quantitative or qualitative estimates of changes to risk in the risk-informed evaluation, an integrated, systematic process must be used. All aspects of the analyses must reasonably reflect the current plant configuration and operating practices, and applicable plant and industry operating experience.

While specific records are not identified for retention in § 50.46a(f)(3),(4) and (5), licensees are expected to retain all documentation so that they could show how they comply with these requirements if inspected.

Section 50.46a(g)(1) would contain reporting requirements for estimating the effects of any changes to or errors in evaluation models, analysis methods, or their applications to determine if the change or error is significant. Section 50.46a(g)(1) mirrors existing reporting requirements in § 50.46(a)(3). Similar to § 50.46(a)(3)(ii), proposed § 50.46a(g) requires at least annual reporting, as specified in § 50.4, of each change to or error discovered in an ECCS evaluation model or in its application that affects the results. If the change or error is determined to be significant, the report must be provided within 30 days and must include a proposed schedule for providing a reanalysis or taking other actions to demonstrate compliance, just as is required by current Section 50.46(a)(3)(ii). Any change or error correction that results in a calculated ECCS performance that does not conform to (e)(3) or (e)(4) acceptance criteria is a reportable event as described in § 50.55(e), § 50.72, and § 50.73; this provision is identical to language in § 50.46(a)(3)(ii). The reporting process and timetables remain the same as existing § 50.46(a)(3). Because NRC assumes no additional items in the annual report and no additional 30-day reports, the proposed rule is expected to create no additional burden of reporting changes or errors. The reporting burden under § 50.46(a)(3) and associated recordkeeping are included in Section 7 of the Part 50 OMB clearance (3150-0011).

Section 50.46a(g)(2) would add a new reporting requirement related to updates of PRAs required by § 50.46a(d)(4). If changes result in a significant reduction in the capability to meet the requirements in paragraph (f), the licensee must file a report within 60 days of completing the PRA update and include required information, such as a description of the relevant PRA updates performed by the licensee, an explanation of the changes that led to the increase(s) in risk estimates, and a description and schedule of any corrective actions required under paragraph (d)(4). Because such changes in risk are not expected, the proposed rule is expected to create no additional reporting burden. Recordkeeping will be needed to demonstrate that reporting is not required. The required recordkeeping burden is included in the burden for the risk assessment update requirement of § 50.46a(d)(4).

Section 50.46a(g)(3) would require each participating licensee to submit, each 24 months, a short description of all changes involving minimal changes in risk made under paragraph (f)(1) of this section since the last report.

Section 50.46a(h) would require that a licensee maintain records sufficient to demonstrate compliance with the requirements in this section in accordance with Section 50.71. Current requirements in Part 50 specify that the FSAR is to be updated such that the FSAR contains complete and accurate information. As a result of implementation of Section 50.46a, licensees will need to revise their FSAR to the extent that it describes facilities and procedures that will be changed (and submit the updated pages to NRC under existing Section 50.71(e)). This requirement is seen as having only a negligible impact, and the burden for periodic

updates of the FSARs is included in Section 27 of the Part 50 OMB clearance (3150-0011).

Section 50.46a(m) would specify that if the transition break size (TBS) is increased, each licensee subject to § 50.46a must perform the ECCS evaluations required by §§ 50.46a(e)(1) and (e)(2) and reconfirm compliance with the acceptance criteria in §§ 50.46a(e)(3) and (e)(4) of this section. If the licensee cannot demonstrate compliance with the acceptance criteria, then the licensee shall change its facility, technical specifications, or procedures so that the acceptance criteria are met. The evaluation required by this paragraph, and any necessary changes to the facility, technical specifications, or procedures as the result of this evaluation, must not be deemed to be backfitting under any provision of this chapter. Changes to TBS would not likely occur until ten or more years following implementation of the rule. Moreover, NRC believes it is unlikely that it will be required to increase the break size in the future; therefore, this provision is not expected to create any additional burden.

Sections 52.47, 52.79, 52.137, and 52.157 would require, as part of the analysis and evaluation of structures, systems and components, an analysis and evaluation of emergency core cooling system cooling performance and the need for high-point vents for designs certified or approved, or facilities licensed, after the effective date of the rule and demonstrated in accordance with 50.46a(1)(2) to be similar to reactor designs licensed before the effective date of the rule. For such designs and facilities, Section 50.46a would be an available option. For facilities licensed after the effective date of the rule that are not demonstrated to be similar to reactor designs licensed before the effective date of this rule, Section 50.46a would not be an available option. Because NRC does not expect any applicants for new reactors to take advantage of 50.46a during this clearance cycle, there is no burden expected under Part 52.

