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 thru RG-1.178) (3150-0011)

Description of 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), and in an overall guide generically applicable to all four of these areas (RG-1.174), 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 Part 50 as detailed below in Section A.1. No changes or additions have been made to those sections of Part 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 acceptable as an alternative to this risk-informed method).

The risk-informed 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 activities to be applied to a wide variety of a plant's systems, structures, 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. This 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 insignificant 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 four areas, the applicable Regulatory Guide (supplemented by additional generic guidance from the overall guide, RG-1.174) 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 the principles that adequate defense-in-depth is maintained, that sufficient safety margins are maintained, and that 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 which 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. Part 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 Part 50 OMB clearance covers the recordkeeping and reporting burdens for inservice inspection and inservice 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 (a 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 expected to be an integral part of these Risk-Informed (RI) 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 In-Service Inspection (ISI) and In-Service Testing (IST), is covered in Section 1 of the OMB clearance for 10 CFR Part 50 (license amendments).

Section 15 of the current 10 CFR Part 50 OMB clearance covers 10 CFR Part 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. Appendix B to 10 CFR Part 50 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 Section A.1 of Section 15 states:

> "Any changes to this {QA} plan must be reported to the NRC like other license conditions of a similar nature. It is estimated that each licensee/applicant will initiate one such change per year. Such changes are included in the total license amendment requests reflected in the Section 1 Supporting Statement."

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 once the changes have been implemented.

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 Part 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):

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 inservice 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 Section 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 inservice inspection programs are voluntary. The availability of the risk-informed alternative for requesting such changes in no way makes the licensee's present inservice 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 inservice 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").

<u>In-Service Testing (IST, RG-1.175, and the generically applicable RG-1.174)</u>:

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 inservice 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 Section 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 inservice testing programs are voluntary. The availability of the risk-informed alternative for requesting such changes in no way makes the licensee's present inservice 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 inservice 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").

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

Appendix B to 10 CFR Part 50, "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 Appendix B to 10 CFR Part 50 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 judgement 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 Appendix B to 10 CFR Part 50 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 (Appendix B to 10 CFR Part 50) 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 Section 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):

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., the requests have become more "risk-informed"). Thus, issuance of the subject RG-1.177 serves more to codify and standardize existing practice than it does to significantly change that practice.

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 Section 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).

2. Agency Use of Information

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

The information expected as described in Section 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 inservice 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):

The information expected as described in Section 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 inservice 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):

For licensees whose license requires NRC approval prior to implementation of the specific type of QA change being requested (see discussion in Section A.1), the submitted information (also described in Section 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 Section 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):

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

3. Reduction of Burden Through Information Technology

Because each submittal is unique, is made only once, and is unlikely to be developed from other compiled information sources, the reports do not lend themselves readily to the use of technological collection techniques for submission. Thus, no reports are submitted electronically, and the NRC foresees no opportunity to reduce the burden of information submittal through the use of information technology.

4. Effort to Identify Duplication and Use Similar Information

These are licensing submittals describing the CLB of the plant. Each submittal is a unique combination of information which is assembled by the licensee for a specific purpose for its specific plant. No similar information exists. The Information Requirements Control Automated System (IRCAS) was searched and no duplication was found.

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

The opportunity for public comment was published in the Federal Register on August 29, 2003 (68 FR 52063). No comments were received.

9. Payment of Gift to Respondents

Not applicable.

10. Confidentiality of the Information

No information normally considered confidential is required.

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 Part 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 Part 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 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. The "FSAR update" burden is shown on a separate line in the "reporting burden" table below.

QA burdens are included in Section 15 of the OMB clearance for 10 CFR Part 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 Part 50 (license amendments). The single submittal listed in the tables below for GQA is the single additional annual submittal that is anticipated as a result of the risk-informed alternative method. This submittal was not anticipated under the present methodology, and thus is not covered by Section 15 and 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.

