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REGULATORY GUIDE

REGULATORY GUIDE 1.134

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MEDICAL ASSESSMENT OF LICENSED OPERATORS OR APPLICANTS FOR OPERATOR LICENSES AT NUCLEAR POWER PLANTS

A. INTRODUCTION

Purpose

This regulatory guide describes methods acceptable to the staff of the U.S. Nuclear Regulatory Commission (NRC) for complying with those portions of the Commission's regulations associated with approval or acceptance of the medical assessment of an applicant or licensee for an operator or senior operator license at nuclear power plants.

Holders of licenses for nuclear power plants issued under Part 50, "Domestic Licensing of Production and Utilization Facilities," (Ref. 1) or Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," (Ref. 2) of Title 10 of the *Code of Federal Regulations* (10 CFR), are required under 10 CFR Part 50.54, "Conditions of Licensees," to use licensed operators as described in 10 CFR Part 55, "Operators' Licenses" (Ref. 3). The guide helps to ensure that medical certifications (and related medical evidence) used to meet the requirements of 10 CFR Part 55 are sufficient. The guide helps to ensure that medical certifications (and related medical evidence) used to meet the requirements of 10 CFR Part 55 are sufficient.

Applicable Rules and Regulations

- This guidance addresses the following aspects of 10 CFR Part 55, "Operators' Licenses," Subpart C, "Medical Requirements,"

  (1) 10 CFR Part 55.21, "Medical examination," requires an applicant for an operator's license to have a medical examination by a physician, and requires an operator licensee to have a medical examination every two years.

  (2) 10 CFR Part 55.23, "Certification," requires that the medical fitness of an applicant be certified by an authorized representative of the facility licensee who shall complete and sign NRC Form 396, "Certification of Medical Examination by Facility Licensee."

Written suggestions regarding this guide or development of new guides may be submitted through the NRC's public Web site under the Regulatory Guides document collection of the NRC Library at http://www.nrc.gov/reading-rm/doc-collections/reg-guides/contactus.html.

Electronic copies of this regulatory guide, previous versions of this guide, and other recently issued guides are available through the NRC's public Web site under the Regulatory Guides document collection of the NRC Library at http://www.nrc.gov/reading-rm/doc-collections/. The regulatory guide is also available through the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html, under ADAMS Accession No. ML14189A388. The regulatory analysis may be found in ADAMS under Accession No. ML13352A279. No public comments were received on DG-1310.

(3) 10 CFR Part 55.25, "Incapacitation because of disability or illness," requires that if during the term of the license, the licensee develops a permanent physical or mental condition that causes the licensee to fail to meet the requirements of 10 CFR Part 55.21, the facility licensee shall notify the Commission within 30 days.

(4) 10 CFR Part 55.27, "Documentation," requires that the facility licensee document and maintain the results of medical qualification data, test results, and each operator's medical history.

- 10 CFR Part 55.33(a), "Requirements for approval of an initial application," states that the Commission will approve an application based on the certification required in 10 CFR 55.23 if it finds that the applicant's or 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.

Purpose of Regulatory Guides

The NRC issues regulatory guides to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations and compliance with them is not required. Methods and solutions that differ from those set forth in regulatory guides will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission.

Paperwork Reduction Act

This regulatory guide contains information collection requirements covered by 10 CFR Part 55 that the Office of Management and Budget (OMB) approved under OMB control number 3150-0018. The NRC may neither conduct nor sponsor, and a person is not required to respond to, an information collection request or requirement unless the requesting document displays a currently valid OMB control number.

B. DISCUSSION

Reason for Revision

This revision of RG 1.134 (Revision 4) updates the guidance to address experience gained since the previous revision of RG 1.134 (Revision 3) was issued in 1998. The guidance is based upon ANSI/ANS-3.4-2013. (Ref. 4) ANSI/ANS-3.4-2013 was revised to provide clarification and comprehensive medical guidance to improve industry's consistent implementation of the standard. This included clarification of specific minimum requirements, disqualifying conditions, conditional restrictions, examination methods, and monitoring methods for each medical area. The 2013 issue also included consideration of other industry medical standards, including those of the U.S. Department of Transportation and Federal Aviation Administration, as well as medical criteria that reflect progressions in medical science, including updated terminology, current medical practices, criteria for normality, and risk assessments.

Background

Regulations

Both applicants and licensees are required under Subpart C of 10 CFR Part 55 to provide the NRC with certification by the facility licensee of their medical condition and general health on Form NRC 396, "Certification of Medical Examination by Facility Licensee." When the certification requests a conditional license, the supporting medical evidence must be submitted with Form NRC 396 to the Commission. The Commission then makes a determination regarding its assessment of the applicant or licensee's medical fitness to actively perform the functions of a licensed operator or senior operator. The detailed medical information collected has changed several times over the years.

