

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

NRC Form 396, "Certification of Medical Examination by Facility Licensee" is used by an authorized facility licensee and applicant/operator to certify the medical condition of the applicant in accordance with 10 CFR Part 55, "Operators' Licenses."

The regulations in 10 CFR Part 55 require facility licensees to certify the medical fitness of the applicant/operator. NRC Form 396 is the mechanism by which NRC is advised of the applicant/operator general health and physical condition.

The information requested includes the applicant/operator identifying information, medical examination information, applicant/operator signature, signature of the certifying representative at the facility, and informing the NRC within 30 days of learning of the diagnosis if a licensee develops a permanent physical or mental condition. Recent changes to the form include the addition of an email address to aid in delivering electronic correspondence; a date of birth field to assist with identification in web-based applications, which will decrease the possibility of duplicating records; and minor edits in the instructions to provide clarity.

A. JUSTIFICATION

1. Need for the Collection of Information

The information is needed in order to determine facility licensee's compliance with the regulations in 10 CFR Part 55. Details of these regulations can be found at the end of this supporting statement in "Description of Information Collection Requirements."

2. Agency Use and Practical Utility of Information

The information assists the Commission in basing its finding upon the certification by facility licensees as detailed on NRC Form 396. NRC Form 396 is the mechanism by which NRC is advised of 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.

3. Reduction of Burden Through Information Technology

The NRC has issued Guidance for Electronic Submissions to the NRC, which provides direction for the electronic transmission and submittal of documents to the NRC. Electronic transmission and submittal of documents can be accomplished via the following avenues: the Electronic Information Exchange

(EIE) process, which is available from the NRC's "Electronic Submittals" Web page; by Optical Storage Media (OSM) (e.g. CD-ROM, DVD); by facsimile or by e-mail. It is estimated that approximately 100% 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.

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.

If the information is not collected, the NRC will not be able to assess and record medical conditions, along with the critical nature of the condition, the permanence, and operational errors the conditions could cause, if any, while operating controls. While the facility is responsible for certifying the medical suitability of an operator, NRC is responsible for assessing an operator's medical fitness. Information from this form is sent to a medical expert to review to determine if a conditional license should be issued.

The collection of this information is on an as-needed basis. Collection for this information is the minimum frequency necessary to assure that licensees will continue to conduct programs in a manner that will assure adequate protection of public health and safety.

7. Circumstances which Justify Variation from OMB Guidelines

Not applicable.

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). The NRC Form 396 does not include a Privacy Act statement because it is completed by a third party, not

the individual. However, once the NRC receives the information on the Form 396, it is covered by NRC System of Records, "NRC 16: Facility Operator Licensee Records," published December 27, 2019 (84 FR 71536).

11. Justification for Sensitive Questions

The information is required to determine the applicant's or operator's medical condition and general health. Without the information the Commission would have no bases for its findings upon the certification by facility licensees. Once the NRC receives the information on the Form 396, it is covered by NRC System of Records, "NRC 16: Facility Operator Licensee Records," published December 27, 2019 (84 FR 71536).

12. Estimated Industry Burden and Burden Hour Cost

(a) Reporting Requirements Burden

Approximately 1,650 NRC Form 396s are expected to be submitted annually (480 applicants plus 630 renewals plus 540 notices of disability). The estimated reporting burden is 1.0 hour per submittal for a total of 1,650 hours. At the hourly cost of \$288, the total burden cost is \$475,200 (See Table 1).

(b) Recordkeeping Requirements Burden

There are 128 facilities that retain the medical documentation for approximately 4300 applicants, reactor operators and senior reactor operators while they are employed in this capacity (10 CFR 55.27). Approximately 1,650 facility records require annual NRC Form 396 maintenance. The estimated recordkeeping burden is .25 hour per record for a total of 413 hours. At the hourly cost of \$288, the total burden cost is \$118,944 (See Table 2).

