

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
WASHINGTON, DC 20555-0001

July 16, 2012

NRC INFORMATION NOTICE 2012-10: RECENT ISSUES ASSOCIATED WITH
SUBMITTAL OF NRC FORM 396,
*CERTIFICATION OF MEDICAL EXAMINATION BY
FACILITY LICENSEE*, FOR APPLICANTS AND
LICENSED OPERATORS AT NON-POWER
REACTORS

ADDRESSEES

All holders of operating licenses for non-power reactors under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," except those who have permanently ceased operations and have returned all of their fuel to the U.S. Department of Energy, and all applicants and holders of non-power reactor operator and senior operator licenses issued under 10 CFR Part 55, "Operators' Licenses."

PURPOSE

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice (IN) to inform addressees about recent issues on the completeness of information required in the "Certification of Medical Examination by Facility Licensee" (NRC Form 396) to meet NRC medical requirements for applicants and holders of operator and senior operator licenses (referred to collectively as "operators"). The NRC expects recipients to review the information contained in this IN for applicability to their facilities and operators and consider actions, as appropriate, to avoid similar issues. Suggestions contained in this IN are not NRC requirements. Therefore, no specific action or written response is required.

DESCRIPTION OF CIRCUMSTANCES

Recently, some facilities have failed to adequately inform the NRC of (1) changes in medical status of licensed individuals, or (2) medical conditions on license applications. Additionally, some facilities have not ensured the examining medical official's information was included on the NRC Form 396 and may not always ensure medical staff are familiar with the medical requirements of 10 CFR Part 55. This has resulted in delays in the issuance of operator licenses, in some cases for extended periods of time, while the errors were resolved. The following examples describe these issues:

- In January 2011, a facility submitted an NRC Form 396 with a license application that did not provide the required explanation or medical evidence on an identified medical condition to allow review by NRC physicians.
- In March 2011, a facility submitted five NRC Form 396s for applicants scheduled to take an NRC license examination. Two of the submittals were incomplete because of the following: (1) Block 5, "Must take medication as prescribed to maintain medical

qualifications,” was selected, but the required explanation or medical evidence was not provided, and (2) Block 5, “Must take medication as prescribed to maintain medical qualifications,” and Block 6, “Must submit medical status report every 3 months,” were selected, but the required explanations or medical evidence were not provided.

- In August 2011, a facility submitted an NRC Form 396 with “No Restrictions” selected. The operator listed on the form had a change in medical status from the operator’s previously submitted NRC Form 396 that showed, “Corrective lenses be worn when Performing Licensed Duties.” The facility should have checked Box 9, “Restriction change from previous submittal,” and provided the required explanation or medical evidence to support the change.
- In 2010 and 2011, several facilities submitted NRC Form 396s that did not include the licensed physician’s information as the examining medical official.
- In January 2012, a facility submitted a request for a senior operator – upgrade examination for an applicant. The NRC Form 396 submitted with the request did not reflect the medical condition requirements stated on the reactor operator license issued in 2011. Communications with the facility and applicant revealed that the applicant’s original diagnosis requiring a license condition restriction was determined to be an error. Additionally, a subsequent diagnosis by the applicant’s personal physician should have required a different medical condition restriction. The facility had not reported the change in medical condition when it occurred, and did not include the required explanation or evidence with the new NRC Form 396.
- In February 2012, a facility submitted five NRC Form 396s for applicants scheduled to take an NRC license examination. Some of the submitted applications contained attachments as a checklist used during the medical examination. Four of the submittals were incomplete with the following problems:
 1. Two of the submittals indicated that the hearing test conducted consisted of speaking and whispering. Section 7.2.4(1) of American Nuclear Standards Institute/American Nuclear Society (ANSI/ANS)-15.4-2007 has specific requirements for hearing ability and the standard allows the method used to test the applicant if the audiometric scores are unacceptable. The examining physician did not explain if the required puretone audiometric scores were outside the normal range requiring the use of the exception.
 2. One submittal indicated that an applicant had been treated for a potentially disqualifying condition and had been under a physician’s care for approximately 5 years for this condition. The examining certifying physician did not reference the status of the condition, nor did the physician acknowledge whether the applicant was on any continuing medication regimen to control the condition.
 3. One submitted NRC Form 396 did not include the licensed physician’s information as the examining medical official.

