

The NRC's public meeting to discuss risk-informing medical exam requirements for Research and Test Reactor (RTR) licensees will begin shortly.

**Please ensure you have connected to MS Teams audio either through your computer or by phone.**

# Discussion of Risk-informing Medical Exam Requirements for Research and Test Reactor (RTR) Licensees

June 15, 2021

Non-Power Production and Utilization Facilities Oversight Branch  
Division of Advanced Reactors and Non-Power Production and Utilization  
Facilities

Office of Nuclear Reactor Regulation  
ADAMS Accession No. ML21166A165

# Today's Meeting

The purpose of this public meeting is to discuss with the research and test reactor (RTR) community the NEI comment received regarding requirements for medical exams for licensing of RTR operators and possible options to move forward with risk-informing the medical exam requirement for RTR operators.

# Today's Agenda

- NRC Staff Presentation
- TRTR Remarks
- NRC and TRTR Panel Discussion
- Short Break
- Open Discussion for Feedback and Questions
  - Submit questions and comments via Chat at any time (we will address them during the Open Discussion portion of the meeting).
  - During the Open Discussion, “raise your hand” so we can enable your microphone.

# NRC Presentation Agenda

- Current legislative authority and regulatory framework
- Retrospective Review of Administrative Requirements (RROAR) process
  - NEI letter with recommendation/comments
  - NRC response
- Feedback and questions

# Current Legislative Authority

- Atomic Energy Act, Sec. 107, Operators' Licenses  
The Commission shall—
  - a. prescribe uniform conditions for licensing individuals as operators of any of the various classes of production and utilization facilities licensed in this Act;
  - b. determine the qualifications of such individuals;
  - c. issue licenses to such individuals in such form as the Commission may prescribe; and
  - d. suspend such licenses for violations of any provision of this Act or any rule or regulation issued thereunder whenever the Commission deems such action desirable

# Current Regulatory Framework

(Slide 1 of 7)

- § 55.33 Disposition of an initial application.
  - (a)(1) *Health*. The applicants 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.

# Current Regulatory Framework

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- § 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 . . . 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.



# Current Regulatory Framework

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- § 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).
    - § 55.33(a)(1): “... applicants 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.”

# Current Regulatory Framework


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- § 55.33 Disposition of an initial application.
  - (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.

# Current Regulatory Framework

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- NRC Form 396:

PERSONALLY IDENTIFIABLE INFORMATION - WITHHOLD UNDER 10 CFR 2.390					
<b>NRC FORM 396</b> (12-2019) 10 CFR 55.21, 55.23, 55.25, 55.27, 55.31 55.33, 55.53, 55.57.				<b>U.S. NUCLEAR REGULATORY COMMISSION</b>	
		<b>CERTIFICATION OF MEDICAL EXAMINATION BY FACILITY LICENSEE</b>		<b>APPROVED BY OMB: NO. 3150-0024</b> <small>Estimated burden per response to comply with this mandatory collection request: 1 hour. 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-6 A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollcts.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NE08-10202, (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: 09/30/2022</b>					
Last Name	First Name	Middle Initial	Suffix	Applicant/Operator Docket Number	Facility
Full Address of Applicant/Operator			Facility Docket Number (Separate multiple docket numbers by ";")		
			<input type="checkbox"/> 050- <input type="text"/> <input type="checkbox"/> 052- <input type="text"/>		
			Date of Most Recent Biennial Examination (MM/DD/YYYY) (See instructions) <input type="text"/>		
<b>A. MEDICAL EXAM INFORMATION</b>					
BASED ON THE RESULTS OF THE PHYSICAL EXAMINATION, INCLUDING INFORMATION FURNISHED BY THE APPLICANT/OPERATOR, I CERTIFY THAT THE ABOVE NAMED APPLICANT/OPERATOR HAS BEEN FOUND TO MEET THE MEDICAL REQUIREMENTS FOR LICENSED OPERATORS AT THIS FACILITY. I ALSO CERTIFY THAT IN REACHING THIS DETERMINATION, THE GUIDANCE CONTAINED IN THE ANSI STANDARD OR AN APPROVED NRC ALTERNATIVE METHOD WAS FOLLOWED AND THAT DOCUMENTATION IS AVAILABLE FOR REVIEW BY THE NRC.					
<b>GUIDANCE USED:</b>					
<input type="checkbox"/> ANSI/ANS 3.4 -- 1983 <input type="checkbox"/> ANSI/ANS 3.4 -- 2013 <input type="checkbox"/> ANSI/ANS 15.4 -- 2007 <input type="checkbox"/> Other (Must specify below)					
<input type="checkbox"/> ANSI/ANS 3.4 -- 1996 <input type="checkbox"/> ANSI/ANS 15.4 -- 1988 <input type="checkbox"/> ANSI/ANS 15.4 -- 2016					
Typed or Printed Name of Physician		Physician's Certification Date (MM/DD/YYYY) (See Instructions)		State	License Number
BASED ON THE RECOMMENDATION OF THE PHYSICIAN, IT IS REQUESTED THAT THE APPLICANT/OPERATOR LICENSE BE CONDITIONED AS FOLLOWS: Check all that apply. For each checked box in Nos. 4 through 11, PROVIDE EXPLANATION IN BOX BELOW AND ATTACH APPLICABLE SUPPORTING MEDICAL EVIDENCE [letter from the examining physician outlining the condition, treatment and/or medication (name, dose, timing & tolerance)] AND MEDICAL EXAMINATION / TEST RESULTS (current blood pressure reading, A1C, TSH levels, etc.).					

