

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
(3150-0024)

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 of learning of the diagnosis 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 qualification 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 NRC 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 NRC Form 396.

This clearance extension request amends the information collection requirements to include the applicant/operators signature. During the past OMB Clearance extension period, the reporting and recordkeeping burdens increased due to larger numbers of NRC Form 396 submittals for aging operators who have more disqualifying medical conditions, as well as a surge in hiring to replace the increasing numbers of retiring operators. The addition of the applicant/operator signature block for the next extension period will also increase the burden hours.

A. JUSTIFICATION

1. Need for the Collection of Information

The regulations in 10 CFR Part 55, as described above, require a license applicant (initial, upgrade, reapplication and renewal) to be examined by a licensed physician. In general, the licensed physician uses the guidance provided by the *American National Standard for Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants - ANSI/ANS 3.4 (1983,1996 or 2013)* and *American National Standard for the Selection and Training of Personnel for Research Reactors (Non-Power) -*

ANSI/ANS 15.4 (1988 or 2007). The licensed physician then submits the diagnostic report to the facility licensee. Subsequently, the applicant/operator signs the NRC Form 396 giving permissions to the facility licensee and the NRC, the facility licensee certifies on NRC Form 396 as to the applicant's or operators general health and physical condition, and then submits NRC Form 396 to the NRC.

In cases where the applicant for an operator's license or renewal does not meet the minimum ANSI/ANS medical requirements, the facility licensee submits recommendations for license conditions, removal of license conditions, or revocation of the license with supporting medical evidence for review by the NRC Contractor Medical Review Officer.

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, within 30 days of learning of the diagnosis, with their conditional license or revocation recommendations and supporting medical evidence for review by the NRC Contractor Medical Review Officer.

Records required by 10 CFR 55.27 are retained by the facility licensee and provided to the NRC upon request to provide documentation that the applicants and licensed operators are physically and mentally fit.

2. Agency Use of Information

The NRC uses the information for determining that the applicant's or operator licensee's 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. The Commission bases its finding upon the certification by facility licensees as detailed on NRC Form 396.

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 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 40% of the potential responses are filed electronically.

4. Effort to Identify Duplication and Use Similar Information

No sources of similar information are available. There is no duplication of requirements. NRC has in place an ongoing 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

Frequency of reporting cannot be discontinued or reduced without violating the NRC licensing requirements as described in 10 CFR 55.31 and 10 CFR 55.57 which would increase the potential for endangering public health and safety.

7. Circumstances which Justify Variation from OMB Guidelines

No variations from OMB guidelines.

8. Consultations Outside the NRC

Opportunity for public comment on the information collection requirements for this clearance package 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 NRC uses the information for determining that the applicant's or operator's 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. The Commission bases its finding upon the certification by facility licensees as detailed on NRC Form 396.

12. Estimated Industry Burden and Burden Hour Cost

(a) Reporting Requirements

Approximately 2,000 NRC Form 396s are expected to be submitted annually (660 applicants plus 700 renewals plus 640 notices of disability). The estimated reporting burden is .834 hour per submittal for a total of 1,668 hours. At the hourly cost of \$279, the total burden cost is \$465,372

(See Table 1).

(b) Recordkeeping Requirements

There are 131 facilities that retain the medical documentation for approximately 4800 applicants, reactor operators and senior reactor operators while they are employed in this capacity (10 CFR 55.27). Approximately 2,000 facility records require annual NRC Form 396 maintenance. The estimated recordkeeping burden is .15 hour per record for a total of 300 hours. At the hourly cost of \$279, the total burden cost is \$83,700 (See Table 2).

(c) Total Industry Cost and Burden

Total Annual Burden: 1,968 (1,668 Reporting hours plus
300 Recordkeeping hours)
Total Burden Hour Cost: \$549,072 (1,968 hours x \$279/hour)

13. Estimate of Other Additional Costs

NRC has determined that the records storage cost is roughly proportional to the recordkeeping burden cost. Based on a typical clearance, the recordkeeping storage cost has been estimated to be equal to .0004 of the recordkeeping burden. Therefore, the recordkeeping storage cost for this collection is estimated to be \$33.48 (300 recordkeeping hours x \$279 x .0004).

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 2,000 NRC Forms 396 will be submitted annually during the clearance period. It is also estimated that 800 of these forms will be required to be reviewed by the NRC Contractor Licensed Physician. NRC staff processing per submission is estimated at .25 hours. Total Federal Government cost includes the following:

NRC Contractor Licensed Physician: 800 NRC Forms 396 reviewed annually x \$50.00 per form = \$40,000. Mailing/shipping: Approximately \$8,500 annually. NRC Staff (Headquarters & Regional) processing: 2,000 forms annually submitted x .25 hours = 500 hours x \$279/hr. = \$136,000. Total annual cost to the Federal Government is \$184,500 (\$40,000 + \$8,500 + \$136,000). All costs are 90% recoverable as general budget items covered by collected annual facility fees.

15. Reasons for Change in Burden or Cost

Even though the number of reporting facilities decreased from 135 to 131 due to decommissioning, the overall number of submissions decreased by only 25 from 2,025 to 2,000 because the number of applicants decreased from 700 to 660; the

number of renewals decreased from 705 to 700, but the number of disability reports increased from 620 to 640. For this renewal period, we are adding a signature block for the applicant/operator that will require an additional average of 10 minutes to complete. The overall annual industry reporting burden increased by 655.5 hours from 1,012.5 hours to 1,668 hours because the time to complete and submit the NRC Form 396 increased by .334 hour (20 minutes) from .50 hour (30 minutes) to .834 hour (50 minutes) as reported by the industry.

The overall annual recordkeeping requirement burden increased from 202.5 hours to 300 hours because the time involved for each record subject to annual maintenance increased by .05 hour (3 minutes) from .10 hour (6 minutes) to .15 hour (9 minutes) as reported by the industry. The change in the rate from \$273/hr. to \$279/hr. had little impact on the costs.

The overall annual industry and Federal Government costs increased by \$114,472.75 from \$516,107.25 to \$630,580 because of the increased costs as reported by the industry, and the increase in the cost of the NRC Medical Review Officer's services. The change in the rate from \$273/hr. to \$279/hr. had little impact on the costs.

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.

TABLE 1
Annual Reporting Burden

	No. of Respondents	Responses per Respondent	Total Responses	Burden Hours per Response	Total Annual Burden Hours	Cost at \$279/hour
NRC Form 396	131	15.267	2,000	.834	1668	\$465,372

TABLE 2
Annual Recordkeeping Burden

	Annual Records Requiring Maintenance	Hours per Recordkeeping	Total Annual Burden Hours	Cost at \$279/hour
NRC Form 396	2,000	.15	300	\$83,700

Total Annual Burden: 1,968 (1,668 Reporting hrs. + 300 Recordkeeping hrs.)
Total Burden Hour Cost: \$549,072 (1,968 hours x \$279/hour)
Total Responses: 2,131 (2000 Responses + 131 Recordkeepers)