

FINAL SUPPORTING STATEMENT
FOR
NRC FORM 396, "CERTIFICATION OF MEDICAL EXAMINATION BY FACILITY LICENSEE"
10 CFR PART 55, SECTIONS 55.23, 55.25, 55.27, 55.31, AND 55.57

(OMB CLEARANCE NO. 3150-0024)

REVISION/EXTENSION

DESCRIPTION OF THE INFORMATION COLLECTION

10 CFR 55.23 requires that the facility licensee certify the medical fitness of an applicant or licensee by completing and signing NRC Form 396.

10 CFR 55.25 requires the facility licensee to notify the NRC within 30 days if a licensee develops a permanent physical or mental condition that causes the licensee to fail to meet the requirements of 10 CFR 55.21. For conditions where a conditional license is requested, the facility licensee must provide medical certification on NRC Form 396.

10 CFR 55.27 requires that the facility licensee document and maintain the results of medical qualifications data, test results, and each operator's or senior operator's medical history for the duration of the operator's or senior operator's tenure and to provide the documentation to the Commission upon request.

10 CFR 55.31(a)(6) requires applicants for a license to provide certification by the facility licensee of medical condition and general health on Form 396 to comply with 10 CFR 55.21, 55.23 and 55.33(a)(1).

10 CFR 55.57(a)(6) requires applicants for renewal of a license to provide certification by the facility licensee of medical condition and general health of the applicant on Form NRC 396.

10 CFR Parts 26 and 73 specify fitness-for-duty and safeguards requirements that licensed operators must meet. In addition to the medical examination certification, NRC Form 396 requires certification that the applicant has been found to meet the fitness-for-duty and safeguards requirements.

The clearance revision request does not amend the information collection requirements, but does increase the burden due to an increase in the number of NRC Form 396's being reviewed annually by the NRC Consultant Examining Physician, in addition to an increase in his/her hourly fee. However, the actual time to perform each of these reviews has decreased by 33 percent.

A. JUSTIFICATION

1. Need for and Practical Utility of the Collection of Information

10 CFR Part 55, "Operators' Licenses," requires an applicant to be examined by a licensed physician who can use guidance provided by *American National Standard for Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants* --ANSI/ANS 3.4-1983 or ANSI/ANS 3.4-1996; and

American National Standard for the Selection and Training of Personnel for Research Reactors ANSI/ANS 15.4-1988 (Non-Power). The licensed physician submits his/her diagnostic report to the facility licensee. The facility licensee, based on the data provided, certifies on NRC Form 396 whether or not the applicant is fit to be licensed.

In cases where the holder of an operator's license develops a permanent mental or physical condition that causes the individual to fail to meet the requirements of 10 CFR 55.21, the facility licensee is required to notify the NRC so that the individual's license can be amended to accommodate the new condition or revoked.

In cases where the applicant for an operator's license or renewal does not meet the appropriate ANSI/ANS medical requirements, or after recovery from a disabling condition, the facility licensee shall submit supporting medical evidence for review by the NRC Consultant Examining Physician. The NRC and the Consultant Physician will review such evidence and decide if a conditional license or reinstatement from the disability shall be approved.

Records required by 10 CFR 55.27 are retained and provided to the NRC upon request to provide assurance that operators are physically and mentally fit.

2. Agency Use of Information

The NRC uses the information as part of the basis for determining the fitness of an individual for licensing as a reactor operator or senior reactor operator.

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. 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. It is estimated that fewer than 5% of the potential responses are filed electronically.

4. Effort to Identify Duplication and Use Similar Information

NRC has in place an on-going 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

Not applicable.

6. Consequences to Federal Program or Policy Activities if the Collection Is Not Conducted or Is Conducted Less Frequently

Information is to be provided only upon request for issuance of a license, renewal of a license (every six years) or upon notification to NRC of disability. Frequency of reporting cannot be reduced without endangering the health and safety of the public.

7. Circumstances which Justify Variation from OMB Guidelines

No variations from OMB guidelines.

8. Consultations Outside the NRC

Opportunity to comment on the information collection was published in the Federal Register on August 2, 2005 (70 FR 147). No comments were received.

