

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 Regulations (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.

An estimated 2,000 licensees, vendors, and fuel facilities are under the scope of 10 CFR Part 21; however, only 355 of these entities are anticipated to submit a report or maintain records during the current clearance period.

Although 10 CFR 21.21(c)(4) prescribes the information required when notifying the NRC of failure to comply or existence of a defect and its evaluation, the report may be submitted in any format. The NRC has not developed a specific reporting form or template. The NRC staff has endorsed industry reporting guidance as developed by the Nuclear Energy Institute for evaluating and reporting under Part 21.

A detailed description of the requirements in Part 21 is included at the end of this supporting statement, along with a list of guidance documents issued by the NRC.

A. JUSTIFICATION

1. Need for and Practical Utility of the Information Collection

NRC regulations in 10 CFR Part 21 pertain to reporting of defects and failures to comply with any applicable regulation in this chapter, order, or license issued by the Commission that could create a substantial safety hazard. Part 21 contains reporting and recordkeeping requirements that ensure the NRC is informed of defects in safety-related components 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 detailed description of Part 21 information collection requirements can be found at the end of this supporting statement.

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 has issued Guidance for Electronic Submissions to the NRC which provides direction for the electronic transmission and submittal of documents to the NRC. Electronic transmission and submittal of documents can be accomplished via the following avenues: the Electronic Information Exchange (EIE) process, which is available from the NRC's "Electronic Submittals" Web page, by Optical Storage Media (OSM) (e.g. CD-ROM, DVD), by facsimile or by e-mail.

The preferred method of initial notification is by facsimile to the NRC Operations Center, however, telephonic, electronic, and paper notification are permitted.

Written or electronic notification to the NRC is required within 30 days from the initial notification. At the current time, approximately 25% of these responses were submitted electronically.

The overall percentage of electronic submissions for all Part 21 reports (both initial and 30-day reports) is estimated to be 25%.

4. Effort to Identify Duplication and Use Similar Information

No sources of similar information are available. There is no duplication of requirements.

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. 10 CFR Part 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.

The NRC staff estimates that 20% of the 355 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.

A supplier of basic components who does not have the capability to perform the evaluation to determine if a defect exists must inform the purchasers or affected licensees within 5 working days of this determination. The 5-day time frame is necessary to ensure that the licensee receiving the notification has the ability to perform an evaluation in a timely manner in accordance with the guidelines set forth in Part 21.

The 10 CFR Part 21 regulation requires records be retained beyond the 3 year limit established by OMB. This longer retention is required because 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 in 10 CFR 9.17(a) and 10 CFR 2.390(b). However, no information normally considered confidential or proprietary is 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 32,083 hours with an estimated cost of \$8,822,688 at \$275 per hour of professional staff time. Following is a summary of burden, responses, and costs at a rate of \$275/hr.

	Part 21 Burden Totals		
	Responses	Hours	Cost at \$275/hr
Reporting	88	6,500	\$1,787,500
Recordkeeping	355	25,215	\$6,934,125
Third Party Disclosure	357	368	\$101,063
TOTAL	800	32,083	\$8,822,688

Additional detail on burden estimates by requirement is included in the supplementary Excel spreadsheet, "Part 21 Burden Tables."

The number of reports submitted annually was estimated based on data from the past three years and staff knowledge of the industry and reporting trends. 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 \$275 hourly rate used in the burden estimates is based on the Nuclear Regulatory Commission's fee for hourly rates as noted in 10 CFR 170.20 "Average cost per professional staff-hour." For more information on the basis of this rate, see the Revision of Fee Schedules; Fee Recovery for Fiscal Year 2018 (83 FR 29622, June 25, 2018).

13. Estimate of Other Additional Costs

The NRC has determined that the quantity of records to be maintained is roughly proportional to the recordkeeping burden and, therefore, can be used to calculate approximate records storage costs. Based on the number of pages maintained for a typical clearance, the records storage cost has been determined to be equal to 0.0004 times the recordkeeping burden cost. Because the recordkeeping burden is estimated to be 24,860 hours, the storage cost for this clearance is \$2,774.00 (25,215 hours x \$275/hour x 0.0004).

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). Based on data from the previous clearance and staff experience, the staff estimates receiving 88 reports annually. At 49 hours per issue, the total cost to the Federal government is \$1,185,800 (88 issues x 49 hours per issues x \$275/hr).

No applications pursuant to 10 CFR 21.7, "Exemptions" are anticipated in the upcoming clearance period; therefore, no burden is estimated for this requirement.

15. Reasons for Changes in Burden or Cost

The estimated burden decreased by 12,015 hours from 43,565 hours (18,023 reporting hours + 25,257 recordkeeping + 285 hours third party disclosure) to 32,083 hours (6,500 reporting hours + 25,215 hours recordkeeping + 368 hours third party disclosure). The estimate is based on a decrease in the actual number of reports received during the past three years (2016-2018). The decrease is due to the near completion of new reactor construction activities, and the decommissioning (no longer operating) of several nuclear

power plant facilities. The NRC staff estimates that we will continue to receive similar numbers of reports in the next three years.

