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

U.S. Nuclear Regulatory Commission (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 Title 10 of the *Code of Federal Regulations* (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 informed 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 creation of the web-based fillable version of the NRC Form 396, allowing facility licensees to complete the form and submit online.

A. <u>JUSTIFICATION</u>

1. Need for the Collection of Information

This information is needed 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 Submittals application, which is available from the NRC's "Electronic Submittals" Web page, by Optical Storage Media (OSM) (e.g. CD-ROM, DVD), by e-mail. The Electronic Submittals application allows electronic transmission of information to the NRC pertaining to licensing actions, associated hearings, and other regulatory matters. The application serves as a secure portal respondents may use to transmit documents to the NRC.

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. <u>Consequences to Federal Program or Policy Activities if the Collection Is Not Conducted or Is Conducted Less Frequently</u>

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. <u>Circumstances which Justify Variation from Office of Management and Budget</u> Guidelines

Not applicable.

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 September 3, 2025 (90 FR 42626). Additionally, staff contacted eight stakeholders via email representing operating reactors, nonpower production and utilization facilities, and research and test reactor stakeholders from Constellation Energy Generation, LLC; Duke Energy Progress, LLC; Entergy Nuclear Operations, Inc.; Luminant Generation Co, LLC; PSEG Nuclear, LLC; Reed College; Talen Energy and The Pennsylvania State University.

No responses or comments were received as a result of the staff's direct solicitation of comments.

As a result of the FRN, the following was received from Duke Energy:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility? Please explain your response.

Comment: The proposed information is not necessary for the NRC to properly perform its functions. The Licensed Operator Requalification Program Inspection biennially reviews the maintenance of operator licenses, including a review of licensed operator performance during requalification exams and operator license restrictions. The ANSI/ANS 3.4 and 15.4 standards clearly define medical restrictions.

NRC Response:

Because the commenter's proposal requires rulemaking, no changes were made to the NRC Form 396.

The NRC staff agrees with the commenter that the biennial licensed operator requalification program and licensed operator performance inspection includes evaluating licensed operator performance during requalification examinations and ensuring that individuals who are licensed to operate the facility satisfy the conditions (or "restrictions") of their licenses.

The NRC staff also agrees with the comment regarding medical standards. As shown on NRC Form 396, the physician and facility licensee may use the 1983, 1996, 2013, or most recently endorsed version of American National Standards Institute (ANSI)/American Nuclear Society (ANS) 3.4, "Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants," or ANSI/ANS 15.4, "American National Standard for the Selection and Training of Personnel for Research Reactors," as applicable, when making their fitness determinations. These standards include provisions for those cases in which the operator can demonstrate complete capacity to perform licensed duties and conditional licenses for those cases in which compensatory measures may be required to ensure public health and safety.

However, 10 CFR 55.57(a)(6) requires an applicant for renewal of a license to, among other things, 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 55.27. Therefore, rulemaking is required to

change the requirement to submit an NRC Form 396 with an application for renewal of a license.

The NRC is preparing a proposed rule titled, "Regulatory Enhancements for Reactor Licensing, Decommissioning, and Operational Oversight" (Docket ID NRC-2025-1138), in response to Executive Order (EO) 14300 of May 23, 2025, titled, "Ordering the Reform of the Nuclear Regulatory Commission." The goal is to enhance regulatory efficiency by retaining safety-significant requirements, reducing unnecessary administrative burden, and aligning NRC regulations with current practices and Executive Orders. The scope includes revisions to 10 CFR Part 55. The NRC will consider this comment during the rulemaking process.

2. Is the burden estimate accurate? Please explain your response.

Comment: Implementing any of the following would minimize burden:

 Reviewing medical restrictions coincident with the 71111.11 inspection versus submitting individual medical status changes on a NRC Form 396.

NRC Response:

Because the commenter's proposal requires rulemaking, no changes were made to the NRC Form 396.

10 CFR 50.74(c) requires a facility licensee to notify the appropriate NRC contact, as described in 10 CFR 55.5, within 30 days of a permanent disability or illness as described in 55.25 for a licensed operator or senior operator (notifications are not required for temporary disability or illness). Per 10 CFR 55.25, for new permanent medical conditions for which a conditional license (as described in 10 CFR 55.33(b)) is requested, the facility licensee must provide medical certification on NRC Form 396 to the Commission (as described in 10 CFR 55.23).

