

SUPPORTING STATEMENT
FOR INFORMATION COLLECTIONS CONTAINED IN RISK-INFORMED,
TECHNOLOGY-INCLUSIVE REGULATORY FRAMEWORK FOR ADVANCED REACTORS
FINAL RULE

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

(3150-XXXX)
NEW

Description of the Information Collection

The U.S. Nuclear Regulatory Commission (NRC) is establishing an optional technology-inclusive regulatory framework for use by applicants for new commercial nuclear plant designs. The regulatory requirements in this rulemaking use methods of evaluation, including risk-informed and performance-based methods, that are flexible and practicable for application to a variety of new reactor technologies. The NRC's goals in amending these regulations are to continue to provide reasonable assurance of adequate protection of public health and safety and the common defense and security at reactor sites at which new nuclear reactor designs are deployed to at least the same degree of protection as required for current-generation light-water reactors; protect health and minimize danger to life or property to at least the same degree of protection as required for current-generation light-water reactors; provide greater operational flexibilities where supported by enhanced margins of safety that may be provided in new nuclear designs; and promote regulatory stability, predictability, and clarity.

The final rule covers a wide range of topics, including the following that result in recordkeeping and reporting requirements:

- Fitness for duty,
- Physical security,
- Cybersecurity,
- Access authorization.
- Plant design and analysis,
- Siting,
- Construction and manufacturing,
- Facility operations,
- Programs,
- Staffing,
- Decommissioning,
- Applications,
- Licensing basis information, and
- Quality assurance.

To certify the medical fitness of applicants for an operator or senior operator license, 10 CFR 53.765, "Medical requirements," requires that NRC Form 396, "Certification of Medical Examination by Facility Licensee," be completed by applicants for or holders of an operating license (OL) or a combined license (COL) under 10 CFR Part 53, "Risk-Informed, Technology-Inclusive Regulatory Framework for Commercial Nuclear Plants," for an interaction-dependent-mitigation facility that has not yet certified the permanent cessation of operations and permanent removal of fuel from the reactor vessel (as described under

10 CFR 53.1070, "Termination of license"). For applications for operator and senior operator licenses at these facilities, NRC Form 396 must also be used to document conditions in the license for which a conditional license is requested under 10 CFR 53.775, "Applications for operators and senior operators" (which may include notices of disability or illness in accordance with 10 CFR 53.770). Applications for operator and senior operator licenses expire 6 years after the date of issuance, and applications for renewal of the licenses must also include certification of medical condition and general health on NRC Form 396 in accordance with 10 CFR 53.795, "Expiration and renewal of operator and senior operator licenses."

Currently, NRC Form 396 is used by authorized facility licensees under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," to certify the medical condition of operators and senior operator applicants and licensees in accordance with 10 CFR Part 55, "Operators' Licenses." NRC Form 396 is the mechanism by which NRC is advised of the applicant/licensee general health and physical condition.

As a result of the Part 53 rulemaking, the instructions for NRC Form 396 are being modified to include references to applicable requirements under 10 CFR Part 53 (in addition to the existing 10 CFR Part 55 references). In addition, the form is being modified to include a checkbox for Part 53 facility docket numbers.

The information requested includes the applicant/operator identifying information, medical examination information, applicant/operator signature, and facility certification.

For the purposes of this supporting statement, the NRC staff estimates that there will be 2 respondents during the three-year period covered by this clearance (2027–2029). During this period, the NRC staff assumes that the respondents will prepare and submit application materials for an OL.

This supporting statement describes how the final rule is impacting the information collections in NRC Form 396. Due to the recent submission of the renewal of this form under the clearance number 3150-0024, the changes to these forms as a result of the final rule are being submitted as a request for a new clearance. The NRC staff intends to transfer the burden associated with this final rule to the 3150-0024 clearance at a later date.

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 53. Details of these regulations can be found at the end of this supporting statement in "Description of Information Collection Requirements."

2. Agency Use of Information

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. The Electronic Submittals application allows electronic transmission of information to the NRC pertaining to licensing actions, associated hearings, and other regulatory matters. The application ensures that information sent to the NRC via the Internet is secure and unaltered during transmission. It operates 24 hours a day, except when it is taken down for scheduled maintenance. 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

The NRC is currently not aware of any known small entities as defined in 10 CFR 2.810 that are planning to apply for a commercial nuclear plant early site permit, construction permit, operating license, manufacturing license, or combined license under 10 CFR Part 53 that will be impacted by this final rule.

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 53.765, 53.770, 53.775, and 53.795 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, the 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

The NRC published a proposed rule in the *Federal Register* for public comment on October 31, 2024 (89 FR 86918). Public comments on the proposed rule recommended that the NRC prepare an OMB Supporting Statement for changes to the information collection burden of Form 396 resulting from the final rule; in response, the NRC developed this Supporting Statement. The NRC prepared a summary and analysis of public comments received on the proposed rule, which totals two volumes (ML26042A229, ML26042A228). The public comment submissions are available from the Federal e-Rulemaking website at <https://www.regulations.gov> under Docket ID NRC-2019-0062.

