

Section 33

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

(Regulatory Guides RG-1.174, General; RG-1.175, IST; RG-1.176, GQA; RG-1.177, TS;
RG-1.178, ISI; RG-1.201, RISC; and RG-1.200, PRA Technical Adequacy)
(3150-0011)

Description of the Information Collection

In the specific areas of In-Service Inspection (ISI, RG-1.178), In-Service Testing (IST, RG-1.175), Graded Quality Assurance (GQA, RG-1.176), Technical Specifications (TS, RG-1.177), Risk-Informed Safety Classification (RISC, RG-1.201), and in an overall guide generically applicable to all five of these areas (RG-1.174), as supported by Probabilistic Risk Assessment (PRA) Technical Adequacy guidance RG-1.200, this series of Regulatory Guides provides a risk-informed method for licensees to use in requesting changes to their current licensing bases (CLB), the requirements for which are stated or referenced in numerous sections of 10 CFR 50 as detailed below in item A.1. No changes or additions have been made to those sections of 10 CFR 50 (nor to any other rules or regulations) in conjunction with the issuance of this series of guides. The risk-informed method is an alternative to the deterministically-based CLB change method, which remains an acceptable approach.

The risk-informed (RI) alternative method allows licensees to concentrate on plant equipment and operations that are most critically important to plant safety. For example, existing regulations require certain quality assurance (QA) activities to be applied to a wide variety of a plant's structures, systems, and components (SSCs). Although the regulations allow these quality assurance activities to be applied in a way that is commensurate with the safety importance of each SSC, historical precedent has resulted in the same quality assurance activities being applied to SSCs that have a wide range of safety significance. The risk-informed alternative encourages quality assurance activities that are compatible with safety significance, thus allowing more effort to be expended on the more important equipment and correspondingly less effort on the less important equipment. In this way, a savings in total effort can be achieved with an acceptably small change in overall safety. This savings, together with the greater operating flexibility that is possible utilizing the risk-informed method, are among the principal incentives for licensees to voluntarily assume the recordkeeping and reporting burdens that come with the risk-informed method.

The guides specify the records, analyses, and documents that licensees are expected to prepare in support of risk-informed changes to their CLB in the specified areas. Within each of the five specific areas, the applicable Regulatory Guide, as supplemented by the additional generic guidance from the overall guide (RG-1.174) and the PRA technical adequacy guide (RG-1.200), specifies that the licensee should consider the following four items. The licensee should:

1. Identify those aspects of the plant's licensing bases that may be affected by the proposed change, including, but not limited to, rules and regulations, final safety analysis report (FSAR), technical specifications, licensing conditions, and licensing commitments; identify all SSCs, procedures, and activities that are covered by the CLB change under evaluation and consider the original reasons for inclusion of each program requirement;

and identify available engineering studies, methods, codes, applicable plant-specific and industry data and operational experience, PRA findings, and research and analysis results relevant to the proposed CLB change;

2. Evaluate the proposed CLB change with regard to meeting the regulations and the principles that adequate defense-in-depth is maintained, that sufficient safety margins are maintained, and that any proposed increases in core damage frequency and risk are small and are consistent with the intent of the Commission's Safety Goal Policy Statement;
3. Develop an implementation and monitoring plan to ensure that the engineering evaluation conducted to examine the impact of the proposed changes continues to reflect the actual reliability and availability of SSCs that have been evaluated and to ensure that the conclusions that have been drawn from the evaluation remain valid; and
4. Review the proposed CLB change in order to determine the appropriate form of the change request; assure that information required by the relevant regulations(s) in support of the request is developed; and prepare and submit the request in accordance with relevant procedural requirements (for those applications where submittal is required, as specified later in this document).

Changes in NRC expectations, regarding licensee recordkeeping and reporting in the technical areas due to a licensee's voluntary use of this alternative risk-informed method for requesting CLB changes, are the subject of this supporting statement. 10 CFR 50 supporting statements describing the current bases for OMB's recordkeeping and reporting approval in these technical areas are as follows:

Section 16 of the current 10 CFR 50 OMB clearance covers the recordkeeping and reporting burdens for in-service inspection and in-service testing programs. Not included in Section 16 are the recordkeeping and reporting needed to convert the bases of ISI and/or IST programs to the risk-informed CLB change methodology (an one-time-only effort, as described in items #1, #2, and #4 above), and the recordkeeping and reporting associated with the implementation and monitoring plan that is an integral part of these risk-informed programs (an ongoing effort, as described in item 3 above, to ensure that no unexpected, adverse, safety degradation occurs after the requested changes have been made). However, the burden for CLB changes, including but not limited to CLB changes related to ISI and IST, is covered in Section 1 of the OMB clearance for 10 CFR 50 (license amendments).