The NRC is preparing a proposed rule titled, "Regulatory Enhancements for Reactor Licensing, Decommissioning, and Operational Oversight" (Docket ID NRC-2025-1138), in response to Executive Order (EO) 14300 of May 23, 2025, titled, "Ordering the Reform of the Nuclear Regulatory Commission." The goal is to enhance regulatory efficiency by retaining safety-significant requirements, reducing unnecessary administrative burden, and aligning NRC regulations with current practices and Executive Orders. The scope includes revisions to 10 CFR Part 55. The NRC will consider this comment while developing the proposed rule.

Comment:

 If a medical restriction already exists, there is no need to submit a NRC Form 396 with modified information. For example, if a licensed operator already has a restriction of shall take medication as prescribed for blood pressure and is adding a new medication for shall take medication as prescribed for another condition, a NRC Form 396 submittal should not be required as the license restriction already exists.

NRC Response:

Because the commenter's proposal requires rulemaking, no changes were made to the NRC Form 396.

10 CFR 50.74(c) requires a facility licensee to notify the appropriate NRC contact, as described in 10 CFR 55.5, within 30 days of a permanent disability or illness as described in 55.25 for a licensed operator or senior operator (notifications are not required for temporary disability or illness). Per 10 CFR 55.25, for conditions for which a conditional (i.e., restricted) license (as described in 10 CFR 55.33(b)) is requested, the facility licensee must provide medical certification on NRC Form 396 to the Commission (as described in 10 CFR 55.23).

Furthermore, as discussed in NUREG-1021, "Operator Licensing Examination Standards for Power Reactors," Revision 12, section ES-5.3, "With regard to prescription medications, it is important that the examining physician understand what medical conditions are contained in the applicable version of ANSI/ANS 3.4. For example, the fact that a licensed operator is diagnosed with gastroesophageal reflux disease and placed on the appropriate prescription medication would, in all likelihood, not be reportable to the NRC, since this condition is not addressed in ANSI/ANS-3.4. However, when assessing any prescription medication, the examining physician needs to consider (1) the possible side effects of the medication, drug interactions, and dosages to ensure that they will not cause operational errors or affect the operator's capacity to safely perform licensed duties and (2) any delay in taking a medication that might be expected to result in the incapacity of the operator. In addition, the actual wording of the license condition on medication will not specify a particular medical condition or medication, but it will simply state that the operator must 'take medication as prescribed.' Therefore, physician-prescribed changes in medication or dosing for an existing medical condition are not required to be reported to the NRC unless the examining physician believes that the operator's medical condition has become unstable (therefore requiring followup medical status reports to the NRC) or that the operator requires a no-solo license restriction. However, any new permanently disqualifying medical condition(s), requiring new medication(s), must be reported to the NRC."

As discussed in NUREG 1021, section ES-2.2, for new initial license applications, "The NRC staff's practice when it receives a new NRC Form 396 has been to send the information for review to a qualified medical expert, except for minor medical items explained below, using NRC Form 396A, 'Transmittal of NRC Form 396 for Medical Review.'

The form instructs the medical reviewer to evaluate facility license condition requests and medical evidence for ANSI standard compliance and to indicate concurrence, recommendations, disqualifications, or requests for additional medical evidence. In response, the medical reviewer may find that, among other things, the applicant's medical status is satisfactory for licensing with no restrictions or conditions, the applicant's medical status is satisfactory for licensing with specific restrictions or conditions, or the identified medical condition disqualifies the applicant from receiving a license. The medical reviewer documents his or her review and provides it to the NRC staff via NRC Form 396A." The same process applies when the NRC staff receives an NRC Form 396 for a licensed operator who is requesting a conditioned license to compensate a new permanent disability or illness.

Accordingly, any new permanent medical condition for which taking one or more medications as prescribed is determined to be a necessary license condition (i.e., restriction) requires submittal of an NRC Form 396 to comply with 10 CFR 55.25 even if the license is already conditioned with "shall take medication(s) as prescribed" due to a previously identified permanent medical condition requiring that license condition to ensure the operator meets the medical fitness requirements.

