

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
(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 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 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 does not amend the information collection requirements. During the past OMB Clearance extension period, the burden increased due to larger numbers of NRC Form 396 submittals, the increased number of submittals requiring NRC review, and the estimated reporting burden per submittal. These increases are projected to continue through the extension period being requested.

A. JUSTIFICATION

1. Need for the Collection of Information

The regulations in 10 CFR Part 55, as described above, requires a license applicant (initial 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 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 then submits the diagnostic report to the facility licensee. Subsequently, the facility licensee certifies on NRC Form 396 as to the applicant's or operator's licensee's general health and physical condition and 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 compensatory recommendations for license restrictions, removal of license restrictions or revocation recommendations with supporting medical evidence for review by the NRC Contractor Licensed Physician.

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 restriction or revocation recommendations and supporting medical evidence for review by the NRC Contractor Licensed Physician.

Records required by 10 CFR 55.27 are retained and provided to the NRC upon request to provide documentation that the 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 25% 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 was published in the Federal Register on November 28, 2011 (76 FR 72983). No comments were received.

The staff contacted licensed operator training/medical personnel at 2 power and 2 non-power facilities for their recent burden experiences preparing the NRC Form 396. Responses indicated an average annual reporting burden of .50 hour per submitted form, and an average annual recordkeeping burden of .10 hour per record maintained.

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 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.

12. Estimated Industry Burden and Burden Hour Cost

(a) Reporting Requirements

Approximately 2,025 NRC Forms 396 are expected to be submitted annually (700 applicants plus 705 renewals plus 620 notices of disability). The estimated reporting burden is .50 hour per submittal for a total of 1,012.5 hours. At the hourly cost of \$273, the total burden cost is \$276,412.50 (See Table 1).

(b) Recordkeeping Requirements

There are 135 facilities that retain the medical documentation for approximately 4893 applicants, reactor operators and senior reactor operators while they are employed in this capacity (10 CFR 55.27). Approximately 2,025 facility records require annual NRC Form 396 maintenance. The estimated recordkeeping burden is .10 hour per record for a total of 202.5 hours. At the hourly cost of \$273, the total burden cost is \$55,282.50 (See Table 2).

(c) Total Industry Cost and Burden

Total Annual Burden: 1,215 (1,012.5 Reporting hours plus
202.5 Recordkeeping hours)
Total Burden Hour Cost: \$331,695 (1,215 hours x \$273/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 \$22.11 (202.5 recordkeeping hours x \$273 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 2,025 NRC Forms 396 will be submitted annually during the clearance period. It is estimated that 850 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: 850 NRC Forms 396 reviewed annually x \$44.36 per form = \$37,706. Mailing/shipping: Approximately \$8,500 annually.
NRC Staff (Headquarters & Regional) processing: 2,025 forms annually

submitted x .25 hours = 506.25 hours x \$273/hr. = \$138,206.25. Total annual

cost to the Federal Government is \$184,412.25 (\$37,706 + \$8,500 + \$138,206.25). All costs are 90% recoverable as general budget items covered by collected annual facility fees.

15. Reasons for Change in Burden or Cost

The number of respondents decreased from 137 to 135 because two non-power facilities have been decommissioned since the last renewal.

The overall annual industry reporting burden increased by 223.5 hours from 789 hours to 1,012.5 because of the increase in operators from 4,658 to 4,893; the increase of applicants from 550 to 700; the increase in renewals from 650 to 705, and the increase in the number of disability notices from 90 to 620 for a total increase of submitted NRC Forms 396 from 1,290 to 2,025. The overall annual industry burden to complete and submit the NRC Form 396 increased from .25/hour (15 minutes) to .50/hour (30 minutes) per form based on consultation with licensees on how long it takes to complete this form. The Federal Government's annual reviewing and processing burden increased from .20/hour (12 minutes) to .25/hour (15 minutes) per submitted form. The significant increase in the number of notices of disability, and the increased average industry burden to submit NRC Form 396 is attributed to the aging workforce and increased changes in the general health of licensed operators that requires documentation and medical evidence to support the associated reportable disabilities.

The overall annual recordkeeping requirement burden decreased from 466 hours to 202.5 hours because all records required to be stored by the industry are not subject to annual maintenance. Only those submitted to the NRC require annual maintenance.

The overall annual industry and Federal Government costs increased from \$257,862.23 to \$516,107.25 because of the increased industry's reporting burden as outlined above; the Federal Government's increased annual reviewing and processing burden; the change in the NRC's reviewing physician from consultant to contractor status that changed the review cost from an hourly rate to a per form rate, and the additions of storage, mailing and shipping costs. Costs also increased because of the rate change from \$238/hr. to \$273/hr.

During this renewal period, the NRC made clarifying changes to NRC Form 396. This form is used only for Medical Certification. Under "*Medical Exam Information*," the words "*Safeguards and Fitness for Duty*" were removed and replaced with the word "*Medical*." In addition, a new condition was added for the convenience of the users. As a result, the conditions were renumbered to add #5 "*Shall Use Therapeutic Device(s) As Prescribed to Maintain Medical*

Qualifications."

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 \$273/hour |
|--------------|--------------------|--------------------------|-----------------|---------------------------|---------------------------|--------------------|
| NRC Form 396 | 135 | 15 | 2,025 | .50 | 1,012.5 | \$276,412.50 |

TABLE 2
Annual Recordkeeping Burden

| | Annual Records Requiring Maintenance | Hours per Recordkeeping | Total Annual Burden Hours | Cost at \$273/hour |
|--------------|--------------------------------------|-------------------------|---------------------------|--------------------|
| NRC Form 396 | 2,025 | .10 | 202.5 | \$55,282.50 |

Total Annual Burden: 1,215 (1,012.5 Reporting hrs + 202.5 Recordkeeping hrs)
 Total Burden Hour Cost: \$331,695 (1,215 hours x \$273/hour)
 Total Responses: 2,160 (2,025 Responses + 135 Recordkeepers)