

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

3150-0035

EXTENSION

DESCRIPTION OF THE INFORMATION COLLECTION

Title 10 of the Code of Federal Regulation (10 CFR) 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 (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 the Nuclear Regulatory Commission (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 of 10 CFR 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 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 Part 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 Part 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 Part 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 Part 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 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 Power Operations and the Nuclear Energy Institute, 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.

The preferred method of initial notification is by facsimile to the NRC Operations Center, however, telephonic notification is permitted. Therefore, none of the initial notifications are received electronically.

Written or electronic notification to the NRC is required within 30 days from the initial notification. At the current time, approximately 90% of these responses are submitted electronically.

The overall percentage of electronic submissions for all Part 21 reports (both initial and 30-day reports) is estimated to be 70%.

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 2,000 licensees and other organizations are under the scope of 10 CFR Part 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 Part 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. Part 21 of 10 CFR 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.

The NRC staff estimates that 20% of the 350 respondents may be small businesses.

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 requires the initial reporting of defects and failures to comply by a responsible officer of the licensee, vendor, or applicant within 2 days after being notified of the evaluation results. Written or electronic

notification to the NRC is required within 30 days from the initial notification. Less frequent reporting 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 the Office of Management and Budget (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.

The 10 CFR Part 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 Part 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 Part 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 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). However, no information normally considered confidential or proprietary is not normally requested.

11. Justification for Sensitive Questions

This information collection does not request sensitive information.

12. Estimated Industry Burden and Burden Hour Cost

The total burden to respondents for reporting, recordkeeping, and third party disclosure in accordance with 10 CFR 21 is estimated to be 34,705 hours with an estimated cost of \$9,439,760 at \$272 per hour of professional staff time.

This estimate includes 9,420 hours for reporting, 25,190 hours for recordkeeping, and 95 hours for third-party disclosures. Details are included in the attached industry burden tables (Table 1-3).

The estimated number of reports is based upon the average number of reports received per year for the past three years (2010 – 2012). During the three-year period from 2010-2012, the NRC received 228 Part 21 reports. The number of distinct issues was 144. Therefore the estimated average number of issues reviewed by the NRC is about 48 issues per year (144 issues / 3 years = 48 issues per year).

The number of recordkeepers is based on the estimated number of licensees, vendors, and fuel facilities who are keeping records under 10 CFR 21.51.

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 \$2,741 (25,190 hours x \$272/hour x .0004).

14. Estimated Annual Cost to the Federal Government

The 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 three-year period from 2010-2012, the NRC

received 228 Part 21 reports. The number of distinct issues was 144. Therefore the estimated average number of issues reviewed by the NRC is about 48 issues per year (144 issues / 3 years = 48 issues per year). At 49 hours per issue, the total cost to the Federal government is \$639,744 (48 issues x 49 hours per issues x \$272/hr).

NRC Annual Burden Table

<u>Activity</u>	<u>Distinct Issues per year</u>	<u>Effort (hour/issue)</u>	<u>Total Burden (hour/year)</u>	<u>Total Cost @\$272/hour</u>
Review 10 CFR 21 issues	48	49	2,352	\$639,744

During the period 2010-2012, no exemption requests were received. No applications pursuant to 10 CFR 21.7, "Exemptions" are anticipated in the upcoming clearance period; therefore, no burden is estimated for this requirement.

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 25,779 hours from 8,926 hours (5,350 hours for reporting and 3,576 hours for recordkeeping) to 34,705 hours (9,420 hours reporting + 25,190 hours recordkeeping + 95 hours third-party disclosure). This increase in the estimate is based on an increase actual number of reports received during the past three years (2010-2012) and a correction in the calculation of recordkeeping hours.

BURDEN HOURS				
	Reporting	Recordkeeping	Third Party Disclosure	TOTAL
2010 submission	5,350	3,576	0	8,926
Current submission	9,420	25,190	95	34,705
Burden Change	4,070	21,614	95	25,779

Reporting. The estimated reporting burden increased from 5,350 hours to 9,420 hours, an increase of 4,070 hours. Reporting estimates are based on actual data from 2010-2012. The increase in burden is due to an increase in the number of interim reports (from 2 to 28) and 30-day reports (from 35 to 48). These estimates are based on actual data from the past three years.