Section 15 of the current 10 CFR 50 OMB clearance covers 10 CFR 50 Appendix B, which contains NRC's requirements regarding the features of the quality assurance (QA) programs that each licensee must establish, update, and follow throughout the life of the plant. 10 CFR 50 Appendix B allows QA activities to be applied in a graded manner and, because there is variety in the exact commitment made by individual licensees in their CLB regarding QA programs, licensees can adopt certain aspects of graded QA programs without prior NRC approval. The last paragraph of item A.1 of Section 15 states:

"Maintenance of a QA program description is a license condition for both the construction and operation phases of a nuclear power plant. Like other license conditions, the description must be maintained current after it has been accepted by the NRC. It is estimated that a licensee/applicant will make one change to the QA program description per year. The burden for Current Licensing Basis (CLB) changes, including

changes to the QA program description, are included in the total license amendment requests in Section 1.”

Thus, the burden for CLB changes, including but not limited to CLB changes related to QA, is covered in Section 1 of the OMB clearance for 10 CFR Part 50 (license amendments).

Section 1 of the Part 50 clearance covers the recordkeeping and reporting required for technical specifications. Technical specifications are required to be part of a licensee’s operating license, and license amendments are issued in response to requests for changes to technical specifications. License amendments for technical specifications changes have been anticipated for the clearance period, and the anticipated recordkeeping and reporting requirements burden has been included within Section 1. Over the past several years, applications for license amendments for technical specification changes have made increasing use of quantitative risk evaluations (i.e., the requests have become more “risk-informed”). Thus, the subject RG-1.177 serves more to codify and standardize existing practice than it does to significantly change that practice. Thus, many of the recordkeeping and reporting expectations associated with conversion to, and later maintenance of, risk-informed technical specification changes are already included within Section 1. This includes the implementation and monitoring plan, since technical specifications are required only for significant, safety-related equipment for which implementation and monitoring activities are currently required by 10 CFR 50.65.

A. JUSTIFICATION

1. Need for and Practical Utility of the Collection of Information

In cases where the licensee chooses to convert from the present deterministically-oriented CLB to the alternative risk-informed CLB in any one of (or combination of) the subject technical areas, the licensee and the NRC must have sufficient information to determine that the plant continues to be operated in a manner that ensures the health and safety of the public upon implementation of the changes.

The information expected to be collected for the above-stated purpose in each of the technical areas considered by the subject Regulatory Guides is specified in various sections of 10 CFR 50, as described below. These regulations remain unchanged by issuance of the subject Regulatory Guides. Only the method for compliance has been changed. The current regulations are:

In-Service Inspection (ISI, RG-1.178, and the generically applicable RG-1.174 and RG-1.200):

10 CFR 50.55a(g) “Inservice inspection requirements,” specifies in detail, according to the date of issuance of the plant’s construction permit, the editions of Section XI of the ASME Boiler and Pressure Vessel Code and Addenda to which the in-service inspection of the plant’s piping and pressure boundary equipment must comply, including the reporting and recordkeeping that is expected as part of the licensee’s ISI program.

In order for the licensee to ensure, and the NRC to verify, that the requirements of this regulation (and the referenced codes and addenda) continue to be met following changes to the licensee’s ISI program, in those cases where the

licensee chooses to use the risk-informed alternative method for requesting such changes, the NRC expects the licensee to document and submit its consideration of the four items described in the above "Description of the Information Collection" section. This documentation is used by the NRC as indicated in item A.2 below.

The NRC expects licensees to maintain sufficient information regarding how the plant meets its CLB to support NRC audit of these bases at any time such audit should become necessary. However, the details regarding the related documentation that must be maintained, and for how long, are not explicitly provided in the regulations (other than that provided by the records-retention aspects of 10 CFR 50.71(c), which are discussed in the next-to-last paragraph under "Technical Specifications" below).