The records and reports that would be required by Section 50.46a are needed to enable the NRC to assure that the licensee is properly exercising the authority granted by this section and complying with its requirements. Without these records and reports, NRC's ability to protect the health and safety of the public would be reduced. These records would be used by NRC inspectors as background information for conducting inspections at a licensed facility. The inspector would use these records to confirm the appropriateness of changes being applied to a plant by confirming that they were properly implemented.

2. Agency Use of Information

The information to be submitted as part of an application that licensees would submit if they chose to adopt the alternative requirements in Section 50.46a, in lieu of other requirements, will be used by NRC to confirm that the change process to be used, as well as the information which will provide results used in the decision process, are adequate to meet the rule requirements to appropriately authorize the changes. Thus, before the licensee would be permitted to revise any existing requirements, NRC would have the opportunity to confirm that the process is satisfactory (e.g., the adequacy of the calculation methods used to evaluate ECCS performance).

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. The NRC encourages respondents to use information technology when it would be beneficial to them. NRC issued a regulation on October 10, 2003 (68 FR 58791), consistent with the Government Paperwork Elimination Act, which allows its licensees, vendors, applicants, and members of the public the option to make submissions electronically via CD-ROM, e-mail, special Web-based interface, or other means. Because of the complexity of this new, voluntary rule, NRC cannot estimate what percent of the potential responses would be filed electronically.

4. Efforts to Identify Duplication and Use Similar Information

No sources of similar information are available. There is no duplication of requirements. NRC has in place an ongoing program to examine all information collections with the goal of eliminating all duplication and/or unnecessary information collections.

5. Effort to Reduce Small Business Burden

This information collection affects only licensees of power reactors who are not small business entities.

6. Consequences to Federal Program or Policy Activities if the Collection is Not Conducted or is Conducted Less Frequently

For licensees who choose to adopt the alternative regulations, the NRC would not be able to ensure the public health and safety with respect to having a sufficient basis to allow revisions to plant design or operations if the information is not submitted for review.

7. Circumstances Which Justify Variation from OMB Guidelines

With the exception of § 50.46a(g)(1), these information collections do not vary from OMB guidelines. Section 50.46a(g)(1) specifies a 30-day reporting period for significant changes or errors in ECCS analyses, which is identical to the existing requirement in § 50.46(a). The 30-day period is necessary in light of the potential safety issues posed by significant changes or errors requiring immediate resolution.

8. Consultations Outside the NRC

The opportunity for public comment on the information collection provided in this supporting statement has been published in the Federal Register.

The NRC decided to reissue this proposed rule because it is considering the adoption of new provisions as an alternative to the provisions previously noticed in the Federal Register. The information collection requirements have been updated in its entirety.

The NRC held a public meeting on August 17, 2004, having first made draft rule language available to the public on August 2, 2004. Several comments oriented toward the regulatory analysis were received in September 2004. Staff provided the proposed rule to the NRC on March 29, 2005.

The proposed rule was published November 7, 2005 in the Federal Register. The NRC also published an opportunity for public comment for its report "Seismic Considerations for the Transition Break Size" in the Federal Register on December 20, 2005. A request for extension of the public comment period was granted, and the public comment period expired March 8, 2006. The NRC held a public workshop on February 16, 2005, and two subsequent public meetings on June 28 and August 17, 2006 to discuss public comments.

The NRC met with the Advisory Committee on Reactor Safeguards (ACRS) on October 31 and November 1, 2006 to discuss the draft final rule. The ACRS provided an evaluation of the draft final rule on November 16, 2006. In response to the ACRS evaluation, the NRC made substantial changes to the rule and decided to re-notice it as a revised proposed rule for additional public comments.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

No confidential information is generally received. However, proprietary or confidential information is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b).

11. Justification for Sensitive Questions

This information collection does not require sensitive information.

12. Estimated Industry Burden and Burden Hour Cost

The NRC burden estimate is shown in the attached tables. Although the information collections primarily are one-time costs, they are expected to be spread over a three-year period after the rule is finalized. There is considerable uncertainty in these estimates for a number of reasons, particularly the voluntary nature of the rule (which affects the number of applicants). Based on licensee burden, NRC estimates that 18 PWRs (or roughly 25 percent) will be affected by the rule. Costs for ECCS re-analysis and development of the risk components of the applications would also vary depending upon the current state of the licensee's processes.

NRC estimates that the cost to industry for preparing the § 50.46a(c)(1) application will require 1,500 hours per application. Assuming that 18 PWRs submit an applicability evaluation over a 3-year period, 6 reactors will submit an evaluation each year for a burden of 9,000 hours (6 x 1,500 hours). Over the 3-year period, the total burden will be 27,000 hours (3 x 9,000). Therefore, the total annualized cost to industry would be $2,142,000 (27,000 hours x $238/hour/3 years).

