FINAL SUPPORTING STATEMENT FOR 10 CFR PART 21

"REPORTING OF DEFECTS AND NONCOMPLIANCE"

(OMB Clearance No. 3150-0035)

Revision Request

DESCRIPTION OF THE INFORMATION COLLECTION

Title 10 of the *Code of Federal Regulations* (10 CFR) 21.21 requires directors and responsible officers of firms and organizations building, operating, owning, or supplying basic components to NRC licensed facilities, or conducting NRC licensed activities, to report defects in components and failures to comply that could create a substantial safety hazard (SSH). 10 CFR 21.51 requires each organization subject to 10 CFR Part 21 to maintain such records as may be required to assure compliance with 10 CFR Part 21.

A. JUSTIFICATION

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

Part 21, "Reporting of Defects and Noncompliance," implements Section 206 of the Energy Reorganization Act of 1974 (42 U.S.C. 5846). Section 206 requires individual directors and responsible officers of firms constructing, owning, operating, or supplying the basic components of any facility or activity licensed under the Atomic Energy Act to report immediately to the Commission the discovery of defects in basic components or failures to comply that could create an SSH. In addition to imposing obligations on the individual directors and responsible officers of NRC licensees, Section 206 also imposes obligations on the directors and responsible officers of non-licensees that construct facilities for or supply basic components to licensed facilities or activities. Any individual officer or director who knowingly fails to comply with the notification requirements is subject to civil penalties.

Part 21 contains reporting and recordkeeping requirements which ensure that the NRC is informed of safety defects so that the agency can take appropriate regulatory action. Records are required to be maintained so that technical issues may be effectively resolved and to facilitate enforceability of the regulations.

Section 21.7 provides that the Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR Part 21.

Section 21.21(a) requires the vendor (not an NRC licensee) or licensee to adopt appropriate procedures to:

(1) evaluate deviations and failures to comply to determine whether a defect exists that could result in an SSH. Depending upon the outcome of the evaluation, a report of the defect must be submitted to NRC as discussed under Section 21.21(d)(1) below.

(2) ensure that if the vendor or licensee cannot complete an evaluation of either the failure to comply or deviation within 60 days of its discovery, an interim written report should be submitted to the Commission describing the deviation or the failure to comply. The report must be submitted within 60 days of discovery of the deviation or the failure to comply.

(3) ensure that a director or responsible officer of a company covered by 10 CFR Part 21 be notified within 5 working days of the determination (based on the evaluation under Section 21.21(a)(1) and (2) above) that a defect or failure to comply exists.

Section 21.21(b) requires that a vendor that lacks the ability and/or information to perform an evaluation of a deviation transmit information to the purchasers of or affected licensees that possess the basic component within 5 working days of the determination. The purchasers or affected licensees are then expected to evaluate the information as discussed under Section 21.21(a)(1) above.

Section 21.21(d)(1) requires that a director or responsible officer subject to 10 CFR Part 21 or a person designated under 21.21(d)(5) notify the Commission when he or she obtains information reasonably indicating a failure to comply or a defect affecting (i) the construction or operation of a facility or an activity within the U.S. that is subject to NRC licensing requirements and that is within his or her organization's responsibility; or (ii) a basic component that is within his or her organization's responsibility and is supplied for a facility or an activity within the U.S. that is subject to NRC licensing requirements.

Section 21.21(d)(2) permits the non-reporting of defects and failures to comply if the individual director or responsible officer has actual knowledge that the NRC has already been notified.

Section 21.21(d)(3)(i) requires the Commission to be notified by the vendor, licensee or dedicating entity via telephone or facsimile within two days following receipt of information by a director or responsible officer that a defect or failure to comply exists.

Section 21.21(d)(3)(ii) requires the submittal of a written report by the vendor, licensee or dedicating entity to the Commission within 30 days of identification of a defect or failure to comply. The report contents are defined in Section 21.21(d)(4).

Section 21.21(e) provides for the Commission to obtain from individuals subject to 10 CFR Part 21 any needed additional information related to a defect or failure to comply.

Section 21.51(a)(1) requires vendors, licensees, or dedicating entity to retain records of evaluations of deviations and failures to comply for 5 years after the date of the evaluation.

Section 21.51(a)(2) requires vendors of basic components to retain notifications of defects or failures to comply that were sent to purchasers and affected licensees for 5 years after the date of the notification.