Licensee requests for CLB changes to various portions of their in-service inspection programs are voluntary. The availability of the risk-informed alternative for requesting such changes in no way makes the licensee's present in-service inspection program unacceptable. Each licensee will therefore request such a change if and when the licensee decides it is to its advantage (by virtue of concentrating its inspection efforts on the more risk-significant portions of its piping and pressure boundaries, and by the resulting increased operating flexibility) to request such a change. Therefore, the frequency of in-service inspection program change submittals using the risk-informed alternative method is not known with any certainty, although the staff's best estimates are used in item 12 below ("Estimate of Burden").

In-Service Testing (IST, RG-1.175, and the generically applicable RG-1.174 and RG-1.200):

10 CFR 50.55a(f), "Inservice testing requirements," specifies in detail, according to the date of issuance of the plant's construction permit, the editions of Section XI of the ASME Boiler and Pressure Vessel Code and Addenda to which the in-service testing of the plant's pumps and valves must comply, including the reporting and recordkeeping that is expected as part of the licensee's IST program.

In order for the licensee to ensure, and the NRC to verify, that the requirements of this regulation (and the referenced codes and addenda) continue to be met following changes to the licensee's IST program, in those cases where the licensee chooses to use the risk-informed alternative method for requesting such changes, the NRC expects the licensee to document and submit its consideration of the four items described in the above "Description of the Information Collection" section. This documentation is used by the NRC as indicated in item A.2 below.

The NRC expects licensees to maintain sufficient information regarding how the plant meets its CLB to support NRC audit of these bases at any time such audit should become necessary. However, the details regarding the related documentation that must be maintained, and for how long, are not explicitly provided in the regulations (other than that provided by the records-retention

aspects of 10 CFR 50.71(c), which are discussed in the next-to-last paragraph under “Technical Specifications” below).

Licensee requests for CLB changes to various portions of their in-service testing programs are voluntary. The availability of the risk-informed alternative for requesting such changes in no way makes the licensee’s present in-service testing program unacceptable. Each licensee will therefore request such a change if and when the licensee decides it is to its advantage (by virtue of concentrating its testing efforts on the more risk-significant pumps and valves, and by the resulting increased operating flexibility) to request such a change. Therefore, the frequency of in-service testing program change submittals using the risk-informed alternative method is not known with any certainty, although the staff’s best estimates are used in item 12 below (“Estimate of Burden”).

Graded Quality Assurance (GQA, RG-1.176, and the generically applicable RG-1.174 and RG-1.200):

10 CFR 50 Appendix B, “Quality Assurance Criteria,” describes the requirements of the quality assurance (QA) program that must be documented and applied to all activities affecting the safety-related functions of the plant’s equipment, including the reporting and recordkeeping that is expected as part of the licensee’s QA program. The overall purpose of the QA program is to establish a set of systematic and planned actions that are necessary to provide adequate confidence that safety-related plant equipment will perform satisfactorily in service.

The requirements delineated in 10 CFR 50 Appendix B allow QA program controls to be applied in a “graded” manner, that is, with greater efforts applied to QA programs related to more safety-significant equipment and activities, and lesser efforts applied to QA programs related to less safety-significant equipment and activities. In the past, engineering judgment provided the general mechanism for evaluating the relative importance to safety of plant equipment and activities, resulting in little advantage being taken of the regulation’s provision that graded QA programs could be applied. The risk-informed alternative for making QA program changes (described in the subject RG-1.176) encourages graded QA (GQA) programs by providing a more systematic methodology for categorizing safety-related equipment and activities according to their safety importance, and for applying commensurate QA activities to each category.

In order for licensees to ensure that the requirements of 10 CFR 50 Appendix B continue to be met following changes to the licensee’s QA program, in those cases where the licensee chooses to use the risk-informed alternative method for requesting such changes, the NRC expects licensees to document their consideration of the four items described in the above “Description of the Information Collection” section. Because the governing regulation (10 CFR 50 Appendix B) allows QA activities to be applied in a graded manner, and because there is variety in the exact commitment made by individual licensees in their CLB regarding QA programs, certain licensees can adopt certain aspects of graded QA programs without prior NRC approval. However, in those cases, the NRC expects licensees to document their consideration of the above-described

four items for NRC's use during later audits of their QA program. This documentation may be used by NRC as indicated in item A.2 below.

The NRC expects licensees to maintain sufficient information regarding how the plant meets its CLB to support NRC audit of these bases at any time such audit should become necessary. However, the details regarding the related documentation that must be maintained, and for how long, are not explicitly provided in the regulations (other than that provided by the records-retention aspects of 10 CFR 50.71(c), which are discussed in the next-to-last paragraph under "Technical Specifications" below).

