



# DRAFT REGULATORY GUIDE

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## DRAFT REGULATORY GUIDE DG-1310

(Proposed Revision 4 of Regulatory Guide 1.134, dated March 1998)

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

## A. INTRODUCTION

### Purpose

This 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 50.54, "Conditions of Licensees," to use qualified licensed operators as described in 10 CFR Part 55, "Operators' Licenses" (Ref. 3).

### Applicable Rules and Regulations

- 10 CFR Part 55, Operators' Licenses

### 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

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This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received final staff review or approval and does not represent an official NRC final staff position. Public comments are being solicited on this draft guide and its associated regulatory analysis. Comments should be accompanied by appropriate supporting data. Comments may be submitted through the Federal-rulemaking Web site, <http://www.regulations.gov>, by searching for Docket ID: NRC-2014-0093. Alternatively, comments may be submitted to the Rules, Announcements, and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Comments must be submitted by the date indicated in the *Federal Register* notice.

Electronic copies of this draft 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/reg-guides/>. The draft 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 Accession No. ML13352A278. The regulatory analysis may be found in ADAMS under Accession No. ML13352A279.

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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**

Proposed Revision 4 to Regulatory Guide (RG) 1.134 has been prepared to update the guidance with additional experience gained since Revision 3 was issued in 1998 and to endorse the current standard ANSI/ANS-3.4-2013. 10 CFR Part 55.21 “Medical Examination” requires an applicant for an operator’s license to have a medical examination by a physician. Once licensed, the operator is required to have a medical examination by a physician every 2 years. The physician is required to determine 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 as described in 10 CFR 55.33(a)(1).

The guide helps to ensure that medical certifications (and related medical evidence) used to meet the requirements of 10 CFR Part 55 are sufficient with respect to (1) medical examination, as described in 10 CFR 55.21; (2) medical certification, as described in 10 CFR 55.23, “Certification”; (3) incapacitation because of disability or illness, as described in 10 CFR 55.25, “Incapacitation Because of Disability or Illness”; (4) medical documentation, as described in 10 CFR 55.27, “Documentation”; (5) disposition of an initial application, as described in 10 CFR 55.33(a)(1) and (b); and (6) renewal of licenses, as described in 10 CFR 55.57(a)(6) and (b)(1).

### **Background**

#### **Regulations**

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. 4). 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. 5).

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. 6).

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 rule, (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. 7).

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. 8).

Both applicants and licensees are required 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. 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 as described in 10 CFR 55.25.

## **Regulatory Guidance**

In September 1977, the staff issued RG 1.134, “Medical Certification and Monitoring of Personnel Requiring Operator Licenses” (Ref. 9), 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. 10). 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. 11), 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. 12), endorsing ANSI/ANS-3.4-1983, “Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants,” dated April 29, 1983 (Ref. 13).

In March 1998, the staff issued Revision 3 of RG 1.134, “Medical Evaluation of Licensed Personnel at Nuclear Power Plants” (Ref. 14), endorsing ANSI/ANS-3.4-1996, “Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants,” dated February 7, 1996 (Ref. 15), 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” (Ref. 16) as an American National Standard. The ANS Standards Committee Working Group ANS-3.4 developed and approved this industry-consensus standard. The 2013 version is the 5th issuance of the standard since its initial approval in 1973. 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 revised standard’s scope continues to establish the requirements for medical and general health including mental health that personnel requiring operator and senior operator licenses at nuclear power plants must meet. The standard also addresses the content, extent, and methods of medical examinations.

As explained in Section C below, the Staff is endorsing ANSI/ANS-3.4-2013 without exceptions.

### **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 regulatory agency, 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 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).

### **Appendices**

Appendix A to this draft guide contains the text of pertinent regulations, 10 CFR 55.21, 55.23, 55.25, 55.27, 55.31(a)(6), 55.33 and 55.57 (a)(6), (b)(1), and (b)(2)(i).

Appendix B to this draft guide contains the Commission’s NRC Form 396, “Certification of Medical Examination by Facility Licensee.”

### **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, NS-G-2.8, “Recruitment, Qualification and Training of Personnel for Nuclear Power Plants,” (Ref. 18).

## 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 sets forth provisions acceptable to the NRC staff for (1) medical fitness and general health certification of applicants and/or licensed operators and senior operators; and (2) addressing content, extent, and methods of examination, and monitoring during the term of the operator and or senior operator license. 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. This draft regulatory guide does not preclude facility licensees from continuing their use of and commitment to historical editions of the standard.