Section 21.51(a)(3) requires vendors of basic components to retain a record of purchasers of basic components for 10 years after delivery of the basic component or service associated with a basic component.

2. Agency Use of the Information

Reports submitted under 10 CFR Part 21 are reviewed by the NRC staff to determine whether the reported defects or failures to comply in basic components at NRC licensed facilities or activities are potentially generic safety problems. These reports have been the basis for the issuance of numerous NRC information notices, generic letters and bulletins that have contributed to the improved safety of the nuclear industry.

The records required to be maintained in accordance with 10 CFR 21.51 are subject to inspection by the NRC to determine compliance with the subject regulation. These records fall into four categories: records relating to evaluations defined by 10 CFR 21.3, records of previously submitted reports pursuant to 10 CFR 21.21, records of procedures required to assure compliance with 10 CFR Part 21, and procurement documents necessary to ensure that background specifications are available to evaluate potential defects and failures to comply.

Industry organizations, such as the Institute for Nuclear Operations (INPO) and the Nuclear Energy Institute (NEI), are urged to share and distribute such information to all affected parties as it becomes available. The NRC further disseminates significant generic information to all affected parties via NRC information notices, generic letters and bulletins, and encourages the elimination of duplicate reporting. Computer databases are used extensively by the NRC and the nuclear industry for tracking these reports.

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. NRC encourages the use of information technology.

4. Effort to Identify Duplication and Use Similar Information

Commission regulations contain several safety deficiency reporting requirements. Distinctions exist between these requirements. Revisions to 10 CFR Part 21 which became effective October 29, 1991, clarified the reporting and evaluation requirements to reduce duplication among 10 CFR Part 21, 10 CFR 50.55(e), 10 CFR 50.72, 10 CFR 50.73 and 10 CFR 73.71. See Section 21.21(d)(2) discussion, above.

The 10 CFR Part 21 regulation implements Section 206 of the Energy Reorganization Act of 1974, as amended. It is the only regulation that currently requires directors and responsible officers of firms and organizations building, operating, or owning NRC licensed facilities, supplying basic components and services, or conducting NRC licensed activities, to report defects and failures to comply that could create an SSH. Similar requirements are not currently available within the NRC or the industry to accomplish the intent of Section 206.

The Information Requirements Control Automated System (IRCAS) was searched for duplication and none was found.

5. Effort to Reduce Small Business Burden

Approximately 10,000 licensees and other organizations are under the scope of 10 CFR Part 21. The majority of these respondents are not considered to be small businesses. The revised 10 CFR Part 21, effective October 29, 1991, reduced the reporting burden for these licensees and other organizations by eliminating the need for duplicate reporting.

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

The 10 CFR Part 21 regulation has no specific period for reporting; instead, it requires the reporting of defects and failures to comply immediately after it is determined that they could create an SSH. Imposing greater restrictions to the collection of such information would reduce NRC effectiveness in the area of assessing potentially generic safety issues and in disseminating such information to affected parties.

7. Circumstances which Justify Variation from OMB Guidelines

The 10 CFR Part 21 regulation requires the reporting of defects and failures to comply that could create an SSH in facilities or activities licensed by the NRC. This information is needed within two days by telephone or facsimile and 30 days by written report to ensure that the NRC receives prompt notification of these defects and failures to comply, evaluates them, and is able to promptly disseminate to other licensees information regarding those defects and failures to comply that are determined to be potentially generic safety problems.

In addition, the 10 CFR Part 21 regulation requires records to be retained beyond the 3-year limit established by OMB. This longer retention is required because review of experience with existing records in recent reviews indicates that a 3-year retention would not be adequate for review and evaluation of recurring defects. It is necessary to be able to verify that the deviation has been adequately evaluated, reported, and corrected as required. Records of evaluations are therefore required to be retained for 5 years. Supplier notifications to purchasers/affected licensees are retained for 5 years. Supplier records of the identification of purchasers of basic components are retained for 10 years after delivery of the basic component.

8. Consultation Outside the NRC

Opportunity to comment on the information collection was published in the Federal Register on April 24, 2001 (66 FR 20691). No comments were received.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of the Information

Information that is identified as proprietary or confidential, which is defined as information that if disclosed could do substantial harm to an organization's competitive position, would be withheld from disclosure under a Freedom of Information Act request if the NRC determines that it is in the public interest to withhold it.