Recordkeeping is estimated at 10 percent of the 1,500 hours or an additional 150 hours per applicability evaluation. In each year of the 3-year period, 6 PWRs will incur recordkeeping for the documentation associated with the evaluation for a total of 900 hours (6 x 150). Therefore, the annualized recordkeeping burden would be 900 hours (900 + 900 + 900 hours/3 years) at a cost of $214,200 (900 hours x $238/hour).

NRC estimates that the burden to industry for preparing the § 50.46a(c)(2) similarity analysis for proposed reactor designs will require 1,000 hours per analysis. A burden for this requirement is not calculated for this information collection because no applicants for new reactors are expected to take advantage of 50.46a within the timeframe of this analysis.

To review plant changes and experience and update its risk assessment as required by § 50.46a(d)(4), it is estimated that a licensee will require 400 hours at least once every two refueling outages (i.e., every three years starting 2014), at a cost of $95,200 (400 hours x $238/hour). Assuming that 18 PWRs' performance of the risk assessment updates is randomly distributed over a three-year period approximating two refueling outages (i.e., two cycles, 18 months each), then the annual burden would be 2,400 hours (6 PWRs x 400 hours). Therefore, the total annualized cost to industry would be $571,200 (2,400 hours x $238/hour), starting in 2014. Recordkeeping is estimated at 10 percent of the burden of 400 hours or an additional 40 hours. This recordkeeping burden commences for each PWR following approval of its amendment request. Thus, after the first three years (i.e., starting in 2014), the annual recordkeeping burden would be 720 hours (18 x 40 hours). Therefore, the annualized recordkeeping burden would be $171,360 (720 hours x $238/hour).

NRC estimates that the burden to evaluate all proposed changes to a facility before such changes are implemented as required by § 50.46a(d)(6) is 500 hours at a cost of $119,000 (500 hours x $238/hour) per affected licensee. Assuming that 18 PWRs use the rule to make changes at their facility over a 3-year period, 6 reactors will evaluate changes under this provision each year for an annual burden of 3,000 hours (6 x 500 hours) at a cost of $714,000 (3,000 hours x $238). Recordkeeping is estimated at 10 percent of the 500 hours, or an additional 50 hours. In each year, 6 PWRs will incur this burden for a total of 300 hours (6 x 50 hours). Therefore, the annualized recordkeeping burden would be 300 hours (300 + 300 + 300 hours/3 years) at a cost of $71,400 (300 hours x $238/hour).

Based on staff experience, the average burden per PWR for performing a § 50.46a(e) ECCS analysis is 2,500 hours, at a cost of $595,000 (2,500 hours x $238/hour). Assuming that 18 PWRs conduct an ECCS re-analysis over a 3-year period, 6 reactors will perform the analysis each year for an annual burden of 15,000 hours (6 x 2,500 hours) at a cost of $3,570,000 (15,000 x $238/hour). Recordkeeping is estimated at 10 percent of the 2,500 hour burden or an additional 250 hours. In each year, 6 PWRs will incur this burden for a total of 1,500 hours (6 x 250). Therefore, the annualized recordkeeping burden would be 1,500 hours (1,500 + 1,500 + 1,500 hours/3 years) at a cost of $357,000 (1,500 hours x $238/hour).

NRC estimates that the cost to industry for preparing the § 50.46a(f) risk-informed evaluation amendment will require 2,000 hours per application. Assuming that 18 PWRs submit the equivalent of two risk-informed assessments each (whether packaged together or separately) over a 3-year period, 6 reactors will submit two risk-informed assessments each year for a burden of 24,000 hours (6 x 2 x 2,000 hours). Over the 3-year period, the total burden will be 72,000 hours (3 x 24,000). Therefore, the total annualized cost to industry would be $5,712,000 (72,000 hours x $238/hour/3 years). Recordkeeping is estimated at 10 percent of the 2,000 hours or an additional 200 hours per risk-informed assessment. Each year, 6 PWRs will incur recordkeeping for the documentation associated with the two risk-informed assessments for a total of 2,400 hours (6 x 2 x 200). Therefore, the annualized recordkeeping burden would be 2,400 hours (2,400 + 2,400 + 2,400 hours/3 years) at a cost of $571,200 (2,400 hours x $238/hour).