### D. IMPLEMENTATION

The purpose of this section is to provide information on how applicants and licensees<sup>1</sup> 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

Facility licensees, and applicants for and holders of operator licenses under 10 CFR Part 55, may voluntarily<sup>2</sup> use the guidance in this document to demonstrate compliance with the underlying NRC

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<sup>1</sup> In this section, unless otherwise provided, “licensees” refers to licensees of 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.

<sup>2</sup> 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.

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 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.

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 licensee to use or commit to using the guidance in this regulatory guide, unless the licensee makes a change to its licensing basis. The NRC staff does not expect or plan to request licensees 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 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 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 licensee that the licensee's failure to comply with the positions in this regulatory guide constitutes a violation.

If an existing 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 the staff's determination of the acceptability of the 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 licensee believes that the NRC is either using this regulatory guide or requesting or requiring the licensee to implement the methods or processes in this regulatory guide in a manner inconsistent with the discussion in this Implementation section, then the licensee may file a backfit appeal with the NRC in accordance with the guidance in NUREG-1409, "Backfitting Guidelines," (Ref. 19) and the NRC Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection" (Ref. 20).



## REFERENCES<sup>3</sup>

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. U.S. Atomic Energy Commission (AEC), “Operator’s Licenses,” *Federal Register*, Vol. 21, No.1, p 6, (21 FR 6), January 4, 1956.
5. AEC, “Operator’s Licenses,” *Federal Register*, Vol. 28, No. 1, p. 3196, (28 FR 3196), April 3, 1963.
6. NRC, “Operator’s Licenses and Conforming Amendments” *Federal Register*, Vol. 52, No. 57, p.9453, (52 FR 9453), March 25, 1987.
7. NRC, “Operator’s Licenses” *Federal Register*, Vol. 56, No. 135, p. 32066, (56 FR 32066), July 15, 1991.
8. NRC, “Reduction of Reporting Requirements Imposed on NRC Licensees,” *Federal Register*, Vol. 60, No. 49, p. 13615, (60 FR 13615), March 14, 1995.
9. NRC, Regulatory Guide 1.134, “Medical Evaluation of Licensed Personnel for Nuclear Power Plants,” Washington DC, March 1979. (ADAMS Accession No. ML13205A203)
10. American Nuclear Society (ANS), ANS-3.4-1976 (N546), “Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants,” ANS, La Grange Park, IL.
11. NRC, Regulatory Guide 1.134, Revision 1, “Medical Evaluation of Licensed Personnel for Nuclear Power Plants,” Washington DC, March 1979. (ADAMS Accession No. ML13038A107)
12. NRC, Regulatory Guide 1.134, Revision 2, “Medical Evaluation of Licensed Personnel for Nuclear Power Plants,” Washington DC, April 1987. (ADAMS Accession No. ML003740138)
13. ANS-3.4-1983, “Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants,” ANS, La Grange Park, IL.
14. NRC, Regulatory Guide 1.134, Revision 3, “Medical Evaluation of Licensed Personnel at Nuclear Power Plants,” Washington DC, March 1998. (ADAMS Accession No. ML003740140)

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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](mailto:pdr.resource@nrc.gov).

15. ANS-3.4-1996, "Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants," ANS, La Grange Park, IL.
16. ANS-3.4-2013, "Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants," ANS, La Grange Park, IL.<sup>4</sup>
17. CFR, "Agency Rules of Practice and Procedure", Part 2, Chapter I, Title 10, "Energy".
18. International Atomic Energy Agency (IAEA) NS-G-2.8, "Recruitment, Qualification and Training of Personnel for Nuclear Power Plants," IAEA, Vienna, Austria, 2011.<sup>5</sup>
19. NRC, NUREG-1409, "Backfitting Guidelines," Washington, DC.
20. NRC Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection."

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<sup>4</sup> 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.

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

## APPENDIX A

### TEXT OF PARAGRAPHS OF 10 CFR Part 55 APPLICABLE TO MEDICAL EVALUATIONS

#### Subpart A—General Provisions

##### § 55.4 Definitions.

As used in this part:

*Facility* means any utilization facility as defined in part 50 of this chapter. In cases for which a license is issued for operation of two or more facilities *facility* means all facilities identified in the license.

