

DRAFT SUPPORTING STATEMENT
FOR
"RISK-INFORMED CATEGORIZATION AND TREATMENT OF STRUCTURES, SYSTEMS,
AND COMPONENTS"

10 CFR 50.69

DESCRIPTION OF THE INFORMATION COLLECTION

Existing regulations in 10 CFR 50 specify recordkeeping and reporting requirements associated with structures, systems, and components (SSCs) used in a nuclear power plant. Certain provisions of these regulations as they pertain to "treatment" requirements, meaning those quality assurance programs, testing, reporting requirements and other activities intended to add confidence that SSCs can perform their intended safety functions when needed, have been revised. A new section 10 CFR 50.69 provides a voluntary alternative set of requirements under which a licensee may obtain relief from some unnecessary regulatory burden for those SSCs that are determined through a risk-informed categorization process to be of low safety-significance. The regulation is intended to provide more flexibility to licensees in the application of treatment requirements for low safety-significant SSCs, by replacing some of the prescriptive programmatic requirements with more general performance requirements. Requirements are also included to specify the process for obtaining NRC approval for implementing the alternative requirements and for licensee preparation of ongoing SSC performance evaluations against established standards. Recordkeeping and reporting requirements are modified only for those licensees or applicants who choose to implement the alternative requirements.

To use the alternative provisions of 10 CFR 50.69, a licensee or applicant must evaluate the safety significant functions of SSCs and categorize each SSC into one of four categories (defined as RISC-1, RISC-2, RISC-3, and RISC-4, depending on its safety-significance function). 10 CFR 50.69 establishes revised treatment and less prescriptive and burdensome information collection requirements for safety and non-safety SSCs categorized as performing low safety-significant functions (RISC-3 and RISC-4), but also contains requirements for on-going evaluations to ensure safety standards are maintained and that records of categorization decisions be kept.

10 CFR 50.69 provisions may be used by applicants for a license to be issued under 10 CFR 50 or 10 CFR 52, as well as by holders of operating licenses issued under 10 CFR 50 or 10 CFR 54. A licensee or applicant choosing to use the provisions of 10 CFR 50.69 is required to obtain NRC approval of its categorization process and supporting probabilistic risk analysis, by either including the information in its application for license, or by submitting a license amendment request with the required information, using the existing processes in 10 CFR 50.34, 10 CFR 50.90 or 10 CFR 52. The exact number of facilities affected is uncertain because the information collection is associated with voluntary alternative requirements, but is estimated at a total of three applications over the next three years.

A. JUSTIFICATION

1. Need for the Collection of Information.

10 CFR 50.69(b)(1) allows power reactor licensees and applicants, licensees having a renewed license, and applicants for design certification, to voluntarily comply with the requirements in 10 CFR 50.69 for components categorized as RISC-3 and RISC-4. This burden is included in 10 CFR 50.69(d) and 10 CFR 50.69(e). This is an alternative to a number of requirements that require information collections, specifically, the reporting requirements in 10 CFR 21; 10 CFR 50.49 qualification requirements, certain 10 CFR 50.55(e) notifications of defects and failures to comply; 10 CFR 50.55a in-service inspection and testing requirements (ISI/IST) and quality qualification requirements; 10 CFR 50.65 maintenance monitoring except for maintenance risk-assessment; 10 CFR 50.72 and 10 CFR 50.73 event reporting; and quality assurance requirements in 10 CFR 50 Appendix B.

For licensees choosing to use 10 CFR 50.69 for SSCs categorized as RISC-3 and RISC-4 in lieu of the regulatory sections cited above, paragraphs (d) and (e) contain new requirements that cover the same basic program elements, but with less specificity on how they are to be conducted and documented. Therefore, although some information collections will still be necessary, the burden should be reduced. Much of the burden reduction will occur during activities, such as when a replacement component is procured or when operational events or equipment problems arise, with potential reportability. In addition, there may be some reduction during periodic inspections and tests.

10 CFR 50.69(b)(2) specifies that a licensee choosing to implement 10 CFR 50.69 must submit an application for a license amendment that includes a description of (1) the categorization process for RISC-1 through RISC-4 SSCs, (2) the measures taken to assure quality of the evaluation methods, including results of a peer review, and (3) the basis for acceptability for evaluations to be conducted to show that the potential increase in risk would be small considering the changes to treatment permitted by implementation of 10 CFR 50.69. An applicant for a license would include this information as part of their application for a license. The categorization process is the fundamental basis supporting the revised rule requirements. The Probabilistic Risk Assessment (PRA) used in the process provides important input to the process, because results can be influenced by the completeness and technical adequacy of the PRA. Therefore, NRC needs to review the PRA and other categorization process information to confirm its acceptability. There is a one-time burden for licensees to prepare and submit this application, with resulting burden reductions expected later in reporting and recordkeeping requirements for RISC-3 and RISC-4 SSCs. Licensees are expected to use RG 1.201 (which endorses NEI 00-04) to develop their submittals. The burden associated with the submittal aspect of 10 CFR 50.69 is addressed in Section 33 of this analysis.