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 NRC 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 NRC 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 Burden and Burden Hour Cost

As a result of the final rule, the list of potential respondents to NRC Form 396 has been expanded to include Part 53 licensees and applicants. The estimated time to complete the form is similar for Part 53 licensees/applicants as for Part 50 and 52 licensees/applicants (1 hour). Additionally, the estimated time to maintain medical documentation is similar for Part 53 licensees/applicants as for Part 50 and 52 licensees/applicants (0.25 hour). The NRC anticipates that there will be initial one-time reporting burdens for new applications for operator and senior operator licenses by applicants and license holders at Part 53 interaction-dependent-mitigation facilities. In addition, the NRC anticipates that there will be ongoing reporting and recordkeeping burdens associated with operator and senior operator license renewals and notices of disability. During the clearance period, the NRC anticipates there being 2 OL applications and 0

COL applications for Part 53 facilities that are required to submit NRC Form 396 and estimates that each facility seeking an OL will have 25 operators submitting NRC Form 396. As a result, the number of respondents for the clearance period increases by 2, and the number of NRC Form 396 submissions increases by 50 during the clearance period (50 submissions over three years = 16.67 submissions annually).

(a) Reporting Requirements Burden

Approximately 16.67 NRC Form 396s are expected to be submitted annually due to the final rule at 1 hour per form, for a total reporting burden of 16.67 hours. At the hourly cost of \$154, the total burden cost is \$2,567.

(b) Recordkeeping Requirements Burden

Approximately 16.67 facility records require annual NRC Form 396 maintenance due to the final rule at 0.25 hours per record, for a total recordkeeping burden of 4.17 hours. At the hourly cost of \$154, the total burden cost is \$642.

(c) Total Industry Burden and Cost

Total Annual Burden: 20.84 hours (16.67 reporting hours + 4.17 recordkeeping hours)

Total Annual Cost: \$3,209 (20.84 hours x \$154/hour)

The NRC's average labor rate of \$154 per hour for FY 2026 was used to calculate burden costs to the public because it aligns with 2024 Bureau of Labor Statistics data showing comparable hourly mean wages across five key occupational groups (executives, management, technical staff, licensing staff, and physicists) within the nuclear industry.

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 annual recordkeeping storage cost as a result of the final rule is estimated to be negligible (less than a dollar), and as a result, reported additional costs have not been increased.

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 16.67 NRC Form 396s will be submitted annually during the clearance period as a result of the final rule. It is also estimated that 6 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:
6 NRC Forms 396 reviewed annually x \$100 per form = \$600.

NRC staff (Headquarters & Regional) processing: 16.67 forms annually submitted x 0.25 hour per submittal = 4.17 hours.

4.17 hours x \$154/hour = \$642.

The total increase in annual cost to the Federal Government is \$1,242 (\$600 + \$642).

15. Reasons for Change in Burden or Cost

As a result of the final rule, NRC Form 396 has been updated to include Part 53 licensees and applicants. Due to the addition of applications for and licensees with operating or combined licenses under Part 53, the total annual burden is expected to increase by 20.84 hours due to an increase in the number of respondents.

16. Publication for Statistical Use

Not applicable.

17. Reason for Not Displaying the Expiration Date

The expiration date is displayed.

18. Exceptions to the Certification Statement

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

The collection of information does not employ statistical methods.

DESCRIPTION OF INFORMATION COLLECTION REQUIREMENTS
CONTAINED IN
NRC FORM 396, "CERTIFICATION OF MEDICAL EXAMINATION BY FACILITY LICENSEE"
10 CFR PART 53, SECTIONS 53.765, 53.770, 53.775, AND 53.795
(3150-XXXX)

10 CFR 53.765 requires that the facility licensee certify the medical fitness of or licensee by completing and signing NRC Form 396.

10 CFR 53.770 requires that the facility licensee 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 53.775(b)(1)(i). For conditions where a conditional license is requested under 10 CFR 53.775, the facility licensee must provide medical certification on NRC Form 396.

10 CFR 53.775 includes the application requirements for operators and senior operators, including use of NRC Form 396 for certification of medical condition and general health and for documentation of conditional licenses.

10 CFR 53.795 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 53, as described above, require a license applicant to be examined by a licensed physician. In general, the licensed physician might use 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, 2007, or 2016)*. The licensed physician would then submit the diagnostic report to the facility licensee. Subsequently, the applicant/operator would sign the NRC Form 396 giving permissions to the facility licensee and the NRC, the facility licensee would certify on NRC Form 396 as to the applicant's or operator's general health and physical condition, and then the facility licensee would submit NRC Form 396 to the NRC.

In cases where the application for an operator's license or renewal is not consistent with the ANSI/ANS guidance, if used, the facility licensee may submit recommendations for license conditions, removal of license conditions, or revocation of the license with supporting medical evidence for review by the NRC.

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 53.775(b)(1)(i), 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.

Records required by 10 CFR 53.765(c) 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.

EXISTING GUIDANCE DOCUMENTS FOR INFORMATION COLLECTION REQUIREMENTS
FOR
NRC FORM 396, "CERTIFICATION OF MEDICAL EXAMINATION BY FACILITY LICENSEE"
(3150-XXXX)

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