

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

3150-0035

EXTENSION

DESCRIPTION OF THE INFORMATION COLLECTION

NRC regulations pertaining to reporting of defects and noncompliance in 10 CFR Part 21 contains reporting and recordkeeping requirements which ensure that 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. An estimated 2,000 licensees, vendors, and fuel facilities are under the scope of 10 CFR Part 21; however, only 350 of these entities are anticipated to submit a report or maintain records during the current clearance period. The NRC staff estimates that 20% of the 350 respondents may be small businesses. Section 206 requires these entities to report to the Commission the discovery of defects in basic components (safety-related) or failures to comply that could create a substantial safety hazard (SSH).

10 CFR 21.21(c)(4)(i-ix) does prescribe the information required in a report. However the report may be submitted in any format. The NRC has not developed a specific reporting form or template.

A. JUSTIFICATION

1. Need for and Practical Utility 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 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.

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.

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 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 91% 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 91%.

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. 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 was published in the Federal Register on September 8, 2016 (81 FR 62184).

The NRC contacted Enertech, Westinghouse Electric Company (WEC), Tennessee Valley Authority (TVA), SCANA, and Ameren, via email to give them the opportunity to provide comments. No comments were received.

The NRC received comments from Dale Porter, GE Hitachi Nuclear Energy (GEH), Dale.Porter@GE.Com as follows:

NRC Question:

Is the proposed collection of information necessary for the NRC to properly perform its functions?

GEH Comment:

Yes. In order to accurately understand the burden placed on suppliers and licensees collection of resource expenditures would be important.

NRC Response:

The NRC staff understands the burden placed on entities that required to

evaluate and report under 10 CFR Part 21. The threshold for evaluating and reporting is reserved for only the most safety significant conditions.

NRC Question:

Does the information have practical utility?

GEH Comment:

Changes in the regulation that impose additional requirements should be based on a value added basis, based on empirical data. Without this data the cost may outweigh the benefit.

NRC Response:

The NRC staff have no current plans to revise the regulation.

NRC Question:

Is the estimate of the burden of the information collection accurate?

GEH Comment:

Since the vast majority of 10 CFR part 21 evaluations do not result in notifications to the NRC the values noted do not seem to accurately reflect the burden imposed by the regulation.

NRC Response:

The NRC staff's estimates are an average based on the entire industry. The burden on some entities may be greater than the average. Typically, architectural engineering and nuclear steam system supplier firms, such as General Electric Hitachi, will evaluate and report a higher number of potential 10 CFR Part 21 reports over the evaluation period.

NRC Question:

Is there a way to enhance the quality, utility, and clarity of the information to be collected?

GEH Comment:

To accurately understand the burden imposed by the implementation of the requirements of 10CFRPart 21 the NRC should solicit information from the largest contributors to the overall industry burden (in a confidential manner) for all aspects of the 10CFR Part 21 process, from initiation through notifications, including all non-reported (i.e. Safe) conditions, as this category (from the GEH perspective) is the largest family of evaluations.

NRC Response:

The NRC staff is currently working with industry stakeholders on accepting a guidance document, Nuclear Energy Institute (NEI) 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance."

The purpose of this guidance is to describe an acceptable approach to comply with the requirements for evaluation and notification in 10 CFR Part 21. This guidance document promotes consistent implementation of NRC requirements.

NRC Question:

How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

GEH Comment:

Automated collection would appear to add additional burden and in many cases may not be possible. GEH believes that a simple request for information (held by the NRC in confidence) would be the best approach.

While it may be important for the NRC to gain the requested information on the burden posed to suppliers and licensees, the fact that the NRC no longer posts the notifications to the 10 CFR Part 21 Notifications portal in a timely manner is disconcerting given the burden that it places on the suppliers and licensees, and defeats the purpose of maintaining plant safety when safety concerns are raised. It is true that 10 CFR Part 21 Reports are posted to the daily event report portal (for 10 CFR 50.72 and 50.73 reports), however, without monitoring on both portals valuable safety information can be missed, and not acted upon in a timely manner.

NRC Response:

The regulations were revised to prevent duplicate reporting of the same event. Licensees were given the option to evaluate and report a potential Part 21 issue under §50.72 and §50.73 in order to relieve licensees of the burden to evaluate and issue multiple reports. Please see §21.29(c) for details.

