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DESIGNATED ORIGINAL

Request for OMB Review

certified by *Paul H. Smith*

U.S. Nuclear Regulatory Commission

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Hazel Smith

301 492-1287

10 CFR 21, Reporting of Defects and Noncompliance

42 2201(o)

X

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the Request is for OMB Review Under Executive Order 12291

Classification
1 ☐ Exempt from review
2 ☐ Proposed rule
3 ☐ Final rule
4 ☐ Final rule without prior proposal
Type of review requested
1 ☐ Standard
2 ☐ Pending
3 ☐ Emergency
4 ☐ Priority of review

10. If a major rule, is there a regulatory impact analysis attached?

11. If a major rule, is there a regulatory impact analysis attached?
1 ☐ Yes 2 ☐ No
3 ☐ Yes 4 ☐ No

Certification for Regulatory Commissions

In submitting this request for OMB review, the authorized regulatory contact and the program official certify that the requirements of E.O. 12291 and any applicable policy directives have been complied with.

Signature of program official

Signature of authorized regulatory contact

12. Other comments

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OMB SUPPORTING STATEMENT FOR 10 CFR PART 21

DESCRIPTION OF THE INFORMATION COLLECTION

10 CFR Part 21.21 requires directors and responsible officers of firms and organizations building, operating, owning or supplying safety-related components to NRC licensed facilities, or conducting NRC licensed activities, to report defects and noncompliances to the NRC. 10 CFR 21.51 requires each organization subject to 10 CFR Part 21 to maintain such records as may be required to assure compliance with 10 CFR Part 21.

A. JUSTIFICATION

1. Need for the Collection of Information.

10 CFR Part 21, "Reporting of Defects and Noncompliance," implements Section 206 of the Energy Reorganization Act of 1974, as amended (42 U.S.C. 5846). It requires that directors and responsible officers of firms and organizations building, operating, or owning NRC licensed facilities, or conducting NRC licensed activities, report defects and noncompliances to the NRC. Defects and noncompliances are defined as deviations in basic components (safety-related equipment and services) and failures to comply with regulatory requirements that could create a substantial safety hazard. Directors and responsible officers of firms and organizations supplying safety-related components (vendors for example) and safety-related design, testing, inspection, and consulting services are also covered by this regulation.

In accordance with 10 CFR 21.21, NRC licensees and other organizations covered by 10 CFR Part 21 shall adopt appropriate procedures to ensure that deviations and failures to comply are evaluated to determine their reportability and ensure that defects and noncompliances are brought to the attention of responsible officers or directors. These individuals, in turn, are required to notify the Commission, either orally or in writing, within 2 days that a potential safety hazard exists, and file a written report within 5 days of learning of the defect or noncompliance. These reporting requirements are intended to ensure that the NRC receives prompt notification concerning defects and noncompliances in facilities or activities licensed by the NRC.

10 CFR 21.51 requires that each organization subject to 10 CFR Part 21 maintain records as necessary to assure compliance with the regulation. Each individual, corporation, partnership, or other entity subject to 10 CFR Part 21 is required to prepare records in connection with the design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of any facility, or to be used in any licensed activity, sufficient to assure compliance with 10 CFR Part 21.

2. Agency Use of Information.

10 CFR Part 21 requires reports describing defects and noncompliances in basic components at NRC licensed facilities or activities. These reports are

reviewed by the NRC staff to determine whether the reported defects or noncompliances 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 noncompliances.

3. Reduction of Burden Through Information Technology.

There are no legal obstacles to reducing the burden associated with this information collection.

4. Effort to Identify Duplication.

The NRC regulations contain several safety deficiency reporting requirements. Although distinctions exist between these requirements, instances have occurred where the same deficiency was evaluated and reported by different organizations, for example one organization attempting to satisfy the criteria of 10 CFR Part 21 and the other attempting to meet the differently worded criteria of 10 CFR 50.55(e). Although the intent of the regulations is for a particular deficiency to be reported under only one reporting requirement, in reality this has not always occurred.

The NRC staff is in the process of revising the current regulations to eliminate this duplicative reporting. The proposed rule was published in the Federal Register on November 4, 1988 (53 FR 44594). The intent of the proposed revisions is to establish the filing of one report for each defect or noncompliance, with the reporting obligation resting on the entity that discovers it.

5. Effort to Use Similar Information.

10 CFR Part 21 implements Section 206 of the Energy Reorganization Act of 1974, as amended (U.S.C. 5846). It is the only regulation that currently requires directors and responsible officers of firms and organizations building, operating, or owning NRC licensed facilities, or conducting NRC licensed activities, to report defects and noncompliances that could create substantial safety hazards. Similar information is not currently available within the NRC or industry to accomplish the intent of Section 206.

Industry organizations, such as the Institute for Nuclear Operations (INPO) and the Nuclear Management and Resources Council (NUMARC), 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.