NRC assumes that 18 licensees will complete an application to meet the requirements of § 50.46a(f)(1) to make facility, technical, or procedural changes without NRC approval. NRC estimates that a § 50.46a(f)(1) application will require 450 hours per application. Assuming that 18 PWRs complete a § 50.46a(f)(1) application over a 3-year period, 6 reactors will submit an application each year for a burden of 2,700 hours (6 x 450 hours). Over the 3-year period, the total burden will be 8,100 hours (3 x 2,700). Therefore, the total annualized cost to industry would be $642,600 (8,100 hours x $238/hour/3 years). The burden associated with this action is included in the Part 50 OMB clearance. Recordkeeping is estimated at 10 percent of the 450 hours or an additional 45 hours per § 50.46a(f)(1) application. The first year, 6 PWRs will incur recordkeeping for the documentation associated with the application for a total of 270 hours (6 x 45); the second year 6 additional PWRs will incur this burden for a total of 540 hours (12 x 45); the third and subsequent years, 18 PWRs will incur this burden for a total of 810 hours per year (18 x 45). Therefore, the annualized recordkeeping burden would be 540 hours (270 + 540 + 810 hours/3 years) at a cost of $128,520 (540 hours x $238/hour).

To prepare biannual short descriptions of changes as required by § 50.46a(g)(3), it is estimated that a licensee will incur a burden of 100 hours every two years, or 6 licensees per year beginning in 2012. This results in a total annualized burden per licensee of 33 hours (100 hours/3 years) over the 3-year analysis period. The total burden is thus 198 hours (6 x 33 hours) at a cost of $47,124 (198 x $238/hour). Recordkeeping is estimated at 10 percent of the burden of 33 hours per licensee or an additional 3 hours per licensee. Therefore, the annualized recordkeeping burden hours is 18 (6 x 3 hours) and the annualized cost would be $4,284 (18 hours x $238/hour).

NRC assumes that 18 PWR licensees will take advantage of this alternative over the three years following its promulgation; the following tables indicate the full estimated burden and cost. While one-time and recurring costs will be incurred by the licensee for conducting the ECCS analyses, development of the risk-informed evaluation, submission of the license amendment request, and risk updates, NRC expects substantial net benefits to result from the added flexibility being provided for licensees to change facility design, procedures, and technical specifications by using Section 50.46a. Some of the savings may be with respect to records and reports, but the vast majority of the benefits is expected to result from facility

changes, such as power uprates. These non-information collection burden benefits are discussed in the regulatory analysis.

NRC does not expect any Part 52 applicants for new reactors to take advantage of the proposed rule over the 3-year analysis period. There is therefore no burden expected for Part 52 applicants.

13. Estimate of Other Additional Costs

None.

14. Estimated Annualized Cost to the Federal Government

The NRC is expected to receive for review from 18 PWRs (a) ECCS re-analyses and (b) two risk-informed evaluations from each PWR. The estimated total review burden is 91,800 hours (5,100 hrs X 18) at a cost of $21,848,400 (91,800 X $238) over a 3-year period, resulting in annual burden of 30,600 hours with an annual cost of 7,282,800.

Review of updated risk assessments will require 200 hours each. Starting about 3 years after approval of the first group of amendment requests, NRC estimates that it will receive 6 risk assessment updates per year to review for an annual burden of 1,134 hours (200 hours x 6) at a cost of $269,892 (1,134 hours x $238).

This cost is fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Parts 180 and 181.

15. Reasons for Change in Burden or Cost

The rule is estimated to result in a net increase of 53,388 hours in the information collection burden. This burden is associated with one-time (48,000 hours) and recurring (5,388 hours) costs to obtain the approval to implement Section 50.46a. The majority of this burden is a one-time burden, which includes fulfilling the requirements of Sections 50.46a(c)(1) (Application), 50.46a(e) (ECCS Evaluations Re-analysis), and 50.46a(f) (Risk-Informed Evaluations). These one-time and annual burdens also have additional associated annual burdens due to recordkeeping requirements.

16. Publication for Statistical Use

The collected information is not published for statistical use.

17. Reason for Not Displaying the Expiration Date

The requirements are contained in regulations. Amending the Code of Federal Regulations to display information that, in an annual publication, could become obsolete would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

None.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.

