

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

3150-0035

EXTENSION WITH BURDEN UPDATE

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 (safety-related) 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.

This extension request reflects the only change made to 10 CFR Part 21 since the last renewal. An amendment to 10 CFR 21.5 (Communications) was approved on December 1, 2009 (74 FR 62680). This amendment provided updated NRC website and email contact information needed to obtain detailed guidance on making electronic submissions. This amendment made no changes to the reporting, record keeping, or storage requirements associated with 10 CFR 21.

A. JUSTIFICATION

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

10 CFR 21.21(a) requires each individual, corporation, partnership, commercial grade dedicating entity, or other entity subject to the regulations in this part 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 supplier 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 supplier 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 supplier, 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. This requirement does not apply to interim reports described in 10 CFR 21.21(a)(2).

10 CFR 21.21(d)(3)(ii) requires the submittal of a written report by the supplier, 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 suppliers, licensees, or commercial grade 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 suppliers 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 suppliers 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.

10 CFR 21.51(a)(4) requires applicants for standard design certification under subpart B of 10 CFR 52 "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Plants" and others providing a design which is the subject of a design certification, during and following Commission adoption of a final design certification rule for that design, to retain any notifications sent to purchasers and affected licensees for a minimum of 5 years after the date of the notification, and retain a record of the purchasers for 15 years after delivery of design which is the subject of the design certification rule or service associated with the design.

10 CFR 21.51(a)(5) requires applicants for or holders of a standard design approval under subpart E of 10 CFR 52 "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Plants" and others providing a design which is the subject of a design approval shall retain any notifications sent to purchasers and affected licensees for a minimum of 5 years after the date of the notification, and retain a record of the purchasers for 15 years after delivery of the design which is the subject of the design approval or service associated with the design.

## 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 12% of the responses are submitted electronically.

4. Effort to Identify Duplication and Use Similar Information

No sources of similar information are available. 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. While the number of small businesses contributing to this total is not known, it can safely be concluded that small businesses falling under the reporting requirements of 10 CFR 21 would be most likely involved in supplying basic components or services associated with basic components to other licensees. The majority of the burden associated with the reporting of defects and noncompliance in this extension is associated with the determination of whether an identified deficiency could create a SSH. Title 10 CFR 21 is written in a manner that permits a supplier of basic components, for this example a small business, to reduce the burden associated with this reporting requirements if the supplier concludes that it does not have the capability to perform the evaluation to determine if a deficiency that could create a SSH exists. The supplier still must inform the purchasers or affected licensees of this basic component so that the purchasers or affected licensees may evaluate the deviation or failure to comply.

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.

The 10 CFR 21 regulation requires records 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 period would not be adequate for review and evaluation of recurring defects. It is necessary to be able to verify that a defect that could create a SSH has been adequately identified, 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.

The 10 CFR 21 regulation also imposes record retention requirements for new reactor licensing activities under 10 CFR Part 52 "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Plants." The 10 CFR 52 process provides for a standard design approval, which is subsequently referenced in a final standard design certification rule, and that standard design certification is, in turn referenced in a combined license issued by the NRC. The NRC imposes longer retention times for records associated with Part 52 licensing because of the potentially longer "regulatory life" of a referenced license, standard design approval or standard design certification. Therefore, those entities providing a certified design or design approval shall retain any notifications sent to purchasers and affected licensees for a minimum of 5 years after the date of the notification, and retain a record of the purchasers for 15 years after delivery of the design which is the subject of the design approval or service associated with the design.

8. Consultation Outside the NRC

Opportunity for public comment on the information collection requirements for this clearance package was published in the Federal Register on June 23, 2010 (75 FR 35845). No comments were received.

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). However, no information normally considered confidential or proprietary is not normally requested.

11. Justification for Sensitive Questions

This provision 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 8,926 hours with an estimated cost of \$2,293,982 at \$257 per hour of professional staff time. This estimate includes 5,350 hours for reporting and 3,576 hours for recordkeeping. Details are included in the attached industry burden tables (Table 1 and Table 2). The estimated number of reports is based upon the average number of reports received per year for the past three years. 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 \$368 (3,576 hours x \$257/hour x .0004).