10 CFR 50.69(c) specifies how the categorization process is to be conducted. After approval of the application, the licensee or applicant then must perform evaluations of the significance of SSC functions, considering both internal and external events, and both active and passive functions in an integrated, systematic process, using an

integrated decisionmaking panel to make the determination. To meet the requirements, a licensee (or applicant) needs to gather information to support preparation of the models (such as the PRA), gather information about the components within the systems, and prepare information about safety-significance. The majority of the burden is associated with the categorization process preparation and implementation. The NRC expects that implementation would occur over a period of years. Once the process has been approved, a licensee can begin to categorize on a system-by-system basis and take advantage of the reductions in treatment requirements for components in those systems. As stated in 10 CFR 50.69(f), records of categorization determinations are required to be prepared and maintained.

10 CFR 50.69(d)(1) contains requirements for a licensee to evaluate treatment being applied to RISC-1 and RISC-2 SSCs to ensure that it is consistent with categorization process assumptions. This is a one-time requirement associated with developing the basis for the categorization process. No explicit recordkeeping requirement is included.

10 CFR 50.69(d)(2) requires that a licensee or applicant develop and implement processes to control the inspection, testing, and corrective action for RISC-3 SSCs to provide reasonable confidence in their capability to perform functions under design basis conditions. These requirements include certain elements presently covered by 10 CFR 50 Appendix B (such as corrective action) and by 10 CFR 50.55a(f) and 10 CFR 50a(g) and 10 CFR 50.49. 10 CFR 50.69 requires that RISC-3 SSCs must be capable of performing their functions under specific conditions (environmental and seismic). Subparagraph (i) requires that inspection and testing activities be conducted. Subparagraph (ii) requires the licensee to identify and correct in a timely manner conditions that could prevent an SSC from performing its required functions. While specific records are not identified for retention, licensees will keep some records so that they can show how they comply with this requirement if inspected. Further, it is anticipated that most licensees will need to review their existing processes to determine whether they comply with the specific requirements and make changes to procedures, data bases, or other activities as a result. Therefore, there is a one-time implementation cost, with some reduction in annual costs for recordkeeping, following implementation for each licensee choosing to implement the 10 CFR 50.69 provisions.

10 CFR 50.69(e)(1) requires the licensee (or applicant) to review changes to the plant, operational practices, and operating experience to update the PRA and SSC categorization at least every 36 months. This requirement will result in a need for a licensee to retain information to be able to perform the required review.

10 CFR 50.69(e)(2) contains requirements for a licensee to monitor performance of RISC-1 and RISC-2 SSCs and make adjustments to either categorization or treatment processes as necessary to maintain the validity of the categorization process and results. This requirement necessitates the collection of information about the performance of SSCs so that the licensee can determine if results are such that changes to its processes are needed.

10 CFR 50.69(e)(3) requires consideration of data being collected to meet the inspection and testing requirements of 10 CFR 50.69(d)(2)(i) for RISC-3 SSCs to determine whether there are any adverse changes in performance and to make

adjustments as necessary to either categorization or treatment processes such that categorization process results remain valid.

10 CFR 50.69(f)(1) requires that records of the categorization of SSCs be prepared. In accordance with 10 CFR 50.71(c), they must be retained until the license is terminated. This burden is included with the estimates for 10 CFR 50.69(c).

10 CFR 50.69(f)(2) requires that a licensee update its Final Safety Analysis Report (FSAR), consistent with provisions of 10 CFR 50.71(e) to reflect which systems have been categorized using 10 CFR 50.69. 10 CFR 50.71(e) specifies that the FSAR is to be updated such that the FSAR contains complete and accurate information. In implementing 10 CFR 50.69, licensees may need to revise their FSAR to the extent that it describes treatment requirements for SSCs (and submit the updated pages to NRC under existing 10 CFR 50.71(e)). A status of which systems fall under 10 CFR 50.69 requirements is required. This requirement has only a negligible impact on the update requirements.

Section 50.69(g) adds a requirement, if not otherwise reportable, to submit a licensee event report under 10 CFR 50.73(b) for any event or condition that would have prevented RISC-1 and RISC-2 SSCs from performing a safety-significant function. A small number of events would now be reportable that were not previously (e.g., some events affecting RISC-1 or RISC-2 SSCs). The NRC staff estimates that this would result in a small increase in reporting burden.

2. Agency Use of Information

The information to be submitted as part of an application to adopt the alternative requirements in 10 CFR 50.69, in lieu of other requirements, will be used by NRC to confirm that the categorization process to be used, as well as the PRA which will provide results used in the decision process, are adequate to meet regulatory requirements to appropriately categorize the SSCs. Thus, before the licensee or applicant is permitted to revise any existing requirements, NRC has the opportunity to confirm that the process is satisfactory.

The agency would use the reports involving safety-significant functions of RISC-1 and RISC-2 SSCs required by 10 CFR 50.69(g) to determine if reported defects or events involve potential generic safety problems that might require action to resolve.

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. However, because of the types of information and the infrequency of submission, the reports do not readily lend themselves to the use of technology collection techniques for submission.