Recordkeeping. For this submission, the NRC staff reviewed the recordkeeping requirements in Part 21 and corrected and updated the number of recordkeepers and burden estimates as follows:

- On the recordkeeping table, the requirement in 21.51(a)(1) for licensees, vendors, and fuel facilities to retain evaluations for 5 years was combined with the requirement in 21.51(a)(2) to retain notifications for 5 years, because the staff determined that these requirements related to the documentation for a single issue and constituted a single record.
- The number of respondents for 21.51(a)(3) was corrected. Section 21.51(a)(3) of 10 CFR requires that suppliers of basic components retain a record of the purchasers of basic components for 10 years after delivery. The NRC staff estimates that there are 350 suppliers of basic components who must retain records of purchasers. In the previous submission, the estimated number of recordkeepers reflected the number of suppliers who had a reportable condition, rather than all suppliers of basic components who were keeping records of purchasers. The NRC staff has corrected the number of recordkeepers from 48 to 350 recordkeepers, resulting in an increase of 21,753.5 hours for this requirement.
- On the recordkeeping table, requirements for applicants and holders of design certifications to retain notifications for 5 years and purchase records for 15 years were combined. The requirements in 21.51(a)(4) for applicants for standard design certification under subpart B of part 52 to retain notifications for 5 years and purchase records for 15 years was combined with the requirement in 21.51(a)(5) for applicants for or holders of a standard design approval to retain notifications for 5 years and purchase records for 15 years. The number of recordkeepers for these requirements decreased from 11 to 10 based on the actual number of known applicants and holders of design certifications.

The number of responses for the collection increased from 122 responses (74 reporting responses + 48 recordkeepers) to 447 responses (96 reporting responses + 350 recordkeepers + 1 third party disclosure response). The increase is primarily due to the correction in the number of recordkeepers for the collection, from 48 to 350 to include all entities subject to Part 21 who are selling basic components and keeping records of their purchasers.

RESPONSES				
	Reporting	Recordkeepers	Third Party Disclosure	TOTAL
2010 submission	74	48	0	122
Current submission	96	350	1	447
Change in Responses	22	302	1	325

In this submission, third-party disclosure requirements have been broken out separately from reporting requirements. In the last submission, the requirement under 10 CFR 21.21(b) was included as a reporting requirement. This requirement specifies that a supplier of basic components must inform the purchasers or affected licensees of their inability to perform the evaluation to determine if a defect exists. The requirement is now correctly categorized as a third-party disclosure requirement (total of 95 hours).

The hourly rate changed from \$257 to \$272 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 Part 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 Part 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 Responses ¹	Burden Per Response	Total Annual Burden Hours	Cost @ \$272/hr)
10 CFR 21.7 (requests for exemption)	0	40	0	\$0
10 CFR 21.21(a)(2) Interim report (evaluation cannot be resolved in 60 days) *	28	95	2,660	\$723,520
10 CFR 21.21(d)(3)(i) Initial notification by facsimile or telephone	20	2	40	\$10,880
10 CFR 21.21(d)(3)(ii) 30-day written notification	48	140	6,720	\$1,827,840
TOTAL	96		9,420	\$ 2,562,240

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

¹ Burden calculations are based on the number of estimated responses. An estimated 2,000 licensees, vendors, and fuel facilities are subject to Part 21; however, only 350 of these entities are anticipated to submit a report or maintain records during the current clearance period.

Table 2
Industry Recordkeeping Requirements for 10 CFR 21

Section	Number of Recordkeepers	Hours Per Recordkeeper	Total Annual Burden Hours	Cost @ \$272/hr)
10 CFR 21.51(a)(1) (retain evaluations for 5 years) and 10 CFR 21.51(a)(2) (retain notifications for 5 years)	48	2.5	120	\$32,640
10 CFR 21.51(a)(3) - retain purchase records for 10 years	350	69.5	24,325	\$6,616,400
10 CFR 21.51(a)(4) (notifications 5 years / purchase records 15 years) and 10 CFR 21.51(a)(5) (notifications 5 years / purchase records 15 years)	10	74.5	745	\$202,640
TOTAL	350		25,190	\$6,851,680

Table 3
Industry Third Party Disclosure Requirements for 10 CFR 21

Section	No. of Responses ²	Burden Per Response	Total Annual Burden Hours	Cost @ \$272/hr)
10 CFR 21.21(b) Supplier does not have capability to perform evaluation	1	95	95	\$25,840

Reporting: 9,420 hours
Recordkeeping: 25,190 hours
Third Party Disclosure: 95 hours
Total: 34,705 hours / \$9,439,760 (34,705 x \$272/hr)
Responses: 447 (96 reporting responses + 1 third party disclosure + 350 recordkeepers)
Respondents: 350 (unduplicated total of respondents and recordkeepers)

² Burden calculations are based on the number of estimated responses. An estimated 2,000 licensees, applicants, and vendors are subject to Part 21; however, only 350 of these entities are anticipated to submit a report or maintain records during the current clearance period.