

Section 16

DRAFT SUPPORTING STATEMENT
FOR
QUALITY ASSURANCE RECORDS

10 CFR 50.55a*, 50.54(a), 50.55(f), APPENDIX A (CRITERION 1), AND APPENDIX B

DESCRIPTION OF THE INFORMATION COLLECTION

Quality Assurance (QA) records associated with the activities listed below are used by the licensee, the National Board of Boiler and Pressure Vessel Inspectors, insurance companies and the NRC in the review and confirmation of quality related activities. Most States and all nuclear insurers require that the ASME Boiler and Pressure Vessel (B&PV) Code (Section III) be used in the design, construction, testing and inspection of nuclear power reactors.

Appropriate records of the design, fabrication, erection and testing of structures, systems and components important to safety shall be maintained by the licensee throughout the life of the plant.

1. Management: QA manual, procedures, and instructions
2. Qualification and training of personnel
3. Design
4. Procurement, items identification/control, acceptance status
5. Manufacture, installation/testing
6. Handling, storage and shipping
7. Inspection, testing and qualifying, including inspection status
8. Calibration
9. Special processes
10. Operation
11. Maintenance
12. Modification and repair
13. Audits
14. Non-conformance, corrective actions

A. JUSTIFICATION

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

Licensee burden hours will be spent on QA records development and maintenance, which pertain to Items 1 through 14 listed above. Appendix B requires that records be maintained for plant equipment that the licensee has designated to be "safety-related." Licensees must also generate records as required by Appendix A for plant equipment that they have determined to be

* See Part 17, separate Supporting Statement, for information collection requirements specified in 10 CFR 50.55a

"important-to-safety." The burden hours are estimated to be inclusive of both Appendix A and B records.

Regulatory Guide 1.28 (Rev. 3), "Quality Assurance Program Requirements (Design and Construction)" describes an acceptable method for complying with QA record requirements in accordance with 10 CFR Part 50. Except for a few regulatory positions in the Regulatory Guide, it endorses the common industry standard ANSI/ASME NQA-1-1983, "Quality Assurance Program Requirements for Nuclear Facilities." Maintenance of records as specified above is necessary so that evidence can be furnished to show that activities affecting quality have been accomplished in accordance with NRC regulations.

The type of records identified specifically in Criterion XVII of Appendix B to 10 CFR Part 50 are of particular importance to provide adequate evidence that licensee activities affecting quality have been accomplished in accordance with NRC regulatory requirements. Records pertaining to items which are important to safety are expected to be available for inspection and audit by the NRC in accordance with Criterion 1 of Appendix A to 10 CFR Part 50.

Reporting of changes to the QA program pursuant to 10 CFR Part 50.54(a) and 50.55(f) has been a requirement since March 1983. The licensee's QA Program Plan, after acceptance by the NRC, is a license condition. Any changes to this 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.

2. Agency Use of Information

Records required to be maintained for a specific activity are specified in the license application, license condition or permit, or NRC-approved documents. These records, some of which will be kept for the life of the facility, are available for inspection by the NRC, and are reviewed and examined to ascertain whether the activities affecting quality have been accomplished in accordance with NRC requirements. Also, in case of malfunction or failure of an item affecting safety, availability of plant records is necessary to aid in the determination of the cause of the failure. In addition, records maintenance is necessary for other important specific functions such as providing baseline data for in service inspection and providing data for trend analyses.

3. Reduction of Burden Through Information Technology

There is no legal obstacle to the use of information technology. Moreover, NRC encourages its use; however, at the current time, no responses are submitted electronically.

4. Effort to Identify Duplication and Use Similar Information

This information is only available from nuclear licensees. These records are not a

duplication of any other records maintained by the licensee or Federal government. The Information Requirements Control Automated System (IRCAS) was searched for agency duplication, and none was found.

5. Effort to Reduce Small Business Burden

The subject provisions do not affect small businesses.

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

QA records are collected as they are generated during design, construction, operation, and decommissioning of the plants. Less frequent collection is not an alternative.

7. Circumstances which Justify Variation from OMB Guidelines

The records must be retained throughout the life of the plant in order to support the review and confirmation of quality related activities.

8. Consultations Outside the NRC

Notice of opportunity for public comment on this information collections has been published in the Federal Register.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of the Information

This information is usually not confidential. If it were, the information would be handled in accordance with 10 CFR 2.790 of the NRC regulations.

11. Justification for Sensitive Questions

These regulations do not require sensitive information.

12. Estimated Industry Burden and Burden Hour Cost

a. Estimated Annual Reporting Burden

Licensee burden for each of
104 operating reactors is
10,000 hours (104 x 10,000) = 1,040,000 hrs/yr

19 permanently shutdown reactors is
2,500 hours (19 x 2,500) = 47,500 hrs/yr

104 licensees expend 160 burden
hrs each per report reporting changes
to the QA Programs (104 x 160) 16,640 hrs/yr

Total Burden Hours: 1,104,140 hrs/yr

Cost is based on \$141 per hour = \$155,683,740

b. Estimated Recordkeeping Burden

Based on staff experience, it is estimated that 75 percent of the total industry reporting burden encompasses hours expended annually for recordkeeping requirements. Recordkeeping requirements are, therefore, estimated to involve 828,105 hours annually.

13. Estimate of other Additional Costs

As discussed in Section 1 above, Regulatory Guide 1.28 describes an acceptable method for complying with QA record requirements. Licensees preserve the records in storage facilities that provide protection from hazards such as winds, floods, fires, and environmental conditions such as adverse humidity conditions. The costs associated with the records storage facilities are not known by the NRC, and would likely be incurred by licensees in the course of doing business.

14. Estimated Annualized Cost to the Federal Government

QA records are generated and maintained by licensees. The incremental cost of NRC audits and inspection of QA records is a small part of the total NRC inspection program consisting of the resident inspectors, regional inspections, and special inspections. Based on NRC staff experience, it is estimated that 333 hours/operating reactor and 83 hours/permanently shutdown reactor of the inspection effort is associated with records review. The total staff hours spent on records review is estimated to be 36,209 hours (333 hrs x 104 operating reactors and 83 hrs x 19 permanently shutdown reactors). Additionally, the annual NRC staff burden to review licensee QA plan changes is approximately 1.5 FTE (3,120 hours).

Therefore the estimated Federal cost is expected to be \$5,545,389 (\$141 x

39,329).

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

15. Reasons for Changes in Burden or Cost

The change reflects a reduction of 5 operating reactors and corresponding increase of 5 permanently shutdown reactors. It also reflects an increase in the base burden cost from \$128 to \$141 per hour.

16. Publication for Statistical Use

The collected information is not published for statistical purposes.

17. Reason for Not Displaying the Expiration Date

The requirement is contained in a regulation. 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.