Licensee requests for CLB changes to various portions of their quality assurance programs are voluntary. The availability of the risk-informed alternative for requesting such changes in no way makes the licensee's present quality assurance program unacceptable. Each licensee will therefore request QA program changes if and when the licensee decides it is to its advantage (by virtue of concentrating its QA efforts on the more risk significant SSCs and activities in its plant, and by the resulting increased operating flexibility) to request such a change. Therefore, the frequency of QA program change submittals using the risk-informed alternative method is not known, although the staff's best estimates are used in item 12 below ("Estimate of Burden").

Technical Specifications (TS, RG-1.177, and the generically applicable RG-1.174 and RG-1.200):

10 CFR 50.36, "Technical Specifications," requires that technical specifications be included as part of the plant's license specifying certain safety and control limits and settings, limiting conditions for operations, surveillance requirements, design features, administrative controls, and required notifications and reports, and it includes specification of the reporting and recordkeeping that is expected as part of the licensee's TS program. Requests for changes to technical specifications are submitted as applications for amendments to the plant's operating license.

Over the past several years, applications for license amendments for technical specification changes have made increasing use of quantitative risk evaluations (i.e., many of the requests are "risk-informed"). Thus, issuance of the subject RG-1.177 serves to standardize the approach to making such risk-informed applications.

In order for the licensee to ensure, and the NRC to verify, that the requirements of this regulation continue to be met following changes to the licensee's TS program, the NRC expects the licensee to document and submit its consideration of the four items described in the above "Description of the Information Collection" section. This documentation is used by the NRC as indicated in item A.2 below.

10 CFR 50.71(c) states, "Records that are required by the regulations in this part, by license condition, or by technical specifications, must be retained for the period specified by the appropriate regulation, license condition, or technical specification. If a retention period is not otherwise specified, these records must

be retained until the Commission terminates the facility license.” Thus, the required retention period varies according to the particular regulations, license conditions, or technical specifications that govern the particular aspect of the plant’s CLB that is being changed.

Licensee requests for license amendments for technical specification changes are usually voluntary, but are sometimes in response to regulatory changes or regulatory positions that reflect changes in risk perspectives (for example, as caused by the occurrence of a significant operating event). Therefore, the frequency of technical specification change submittals using the risk-informed alternative method is not known with any certainty, although the staff’s best estimates are used in item 12 below (“Estimate of Burden”).

Risk-Informed Safety Classification (RISC, RG-1.201, and the generically applicable RG-1.174 and RG-1.200):

Existing regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, specify recordkeeping and reporting requirements associated with structures, systems, and components (SSCs) used in a nuclear power plant. Certain provisions of these regulations 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.

On November 22, 2004, the U.S. Nuclear Regulatory Commission (NRC) adopted 10 CFR 50.69 (69 FR 68008). This regulation permits power reactor licensees and license applicants to implement an alternative regulatory framework with respect to “special treatment,” where special treatment refers to those requirements that provide increased assurance beyond normal industrial practices that SSCs perform their design-basis functions. Under this framework, licensees using a risk-informed process for categorizing SSCs according to their safety significance can remove SSCs of low safety significance from the scope of certain identified special treatment requirements.

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 included to specify the process for obtaining the Nuclear Regulatory Commission (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 voluntarily choose to implement the alternative requirements of 10 CFR 50.69.

To use the alternative provisions of 10 CFR 50.69, a licensee or applicant must evaluate the safety significance of SSCs and categorize each SSC into one of four categories defined as risk-informed safety class (RISC)-1, RISC-2, RISC-3,

and RISC-4. Section 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 are maintained.

10 CFR 50.69 provisions may be used by power reactor applicants for a Part 50 or Part 52 license, 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 prior 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 licensing processes in 10 CFR 50.34, 10 CFR 50.90 or 10 CFR 52.

In May 2006, the NRC issued for trial use, Regulatory Guide (RG) 1.201, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance," which describes a method that the NRC staff considers acceptable for use in complying with the Commission's requirements in 10 CFR 50.69 with respect to the categorization of SSCs that are considered in risk-informing special treatment requirements. This categorization method endorses, with a number of clarifications, the process that the Nuclear Energy Institute (NEI) describes in Revision 0 of its guidance document NEI 00-04, "10 CFR 50.69 SSC Categorization Guideline," dated July 2005. Specifically, this process determines the safety significance of SSCs and categorizes them into one of four risk-informed safety class (RISC) categories.