Following is a summary of the estimate changes in burden and responses:

	Change in Burden and Responses					
	2016 renewal		Current Request		Change	
	Responses	Hours	Responses	Hours	Responses	Hours
Reporting	178	18,023	88	6,500	-90	-11,523
Recordkeeping	350	25,257	355	25,215	5	-42
Third Party Disclosure	3	285	357	368	354	83
TOTAL	531	43,565	800	32,083	269	-11,483

Reporting. The estimated reporting burden decreased from 18,023 hours to 6,500 hours, a decrease of 11,523 hours. Reporting estimates are based on actual data from 2016-2018 and staff knowledge of industry trends. The decrease in burden is due to an decrease in the number of interim reports (from 95 to 22) and 30-day reports (from 140 to 31). The NRC staff anticipates that we will continue to receive similar numbers of reports in the next three years.

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

- The number of recordkeepers maintaining evaluations and notifications under 10 CFR 21.51(a)(1) and (2) increased from 48 to 65, increasing the burden by 42.5 hours. The increase in the number of entities maintaining these records is attributed to notifications received during the licensing phase of an application.
- The number of recordkeepers maintaining notifications and purchase records under 10 CFR 21.51(a)(4) and (5) decreased from 10 to 5, decreasing the burden by 372.5 hours. The change in the number of recordkeepers for these requirements is due to changes in the number of licensees planning to construct new reactors and some licensees who asked for their applications to be rescinded.
- Burden has been added for maintenance of procedures for Part 21.21(a). This is not a new requirement, but the previous submission did not include burden for these procedures. This correction added 355 hours of recordkeeping burden to the overall totals.

Third-Party Disclosure

An existing third-party disclosure requirement in 10 CFR Part 21 was identified and burden added to the table for this requirement. 10 CFR Part 21.6 requires the posting of procedures and the name of the individual to whom reports can be made. This increased the third-party disclosure burden by 177.5 hours and 355 responses.

The number of responses for the collection decreased from 531 responses (170 reporting responses + 350 recordkeepers + 3 disclosure response) to 800 responses (88 reporting responses + 355 recordkeepers + 357 third party disclosure responses). The decrease in reporting responses is due to the near completion of new reactor construction activities, and the decommissioning (no longer operating) of several nuclear

power plant facilities. The increase in the number of third-party disclosure responses is due to the inclusion of responses for 10 CFR 21.6 posting requirements for all respondents.

The hourly rate changed from \$265 to \$275 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 and staff knowledge of industry trends. However, the number of 10 CFR Part 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. The data are not published for statistical use.

17. Reason for Not Displaying the Expiration Date

The recordkeeping and reporting requirements for this information collection are associated with regulations and are not submitted on instruments such as forms or surveys. For this reason, there are no data instruments on which to display an OMB expiration date. Further, amending the regulatory text of the CFR 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.

DESCRIPTION OF INFORMATION COLLECTION REQUIREMENTS
CONTAINED IN

10 CFR PART 21
"REPORTING OF DEFECTS AND NONCOMPLIANCE"

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10 CFR 21.6 requires each individual, partnership, corporation, dedicating entity, or other entity subject to the regulations in this part to post procedures adopted pursuant to the Part 21 regulations. If posting the procedures is not practicable, the licensee or firm may post a notice describing the regulations and procedures and stating where they may be examined, which includes the name of the individual to whom reports may be made.

10 CFR 21.7 allows any interested person to apply to the Commission for an exemption from the requirements of the regulations in this part

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 manufacture, 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)(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) which states the written report required by this paragraph shall include, but need not be limited to, the following information, to the extent known:

- (i) Name and address of the individual or individuals informing the Commission.
- (ii) Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect.
- (iii) Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.
- (iv) Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.
- (v) The date on which the information of such defect or failure to comply was obtained.
- (vi) In the case of a basic component which contains a defect or fails to comply, the number and location of these components in use at, supplied for, being supplied for, or may be supplied for, manufactured, or being manufactured for one or more facilities or activities subject to the regulations in this part.
- (vii) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.
- (viii) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees.
- (ix) In the case of an early site permit, the entities to whom an early site permit was transferred.

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.

GUIDANCE DOCUMENTS FOR INFORMATION COLLECTION REQUIREMENTS
CONTAINED IN
10 CFR PART 21
"REPORTING OF DEFECTS AND NONCOMPLIANCE"

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Title	Accession number
Regulatory Guide 1.234, "Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21"	ML17338A072
Nuclear Energy Institute (NEI) 14-09, "Guidelines for Implementations of 10 CFR Part 21 Reporting of Defects and Noncompliance," Revision 1	ML16054A825