14. Estimated Annual Cost to the Federal Government

NRC Burden Table

<u>Activity</u>	<u>Reports*</u> (issues/year)	<u>Effort</u> (hour/issue)	<u>Total Burden</u> (hour/year)	<u>Total Cost</u> (\$/year@\$257/hour)
Review 10 CFR 21 issues	31	49	1,519	\$390,383

\*NRC currently reviews reports by issue, not by the type of report (e.g. initial notification, interim reports, written reports within 30 days, or reports if not resolved within 60 days). During the period 2007-2009, NRC received 109 Part 21 reports. The number of distinct issues was 92. Therefore the estimated average number of issues reviewed by the NRC is about 31 issues per year.

During the period 2007-2009, the average annual number of reports received later than 60 days was close to zero. 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 increased by 914 hours from 8,012 hours (5,254 reporting and 2,758 recordkeeping) to 8,926 hours (5,350 hours for reporting and 3,576 hours for recordkeeping). This increase in the estimate is based on past experience and the actual number of reports received during the past three years (2007-2009). NRC received 109 10 CFR 21 reports (92 initial notifications and 17 follow-up reports) during the three year period, which averages to about 37 initial and follow-up reports per year.

The reporting burden increased by 96 hours, from 5,254 to 5,350 hours, because the number of interim reports 10 CFR 21.21(a)(2) received by the agency during the period 2007-2009 increased from 0 to 2 expected per year over the extension period. The estimated number of initial notifications and follow-up reports per year remained unchanged.

The recordkeeping burden increased by 818 hours largely because of work associated with 10 CFR 52 new reactor licensing. The number of recordkeepers required by 10 CFR 21.51(a)(4) for standard design certification applicants under subpart B of 10 CFR 52 "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Plants" increased from 2 to 10, with a corresponding burden increase of 596 hours. The number of record keepers required by 10 CFR 21.51(a)(5) for design approval under subpart E of 10 CFR 52 "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Plants" increased from 0 to 1, with a corresponding burden increase of 74.5 hours. The recordkeeping burden also increased because the number of evaluations records required for 21.51(a)(1), 21.51(a)(2), and 21.51(a)(3) increased from 35 to 37. The overall recordkeeping burden increased from 2,758 hours to 3,576.

The hourly rate changed from \$258 to \$257 per hour. 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 or 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. Incoming 10 CFR 21 Reports are posted to the NRC's public Web page.

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.



Table 1  
Industry Reporting Requirements for 10 CFR 21

Section	No. of Respondents (# of entities subject to reporting)	No. of Responses per Respondent	No. of Responses	Burden Per Response	Total Annual Burden Hours	Cost @ \$257/hr)
10 CFR 21.7 (requests for exemption)	2,000	0	0	0	0	0
10 CFR 21.21(a)(2) Interim report (evaluation cannot be)	2,000	0.001	2	95	190	\$48,830
10 CFR 21.21(b) Supplier does not have capability to perform evaluation	2,000	0.001	2	95	190	\$48,830
10 CFR 21.21(d)(3)(i) Initial notification by facsimile or telephone	2,000	0.0175	35	2	70	\$17,990
10 CFR 21.21(d)(3)(ii) 30-day written notification	2,000	0.0175	35	140	4,900	\$1,259,300
TOTAL	2,000	0.037	74		5,350	\$1,374,950

\* = Requirement to submit initial notification under 10 CFR 21.21(d)(3)(i) does not apply to interim reports.

Table 2  
Industry Recordkeeping Requirements for 10 CFR 21

Section	Number of Recordkeepers	Hours Per Recordkeeper	Total Annual Burden Hours	Cost @ \$257/hr)
10 CFR 21.51(a)(1) (retain evaluations for 5 years)	37	2.5	92.5	\$23,772.50
10 CFR 21.51(a)(2) (retain notifications for 5 years)	37	2.5	92.5	\$23,772.50
10 CFR 21.51(a)(3) (retain purchase records for 10 years)	37	69.5	2,571.5	\$660,875.50
10 CFR 21.51(a)(4) (notifications 5 years / purchase records 15 years)	10	74.5	745	\$191,465.00
10 CFR 21.51(a)(5) (notifications 5 years / purchase records 15 years)	1	74.5	74.5	\$19,146.50
TOTAL	48		3,576	\$919,032

Reporting:	5,350 hours
Recordkeeping:	3,576 hours (hrs per recordkeeper were rounded to the nearest half hour)
Total:	8,926 hours / \$2,293,982 (8,926 x \$257/hr)
Responses:	122 (74 reporting responses plus 48 recordkeepers)
Respondents:	48