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 43,565 hours with an estimated cost of \$11,544,725 at \$265 per hour of professional staff time.

This estimate includes 18,023 hours for reporting, 25,257 hours for recordkeeping, and 285 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 (2013 – 2015). During the three-year period from 2013-2015, the NRC received 210 Part 21 reports. The number of distinct issues was 191. Therefore the estimated average number of issues reviewed by the NRC is about 64 issues per year (191 issues / 3 years = 64 issues per year). The NRC staff estimates that we will continue to receive similar numbers of reports in the next three years.

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 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 25,257 hours, the storage cost for this clearance is \$2,677 (25,257 hours x \$265/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). During the three-year period from 2013-2015, the NRC received 210 Part 21 reports. The number of distinct issues was 191. Therefore the estimated average number of issues reviewed by the NRC is about 64 issues per year (191 issues / 3 years = 64 issues per year). At 49 hours per issue, the total cost to the Federal government is \$831,040 (64 issues x 49 hours per issues x \$265/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 @\$265/hour</u>
Review 10 CFR 21 issues	64	49	3,136	\$831,040

During the period 2013-2015, 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 8,860 hours from 34,705 hours (9,420 hours reporting + 25,190 hours recordkeeping + 95 hours third-party disclosure) to 43,565 hours (18,023 hours reporting + 25,257 hours recordkeeping + 285 hours third-party disclosure). This increase in the estimate is based on an increase actual number of reports received during the past three years (2013-2015). The increase is due to new reactor construction activities. The NRC staff estimates that we will continue to receive similar numbers of reports in the next three years.

BURDEN HOURS				
	Reporting	Recordkeeping	Third Party Disclosure	TOTAL
2013 submission	9,420	25,190	95	34,705
Current submission	18,023	25,257	285	43,565
Burden Change	8,603	67	190	8,860

Reporting. The estimated reporting burden increased from 9,420 hours to 18,023 hours, an increase of 8,603 hours. Reporting estimates are based on actual data from 2013-2015. The increase in burden is due to an increase in the number of interim reports (from 28 to 95) and 30-day reports (from 48 to 64). 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.
- 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. The estimated number of recordkeepers remains unchanged from the previous submission.
- 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 remained the same based on the actual number of known applicants and holders of design certifications.

The number of responses for the collection increased from 447 responses (96 reporting responses + 350 recordkeepers + 1 disclosure response) to 531 responses (178 reporting responses + 350 recordkeepers + 3 third party disclosure responses). The increase is primarily due to reporting related to new reactor construction activities.

RESPONSES				
	Reporting	Recordkeepers	Third Party Disclosure	TOTAL
2013 submission	96	350	1	447
Current submission	178	350	3	531
Change in Responses	82	0	2	84

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 285 hours).

The hourly rate changed from \$272 to \$265 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. 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.

Table 1
Industry Reporting Requirements for 10 CFR 21

Section	No. of Responses ¹	Burden Per Response	Total Annual Burden Hours	Cost @ \$265/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) *	95	95	9,025	\$2,391,625
10 CFR 21.21(d)(3)(i) Initial notification by facsimile or telephone	19	2	38	\$10,070
10 CFR 21.21(d)(3)(ii) 30-day written notification	64	140	8,960	\$2,374,400
TOTAL	178		18,023	\$4,776,095

* = 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 @ \$265/hr)
10 CFR 21.51(a)(1) (retain evaluations for 5 years) and 10 CFR 21.51(a)(2) (retain notifications for 5 years)	75	2.5	187	\$49,555
10 CFR 21.51(a)(3) - retain purchase records for 10 years	350	69.5	24,325	\$6,446,125
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	\$197,425
TOTAL	350		25,257	\$6,693,105

Table 3
Industry Third Party Disclosure Requirements for 10 CFR 21

Section	No. of Responses ²	Burden Per Response	Total Annual Burden Hours	Cost @ \$265/hr)
10 CFR 21.21(b) Supplier does not have capability to perform evaluation	3	95	285	\$75,525

Reporting: 18,023 hours
Recordkeeping: 25,257 hours
Third Party Disclosure: 285 hours
Total: 43,565 hours / \$11,544,725 (43,565 x \$265/hr)
Responses: 531 (178 reporting responses + 3 third party disclosures + 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.