This trial regulatory guide provides interim guidance for complying with the NRC's requirements in 10 CFR 50.69, by using the process described in Revision 0 of NEI 00-04 to determine the safety significance of SSCs and placing them into the appropriate RISC categories. The safety significance of SSCs is determined using an integrated decision-making process, which incorporates both risk and traditional engineering insights. The safety functions of SSCs include both the design-basis functions (derived from the safety-related definition) and functions credited for preventing and/or mitigating severe accidents. Treatment requirements are then commensurately applied for the categorized SSCs to maintain their functionality.

Aspects of the rule that impact reporting and recordkeeping involve the following:

10 CFR 50.69(b)(1) identifies the special treatment requirements for which the alternative 50.69 treatment requirements may be substituted for licensees and applicant voluntarily implementing section 50.69. These alternative treatment requirements are in 10 CFR 50.69(d) and 10 CFR 50.69(e). This is an alternative to a number of the special treatment 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 address 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 power reactor licensee choosing to implement 10 CFR 50.69 must submit an application for a license amendment pursuant to 10 CFR 50.90. This requirement exists because 10 CFR 50.69 relies on a robust categorization process, as described in RG 1.201 and NEI 00-04, to provide reasonable confidence that the safety significance of SSCs is correctly determined. To ensure a robust categorization is employed, 10 CFR 50.69 requires the categorization process to be reviewed and approved by the NRC prior to implementation of 10 CFR 50.69. As described by the rule in this subsection, the license amendment contains the following information:

- (i) A description of the categorization process that meets the requirements of 10 CFR 50.69(c);
- (ii) 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 (including the plant-specific PRA, margins-type approaches, or other systematic evaluation techniques used to evaluate severe accident vulnerabilities) are adequate for the categorization of SSCs;
- (iii) Results of the PRA review process to be conducted to meet 10 CFR 50.69(c)(1)(i); and,
- (iv) A description of, and basis for acceptability of, the evaluations to be conducted to satisfy 10 CFR 50.69(c)(1)(iv) to show that the potential increase in risk would be small considering the changes to treatment permitted by implementation of 10 CFR 50.69. The evaluations shall include the effects of common cause interaction susceptibility, and the potential impacts from known degradation mechanisms for both active and passive functions, and address internally and externally initiated events and plant operating modes (e.g., full power and shutdown conditions).

An applicant for a Part 50 or Part 52 license would include this information as part of their application. A robust, risk-informed categorization process that provides high confidence that the safety significance of SSCs is correctly determined is the cornerstone of 10 CFR 50.69. The Probabilistic Risk Assessment (PRA) used to support SSC categorization provides important input to the categorization 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 license amendment 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 decision-making 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), these records 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.

Properly implemented, the above requirements ensure that the validity of the categorization process and results are maintained throughout the operational life of the plant.

In addition, the NRC has reviewed and updated, as appropriate, the current inspection procedures under the NRC Reactor Oversight Process to incorporate inspection guidance for monitoring the implementation of 10 CFR 50.69 at nuclear power plants. The NRC intends to conduct sample inspections of plants implementing 10 CFR 50.69 in a manner that is sensitive to conditions that could significantly increase risk. The sample inspections will focus on the

implementation of the categorization process approved as part of the NRC review of the 10 CFR 50.69 license amendment request. The sample inspections will also evaluate the treatment processes established under 10 CFR 50.69 with primary attention directed to programmatic and common-cause issues; including those associated with known degradation mechanisms. The inspections may provide operating experience information on RISC-3 SSCs that can also be provided to other licensees.

The exact number of facilities affected by the section 50.69 information collection requirements is uncertain because of the voluntary nature of these requirements. Recently the licensee for Vogtle, Units 1 and 2 submitted a pilot application requesting approval to implement 10 CFR 50.69. This pilot is expected to take two years to complete, which will then be followed by incorporating lessons learned into industry and regulatory guidance documents prior to receiving additional applications. Thus, for the next three years, this application for two plant licenses is the only active review expected and used in item 12 below ("Estimate of Burden").

2. Agency Use of Information

In-Service Inspection (RG-1.178, and the generically applicable RG-1.174 and RG-1.200):

The information expected as described in item A.1 will be used by responsible NRC personnel to make the finding that the requirements of the plant's CLB in areas related to in-service inspection will continue to be satisfied once the requested changes are made, thus insuring the continuing validity of the plant's operating license.