11. Justification for Sensitive Questions

This rule does not request sensitive information.

12. Estimated Industry Burden and Burden Hour Cost

The total burden to respondents for reporting and recordkeeping in accordance with 10 CFR Part 21 is estimated to be 12,565 hours and $1,884,750 at $150 per hour of professional staff time. This estimate includes 9,640 hours for reporting and 2,925 hours for recordkeeping. Details are included in the attached industry burden table.

13. Estimate of Other Additional Costs

None.

14. Estimated Annual Cost to the Federal Government

NRC Burden Table

Activity	Reports* (issues/year)	Effort (hour/issue)	Total (hour/year)	Cost ($/year @$150/hour)
Review Part 21 issues	70	60	4,200	$630,000

*NRC currently reviews reports by issue, not by the type of report (initial notification, reports within 30 days, or reports if not resolved within 60 days). During the period 1996-2000, NRC received 824 Part 21 reports. The number of initial notifications of distinct issues was 330 and the number of followup documents was 494. Annual averages are thus about 70 issues per year and about 100 followup reports per year.

During the period 1998-2000, the average annual number of reports received later than 60 days was about 10, leaving an annual average of 90 followup reports within 30 days.

No applications pursuant to 10 CFR 21.7, Exemptions, are anticipated; thus, no burden is estimated.

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

15. Reasons for Changes in Burden or Cost

The estimated number of annual respondents has decreased from 100 to 70, based on the number of reports received during the past five years (1996-2000). NRC received 824 Part 21 reports (330 initial notifications and 494 follow-up documents). Annual averages are thus about 70 issues per year (equivalent to the number of respondents) and about 100 follow-up reports per year. During the period 1998-2000, the average annual number of reports received later than 60 days was about 10, leaving an annual average of 90 follow-up reports within 30 days.

The estimated number of annual initial notifications has thus decreased from 90 to 70, the estimated number of annual 30-day follow-up reports has not changed from 90, and the estimated number of annual reports received later than 60 days has decreased from 50 to 10. Consequently, the estimated total number of annual reports has decreased from 230 to 170.

The estimated burden has decreased from 17,093 hours (13,480 reporting and 3,613 recordkeeping) to 12,565 hours (9,640 reporting and 2,925 recordkeeping) based on past experience with actual reports received during the past five years. The reduced reporting resulted from a decrease in the number of annual reports from 230 to 170. The number of initial notifications has been reduced from 90 to 70, with a reduction of 40 burden hours (2 hrs per report x 20 reports). The estimated number of follow-up reports remained unchanged and the number of interim reports (reports not resolved within 60 days) decreased from 50 to 10, with a reduction of 3,800 burden hours (95 hrs per report x 40 reports).

The recordkeeping burden was reduced because the number of evaluations decreased from 800 to 350 and the burden to retain these records was reduced from 300 to 175 hours (0.5 hrs per record x 350 records). However, there was a slight increase in the burden estimate to generate and maintain a record based on what we consider a more realistic estimate, an increase from 0.38 hrs per record to 0.5 hrs per record. The burden to maintain record purchases was decreased by 625 hours from 3,125 to 2,500 hours because we believe a more realistic estimate per record is 0.1 hrs in lieu of the original estimate of 0.125 hrs (25,000 records x 0.10 = 2,500 hrs.). Although the burden to keep notifications records increased from 188 to 250 hrs because of the re-estimated burden per record from 0.38 hrs to 0.5 hrs., the net effect for recordkeeping is a reduction of 688 hours.

The estimated total cost decreased from $2,119,532 to $1,884,750, a reduction of $234,782 because of the decrease in burden for reporting and recordkeeping.

However, the hourly rate for professional staff time increased from $124 per hour to $150 per hour.

16. Publication for Statistical Use

The data collected through this regulation provide input for generic communications issued by the NRC such as information notices, generic letters, and bulletins. Each report received is coded and entered into a computer database system that is used for tracking these reports. The data are not published except as reflected in notices and bulletins.

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

Not applicable.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in the collection of information.