Of the facilities with multiple NRC Form 396 errors, a common trait was that several different doctors performed physical examinations who may or may not have been familiar with the ANSI Standards.

BACKGROUND

Related NRC Generic Communications

NRC IN 2009-21, "Incomplete Medical Testing for Licensed Operators," dated September 30, 2009, (Agencywide Documents Access and Management System (ADAMS) Accession No. ML092520457).

NRC IN 2004-20, "Recent Issues Associated with NRC Medical Requirements for Licensed Operators," dated November 24, 2004, (ADAMS Accession No. ML042510509).

NRC IN 1994-14, "Failure to Implement Requirements for Biennial Medical Examinations and Notification to the NRC of Changes in Licensed Operator Medical Conditions," dated February 24, 1994 (ADAMS Accession No. ML031060622), and Supplement 1, dated April 14, 1997 (ADAMS Accession No. ML031060468).

NRC IN 1991-08, "Medical Examinations for Licensed Operators," dated February 5, 1991 (ADAMS Accession No. ML031190668).

General questions applicable to medical issues and the NRC Form 396 can be found at <http://www.nrc.gov/reactors/operator-licensing/op-licensing-files/ol-feedback.pdf>.

DISCUSSION

Regulatory Basis of Licensed Operator Medical Requirements

The NRC's requirements related to the conduct and documentation of medical examinations for operators are contained in Subpart C, "Medical Requirements," of 10 CFR Part 55, "Operators' Licenses." Specifically, 10 CFR 55.21, "Medical Examination," requires every operator to be examined by a physician when he or she first applies for a license and every 2 years thereafter. The physician must determine whether the operator meets the requirements of Subpart D, "Applications," of 10 CFR 55.33(a)(1), "Health," (i.e., the operator's medical condition and general health will not adversely affect the performance of assigned operator duties or cause operational errors that endanger public health and safety). When an operator applies for or renews a license pursuant to 10 CFR 55.31, "How to Apply," or Subpart D of 10 CFR 55.57, "Renewal of Licenses," an authorized representative of the facility licensee must complete and sign NRC Form 396 pursuant to Subpart C of 10 CFR 55.23, "Certification," certifying that a physician has conducted the required medical examination and determined that the operator's medical condition and general health meet the requirements of 10 CFR 55.33(a)(1).

The facility licensee must also certify which industry standard (i.e., the 1988 or 2007 version of ANSI/ANS-15.4, "Selection and Training of Personnel for Research Reactors," the 1983 or 1996 version of ANSI/ANS-3.4, "Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants," or "other" guidance that may be approved by the NRC) was used in making the medical determination.

The ANSI standards describe a number of specific operator minimum medical requirements and disqualifying conditions. If an operator's medical status does not meet the minimum standards, the facility licensee must request a conditional license in accordance with 10 CFR 55.23(b) by submitting the appropriate medical explanation and evidence on or attached to NRC Form 396. Pursuant to 10 CFR 55.33, "Disposition of an Initial Application," and Subpart F, "Licenses," of

10 CFR 55.57, the Commission will review the license application based on requested restrictions and supporting explanations or medical evidence.

Subpart C of 10 CFR 55.27, "Documentation," requires the facility licensee to document and maintain the medical qualifications data, test results, and each operator's medical history. In addition, 10 CFR 55.27 requires the facility licensee to retain each operator's medical history for the current license period and provide that information to the NRC upon request.

Medical information must be sent to the NRC: (1) as part of an initial, upgrade, or renewal application per 10 CFR 55.31(6) and 55.57(6) and (2) if, at any time during the term of an operator's license, the operator develops a permanent physical or mental condition that causes the operator to fail to meet the requirements of 10 CFR 55.21. The facility licensee must notify the Commission, pursuant to 10 CFR 55.25, "Incapacitation Because of Disability or Illness," and 10 CFR 50.74(c) within 30 days of learning of the diagnosis. If a conditional license is requested, the facility licensee must forward the requested restriction and medical evidence and explanation on NRC Form 396, as described in 10 CFR 55.23. The facility must maintain that medical evidence pursuant to 10 CFR 55.27.