*Facility licensee* means an applicant for or holder of a license for a facility.

*Licensee* means an individual licensed operator or senior operator.

*Operator* means any individual licensed under this part to manipulate a control of a facility.

*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.

*Senior Operator* means any individual licensed under this part to manipulate the controls of a facility and to direct the licensed activities of licensed operators.

##### § 55.8 Information collection requirements: OMB approval.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In §§55.23, 55.25, 55.27, 55.31, NRC Form 396 is approved under control number 3150-0024.

[62 FR 52188, Oct. 6, 1997, as amended ...]

#### Subpart C – Medical Requirements

##### § 55.21 Medical examination.

An applicant for a license shall have a medical examination by a physician. A licensee shall have a medical examination by a physician every two years. The physician shall determine that the applicant or licensee meets the requirements of §55.33(a)(1).

##### § 55.23 Certification.

To certify the medical fitness of the applicant, an authorized representative of the facility licensee shall complete and sign NRC Form 396, “Certification of Medical Examination by Facility Licensee,” which can be obtained by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling 301-415-5877, or by visiting the NRC’s Web site at <http://www.nrc.gov> and selecting forms from the index found on the home page.

(a) Form NRC-396 must certify that a physician has conducted the medical examination of the applicant as required in §55.21.

(b) When the certification requests a conditional license based on medical evidence, the medical evidence must be submitted on NRC Form 396 to the Commission and the Commission then makes a determination in accordance with §55.33.

[52 FR 9460, Mar. 25, 1987, as amended ...]

**§ 55.25 Incapacitation because of disability or illness.**

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 §55.21 of this part, the facility licensee shall notify the Commission, within 30 days of learning of the diagnosis, in accordance with §50.74(c). For conditions for which a conditional license (as described in §55.33(b) of this part) is requested, the facility licensee shall provide medical certification on Form NRC-396 to the Commission (as described in §55.23 of this part).

[60 FR 13617, Mar. 14, 1995]

**§ 55.27 Documentation.**

The facility licensee shall document and maintain the results of medical qualifications data, test results, and each operator's or senior operator's medical history for the current license period and provide the documentation to the Commission upon request. The facility licensee shall retain this documentation while an individual performs the functions of an operator or senior operator.

**Subpart D – Applications**

**§ 55.31 How to apply.**

(a) The applicant shall:

(6) Provide certification by the facility licensee of medical condition and general health on Form NRC-396, to comply with §§55.21, 55.23 and 55.33(a)(1).

[52 FR 9460, Mar. 25, 1987, as amended ...]

**§ 55.33 Disposition of an initial application.**

(a) *Requirements for the approval of an initial application.* The Commission will approve an initial application for a license pursuant to the regulations in this part, if it finds that-

(1) *Health.* The applicant'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. The Commission will base its finding upon the certification by the facility licensee as detailed in §55.23.

(b) *Conditional license.* If an applicant's general medical condition does not meet the minimum standards under §55.33(a)(1) of this part, the Commission may approve the application and include conditions in

the license to accommodate the medical defect. The Commission will consider the recommendations and supporting evidence of the facility licensee and of the examining physician (provided on Form NRC-396) in arriving at its decision.

## **Subpart F – Licenses**

### **§ 55.53 Conditions of licenses.**

Each license contains and is subject to the following conditions whether stated in the license or not:

- (i) The licensee shall have a biennial medical examination.
  
- (j) The licensee shall not consume or ingest alcoholic beverages within the protected area of power reactors, or the controlled access area of non-power reactors. The licensee shall not use, possess, or sell any illegal drugs. The licensee shall not perform activities authorized by a license issued under this part while under the influence of alcohol or any prescription, over-the-counter, or illegal substance that could adversely affect his or her ability to safely and competently perform his or her licensed duties. For the purpose of this paragraph, with respect to alcoholic beverages and drugs, the term “under the influence” means the licensee exceeded, as evidenced by a confirmed positive test, the lower of the cutoff levels for drugs or alcohol contained in 10 CFR Part 26, Appendix A, of this chapter, or as established by the facility licensee. The term “under the influence” also means the licensee could be mentally or physically impaired as a result of substance use including prescription and over-the-counter drugs, as determined under the provisions, policies, and procedures established by the facility licensee for its fitness-for-duty program, in such a manner as to adversely affect his or her ability to safely and competently perform licensed duties.