Industry Burden Table

Reporting Requirements

Section	Number of Reports (Annually)	Effort (hour/reporting)	Total (hour/year)	Cost ($/year @$150/hr)
21.7 (requests for exemption)	0	0	0	0
21.21(a)(2) (interim report if not resolved in 60 days)	10*	95	950	$142,500
21.21(d)(1)** (report of failure to comply or defect)				
● Initial Notification (21.21(d)(3)(I))	70	2	140	21,000
● 30-day written followup (21.21(d)(3)(ii))	90	95	8,550	1,282,500
Total	170	-	9,640	$1,446,000

*Rounded estimate of average annual number of reports received later than 60 days for the past 3 years.

**Includes effort for 21.21(a)(1) and (3), 21.21(b), and 21.21(e).

Recordkeeping Requirements

Section	Number of Records	Burden Total (hour/record.)	(hour/year)	Cost ($/year @$150/hr)
21.51(a)(1) (retain evaluations for 5 years)	350*	.5	175	$ 26,250
21.51(a)(2) (retain notifications for 5 years)	500**	.5	250	37,500
21.51(a)(3) (retain purchase records for 10 years)	25,000***	.1	2,500	375,000
Total			2,925	$438,750

*Rounded estimate from the average number of issues per year for five years.

**Rounded estimate from the number of documents received during 1996-2000 less the number of initial notifications (number of evaluations) received during that time.

***Assuming 25 purchase orders per year at each of 100 plants for 10 years.

NOTE: There is one recordkeeper per organization conducting NRC licensed activities.

Total Burden

Type	Burden Total (hour/year)	Cost ($/year) @$150/hr)*
Reporting	9,640	$1,446,000
Recordkeeping	2,925	438,750
Total	12,565	1,884,750

NOTE: The estimated number of respondents is 70.

[7590-01-P]

U. S. NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Submission for the Office of Management and Budget (OMB) Review; Comment Request

AGENCY: U. S. Nuclear Regulatory Commission (NRC)

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

1. Type of submission, new, revision, or extension: Revision

2. The title of the information collection: 10 CFR Part 21, “Reporting of Defects and Noncompliance”

3. The form number if applicable: Not applicable

4. How often the collection is required: On occasion

5. Who will be required or asked to report: All directors and responsible officers of firms and organizations building, operating, or owning NRC licensed facilities as well as directors and responsible officers of firms and organizations supplying basic components and safety related design, analysis, testing, inspection, and consulting services of NRC licensed facilities or activities.

6. An estimate of the number of responses: 170

7. The estimated number of annual respondents: 70 respondents

8. An estimate of the total number of hours needed annually to complete the requirement or request: 12,565 (9,640 reporting hours and 2,925 recordkeeping hours)

9. An indication of whether Section 3507(d), Pub. L. 104-13 applies: Not applicable

10. Abstract: 10 CFR Part 21 Implements Section 206 of the Energy Reorganization Act of 1974, as amended. It requires directors and responsible officers of firms and organizations building, operating, owning, or supplying basic components to

NRC licensed facilities or activities to report defects and noncompliance that could create a substantial safety hazard at NRC licensed facilities or activities. Organizations subject to 10 CFR Part 21 are also required to maintain such records as may be required to assure compliance with this regulation.

A copy of the final supporting statement may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O-1 F23, Rockville, MD 20852. OMB clearance requests are available at the NRC worldwide web site: http://www.nrc.gov/NRC/PUBLIC/OMB/index.html. The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions should be directed to the OMB reviewer listed below by (insert date 30 days after publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Bryon Allen
Office of Information and Regulatory Affairs (3150-0035)
NEOB-10202
Office of Management and Budget
Washington, DC 20503

Comments can also be submitted by telephone at (202) 395-3087.

The NRC Clearance Officer is Brenda Jo. Shelton, 301-415-7233.

Dated at Rockville, Maryland, this 18th day of July 2001.

For the Nuclear Regulatory Commission.

/RA/

Brenda Jo. Shelton, NRC Clearance Officer
Office of the Chief Information Officer

The NRC Clearance Officer is Brenda Jo. Shelton, 301-415-7233.

Dated at Rockville, Maryland, this 18th day of July 2001.

For the Nuclear Regulatory Commission.

/RA/

Brenda Jo. Shelton, NRC Clearance Officer
Office of the Chief Information Officer

ADAMS ACCESSION NUMBER: ML011760590 (Package)
*see previous concurrence

OFFICE	REXB:DRIP:NRR	REXB:DRIP:NRR	C:REXB:DRIP:NRR	D:DRIP
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DATE	07/09/2001	07/18/2001		

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