One-Time and Annual Information Collection and Reporting Burdens and Costs to Industry

Information Collection Section	Number of Respondents	Number of Responses Per Respondent	Total Responses	Burden per Response	Total Burden Hours	Industry Cost @ $238/Hour
One-Time Annualized Information Collection and Reporting Burden and Cost to Industry						
50.46a(c)(1) Application[1/]	6	1	6	1,500	9,000	$2,142,000
50.46a(e) ECCS Evaluations (Re-analyses)[1/]	6	1	6	2,500	15,000	$3,570,000
50.46a(f) Risk-Informed Evaluations[1/]	6	2	12	2,000	24,000	$5,712,000
50.46a(m) Evaluation Triggered by Increases to TBS[2/]	18	N/A	N/A	N/A	N/A	N/A
52.47, 52.79, 52.137, 52.157 New Nuclear Power Plants[3/]	N/A	N/A	N/A	N/A	N/A	N/A
Total*	**6**	**4**	**24**	**N/A**	**48,000**	**$11,424,000**
Annual Information Collection and Reporting Burden and Cost to Industry						
50.46a(d)(4) Risk Assessment Update[4/]	18	1	0	0	0	0
50.46a(d)(6) Evaluation of proposed changes[5/]	6	1	6	500	3,000	$714,000
50.46a(f)(1) Reporting Associated with (f)(1)[6/]	18	0	0	0	0	0
50.46a(g)(1) Reporting Changes in ECCS[7/]	18	0	0	0	0	0
50.46a(g)(2) Reporting Changes in Risk Estimates[8/]	18	0	0	0	0	0
50.46a(g)(3) Biennial Short Description of Changes[9/]	6	1	6	33	198	$47,124
50.46a(h) FSAR Updates[10/]	18	0	0	0	0	0
Total	**6**	**2**	**12**	**N/A**	**3,198**	**$761,124**

[1/] 6 one-time submittals expected annually during 2010 through 2012.
[2/] Not expected to occur until 10 or more years following rule implementation.
[3/] No use of 50.46a by Part 52 applicants during the analysis period.
[4/] Every three years starting in 2014. At that time the burden will be included in the 10 CFR 50 clearance renewal (3150-0011).
[5/] 6 annual submittals expected during 2010 through 2012.
[6/] Burden included in Section 17 of Part 50 (Final Supporting Statement for Reports and Records for Changes, Tests and Experiments).
[7/] Burden included in Section 7 of Part 50 (Final Supporting Statement for Acceptance Criteria for Emergency Core Cooling Systems (ECCS)).
[8/] Burden included in Section 50.46a(d)(4).
[9/] Biennial submittals requiring 100 hours per licensee expected beginning in 2012, thus the annualized burden is 33 hours (100/3 years) over the 2010-2012 analysis period.

[10/] Burden included in Section 27 of Part 50 (Final Supporting Statement for Periodic Update of the Final Safety Analysis Report).

Annual Recordkeeping Burden and Cost to Industry[1/]

Recordkeeping Section	Annual Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours	Annual Industry Cost @ $238/Hour
50.46a(c)(1) Records of applications	6	150	900	$214,200
50.46a(d)(4) Risk Assessment Update[2/]	6	N/A	N/A	N/A
50.46a(d)(6) Evaluation of Proposed Changes	6	50	300	$71,400
50.46a(e) Records of ECCS Evaluations	6	250	1,500	$357,000
50.46a(f) & (f)(3)-(5) Recordkeeping for Two Risk-informed Evaluations	6	400[7/]	2,400	$571,200
50.46a(f)(1) Records of Changes Made Without NRC Review or Approval[3/]	6	45	270	$64,260
50.46a(g)(3) Biennial Short Description of Changes[4/]	6	3	18	$4,284
50.46a(m) Records of Evaluations and Actions Triggered by Increases to TBS[5/]	N/A	N/A	N/A	N/A
52.47, 52.79, 52.137, and 52.157 Analyses for Nuclear Power Plants[6/]	0	0	0	0
Total	**6**	**898**	**5,388**	**$1,282,344**

[1/] No recordkeeping would be implemented until 2010. Starting in 2010, 6 licensees will be subject to the recordkeeping; in 2011, 12 will be subject; and in 2012 and the following years 18 PWR licensees will be subject to the recordkeeping requirements. The burden has been annualized for years 2010 through 2012.
[2/] Recordkeeping burden will not be in effect until 2014.
[3/] One-time records will be generated during 2010 – 2012.
[4/] 6 annual submittals of 100 hours each beginning in 2012.
[5/] Not expected to occur until 10 or more years following rule implementation.
[6/] No applications are expected under Part 52 during the analysis period.
[7/] Recordkeeping burden is associated with two submissions per licensee for risk-informed evaluations.

TOTAL RESPONDENTS: 6 - initial
TOTAL RESPONSES: 12 (6 – initial + 6 additional recordkeepers)
TOTAL ANNUAL BURDEN (Years 2010-2012): 53,388 hours [(Reporting = 48,000 hours reporting (8,000 per respondent)) + (Recordkeeping = 5,388 hours (898 per recordkeepers))]