[52 FR 9460, Mar. 25, 1987, as amended ...]

### **§ 55.57 Renewal of licenses.**

- (a) The applicant for renewal of a license shall-
  - (6) Provide certification by the facility licensee of medical condition and general health on Form NRC-396, to comply with §§55.21, 55.23 and 55.57.
  
- (b) The license will be renewed if the Commission finds that-
  - (1) The medical condition and the general health of the licensee continue to be such as not to cause operational errors that endanger public health and safety. The Commission will base this finding upon the certification by the facility licensee as described in §55.23.
  
  - (2) The licensee-
    - (i) Is capable of continuing to competently and safely assume licensed duties; ...

[52 FR 9460, Mar. 25, 1987, as amended ...]

*This appendix provides the applicable regulatory text of 10 CFR 55 so that the public can follow and discern the applicable references mentioned in this draft regulatory guide. The final guide may or may not include this appendix.*

# APPENDIX B

## CERTIFICATION OF MEDICAL EXAMINATION BY FACILITY LICENSEE (FORM NRC 396)

PERSONALLY IDENTIFIABLE INFORMATION - WITHHOLD UNDER 10 CFR 2.390			
<b>NRC FORM 396</b> <small>(05-2012)                      10 CFR 55.21, 55.23,                      55.25, 55.27, 55.31,                      55.33, 55.57</small>	<b>U.S. NUCLEAR REGULATORY COMMISSION</b>	<b>APPROVED BY OMB: NO. 3150-0024</b> <small>Estimated burden per response to comply with this mandatory collection request: 30 minutes. NRC requires this information to determine that the physical condition and health of operator licensees is such that the applicant would not be expected to cause operational errors endangering the public health and safety. Send comments regarding burden estimate to the Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0024), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.</small>	<b>EXPIRES: (04/30/2015)</b>
<b>CERTIFICATION OF MEDICAL EXAMINATION BY FACILITY LICENSEE</b>			
NAME OF APPLICANT AND DOCKET NUMBER		FACILITY	FACILITY DOCKET NUMBER
			050-
<b>A. MEDICAL EXAM INFORMATION</b>			
THIS IS TO CERTIFY THAT THE ABOVE NAMED APPLICANT FOR AN OPERATOR/SENIOR OPERATOR LICENSE HAS BEEN EXAMINED BY A PHYSICIAN AND THAT THE APPLICANT HAS BEEN FOUND TO MEET THE MEDICAL REQUIREMENTS FOR LICENSED OPERATORS AT THIS FACILITY.			
PRINTED NAME <i>(of physician and other medical professionals)</i>	STATE	LICENSE NUMBER	MOST RECENT BIENNIAL MEDICAL EXAMINATION DATE
<small>BASED ON THE RESULTS OF THE PHYSICAL EXAMINATION, INCLUDING INFORMATION FURNISHED BY THE APPLICANT, THE PHYSICIAN HAS DETERMINED THAT THE APPLICANT'S PHYSICAL CONDITION AND GENERAL HEALTH ARE SUCH THAT THE APPLICANT WOULD NOT BE EXPECTED TO CAUSE OPERATIONAL ERRORS ENDANGERING PUBLIC HEALTH AND SAFETY. I CERTIFY THAT IN REACHING THIS DETERMINATION, THE GUIDANCE CONTAINED IN THE ANSI STANDARD (AS ENDORSED BY THE APPLICABLE NRC REGULATORY GUIDE) OR AN ACCEPTABLE ALTERNATIVE METHOD APPROVED BY THE NRC, AS INDICATED BELOW, WAS FOLLOWED, AND THAT DOCUMENTATION IS AVAILABLE FOR REVIEW BY NRC.</small>			
<small>GUIDANCE USED:</small> <input type="checkbox"/> ANSI/ANS 3.4 -- 1996 <input type="checkbox"/> ANSI/ANS 3.4 -- 1983 <input type="checkbox"/> ANSI/ANS 15.4 -- 1988 <input type="checkbox"/> ANSI/ANS 15.4 -- 2007 <input type="checkbox"/> OTHER _____			
<small>ON THE BASIS OF THE RECOMMENDATION OF THE PHYSICIAN, IT IS REQUESTED THAT THE APPLICANT'S OPERATOR LICENSE BE CONDITIONED AS FOLLOWS: Check all that apply. <b>(PROVIDE EXPLANATION AND ATTACH SUPPORTING MEDICAL EVIDENCE FOR NRC REVIEW).</b></small>			