The Atomic Energy Act of 1954, as amended, requires the NRC to determine, among other things, the medical qualifications for licensing individuals as operators of utilization facilities. Beginning in 1956, the Commission's regulations (under the Atomic Energy Commission (AEC)) required an applicant to furnish a report (e.g., Examination Form, "Certificate of Medical Examination for Operator's License") of a medical examination performed and signed by a licensed medical practitioner (Volume 21, page 6, of the *Federal Register* (21 FR 6; January 4, 1956)) (Ref. 5). The report recorded results in the following topical areas: (1) medical history; (2) eyes; (3) ears; (4) gastro-intestinal; (5) heart and blood vessels; (6) lungs; (7) deformities, atrophies, and other abnormalities, and diseases not included above; and (8) the nervous system.

In April 1963, the AEC amended 10 CFR 55.60 to require both the applicant and the examining physician to complete and sign Form AEC-396, "Certificate of Medical Examination" (28 FR 3200; April 3, 1963) (Ref. 6).

In March 1987, the NRC amended 10 CFR Part 55 to clarify, among other things, the medical certification process for issuing licenses to operators and senior operators; it also changed the title of Form NRC-396 to "Certification of Medical Examination by Facility Licensee." Responsibilities were clarified to reinforce that facility management is responsible for certifying the medical suitability and fitness for duty of the applicant for a license and that the NRC is responsible for making an assessment of the applicant's qualifications for a license, including the applicant's medical fitness (52 FR 9460; March 25, 1987) (Ref. 7).

In July 1991, the NRC amended 10 CFR Parts 2 and 55 to specify that the conditions and cutoff levels established under the Commission's Fitness-for-Duty (FFD) Programs are applicable to licensed operators as conditions of their licenses. The final rule provided a basis for taking enforcement actions against licensed operators who: (1) use drugs or alcohol in a manner that would exceed the cutoff levels contained in the FFD regulations in 10 CFR Part 26, (2) are determined by a facility medical review officer (MRO) to be under the influence of any prescription or over-the-counter drug that could adversely affect his or her ability to safely and competently perform licensed duties, or (3) sell, use, or possess illegal drugs (56 FR 32070; July 15, 1991) (Ref. 8).

In March 1995, the NRC amended 10 CFR 55.25 to require that if during the term of the license, the licensee develops a permanent physical or mental condition that causes the licensee to fail to meet the medical requirements, the facility licensee must notify the Commission within 30 days of learning of the diagnosis (60 FR 13617; March 14, 1995) (Ref. 9).

Regulatory Guidance

In September 1977, the staff issued RG 1.134, "Medical Certification and Monitoring of Personnel Requiring Operator Licenses" (Ref. 10), endorsing industry's consensus on the American National Standards Institute/American Nuclear Society (ANSI/ANS) standard ANSI/N546-1976, "Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power

Plants," dated April 12, 1976 (Ref. 11). ANSI/N546-1976 described a method acceptable to the NRC staff for complying with the Commission's regulations for evaluation of the medical qualifications of applicants for initial or renewed operator or senior operator licenses.

In March 1979, the staff issued Revision 1 of RG 1.134, "Medical Evaluation of Nuclear Power Plant Personnel Requiring Operator Licenses" (Ref. 12), endorsing ANSI/N546-1976 with two clarifications: (1) the facility operator should forward only the information that has been specified or requested by the designated medical examiner; and (2) if, in the medical evaluation of the operator, there is an indication of a potentially disqualifying condition in areas such as mental and psychiatric health, an evaluation of the condition should be conducted by a licensed psychologist, psychiatrist, or physician professionally trained to identify and evaluate such conditions.

In April 1987, the staff issued Revision 2 of RG 1.134, "Medical Evaluation of Licensed Personnel for Nuclear Power Plants" (Ref. 13), endorsing ANSI/ANS-3.4-1983, "Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants," dated April 29, 1983 (Ref. 14).

In March 1998, the staff issued Revision 3 of RG 1.134, "Medical Evaluation of Licensed Personnel at Nuclear Power Plants" (Ref. 15), endorsing ANSI/ANS-3.4-1996, "Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants," dated February 7, 1996 (Ref. 16), with two exceptions: (1) the examining physician should have the flexibility to use medical judgment regarding asymmetric peripheral pulses and pulse rates out of the specified range; and (2) the decision about whether to perform liver function tests should be subject to the medical judgment of the examining physician.