The NRC is preparing a proposed rule titled, "Regulatory Enhancements for Reactor Licensing, Decommissioning, and Operational Oversight" (Docket ID NRC-2025-1138), in response to Executive Order (EO) 14300 of May 23, 2025, titled, "Ordering the Reform of the Nuclear Regulatory Commission." The goal is to enhance regulatory efficiency by retaining safety-significant requirements, reducing unnecessary administrative burden, and aligning NRC regulations with current practices and Executive Orders. The scope includes revisions to 10 CFR Part 55. The NRC will consider this comment while developing the proposed rule.

Comment:

 Eliminating signatures on the NRC Form 396. The utility could streamline reviews per internal processes and utilize electronic reviews versus (in some cases) hard copy circulation for signatures.

NRC Response:

Because part of the commenter's proposal requires rulemaking, no changes were made to the NRC Form 396 to remove signatures.

A request to issue a new license or to amend an operator's license (i.e., to amend the license to add or remove a license condition associated with a medical condition) requires a signature from the affected licensed operator in accordance with 10 CFR 55.31(b); 10 CFR 55.31(d); 10 CFR 55.9, "Completeness and accuracy of information"; 10 CFR 55.61, "Modification and revocation of licenses;"

and Sections 107 and 182a of the Atomic Energy Act of 1954, as amended. The facility licensee must also certify that the information provided on the NRC Form 396 is true and accurate per 55.31(a)(6) and 55.57(a)(6).

The NRC staff agrees that the ability to sign NRC Form 396 electronically improves efficiency. The NRC already accepts electronic submissions as discussed below:

- 1. Any handwritten, optically scanned signature will be accepted, regardless of transmission process used (hardcopy, Part 55 EIE, or e-mail).
- Facility licensees may use any generally recognized form of electronic signature for forms being submitted through Part 55 EIE. The digital trail created by the EIE credential registration/issuance process, EIE system login, and other system database timestamps, offers sufficient documentation of authenticity.
- Any utility desiring to use a digital certificate to sign the documents needs to obtain specific approval from the NRC by sending in a request detailing how the facility meets the attributes in Table 1 below. The NRC may approve use of this certificate for signing and submitting Forms 398 and 396 through either e-mail or Part 55 EIE.
- 4. Facility licensees may NOT use electronic signatures for forms submitted through email. The only possible exception is if the facility uses a digital certificate that the NRC has reviewed and determined to be acceptable per item 3 above. The document must contain the digital certificate information (it cannot digitally sign the document and then convert the file in such a way that the digital certificate information is lost). An EIE certificate is not sufficient to send documents using e-mail.

Additionally, the NRC intends to provide an option for web-based submissions for NRC Form 396 and NRC For 398.

Comment:

 Eliminating information only submittals. If these truly are for informational purposes, they are not necessary for the NRC to perform its function.

NRC Response:

The NRC staff partially agrees with the commenter. The NRC Form 396 has been revised.

The form instructions for box 11, "Information only," stated, "Check box if providing required established medical status updates that do

not request new restrictions, removal of restrictions or change in status report frequency. Use for reporting any other medical situation you determine that needs to be reported to the NRC. Do not report temporary medical conditions for operators on administrative hold." Box 11 was included in section A of the form, under the heading that states, "Based on the recommendation of the physician, it is requested that the applicant/operator license be conditioned as follows: check all that apply. (See instructions)."

As stated in the form instructions, box 11 is to be used for providing required established medical status updates (i.e., to comply with a license condition that requires the submittal of medical status reports at a certain periodicity; this condition is box 7 on the NRC Form 396). Accordingly, the NRC staff has revised the NRC Form 396 so that box 11 is separate from the license conditions in boxes 1-9, and it has been renamed to "Transmittal of required medical status report." The form instructions have also been revised to delete the statement, "Use for reporting any other medical situation you determine that needs to be reported to the NRC. Do not report temporary medical conditions for operators on administrative hold." Because an NRC Form 396 submittal is only required to certify the medical fitness of an applicant per 55.23(a) and an applicant for renewal per 55.57(a)(6) and/or to provide medical evidence with a request for a conditional license based on the medical evidence per 55.23(b) and 55.25, the NRC Form 396 is not intended to be used for communicating other information to the NRC. Instead, facility licensees and operators should refer to 55.5 for any other matter. Instructions for Section A for physician's certification date have also been updated to reflect box 11 vs 7.