4. Efforts to Identify Duplication and Use Similar Information

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 only affects licensees of power reactors (or applicants for licenses) 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

The NRC would not be able to ensure the public health and safety with respect to having a sufficient basis to allow revisions to treatment of SSCs if the categorization information is not submitted for review.

7. Circumstances Which Justify Variation from OMB Guidelines

These information collections do not vary from OMB guidelines.

8. Consultations Outside the NRC

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

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

Confidential and proprietary 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 burden from recordkeeping and reporting requirements arising from this rulemaking is estimated as shown in the attached Tables. The burden estimate, including an estimate of one-time costs, is shown in the attached Tables. As noted, the NRC concludes that the effect of the changes on recordkeeping and reporting requirements will be a small increase in the current burden, because of the one-time implementation burden, with burden reductions expected in subsequent years. There is considerable uncertainty in these estimates for a number of reasons: voluntary nature (which affects

the number of applicants); extent of SSCs that are RISC-3 or RISC-4 (which depends upon plant design); and burden impact (which depends upon events, need for replacement equipment, etc.). Costs for development of PRA and revisions to procedures would also vary depending upon the current state of the licensee's processes. Costs for applicants would be expected to be less since they would not yet have developed the programs and could factor the requirements into their process.

While one-time costs will be incurred by the licensee/applicant for development of PRA and procedures, conducting the categorization, and NRC review, NRC expects cost savings to result from the added flexibility being provided for licensees to apply less prescriptive requirements to some SSCs in using 10 CFR 50.69. Some of the savings will be with respect to records and reports, but the vast majority of the savings is expected to result from procurement of equipment at reduced costs and savings in licensee staff hours to implement the lesser treatment requirements for some SSCs.

13. Estimate of Other Additional Costs

The quantity of records to be maintained is roughly proportional to the recordkeeping burden and therefore can be used to calculate approximate records storage costs. Based on the number of pages maintained for a typical clearance, the records storage cost has been determined to be equal to .0004 times the recordkeeping burden cost. Therefore, the storage cost for this clearance is estimated to be \$279 (3,220 x \$217 x .0004) and is insignificant.

14. Estimated Annualized Cost to the Federal Government

The estimated annualized burden and cost to the government is 100 hours per submittal for a total of \$21,700 (100 hrs. x 217/hr.). This cost is fully recovered through fee assessments to NRC licensees pursuant to 10 CFR 170 and 10 CFR 171.

15. Reasons for Change in Burden or Cost

The NRC anticipates that one licensee annually will choose to implement this voluntary alternative, thereby adding an estimated 3,220 hours annually until the one-time burden requirements have been completed. Because licensees will be choosing to implement the requirements in this section in lieu of the requirements in other current sections, the burden for those sections will be reduced by approximately 1,540 hours.

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.

ANNUAL REPORTING BURDEN

SECTION (3150-0011)	ESTIMATED NO. OF RESPONDENTS	ANNUAL RESPONSES PER RESPONDENT	TOTAL ANNUAL RESPONSES	BURDEN HOURS PER RESPONSE	TOTAL BURDEN HRS	COST @\$217/HR
50.69(g)	1	1	1	50	50	\$10,850
TOTAL ANNUAL REPORTING BURDEN					50	\$10,850

ANNUAL RECORDKEEPING BURDEN

SECTION (3150-0011)	ESTIMATED NO. OF RECORDKEEPERS*	BURDEN HOURS PER RECORDKEEPER	TOTAL ANNUAL BURDEN HRS	COST @\$217/HR
50.69(d)(2)	2	535	1,070	\$232,190
50.69(e)	2	615	1,230	\$266,910
TOTAL ANNUAL RECORD- KEEPING BURDEN			2,300	\$499,100

Note: Estimates assume one third of current safety-related SSCs are RISC-3 and that burden of substitute requirements is in range of 1/3 to 3/4 of existing burden for data collections, depending upon the requirement. Estimates also include PRA update requirements and enhanced requirements for RISC-2 SSCs.

*One application each year results in 1 recordkeeper the first year, 2 the second year, and 3 the third year for a total of 6/3 years = 2 recordkeepers annually.)

ANNUALIZED ONE-TIME RECORDKEEPING BURDEN

SECTION	NO. OF RESPONDENTS	BURDEN HOURS PER RECORDKEEPER	TOTAL ANNUAL BURDEN HRS	COST @\$217/HR
50.69(d)(1)	1	20	20	\$4,340
50.69(c)	1	800	800	\$173,600
50.69(d)(2) and (e)	1	100	100	\$21,700
TOTAL ONE-TIME RECORDKEEPING BURDEN			920	\$199,640

Estimated cost for review and revision of licensee procedures for treatment practices to meet 10 CFR 50.69(d) and (e). Annualized cost for categorization and documentation of basis for decisions under 10 CFR 50.69(c) assumes implementation occurs over 3 years, but the licensee has the option to use a different period.

Total responses: 1

Total respondents: 1

Total annualized burden: 3,270 hours (50 hrs. reporting + 3,220 hrs. recordkeeping)

Total cost: \$709,590 (3,270 burden hrs. X \$217/hr)