

DRAFT 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

DESCRIPTION OF THE INFORMATION COLLECTION

10 CFR Part 55, "Operators' Licenses," requires a license applicant to be examined by a 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 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.

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 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 the Collection of Information

The NRC licenses all individuals who either operate or supervise the operation of the controls of commercially owned nuclear power reactors and test/research (i.e., non-power) reactors in the United States. *"An applicant for a license shall have a medical examination by a physician. A licensee shall have a medical examination by a physician every two years"* (10 CFR 55.21). *"If, during the term*

of the license, the licensee develops a permanent physical or mental condition that causes the licensee to fail to meet the requirements of § 55.21 of this part, the facility licensee shall notify the Commission, within 30 days of learning of the diagnosis, in accordance with § 50.74(c). For conditions for which a conditional license (as described in § 55.33(b) of this part) is requested, the facility licensee shall provide medical certification on Form NRC 396 to the Commission (as described in § 55.23 of this part)."

"To certify the medical fitness of the applicant, an authorized representative of the facility licensee shall complete and sign NRC Form 396."(10 CFR 55.23)

10 CFR 55.33 requires that *"(a) The Commission will approve an initial application for a license pursuant to the regulations in this part, if it finds that-*

(1) Health. The applicants' medical condition and general health will not adversely affect the performance of assigned operator job duties or cause operational errors endangering public health and safety.

(b) Conditional license. If an applicant's general medical condition does not meet the minimum standards under § 55.33(a)(1) of this part, the Commission may approve the application and include conditions in the license to accommodate the medical defect. The Commission will consider the recommendations and supporting evidence of the facility licensee and of the examining physician (provided on Form NRC-396) in arriving at its decision."

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 10% of the potential responses are filed electronically.

4. Effort to Identify Duplication and Use Similar Information

There is no duplication of requirements. 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

The staff contacted licensed operator training/medical personnel at 4 nuclear power facilities, and 1 non-power facility with recent experience preparing NRC Form 396. Results are shown on the enclosed Supporting Statement.

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.

Opportunity to comment on the information collection has been published in the Federal Register.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

Confidential and proprietary information is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b)

11. Justification for Sensitive Questions

The facility licensee must certify that an applicant for, or a licensee with, 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 and licensees. NRC Form 396 also requires certification that applicants and licensees 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 550 new and 650 renewal applicant certifications are expected to be completed by facility licensees annually. Approximately 90 notifications of disability are also expected annually. The estimated annual reporting burden per applicant is .25 hours.

550 New Applicants X .25 hours = 137.50 hours
 650 Renewal Applicants X .25 hours = 162.50 hours
 90 Notices of Disability X .25 hours = 22.50 hours

Total annual responses = 1290 (550 + 650 + 90).
 Total burden = 322.5 hours (137.50 + 162.50 + 22.50).

(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

550 New Applicants X .25 hours = 137.5 hours X \$238/hr.= \$32,725.00
 650 Renewal Applicants X .25 hours=162.5 hours X \$238/hr.=\$38,675.00
 90 Notices of Disability X .25 hours = 22.50 hours x \$238/hr.= \$5,355.00
 4700 Records Retained X .10 hours=470 hours X \$238/hr. = \$111,860.00
 Total responses = 1,427 (1,290 responses + 137 recordkeepers)

Total annual industry burden is 793 (137.5 + 162.5 + 22.50 + 470 = 792.5) hours. Total annual industry cost is \$188,615.00 (\$32,725.00 + \$38,675.00 + \$5,355.00 + \$111,860.00 = \$188,615.00)

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 1290 certificates (NRC Forms 396) will be submitted annually during the clearance period. Also, it is estimated that 735 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: 735 Forms 396 reviewed annually x .17 hours each = 124.95 hours @ \$70.39/hour (actual fee) = \$8,795.23.
Initial and final staff review: 1290 X .2 hours = 258 hours X \$238/hr. = \$61,404.00

Total annual cost to the government is \$70,199.00 (\$8,795.23 + \$61,404.00 = \$70,199.23). 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 35 hours from 758 to 793 hours because of the following: the number of new applicants increased by 75 from 475 to 550, thereby increasing the burden by 18.75 hours; the number of renewals increased by 50 from 600 to 650, thereby increasing the burden by 12.50 hours, and the number of notices of disability increased by 15 from 75 to 90, thereby increasing the burden by 3.75 hours. There has been an increase in the overall cost as a result of an increase in the rate from \$205/hr to \$238/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.

SUPPLEMENT

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.