Comment:

Changing the reporting frequency of required medical updates. Utility
processes require controls for medical status changes. These
changes are auditable at any time by the NRC/NRC residents.
Reducing the frequency of required submittals reduces the
administrative burden associated with NRC submittals.

NRC Response:

Because the commenter's proposal requires rulemaking, no changes were made to the NRC Form 396.

10 CFR 55.57(a)(6) requires an applicant for renewal of a license to, among other things, 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 55.27. Licenses currently expire 6 years after the date of issuance; accordingly, renewals of licenses occur on a 6-year frequency. Therefore, rulemaking is required to change the requirement. The NRC is preparing a proposed rule titled, "Regulatory Enhancements for Reactor Licensing, Decommissioning, and Operational Oversight" (Docket ID NRC-2025-1138), in response

to Executive Order (EO) 14300 of May 23, 2025, titled, "Ordering the Reform of the Nuclear Regulatory Commission." The goal is to enhance regulatory efficiency by retaining safety-significant requirements, reducing unnecessary administrative burden, and aligning NRC regulations with current practices and Executive Orders. The scope includes revisions to 10 CFR Part 55. The NRC will consider this comment while developing the proposed rule.

Additionally, other medical status reports that are required to be provided to the NRC to comply with a license condition are determined on a case-by-case basis by the examining physician. A license condition to provide a medical status report on a certain periodicity is based on a review of the medical evidence that demonstrates that the operator's medical condition requires more frequent monitoring than the two (2) years required by 10 CFR 55.21.

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

Comment: Box 10 instructions need additional clarity. Is the intent of this Box to indicate a different restriction (e.g. a licensed operator now requires restriction of solo operation is not authorized where previously they did not) or is the intent of this Box to indicate a change in restriction (e.g. a licensed operator used to require a restriction of shall take medication as prescribed for Condition A and now requires a restriction of shall take medication as prescribed for Condition B (two different medical conditions) or e.g. a licensed operator requires a restriction of shall take medication as prescribed for Condition A and takes Medication A. The licensed operator now requires a restriction of shall take medication as prescribed for Condition A and takes Medication B (same medical condition, different medication)).

NRC Response:

The NRC staff agrees with the commenter, and the NRC Form 396 has been revised.

Per the form instructions, Box 10 is checked for an "additional license condition request, modification of an existing license condition, or deletion of an existing license condition." The intention is to indicate whether a license amendment (i.e., a change to a license) is being requested. The instructions have been revised to clarify that box 10 should be checked when a change or amendment to a license is being requested.

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

Comment:

 Recommend combining "Proposed Wording of Restriction" and "Relationship of Restriction to Disqualifying Condition" Boxes as these two boxes are only used when Box 9 is checked.

NRC Response:

The NRC staff partially agrees with the commenter, and the NRC Form 396 was revised.

The NRC staff agrees that the "Proposed Wording of Restriction" and "Relationship of Restriction to Disqualifying Condition" boxes only need to be completed if box 9 is checked. However, the NRC staff do not agree with the recommendation to combine the boxes. The proposed wording of a restriction (i.e., license condition) and its relationship to the disqualifying medical condition are separate pieces of information that need to be provided when "other" (i.e., box 9) is selected as a recommended license condition. Requesting two pieces of information to be provided in a single box on the form may result in submittals that lack one of the two required pieces of information. Additionally, combining the items into one box would not change the burden associated with completing the form. However, additional clarity can be provided by adding "for box 9 only" in the "Proposed Wording of Restriction" and "Relationship of Restriction to Disgualifying Condition" boxes. This will result in reduced burden for users who have been providing that information even if box 9 is not checked.

Comment:

 Recommend moving "Explanations" Box above "Proposed Wording of Restriction" and "Relationship of Restriction to Disqualifying Condition" Boxes. Explanations Box is used much more frequently.

NRC Response:

The NRC staff partially agrees with the commenter. No changes were made to the NRC Form 396.

The NRC staff agrees that the "explanation" box is used more frequently than the Proposed Wording of Restriction" and "Relationship of Restriction to Disqualifying Condition" boxes. However, moving the boxes would not reduce burden.

Comment:

 Clarify intent of Box 12. Supporting information (Medical Evidence) is provided for restriction changes. Instructions indicate this is for new applicants.