On May 3, 2013, ANSI approved ANSI/ANS-3.4-2013, "Medical Certification and Monitoring of Personnel Requiring Licenses for Nuclear Power Plants," as an American National Standard. The ANS Standards Committee Working Group ANS-3.4 developed and approved this industry-consensus standard. The ANS-3.4 Working Group comprised a wide range of utility, independent, and industry-oversight organizations (including official representatives from the NRC) during the development of the revised standard. The 2013 version is the 5th issuance of the standard since its initial approval in 1973. The revised standard's scope continues to establish the requirements for medical and general health, including mental health, that must be met by personnel requiring operator and senior operator licenses at nuclear power plants. The standard also addresses the content, extent, and methods of medical examinations.

Role of Medical Examinations in Operator Licensing

Facility licensees are responsible for ensuring that individuals who receive operator or senior operator licenses possess the knowledge, skills, and abilities necessary to operate the nuclear facility in a safe and competent manner. They are also responsible for ensuring that an applicant's or licensee's general health and medical condition will not adversely affect the performance of assigned job duties or cause operational errors that endanger public health and safety. Since 1956, the AEC and then the NRC, as well as facility licensees, have relied on and used medical examinations performed by licensed physicians to certify whether or not an applicant for an operator's license or a licensee meets the Commission's medical requirements as described in 10 CFR Part 55.

The Commission's regulations in 10 CFR 55.4, "Definitions," define the following three terms, which are important to understanding the staff's perspective on reviewing Form NRC-396 medical certifications:

(1) "Actively performing the functions of an operator or senior operator" means that an individual has a position on the shift crew that requires the individual to be licensed as defined in the facility's technical specifications, and that the individual carries out and is responsible for the duties covered by that position.

(2) "Physician" means an individual licensed by a State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to dispense drugs in the practice of medicine.

(3) "Licensee" means an individual licensed operator or senior operator.

Form NRC-396, "Certification of Medical Examination by Facility Licensee"

Form NRC-396 is used to provide the Commission information required by Commission's regulations regarding an individual's medical fitness. The information provided is considered personal private information and is withheld from public disclosure under 10 CFR 2.390, "Public Inspections, Exemptions, and Requests for Withholding" (Ref. 17).

Section A, "Medical Exam Information," of the form (1) certifies that the applicant or licensee has been examined by a physician and that he or she has been found to meet the safeguards and fitness for duty requirements for licensed operators at the facility of record; (2) certifies that in reaching this determination, the guidance contained in ANSI/ANS-3.4-1996 (-1983), or an acceptable alternative method approved by the NRC, was followed and that documentation (medical evidence) is available for review by the NRC; and (3) identifies the type of licensed condition(s), if any, requested based on medical evidence. A brief explanation of the requested licensed condition and its relationship is also annotated. The following line items are provided for selection by the examining physician:

- No restrictions.
- Corrective lenses shall be worn when performing licensed duties.
- Hearing aid shall be worn when performing licensed duties.
- Shall take medication as prescribed to maintain medical qualifications.
- Shall use therapeutic device(s) as prescribed to maintain medical qualifications.
- Solo operation is not authorized.
- Shall submit medical status report every 3, 6, or 12 months.
- Shall not perform licensed duties requiring a respirator.
- Other restriction or exception.
- Restriction change from previous submittal.
- Information only.

Section B, "Certification," of the form certifies that the information in this document and related attachments is true and correct. It must be signed and dated by the facility licensee's authorized representative (e.g., the senior management representative on site).

The form NRC-396 is also used to document medical certification for licensing of test and research reactor operators and is the subject of ANSI/ANS 15.4, "Selection and Training of Personnel for Research Reactors." (Ref. 18)

Harmonization with International Standards

The NRC staff reviewed guidance from the International Atomic Energy Agency (IAEA) and found that this regulatory guide is consistent with the medical fitness for duty requirements identified in

IAEA Safety Guide NS-G-2.8, "Recruitment, Qualification and Training of Personnel for Nuclear Power Plants" (Ref. 19).

Documents Discussed in Staff Regulatory Guidance

This regulatory guide endorses the use of one or more codes or standards developed by external organizations, and other third party guidance documents. These codes, standards and third party guidance documents may contain references to other codes, standards or third party guidance documents ("secondary references"). If a secondary reference has itself been incorporated by reference into NRC regulations as a requirement, then licensees and applicants must comply with that standard as set forth in the regulation. If the secondary reference has been endorsed in a regulatory guide as an acceptable approach for meeting an NRC requirement, then the standard constitutes a method acceptable to the NRC staff for meeting that regulatory requirement as described in the specific regulatory guide. If the secondary reference has neither been incorporated by reference into NRC regulations nor endorsed in a regulatory guide, then the secondary reference is neither a legally-binding requirement nor a "generic" NRC approved acceptable approach for meeting an NRC requirement. However, licensees and applicants may consider and use the information in the secondary reference, if appropriately justified, consistent with current regulatory practice, and consistent with applicable NRC requirements.