<input type="checkbox"/> 1. NO RESTRICTIONS <input type="checkbox"/> 2. CORRECTIVE LENSES SHALL BE WORN WHEN PERFORMING LICENSED DUTIES <input type="checkbox"/> 3. HEARING AID SHALL BE WORN WHEN PERFORMING LICENSED DUTIES <input type="checkbox"/> 4. SHALL TAKE MEDICATION AS PRESCRIBED TO MAINTAIN MEDICAL QUALIFICATIONS <input type="checkbox"/> 5. SHALL USE THERAPEUTIC DEVICE(S) AS PRESCRIBED TO MAINTAIN MEDICAL QUALIFICATIONS <input type="checkbox"/> 6. SOLO OPERATION IS NOT AUTHORIZED <input type="checkbox"/> 7. SHALL SUBMIT MEDICAL STATUS REPORT EVERY <input type="checkbox"/> 3, <input type="checkbox"/> 6, OR <input type="checkbox"/> 12 MONTHS <input type="checkbox"/> 8. SHALL NOT PERFORM LICENSED DUTIES REQUIRING A RESPIRATOR <input type="checkbox"/> 9. OTHER RESTRICTION OR EXCEPTION <input type="checkbox"/> 10. RESTRICTION CHANGE FROM PREVIOUS SUBMITTAL <input type="checkbox"/> 11. INFORMATION ONLY			
PROPOSED WORDING OF RESTRICTION <i>(Block 9 above)</i>			
RELATIONSHIP OF RESTRICTION TO DISQUALIFYING CONDITION <i>(Briefly indicate how restriction will correct the disqualifying condition)</i>			
EXPLANATION (S)			
<b>B. CERTIFICATION</b>			
<small>ANY FALSE STATEMENT OR OMISSION IN THIS DOCUMENT, INCLUDING ATTACHMENTS, MAY BE SUBJECT TO CIVIL AND CRIMINAL SANCTIONS. I CERTIFY UNDER PENALTY OF PERJURY THAT THE INFORMATION IN THIS DOCUMENT AND ATTACHMENTS IS TRUE AND CORRECT.</small>			
PRINTED NAME AND TITLE <i>(Senior Management Representative on Site)</i>	SIGNATURE	DATE	
<small>In accordance with 10 CFR 55.5, Communications, this original form shall be submitted to the appropriate NRC office as follows: <b>BY MAIL ADDRESSED TO:</b></small>			
<small>REGIONAL ADMINISTRATOR, REGION I                      U.S. NUCLEAR REGULATORY COMMISSION                      2100 RENAISSANCE BOULEVARD, SUITE 100                      KING OF PRUSSIA, PA 19406-2713</small>	<small>REGIONAL ADMINISTRATOR, REGION II                      U.S. NUCLEAR REGULATORY COMMISSION                      245 PEACHTREE CENTER AVENUE, NE., SUITE 1200                      ATLANTA, GA 30303-1257</small>	<small>REGIONAL ADMINISTRATOR, REGION III                      U.S. NUCLEAR REGULATORY COMMISSION                      2443 WARRENVILLE ROAD, SUITE 210                      LISLE, IL 60532-4352</small>	
<small>REGIONAL ADMINISTRATOR, REGION IV                      U.S. NUCLEAR REGULATORY COMMISSION                      1600 E. LAMAR BOULEVARD                      ARLINGTON, TX 76011-4511</small>	<small>U.S. NUCLEAR REGULATORY COMMISSION                      OPERATOR LICENSING AND TRAINING BRANCH                      DIVISION OF INSPECTION AND REGIONAL SUPPORT                      WASHINGTON, DC 20555-0001</small>		
<small>U.S. NUCLEAR REGULATORY COMMISSION                      RESEARCH AND TEST REACTORS                      OVERSIGHT BRANCH                      DIVISION OF POLICY AND RULEMAKING                      WASHINGTON, DC 20555-0001</small>			

NRC FORM 396 (05-2012)

The draft regulatory guide includes this appendix so that the public can discern and appreciate the type of information required by the Commission for assessment of an applicant's or licensee's medical status for obtaining an operator or senior operator license. The final guide may or may not include this appendix. See ADAMS Accession No ML023010046 for a full size duplicate of NRC Form 396.