

June 10, 2010

## **DRAFT SUMMARY OF INFORMATION COLLECTION REQUEST**

Title: 10 CFR 21, Reporting of Defects and Noncompliance

Current Burden/Responses: 8,012 hours/ 109 (74 responses plus 35 recordkeepers)

Proposed Burden/Responses: 8,926 hours/ 122 (74 responses plus 48 recordkeepers)

Number of Respondents: 48 respondents

Burden Attributable to Third-Party Collections: None

Frequency of Response: As needed

Reasons for Changes in Burden/Responses: The estimated burden increased by 914 hours from 8,012 hours (5,254 reporting and 2,758 recordkeeping) to 8,926 hours (5,350 hours for reporting and 3,576 hours for recordkeeping). This increase in the estimate is based on past experience and the actual number of reports received during the past three years (2007-2009). NRC received 109 10 CFR 21 reports (92 initial notifications and 17 follow-up reports) during the three year period, which averages to about 37 initial and follow-up reports per year.

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

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

The hourly rate changed from \$258 to \$257 per hour. The estimated cost per burden hour is based upon NRC's annual fee recovery rate, as published in NRC's annual fee recovery rule.

It is important to note that these estimates are based on historical data. The number of 10 CFR 21 reports generated or received in any given year is dependent upon the number or issues that arise, that is, this is an event-based burden, not a burden as a consequence of a regular reporting requirement.

Level of Concurrence: Deputy Director  
Division of Inspection and Regional Support  
Office of Nuclear Reactor Regulations

Recordkeeping Requirements in Accordance with the Retention Periods for Records Rule: Licensees must retain some records for 5 years under Part 21. 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. New reactor licensing recordkeeping activities dictated by Part 21 are for “regulatory life” of the licensee.

Abstract: The 10 CFR 21 regulation requires each individual, corporation, partnership, commercial grade dedicating entity, or other entity subject to the regulations in this part to adopt appropriate procedures to evaluate deviations and failures to comply to determine whether a defect exists that could result in a substantial safety hazard. Depending upon the outcome of the evaluation, a report of the defect must be submitted to NRC. Reports submitted under 10 CFR 21 are reviewed by the NRC staff to determine whether the reported defects or failures to comply in basic components at NRC licensed facilities or activities are potentially generic safety problems. These reports have been the basis for the issuance of numerous NRC Generic Communications that have contributed to the improved safety of the nuclear industry. The records required to be maintained in accordance with 10 CFR 21 are subject to inspection by the NRC to determine compliance with the subject regulation.

ADAMS #: ML101300309 (package)  
ML101190510 (supporting statement)