ANNUAL REPORTING REQUIREMENTS
FOR SUBMITTALS REQUESTING RI PROGRAM APPROVALS

Section/ Reg. Guide	Number of Lic. Submittals	Hours per Submittal	Total Annual Burden (Hrs.)	Cost @ $156/Hr.
10CFR50.55a(g) RG-1.178, ISI	6	530	3,180	$496,080
(FSAR Update)	6	20	120	18,720
10CFR50.55a(f) RG-1.175, IST	3	550	1,650	257,400
10CFR50 App B RG-1.176, GQA	1	550	550	5,800
TOTALS	16		5,500	$858,000

ANNUAL RECORDKEEPING REQUIREMENTS
TO SUPPORT SUBMITTALS REQUESTING RI PROGRAM APPROVALS

Section/ (Reg. Guide)	Number of Lic. Program Changes	Hours per Program Change	Total Annual Burden (Hrs.)	Cost @ $156/Hr.
10CFR50.55a(g) RG-1.178, ISI	6	3,750	22,500	$3,510,000
10CFR50.55a(f) RG-1.175, IST	3	2,250	6,750	1,053,000
10CFR50 App B RG-1.176, GQA	1	2,250	2,250	351,000
TOTALS	10		31,500	$4,914,000

ANNUAL RECORDKEEPING REQUIREMENTS
TO SUPPORT IMPLEMENTATION AND MONITORING PLAN

Section/ (Reg. Guide)	Number[1] of Lic. Program Changes	Hours per Program Change	Total Annual Burden (Hrs.)	Cost @ $156/Hr.
10CFR50.55a(g) RG-1.178, ISI	48	200	9,600	$1,497,600
10CFR50.55a(f) RG-1.175, IST	24	200	4,800	748,800
10CFR50 App B RG-1.176, GQA	8	200	1,600	249,600
TOTAL	80	200	16,000	$2,496,000

Total reporting burden = 5,500 hours
Total recordkeeping burden = 47,500 hours (31,500 + 16,000 hours)
Total burden = 53,000 hours

[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. Thus, after the first three years there will be (using, for example, ISI, for which the tables on the previous page indicate 6 submittals are expected each year) 36 such efforts are underway, and 42 in the fourth year, 48 such efforts in the fifth year, and 54 such efforts in the sixth year, for an average per year for the three-year reporting period of 48 (42 + 48 + 54 = 144 / 3). This same calculation has been applied to the recordkeeping for the submittals expected each year for ISI, IST, and GQA, (as given in the recordkeeping table on the previous page).

13. Estimate of Other Additional Costs

Based on the number of pages maintained for a typical clearance, the records storage cost has been determined to be equal to .0004 percent of the recordkeeping burden cost. Therefore, the storage cost for this clearance is estimated to be $2,964 (47,500 hours x $156 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 @ $156/Hr.
10CFR50.55a(g) RG-1.178, ISI	6	1,000	6,000	$936,000
10CFR50.55a(f) RG-1.175, IST	3	1,000	3,000	468,000
10CFR50 App B RG-1.176, GQA	1	750	750	117,000
TOTAL	10		9,750	$1,521,000

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

Section/ (Reg. Guide)	Number[2] of Reviews/Audits	Hours per Review/Audit	Total Annual Rev./Aud. (Hrs.)	Cost @ $156/Hr.
10CFR50.55a(g) RG-1.178, ISI	48	50	2,400	$374,400
10CFR50.55a(f) RG-1.175, IST	24	40	960	149,760
10CFR50 App B RG-1.176, GQA	8	45	360	56,160
TOTAL	80	135	3,720	$580,320

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

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

15. Reason for Change in Burden or Cost

The burden was changed to reflect the ongoing recordkeeping related to plants that made licensing changes in the previous reporting period. Also, there has been a change to the base burden cost from $141 to $156.

16. Publication for Statistical Use

This information will not be published for statistical use.

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 scarce 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.