In-Service Testing (RG-1.175, and the generically applicable RG-1.174 and RG-1.200):

The information expected as described in item A.1 will be used by responsible NRC personnel to make the finding that the requirements of the plant's CLB in areas related to in-service testing will continue to be satisfied once the requested changes are made, thus insuring the continuing validity of the plant's operating license.

Quality Assurance (RG-1.176, and the generically applicable RG-1.174 and RG-1.200):

For licensees whose license requires NRC approval prior to implementation of the specific type of QA change being requested (see discussion in item A.1), the submitted information (also described in item A.1) is used by the responsible NRC personnel to make the finding that the QA requirements will continue to be met once the requested QA changes are made. For licensees whose license does not require prior approval (see discussion in item A.1), the same information should be used by the licensee to determine that the QA requirements will continue to be met once the requested changes are made, and also should be retained on-site for possible NRC inspection to confirm that the plant continues to conform to its CLB in areas related to quality assurance.

Technical Specifications (RG-1.177, and the generically applicable RG-1.174 and RG-1.200):

The information expected as described in item A.1 is used by responsible NRC personnel in the review and approval of the requested license amendment, thus ensuring the continuing validity of the plant's operating license once the requested technical specification changes are made.

Risk-Informed Safety Classification (RISC, RG-1.201, and the generically applicable RG-1.174 and RG-1.200):

The information expected as described in item A.1 is used by responsible NRC personnel in the review and approval of the requested license amendment, thus ensuring the continuing validity of the plant's operating license once the requested changes are made.

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. It is estimated that approximately 60% of the potential responses are filed electronically.

4. Effort 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

Not applicable. These submittals are prepared by licensees of nuclear power plants, which are not small businesses.

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

These voluntary collections are not required on a specified frequency (or at all). The only effect on Federal Programs of not receiving information, or receiving it less frequently, would be that of not allowing licensees the possible savings in resources and the increased operating flexibility that would otherwise result from such submittals.

7. Circumstances which Justify Variation from OMB Guidelines

These records and reports become part of the licensing basis of the plant (or the license itself, as noted in the sections that discuss technical specifications). The NRC expects licensees to maintain sufficient information regarding how the plant meets its CLB to support NRC audit of these bases at any time such audit should become necessary. However, the details regarding how much related documentation must be maintained, and for how long, are not explicitly provided in the regulations (other than that provided by the records-retention aspects of 10 CFR 50.71(c), which are discussed in the next-to-last paragraph under “Technical Specifications” above).

8. Consultations Outside NRC

Opportunity for public comment on the information collection requirements for this clearance package was published in the Federal Register on May 14, 2013 (78 FR 28244). No comments were received.

9. Payment of Gift to Respondents

Not applicable.

10. Confidentiality of the Information

Confidential and proprietary information is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b). However, no information normally considered confidential or proprietary information is typically requested.

11. Justification for Sensitive Questions

No sensitive information is requested.

12. Estimate of Burden and Burden Hour Cost

ISI and IST burdens are included in Section 16 of the OMB clearance for 10 CFR 50. However, the burden for CLB changes, including but not limited to CLB changes related to ISI and IST, is covered in Section 1 of the OMB clearance for 10 CFR 50 (license amendments). The number of licensing submittals listed in the tables below for ISI and IST are the additional annual submittals that are anticipated as a result of the risk-informed alternative method. These submittals were not anticipated under the present methodology, and thus are not covered by Section 16 and Section 1 of the present OMB clearance.

Plant licenses require that the sections of the licensees' Final Safety Analysis Reports (FSARs) that describe its ISI program be updated when the ISI programs are changed (e.g., when a risk-informed ISI program is adopted). This is a relatively minor effort since the necessary information will already have been collected in support of the submittal that requests the change. Therefore, the “FSAR update” burden is included in the line items provided in the table below.

QA burdens are included in Section 15 of the OMB clearance for 10 CFR 50.

However, the burden for CLB changes, including but not limited to CLB changes related to QA, is covered in Section 1 of the OMB clearance for 10 CFR 50 (license amendments). Due to the pilot activities associated with 10 CFR 50.69, risk-informed special treatment requirements, GQA applications under RG 1.176 are no longer anticipated. The single submittal listed in the tables below for the risk-informed special treatment program is the current pilot application. No other applications are anticipated during this 3-year period while the pilot application is reviewed and lessons learned from the pilot are integrated into the associated guidance. This submittal is not anticipated under the present methodology, and thus is not covered by Section 15 and Section 1 of the present OMB clearance.