C. STAFF REGULATORY GUIDANCE

1. NRC Acceptance and Endorsement of ANSI/ANS 3.4-2013

   a. ANSI/ANS-3.4-2013 provides methods acceptable to the NRC staff for facility licensees to demonstrate that, through meeting the criteria of the standard, an applicant or licensee at utilization facilities, as defined in 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," will possess a degree of medical fitness sufficient to meet the medical requirements of 10 CFR Part 55.

   b. In regard to ANSI/ANS-3.4-2013, Section 5, "Health requirements and disqualifying conditions," a current diagnosis of sleep apnea is listed as a disqualifying condition. The examining physician should also consider other sleep disorders that can degrade the individual's ability to remain alert.

D. IMPLEMENTATION

The purpose of this section is to provide information on how applicants for and holders of facility licenses[1] and operator licenses under 10 CFR Part 55 may use this guide and information regarding the NRC's plans for using this regulatory guide. In addition, it describes how the NRC staff complies with 10 CFR 50.109, "Backfitting" and any applicable finality provisions in 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

Use by Applicants and Licensees

Applicants and facility licensees, and applicants for and holders of operator licenses under 10 CFR Part 55, may voluntarily[2] use the guidance in this document to demonstrate compliance with the underlying NRC regulations. Methods or solutions that differ from those described in this regulatory guide may be deemed acceptable if they provide sufficient basis and information for the NRC staff to verify that the proposed alternative demonstrates compliance with the appropriate NRC regulations. Current facility licensees and holders of operator licenses under 10 CFR Part 55 may continue to use guidance the NRC found acceptable for complying with the identified regulations as long as their current licensing basis remains unchanged**.**

Facility licensees and holders of operator licenses under 10 CFR Part 55 may use the information in this regulatory guide or applicable parts to resolve regulatory or inspection issues.

Use by NRC Staff

The NRC staff does not intend or approve any imposition or backfitting of the guidance in this regulatory guide. The NRC staff does not expect any existing facility licensee or holder of an operator license to use or commit to using the guidance in this regulatory guide, unless the facility licensee makes a change to its licensing basis. The NRC staff does not expect or plan to request facility licensees or holders of operator licenses to voluntarily adopt this regulatory guide to resolve a generic regulatory issue. The NRC staff does not expect or plan to initiate NRC regulatory action which would require the use of this regulatory guide. Examples of such unplanned NRC regulatory actions include issuance of an order requiring the use of the regulatory guide, requests for information under 10 CFR 50.54(f) as to whether a facility licensee intends to commit to use of this regulatory guide, generic communication, or promulgation of a rule requiring the use of this regulatory guide without further backfit consideration.

During regulatory discussions on plant specific operational issues, the staff may discuss with facility licensees various actions consistent with staff positions in this regulatory guide, as one acceptable means of meeting the underlying NRC regulatory requirement. Such discussions would not ordinarily be considered backfitting even if prior versions of this regulatory guide are part of the licensing basis of the facility. However, unless this regulatory guide is part of the licensing basis for a facility, the staff may not represent to the facility licensee that the facility licensee's failure to comply with the positions in this regulatory guide constitutes a violation.

If an existing facility licensee voluntarily seeks a license amendment or change and (1) the NRC staff's consideration of the request involves a regulatory issue directly relevant to this new or revised regulatory guide and (2) the specific subject matter of this regulatory guide is an essential consideration in

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[1] In this section, unless otherwise provided, "facility licenses" refers to licenses for nuclear power plants under 10 CFR Parts 50 and 52; and the term "applicants," refers to applicants for licenses and permits for (or relating to) nuclear power plants under 10 CFR Parts 50 and 52.

[2] In this section, "voluntary" and "voluntarily" means that the licensee is seeking the action of its own accord, without the force of a legally binding requirement or an NRC representation of further licensing or enforcement action.

the staff's determination of the acceptability of the facility licensee's request, then the staff may request that the licensee either follow the guidance in this regulatory guide or provide an equivalent alternative process that demonstrates compliance with the underlying NRC regulatory requirements. This is not considered backfitting as defined in 10 CFR 50.109(a) (1) or a violation of any of the issue finality provisions in 10 CFR Part 52.