NRC Response:

The NRC staff agrees with the commenter, and the NRC Form 396 was revised. The form instructions for box 12 were edited to say, "for new applicants/operators."

9. Payment or Gift to Respondents

Not applicable.

10. <u>Confidentiality of Information</u>

Confidential and proprietary information is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b). 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 March 19, 2025 (90 FR 12805).

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 basis 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 March 19, 2025 (90 FR 12805).

12. <u>Estimated Industry Burden and Burden Hour Cost</u>

(a) Reporting Requirements Burden

Approximately 1,729 NRC Form 396s are expected to be submitted annually (includes applicants, renewals and notices of disability). The estimated reporting burden is 1.0 hour per submittal for a total of 1,729 hours. At the hourly cost of \$317 the total burden cost is \$548,093 (See Table 1).

(b) Recordkeeping Requirements Burden

There are 133 facilities that retain the medical documentation for approximately 4,310 applicants, reactor operators and senior reactor operators while they are employed in this capacity (10 CFR 55.27). Approximately 1,729 facility records require annual NRC Form 396 maintenance. The estimated recordkeeping burden is 0.25 hour per record for a total of 432 hours. At the hourly cost of \$317, the total burden

cost is \$136,944 (See Table 2).

(c) <u>Total Industry Burden and Cost</u>

Total Annual Burden: 2,161 (1,729 Reporting hours plus 432 Recordkeeping hours)

Total Burden Hour Cost: \$685,037 (2,161 hours x \$317 per hour)

The \$317 hourly rate used in the burden estimates is based on the NRC's fee for hourly rates as noted in 10 CFR 170.20 "Average cost per professional staff-hour." For more information on the hourly rate, see the "Revision of Fee Schedules, Fee Recovery for Fiscal Year 2024" final rule (89 FR 51789; June 20, 2024).

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 \$54.77 (432 Recordkeeping hours x \$317 x 0.0004).

14. <u>Estimated Annualized Cost to the Federal Government</u>

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 1,729 NRC Form 396s will be submitted annually during the clearance period. It is also estimated that 622 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: 622 NRC Forms 396 reviewed annually x \$102.49 per form = \$63,749.

NRC staff (Headquarters & Regional) processing: 1,729 forms annually submitted x 0.25 hour per submittal = 432 hours. 432 hours x \$317 per hour = \$136,944.

Total annual cost to the Federal Government is \$200,693 (\$63,749 + \$136,944).

15. Reasons for Change in Burden or Cost

The number of total responses has increased from 1,778 in the prior cycle to 1,862 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 increase in projected submissions is due to the increase in licensed individuals, operating reactor plants, and projected license renewals being subject to Part 55 requirements.

Currently, NRC uses the Electronic Information Exchange (EIE), OSM, facsimile, or e-mail to deliver NRC Form 396 and receive the completed medical reviews from the NRC Contractor. The facility licensees submit a scanned pdf version of NRC Form 396 via EIE. NRC Form 396 was updated to clarify instructions.

In addition, the fee rate has increased from \$288 to \$317 per hour.

16. Publication for Statistical Use

None.

17. Reason for Not Displaying the Expiration Date

The expiration date is displayed on form.

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 \$317 per hour
NRC Form 396	133	13	1,729	1.0	1,729	\$548,093
1			1			

TABLE 2 Annual Recordkeeping Burden

	Annual Records Requiring Maintenance	Hours per Recordkeeping	Total Annual Burden Hours	Cost at \$317 per hour
NRC Form 396	1,729	0.25	432	\$136,944

Total Annual Burden: 2,161 hours (1,729 Reporting hours + 432 Recordkeeping

hours)

Total Burden Hour Cost: \$685,037 (2,161 hours x \$317/per hour)

Total Responses: 1,862 (1,729 Responses + 133 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.

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.

NRC FORM 396, "CERTIFICATION OF MEDICAL EXAMINATION BY FACILITY LICENSEE" GUIDANCE DOCUMENTS

Title	Agencywide Documents Access and		
	Management System (ADAMS)		
	Accession No.		
NUREG-1021 "Operator Licensing	ML21256A276		
Examination Standards for Power Reactors"			
NUREG-1478 "Operator Licensing Examiner	ML072000059		
Standards for Research and Test Reactors"			