In addition to the other requirements under Subpart F, "Licenses," of 10 CFR 55.53, "Conditions of Licenses," including 10 CFR 55.53(g) and (k), the licensed operator or applicant must notify the facility licensee of any change in medical or psychological status including, but not limited to, new medications and change in medications or treatment regimen. The licensed operator or applicant shall provide any medical records that the designated medical examiner deems necessary to complete the medical examination.

NRC Form 396 requires the signature of the senior management representative onsite, and by signing the NRC Form 396, the facility certifies that the guidance identified was followed in determining the medical fitness of an operator for non-power reactors. This is subject to the requirements of 10 CFR 50.9, "Completeness and Accuracy of Information." Any material false statement or omission on an NRC Form 396, including attachments, may represent a violation of NRC requirements that could lead to enforcement action.

CONCLUSION

A successful submission of NRC Form 396 for applications or renewals contains the following attributes, in part:

- If requesting a restriction or removal of a restriction, include a complete and concise explanation and provide appropriate medical evidence, as explicitly stated on the form in the restrictions section.
- Use the provided block on NRC Form 396 to clearly link the proposed restriction to the guidance standard's disqualifying condition (e.g., ANSI/ANS-15.4 or 3.4).
- When proposing an "other" restriction or exception (Box 9 on NRC Form 396), use the "proposed wording of restriction" block to clearly state what the license condition should say to ensure there is no misunderstanding.
- If medical information is being submitted as "information only," indicate such by checking Box 11 on NRC Form 396. Use the "explanation" block or clearly indicate in attached correspondence whether there is a relationship to ANSI/ANS-15.4 or 3.4 or other

guidance standard disqualifying condition. If a guidance standard condition is involved, clearly state the impact (or absence thereof) of the information on the individual's qualification relative to that condition. If not related to a specific guidance standard disqualifying condition but to a medication, include a statement that addresses the name and strength of the medication and the dosage and side effects, if any.

- When making a submittal that involves a change in medication, include a brief statement of the reason for the medication change, a confirmation that the guidance standard requirements continue to be met, and that the existing license conditions remain adequate (e.g., the medical situation is stable such that more frequent monitoring or “no solo” changes are not warranted). This provides a complete basis for the NRC medical reviewer for the reported change and allows for an evaluation of the impact on overall medical qualifications in accordance with the guidance standard.
- Fill out, as applicable, the blocks in NRC Form 396 titled “relationship of restriction to disqualifying condition.” Briefly indicate how restriction will correct the disqualifying condition and fill out “explanation(s).”
- Ensure the examining medical official's complete information required on NRC Form 396 is included on the NRC Form 396. Additionally, ensure involved medical staff are trained or otherwise familiar with the medical requirements of 10 CFR Part 55.

When an NRC physician's review is required, information should be included on the NRC Form 396 to enable the NRC's physician to perform a timely review of the requested condition or reported change. This can be achieved by including a statement addressing the following elements:

- medical condition or issue linked to guidance standard (e.g., ANSI/ANS-15.4 or ANSI/ANS-3.4 disqualifying condition).
- supporting medical evidence (examination and diagnostic studies results).
- current diagnosis (controlled, stable, uncontrolled).
- treatment plan (for medication, include the name, dose, and side effects, if any).
- proposed license restriction.
- format is not as important as content (a memorandum addressing the bullets above is sufficient; however, it is helpful to avoid handwritten notes, such as prescription pads, which can be difficult to read).

CONTACT

This IN requires no specific action or written response. Please direct any questions about this matter to the technical contacts listed below or the appropriate Office of Nuclear Reactor Regulation operator license examiner.

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Note: NRC generic communications may be found on the NRC public Web site at <http://www.nrc.gov> under NRC Library/Document Collections.

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