The public has been provided an opportunity to comment on the burden estimates each time the clearance package has been renewed. Five different facilities were contacted and all agreed that the estimated burden in this package is appropriate.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

NRC 16, "Privacy System of Records," specifies confidentiality of these records. These records are limited to those persons whose official duties require such access.

11. Justification for Sensitive Questions

The facility licensee must certify that an applicant for an NRC operator's license meets the medical fitness requirements to be licensed as an operator at the facility. The certification involves supplying medical information on applicants. NRC Form 396 also requires certification that applicants meet fitness-for-duty and safeguards requirements for unescorted access to vital areas of a nuclear power plant. This latter certification requires knowledge of an applicant's drug testing results and a facility review of the applicant's criminal history, if any.

12. Estimated Industry Burden and Burden Hour Cost

(a) Reporting Requirements

Approximately 475 new and 600 renewal applicant certifications are expected to be completed by facility licensees annually. Approximately 75 notifications of disability are also expected annually. The estimated annual reporting burden per applicant is .25 hours.

475 New Applicants X .25 hours = 118.75 hours
600 Renewal Applicants X .25 hours = 150 hours
75 Notices of Disability X .25 hours = 18.75 hours

Total annual responses = 1150 (475 + 600 + 75).
Total burden = 288 hours (118.75 + 150 + 18.75).

(b) Recordkeeping Requirements

There are 137 (104 power and 33 non power) facilities that shall retain the medical documentation for approximately 4700 reactor operators and senior reactor operators while they are employed in this capacity (10 CFR 55.27). The facility licensees retain 4700 records annually or an average of 34 records per licensee with an approximate burden of .10 hour per record. The total annual burden is 470 hours (approximately 34 records per facility licensee x 137 facility licensees x .10 hour per record).

(c) Total Industry Cost and Burden

475 New Applicants X .25 hours = 118.75 hours X \$205/hr. = \$24,343.75
600 Renewal Applicants X .25 hours = 150 hours X \$205/hr. = \$30,750.00
75 Notices of Disability X .25 hours = 18.75 hours x \$205/hr. = \$3,843.75
4700 Records Retained X .10 hours = 470 hours X \$205/hr. = \$96,350.00

Total responses = 1,287 (1,150 responses + 137 recordkeepers)

Total annual industry burden is 758 (118.75 + 150 + 18.75 + 470 = 757.5) hours. Total annual industry cost is \$155,288 (\$24,343.75 + \$30,750.00 + \$3,843.75 + \$96,350.00 = \$155,287.50)

13. Estimate of Other Additional Costs

None.

14. Estimated Annualized Cost to the Federal Government

Estimate of annual cost to the Federal Government is based on staff experience. It is estimated that 1150 certificates (NRC Forms 396) will be submitted annually during the clearance period. Also, it is estimated that 400 of these certificates will be required to be reviewed by the NRC Consultant Physician and would require approximately 10 minutes review each. Total Federal Government cost includes the following:

NRC Consultant Examining Physician: 400 Forms 396 reviewed annually x .17 hours each = 68.0 hours @ \$66/hour (actual fee) = \$4,488.00.

Initial and final staff review: 1150 X .2 hours = 230 hours X \$205/hr. = \$47,150.00

Total annual cost to the government is \$51,638.00 (\$4,488.00 + \$47,150.00). This

cost is fully recovered by fee assessments to NRC licensees pursuant to 10 CFR Part 171.

15. Reasons for Change in Burden or Cost

The overall burden increased by 7 hours from 751 to 758 hours because the number of notices of disability increased by 50 from 25 to 75, thereby increasing the burden by 12.5 hours. However, the number of records retained decreased by 60 from 4,760 to 4,700, decreasing the burden by 6 hours (60 x .10), because of license terminations and the decrease in the number of facilities by 3, from 140 to 137. There has been an increase in the overall cost as a result of an increase in the rate from \$157/hr to \$205/hr.

16. Publication for Statistical Use

None.

17. Reason for Not Displaying the Expiration Date

The expiration date is displayed.

18. Exceptions to the Certification Statement

Not applicable.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.

Enclosure:
NRC Form 396