Burdens for all types of TS changes are included in Section 1 (license amendments) of the OMB clearance package for 10 CFR 50. Section 1 includes, but is not limited to, the relatively small sub-set of all TSs that are related to allowed outage times (AOTs) and surveillance test intervals (STIs), which are the only types of TSs that can be changed utilizing the risk-informed alternative method presented by the subject regulatory guides. Because the burden is accounted for in Section 1, no additional burden is included in this Section.

The estimated burden has been revised based on the actual reporting and ongoing recordkeeping related to plants that have made licensing changes. Also, there has been a change to the base burden cost from \$274 per hour. The reason for each change is discussed in the corresponding paragraph in Item 15 below.

ANNUAL REPORTING REQUIREMENTS
FOR SUBMITTALS REQUESTING RI PROGRAM APPROVALS

Section/ Reg. Guide	Number ¹ of Lic. Submittals	Hours per Submittal	Total Annual Burden (Hrs.)	Cost @ \$274/Hr.
10CFR50.55a(g) RG-1.178, ISI	10	530	5,300	\$1,452,200
10CFR50.55a(f) RG-1.175, IST ^(a)	0	550	0	0
10CFR50 App B RG-1.176, GQA ^(a)	0	550	0	0
10CFR50.36 RG-1.177, (TS)	12	400	4,800	1,315,200
10CFR50.36 RG-1.177, Emer./Exigent	5	100	500	137,000
10CFR50.69 RG 1.201, (RISC) ^(b)	0.333	600	200	54,800
TOTALS	27.333		10,800	\$2,959,200

(a) RG 1.175 (IST) submittals have ceased due to equivalent relief from ASME Code Case OMN-3, and RG 1.176 (GQA) submittals have ceased due to issuance of 10 CFR 50.69 (RG 1.201, RISC).

(b) During the first two years of the pilot, the license application will be under NRC review and the licensee will not have implemented the program. It is estimated that during the third year, when the licensee implements the program that one 50.69(g) action will be taken. Thus, 1 over 3 years = 0.333 respondents annually.

¹ Recordkeeping for the implementation and monitoring plan is a continuing effort. After making a risk-informed change in the CLB, each licensee would be expected to expend this effort every year on a continuing basis.

ANNUAL RECORDKEEPING REQUIREMENTS
TO SUPPORT SUBMITTALS REQUESTING RI PROGRAM APPROVALS

Section/ (Reg. Guide)	Number ² of Lic. Program Changes	Hours per Program Change	Total Annual Burden (Hrs.)	Cost @ \$274/Hr.
10CFR50.55a(g) RG-1.178, ISI	10	3,750	37,500	\$10,275,000
10CFR50.55a(f) RG-1.175, IST ^(a)	0	2,250	0	0
10CFR50 App B RG-1.176, GQA ^(a)	0	2,250	0	0
10CFR50.36 RG-1.177, (TS)	12	1,000	12,000	3,288,000
10CFR50.36 RG-1.177, Emer./Exigent	5	100	500	137,000
10CFR50.69 RG 1.201, (RISC) ^(b)	0.333	1,150	383	104,942
TOTALS	27.333		50,383	\$13,804,942

(a) RG 1.175 (IST) submittals have ceased due to equivalent relief from ASME Code Case OMN-3, and RG 1.176 (GQA) submittals have ceased due to issuance of 10 CFR 50.69 (RG 1.201, RISC).

(b) One application representing two plant licenses for the three year period results in 1 recordkeeper. However, over the first two years the pilot application will be under review and not implemented at the plant. As such, the 1 recordkeeper is not utilized until the third year. Thus, 1 over 3 years = 0.333 recordkeepers annually. Also note the burden 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. These aspects are in 10 CFR 50.69(d)(2) and (e)

² Recordkeeping for the implementation and monitoring plan is a continuing effort. After making a risk-informed change in the CLB, each licensee would be expected to expend this effort every year on a continuing basis.