(c) Total Industry Burden and Cost

Total Annual Burden: 2,063 (1,650 Reporting hours plus 413 Recordkeeping hours)
Total Burden Hour Cost: \$ 594,144 (2,063 hours x \$288/hour)

The \$288 hourly rate used in the burden estimates is based on the Nuclear Regulatory Commission's fee for hourly rates as noted in 10 CFR 170.20, "Average cost per professional staff-hour." For more information on the basis of this rate, see the Revision of Fee Schedules; Fee Recovery for Fiscal Year 2019 (86 FR 32146, June 16, 2021).

13. Estimate of Other Additional Costs

NRC has determined that the records storage cost is approximately proportional to the recordkeeping burden cost. Based on a typical clearance, the recordkeeping storage cost has been estimated to be equal to 0.0004 of the recordkeeping burden. Therefore, the recordkeeping storage cost for this collection is estimated to be \$47.57 (413 Recordkeeping hours x \$288 x 0.0004).

14. Estimated Annualized Cost to the Federal Government

The staff has developed estimates of annualized costs to the Federal Government related to the conduct of this collection of information. These estimates are based on staff experience and subject matter expertise and include the burden needed to review, analyze, and process the collected information and any relevant operational expenses. It is estimated that 1,650 NRC Form 396s will be submitted annually during the clearance period. It is also estimated that 615 of these forms will be required to be reviewed by the NRC Contractor Licensed Physician. NRC staff processing per submission is estimated at 0.25 hours. Total Federal Government cost includes the following:

NRC Contractor Licensed Physician:

615 NRC Forms 396 reviewed annually x \$100 per form = \$61,500.

NRC staff (Headquarters & Regional) processing: 1,650 forms annually submitted x 0.25 hour per submittal = 413 hours.

413 hours x \$288/hour = \$118,944.

Total annual cost to the Federal Government is \$180,444 (\$61,500 + \$118,944).

15. Reasons for Change in Burden or Cost

The number of total responses overall has decreased from 1882 in the prior cycle to 1778 in this cycle. NRC Form 396 is the mechanism by which NRC is advised of the applicant/operator general health and physical condition, and when a facility and/or individual is no longer subject to the requirements of 10 CFR Part 55, they will no longer submit NRC Form 396. Therefore, the decrease in projected submissions is due to the decrease in licensed individuals and operating reactor plants being subject to Part 55 requirements.

There is a projected minimal increase in respondents up from 125 (94 operating reactors + 31 research and test reactor facilities) in the prior cycle to 128 (89 operating reactors + 31 research and test reactor facilities + 8 combined operating license holders), this increase is due to the addition of eight Combined Operating License Holders who are subjected to the requirements of 10 CFR Part 55 and a reduction of 5 operating reactor facilities no longer licensed and are not subject to the requirements of 10 CFR Part 55.

There is an approximately 50% increase in NRC Contractor Licensed Physician review fee per form per agreed contract.

There is a minimal increase in projected disability submissions, up 10 submissions annually from 530 in the prior cycle to 540 for this cycle. Staff believes this is a reasonable projection in line with current health trend data.

Additionally, NRC currently uses the EIE, OSM, facsimile, or e-mail to deliver NRC Form 396s and receive the completed medical reviews from the NRC Contractor. The agency no longer uses mailing/shipping services to deliver forms to the NRC Contractor, which eliminated the prior mailing/shipping 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 \$288/hour
NRC Form 396	128	13	1,650	1.0	1,650	\$475,200

Total Annual Burden: 2,063 hours (1,650 Reporting hours + 413 Recordkeeping hours)
 Total Burden Hour Cost: \$594,144 (2,063 hours x \$288/hour)
 Total Responses: 1,778 (1,650 Responses + 128 Recordkeepers)

DESCRIPTION OF INFORMATION COLLECTION REQUIREMENTS
CONTAINED IN
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)

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.

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.

TABLE 2

	Annual Records Requiring Maintenance	Hours per Recordkeeping	Total Annual Burden Hours	Cost at \$288/hour
NRC Form 396	1,650	.25	413	\$118,944

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.

GUIDANCE DOCUMENTS FOR INFORMATION COLLECTION REQUIREMENTS
CONTAINED IN
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Title	Accession number
NUREG-1021 "Operator Licensing Examination Standards for Power Reactors"	ML21256A276
NUREG-1478 "Operator Licensing Examiner Standards for Research and Test Reactors"	ML072000059