6. Effort to Reduce Small Business Burden.

Approximately 12,000 licensees and other organizations are under the scope of 10 CFR Part 21. Approximately 300 reports are received annually by the NRC pursuant to 10 CFR Part 21 from approximately 100 respondents. The majority of these respondents are not considered to be small businesses. The NRC has studied the possibility of reducing the burden on small businesses and has concluded that it would not be possible to lessen the burden on small businesses and still fulfill the requirements of Section 206 of the Energy Reorganization Act of 1974, as amended.

7. Consequences of Less Frequent Collection.

10 CFR Part 21 has no specific period for reporting; instead, it requires the reporting of defects and noncompliances immediately after it is determined that they could create a substantial safety hazard. Less frequent collection of such information could reduce the NRC effectiveness in the area of assessing potentially generic safety issues and in disseminating such information to affected parties.

8. Circumstances which Justify Variation from OMB Guidelines.

10 CFR Part 21 requires the reporting of defects and noncompliances that could create a substantial safety hazard in facilities or activities licensed by the NRC. This information is needed in less than 30 days to ensure that the NRC receives prompt notification of these defects and noncompliances, evaluates them, and is able to promptly disseminate information regarding those defects and noncompliances that are determined to be potentially generic safety problems.

9. Consultation Outside the NRC.

The staff has solicited comments from licensees and other organizations regarding the reporting requirements of 10 CFR Part 21. The NRC staff is in the process of revising 10 CFR Part 21 (see 53 FR 44594, November 4, 1988), and other reporting requirements, and will include these comments and the recommendations of the Presidential Commission on the Accident at Three Mile Island (Kemeny Commission) relating to the safety defect reporting system into this revision.

10. Confidentiality of Information.

Information that is identified as proprietary or confidential, which is defined as information that if disclosed could do substantial harm to an organization's competitive position, would be withheld from disclosure under a Freedom of Information Act request if the NRC determines that it is in the public interest to withhold it.

11. Justification for Sensitive Questions.

This rule does not request sensitive information.

12. Estimate of the Cost to the Federal Government.

The total annual cost to the Federal Government is estimated to be 4,860 hours based on 300 reports annually, or \$291,600 at \$60 per hour of professional staff time. This estimated cost is itemized as follows:

- a. Initial notifications pursuant to 21.21(b)(2) will require approximately 1 hour per notification. The total required staff time is 300 hours based on 300 reports annually, or \$18,000 at \$60 per hour.
- b. Written notifications required by 21.21(b)(3) will require approximately 11 hours per notification. The total required staff time for these notifications is 3300 hours annually, or \$198,000 at \$60 per hour.
- c. NRC inspection of records retained in accordance with 21.51 will require approximately 1,260 hours annually for all respondents, or \$75,600 at \$60 per hour.

13. Estimate of Burden

The total burden to respondents for reporting and recordkeeping in accordance with 10 CFR Part 21 is estimated to be 27,988 hours based on 300 notifications annually from 100 respondents, or \$1,679,250 at \$60 per hour of professional staff time. These estimates are discussed below in more detail.

The total burden for reporting pursuant to 10 CFR Part 21 is estimated to be 24,300 hours based on 300 notifications annually, or \$1,458,000 at \$60 per hour, and is itemized as follows:

- a. Initial notifications pursuant to 21.21(b)(2) will require approximately 1 hour per notification; therefore, the total burden for 300 telephone notifications is 300 hours, or \$18,000.
- b. Written notification required by 21.21(b)(3) will require approximately 80 hours per notification; therefore, this burden is estimated to be 24,000 hours annually based on 300 notifications, or \$1,440,000.

The total burden for recordkeeping pursuant to 10 CFR 21.51, which requires the maintenance of records as may be required to assure compliance with 10 CFR Part 21, is estimated to be 3,688 hours annually, or \$221,250 at \$60 per hour, and is itemized as follows:

- a. The burden associated with 21.51 involves retaining approximately 8 evaluations annually per respondent with an estimated burden of 0.375 hours per evaluation. The total annual burden for 100 respondents is estimated to be 300 hours, or \$18,00 based on \$60 per hour.
- b. 21.51 will also require that each respondent retain approximately 5 notifications that were sent to affected purchasers or licensees at an estimated burden of 0.375 hours per notification. The total annual burden for 100 respondents is estimated to be 188 hours, or \$11,250 at \$60 per hour.
- c. In addition, the provisions of 21.51 will require retaining approximately 250 documents listing purchasers of basic components at an estimated burden of 32 hours per respondent. The total burden is estimated to be 3,200 hours, or \$192,000, based on 100 respondents.

14. Reasons for Change in Burden

The estimated burden represents a decrease of 44,612 hours, or \$2,676,750, from the current OMB clearance. The new estimate reflects the decreased number of reports expected in the next few years, 300 versus 450 annually, based on the decreased number that have been received in the last few years. It also reflects a new estimate that more accurately represents the burden to respondents based on discussions with respondents and includes a correction and new estimate of the actual burden imposed by the current regulations.

15. Publication for Statistical Use.

The data collected through this regulation provides input for generic communication 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. A printout of the information in the database is distributed to several NRC offices approximately each month to inform them of the 10 CFR Part 21 reports that have been received by the NRC, their review status, and the reason for closeout.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in the collection of information.