ANNUAL RECORDKEEPING REQUIREMENTS
TO SUPPORT IMPLEMENTATION AND MONITORING PLAN

Section/ (Reg. Guide)	Number ³ of Lic. Program Changes	Hours per Program Change	Total Annual Burden (Hrs.)	Cost @ \$274/Hr.
10CFR50.55a(g) RG-1.178, ISI	98	200	19,600	\$5,370,400
10CFR50.55a(f) RG-1.175, IST ^(a)	3	200	600	164,400
10CFR50 App B RG-1.176, GQA ^(a)	1	200	200	54,800
10CFR50.36 RG-1.177, (TS)	100	50	5,000	1,370,000
10CFR50.36 RG-1.177, Emer./Exigent	0	0	0	0
10CFR50.69 RG 1.201, (RISC) ^(b)	0.333	920	307	84,118
TOTAL	202.333		25,707	\$7,043,718

(a) RG 1.175 (IST) submittals have ceased due to equivalent relief from ASME Code Case OMN-3, and RG 1.176 (GQA) submittals have ceased due to issuance of 10 CFR 50.69 (RG 1.201, RISC).

(b) Annualized cost for categorization and documentation of basis for decisions under 10 CFR 50.69(c) assumes implementation for 1 application, which applies to 2 plant licenses, occurs over 3 years, but the licensee has the option to use a different period. Since for the first two years the categorization process application is under review by the NRC, the licensee will not implement the program until the third year. Thus, 1 application over 3 years = 0.333 annual applications. This also represents the estimated cost for review and revision of licensee procedures for treatment practices to meet 10 CFR 50.69(d) and (e).

Total reporting burden = 10,800 hours

Total recordkeeping burden = 76,090 hours (50,383 + 25,707 hours)

Total burden = 86,890 hours

³ Recordkeeping for the implementation and monitoring plan is a continuing effort. After making a risk-informed change in the CLB, each licensee would be expected to expend this effort every year on a continuing basis.

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 \$8,339 (76,090 hours x \$274 x .0004).

14. Estimated Annualized Cost to the Government

The following tables and text present this information.

ANNUAL GOVERNMENT REVIEW OF
REQUESTS FOR RI PROGRAM APPROVAL

Section/ (Reg. Guide)	Number of Reviews	Hours per Review	Total Annual Review (Hrs.)	Gov. Cost @ \$274/Hr.
10CFR50.55a(g) RG-1.178, ISI	10	400	4,000	\$1,096,000
10CFR50.55a(f) RG-1.175, IST ^(a)	0	1,000	0	0
10CFR50 App B RG-1.176, GQA ^(a)	0	750	0	0
10CFR50.36 RG-1.177, (TS)	12	400	4,800	1,315,200
10CFR50.36 RG-1.177, Emer./Exigent	5	100	500	137,000
10CFR50.69 RG 1.201, (RISC)	0.333	1,000	333	91,242
TOTAL	27.333		9,633	\$2,639,442

(a) RG 1.175 (IST) submittals have ceased due to equivalent relief from ASME Code Case OMN-3, and RG 1.176 (GQA) submittals have ceased due to issuance of 10 CFR 50.69 (RG 1.201, RISC).

ANNUAL GOVERNMENT REVIEWS/AUDITS OF RECORDS
SUPPORTING IMPLEMENTATION AND MONITORING PLAN

Section/ (Reg. Guide)	Number ⁴ of Reviews/Audits	Hours per Review/Audit	Total Annual Rev./Aud. (Hrs.)	Cost @ \$274/Hr.
10CFR50.55a(g) RG-1.178, ISI	98	50	4,900	\$1,342,600
10CFR50.55a(f) RG-1.175, IST	3	40	120	32,880
10CFR50 App B RG-1.176, GQA	1	45	45	12,330
10CFR50.36 RG-1.177, (TS)	100	50	5,000	1,370,000
10CFR50.36 RG-1.177, Emer./Exigent	0	0	0	0
10CFR50.69 RG 1.201 (RISC)	0.333	100	33	9,042
TOTAL	202.333		10,098	\$2,766,852

This cost is fully recovered through fee assessments to NRC licensees pursuant to 10 CFR 170 and/or 10 CFR 171.

15. Reason for Change in Burden or Cost

There is an overall reduction of 3,210 hours, mainly in recordkeeping, due to the reduction of expected submittals under 50.69(g) during this clearance period; down from 1 to .333. There is an increase in costs due to the increase in the fee rate from \$257 to \$274.

16. Publication for Statistical Use

The information will not be published for statistical use.

4 [?]See footnote #1 (under previous table related to recordkeeping for implementation and monitoring plan)

17. Reason for Not Displaying the Expiration Date

The information collections contained in these regulatory guides are contained in a regulation. Revising the guides merely to update the expiration date unnecessarily expends agency resources.

18. Exceptions to the Certification Statement

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in this collection of information.