

DRAFT SUPPORTING STATEMENT FOR
10 CFR 21
"REPORTING OF DEFECTS AND NONCOMPLIANCE"

(OMB Clearance No. 3150-0035)
Revision Request

DESCRIPTION OF THE INFORMATION COLLECTION

10 CFR 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 a substantial safety hazard (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.

10 CFR 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.

A. JUSTIFICATION

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

10 CFR 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 10 CFR 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 21 be notified within 5 working days of the determination, based on the evaluation under 10 CFR 21.21(a)(1) and (2) above, that a defect or failure to comply exists.

10 CFR 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 10 CFR 21.21(a)(1) above.

10 CFR 21.21(d)(1) requires that a director or responsible officer subject to 10 CFR 21, or a person designated under 10 CFR 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.

10 CFR 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 in writing.

10 CFR 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.

10 CFR 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 10 CFR 21.21(d)(4).

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

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

10 CFR 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.

10 CFR 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 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 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 Power 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. The NRC encourages respondents to use information technology when it would be beneficial to them. The 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. At the current time, approximately 15% of the responses are submitted electronically.

4. Effort to Identify Duplication and Use Similar Information

There is no duplication of requirements. The 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

Approximately 10,000 licensees and other organizations are under the scope of 10 CFR 21. The majority of these respondents are not considered to be small businesses. The revised 10 CFR 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 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 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 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

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

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of 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).

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 21 is estimated to be 7,574 hours with an estimated cost of \$1,643,558 at \$217 per hour of professional staff time. This estimate includes 4,970 hours for reporting and 2,604 hours for recordkeeping. Details are included in the attached industry burden table. The estimated cost per burden hour is based upon NRC's annual fee recovery rate, as published in NRC's annual fee recovery rule.

13. Estimate of Other Additional Costs

The quantity of records to be maintained is roughly proportional to the recordkeeping burden. Based on the number of pages maintained for a typical clearance, the records storage cost has been determined to be .0004 times the recordkeeping burden cost. Therefore, the storage cost for this clearance is estimated to be \$226 (2,604 hours x \$217/hour x .0004).

14. Estimated Annual Cost to the Federal Government

NRC Burden Table

<u>Activity</u>	<u>Reports* (issues/year)</u>	<u>Effort (hour/issue)</u>	<u>Total (hour/year)</u>	<u>Cost (\$/year @\$217/hour)</u>
Review 10 CFR 21 issues	35	45	1,575	\$341,775

*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 2004-2006, NRC received 104 10 CFR 21 reports. The number of initial notifications of distinct issues was 66 and the number of follow up documents was 38. Annual averages are thus about 22 issues per year and about 13 follow up reports per year.

During the period 2004-2006, the average annual number of reports received later than 60 days was close to zero, leaving an annual average of 35 follow up reports within 30 days.

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

The estimated cost per burden hour is based upon NRC's annual fee recovery rate, as published in NRC's annual fee recovery rule. Where applicable, this cost is fully recovered by fee assessments to NRC licensees pursuant to 10 CFR 170. Licensees that are non-profit education institutions or Government agencies are exempt from fee recovery under 10 CFR 170.11.

15. Reasons for Changes in Burden or Cost

The estimated burden decreased by 216 hours from 7,790 hours (5,112 reporting and 2,678 recordkeeping) to 7,574 hours (4,970 hours for reporting and 2,604 hours for recordkeeping) based on past experience and the actual number of reports received during the past three years (2004-2006). NRC received 104 10 CFR 21 reports (66 initial notifications and 38 follow-up reports), which averages to about 35 initial and follow-up reports per year.

The reporting burden decreased by 142 hours, from 5,112 to 4,970 hours, because the number of initial notifications decreased from 36 to 35, the number of follow-up reports decreased from 36 to 35 and the number of interim reports stayed unchanged, which are all based on a reduction in the actual number of reports received from 36 to 35 with a corresponding burden reduction.

The recordkeeping burden decreased by 74 hours because the number of evaluations required for 21.51(a)(1) decreased from 36 to 35 and the number of notifications required for 21.51(a)(2) decreased from 36 to 35, with a corresponding burden reduction. The overall recordkeeping burden decreased from 2,678 hours to 2,604.

Overall costs increased, however, due to the hourly rate increasing from \$157 to \$217. The estimated cost per burden hour is based upon NRC's annual fee recovery rate, as published in NRC's annual fee recovery rule.

It is important to note that these estimates are based on historical data. The number of 10 CFR 21 reports generated or received in any given year is dependent upon the number of issues that arise, that is, this is an event-based burden, not a burden as a consequence of a regular reporting requirement.

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	No. of Respondents	Responses Per Respondent	No. of Responses	Burden Per Response	Total Annual Burden Hours	Cost @ \$217/hr)
10 CFR 21.7 (requests for exemption)	0	0	0	0	0	0
10 CFR 21.21(a)(2) (interim report if not resolved in 60 days)	0*	1	0	95	0	0
10 CFR 21.21(d)(1)** (report of failure to comply or defect)						
10 CFR 21.21(d)(3)(i) Initial Notification	35	1	35	2	70	\$15,190
10 CFR 21.21(d)(3)(ii) 30-day written follow up	35	1	35	140	4,900	\$1,063,300
TOTAL	70		70		4,970	\$1,078,490

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

**Includes effort for 10 CFR 21.21(a)(1) and (3), 21.21(b), and 21.21(e).

Recordkeeping Requirements

Section	Number of Recordkeepers	Hours Per Recordkeeper	Total Annual Burden Hours	Cost @ \$217/hr)
10 CFR 21.51(a)(1) (retain evaluations for 5 years)	35	2.44	86	\$18,662
10 CFR 21.51(a)(2) (retain notifications for 5 years)	35	2.5	88	\$19,096
10 CFR 21.51(a)(3) (retain purchase records for 10 years)	35	69.44	2,430	\$527,310
TOTAL	35		2,604	\$565,068

NOTE: The estimated number of respondents and recordkeepers is 35.

The total burden is 7,574 hours (4,970 hours for reporting and 2,604 hours for recordkeeping), at a cost of \$1,643,558 (7,574 x \$217/hr).