Additionally, an existing applicant may be required to comply to new rules, orders, or guidance if 10 CFR 50.109(a) (3) applies.

If a facility licensee believes that the NRC is either using this regulatory guide or requesting or requiring the facility licensee to implement the methods or processes in this regulatory guide in a manner inconsistent with the discussion in this Implementation section, then the facility licensee may file a backfit appeal with the NRC in accordance with the guidance in NUREG-1409, "Backfitting Guidelines," (Ref. 20) and the NRC Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection" (Ref. 21).

REFERENCES[3]

1. U. S. Code of Federal Regulations (CFR), "Domestic Licensing of Production and Utilization Facilities" Part 50, Chapter I, Title 10, "Energy"

2. CFR, "Licenses, Certifications, and Approvals for Nuclear Power Plants," Part 52, Chapter I, Title 10, "Energy"

3. CFR, "Operators' Licenses," Part 55, Chapter I, Title 10, "Energy"

4. ANSI/ANS 3.4-2013, "Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants," ANS, La Grange Park, IL

5. U.S. Atomic Energy Commission (AEC), "Operator's Licenses," *Federal Register*, Vol. 21, No.1, p 6, (21 FR 6), January 4, 1956

6. AEC, "Operator's Licenses," *Federal Register*, Vol. 28, No. 1, p. 3196, (28 FR 3196), April 3, 1963

7. U.S. Nuclear Regulatory Commission,(NRC), "Operator's Licenses and Conforming Amendments" *Federal Register*, Vol. 52, No. 57, p.9453, (52 FR 9453), March 25, 1987

8. NRC, "Operator's Licenses" *Federal Register*, Vol. 56, No. 135, p. 32066, (56 FR 32066), July 15, 1991

9. NRC, "Reduction of Reporting Requirements Imposed on NRC Licensees," *Federal Register*, Vol. 60, No. 49, p. 13615, (60 FR 13615), March 14, 1995

10. NRC, Regulatory Guide 1.134, "Medical Evaluation of Licensed Personnel for Nuclear Power Plants," Washington DC, September 1977 (ADAMS Accession No. ML13205A203)

11. American National Standards Institute (ANSI) /American Nuclear Society (ANS), ANSI/ANS-3.4-1976 (N546), "Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants," ANS, La Grange Park, IL[4]

12. NRC, Regulatory Guide 1.134, Revision 1, "Medical Evaluation of Licensed Personnel for Nuclear Power Plants," Washington DC, March 1979 (ADAMS Accession No. ML13038A107)

13. NRC, Regulatory Guide 1.134, Revision 2, "Medical Evaluation of Licensed Personnel for Nuclear Power Plants," Washington DC, April 1987 (ADAMS Accession No. ML003740138)

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3 Publicly available NRC published documents are available electronically through the NRC Library on the NRC's public Web site at http://www.nrc.gov/reading-rm/doc-collections/ and through the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html The documents can also be viewed online or printed for a fee in the NRC's Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD. For problems with ADAMS, contact the PDR staff at 301-415-4737 or (800) 397-4209; fax (301) 415-3548; or e-mail pdr.resource@nrc.gov.

4 Copies of American Nuclear Society (ANS) standards may be purchased from the ANS Web site (http://www.new.ans.org/store/); or by writing to: American Nuclear Society, 555 North Kensington Avenue, La Grange Park, Illinois 60526, U.S.A., Telephone 800-323-3044.

14. ANSI/ANS-3.4-1983, "Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants," ANS, La Grange Park, IL

15. NRC, Regulatory Guide 1.134, Revision 3, "Medical Evaluation of Licensed Personnel at Nuclear Power Plants," Washington DC, March 1998 (ADAMS Accession No. ML003740140)

16. ANSI/ANS-3.4-1996, "Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants," ANS, La Grange Park, IL

17. CFR, "Agency Rules of Practice and Procedure," Part 2, Chapter I, Title 10, "Energy"

18. ANSI/ANS 15.4-2007, "Selection and Training of Personnel for Research Reactors," ANS, La Grange Park, IL

19. International Atomic Energy Agency (IAEA) NS-G-2.8, "Recruitment, Qualification and Training of Personnel for Nuclear Power Plants," Vienna, Austria, 2011[5]

20. NRC, NUREG-1409, "Backfitting Guidelines," Washington, DC

21. NRC Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection," Washington, DC

5 Copies of International Atomic Energy Agency (IAEA) documents may be obtained through their Web site: WWW.IAEA.Org/ or by writing the International Atomic Energy Agency, P.O. Box 100 Wagramer Strasse 5, A-1400 Vienna, Austria.