# Current Regulatory Framework

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- Summary of Public Comments and Final Actions from Final Rule affecting 10 CFR Parts 50 and 55 (selected excerpts)<sup>1</sup>:
  - “The intent is to prevent the manipulation of the controls by an operator whose medical condition and general health would cause operational errors endangering public health and safety.”
  - “The NRC has the responsibility for making an assessment of the applicant for a license, including the applicant’s medical fitness. Neither the facility nor the NRC staff will make medical judgments.”

<sup>1</sup> - Nuclear Regulatory Commission; Operators' Licenses and Conforming Amendments; Final Rule, 52 FR 9453 (March 25, 1987).

# Current Regulatory Framework

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- Existing regulatory process and flexibilities:
  - 10 CFR 55.33(b) provides a process for conditional license if an applicant's general medical condition does not meet minimum standards.
  - NRC Form 396 identifies multiple versions of industry-developed consensus standards as guidance for medical exams.
  - NRC Form 396 identifies the potential to use an "Other" alternative guidance document for medical exams.
  - NRC Form 396 could be revised if industry opts to revise ANSI/ANS 15.4 or develop a new consensus standard for medical exams.
- There may be additional flexibilities not considered here.

# What is Retrospective Review of Administrative Requirements (RROAR)?

- Purpose:
  - Identify outdated or duplicative administrative requirements (recordkeeping or reporting) that may be eliminated or modified.
- Method:
  - Collect suggestions from the NRC staff, industry, and members of the public.
  - Apply a set of five Commission-approved evaluation criteria.
- For more information see: [RIC 2020 Digital Exhibit](#)

# Important Documents

- **February 4, 2020 *Federal Register* notice** regarding request for comments applicable to RROAR ([85 FR 6103](#))
- **NEI letter dated May 6, 2020 ([ML20128J340](#))** submitted in response to *Federal Register* notice

# Partial Text of NEI Comment on 10 CFR 55.33(a) (Slide 1 of 2)

- This requirement should be modified to allow for alternate means for operator medical qualification at non-power utilization facilities (NPUFs), in order to 1) better align with the Atomic Energy Act of 1954, as amended, which dictates “minimum regulations” be imposed upon NPUFs and 2) align with their inherently low risk-profile.
- One alternative is to incorporate ANSI/ANS Standard 15.4, Section 7.3, which NRC has previously endorsed. It permits in 7.3.1(3), “Certification from Level 2 indicating that the individual can safely perform his or her assigned duties.”
- Source: [ML20128J340](#)  
*[see next slide]*



# Partial Text of NEI Comment on 10 CFR 55.33(a) (Slide 2 of 2)

- 10 CFR 55.33 could incorporate a new part (c), which states, “Medical qualification for facilities licensed under 104(a), (b), or (c) of this part may be justified at the time of initial application and subsequent renewal by having a valid U.S. driver’s license, by consent of the Level 2 individual, or in accordance with the established Requalification Plan. An operator shall obtain written statement from a licensed physician, physician’s assistant, or nurse practitioner stating the individual can reasonably be expected to perform operations consistent with those necessary to operate a commercial motor vehicle” (NEI Table 18: Medical Requirements for Research and Test Reactor Operators).
- Source: [ML20128J340](#)

# NRC Response in SECY-21-0056 to NEI RROAR submission (Slide 1 of 2)

- The NRC staff screened out this item because it is outside of the scope of the RROAR initiative.
- From SECY-21-0056, Enclosure 1 ([ML21012A439](#)):
  - “10 CFR 55.33(a) does not include a recordkeeping or reporting requirement. The burden can be reduced in another path outside of the RROAR initiative.”

*[see next slide]*

# NRC Response in SECY-21-0056 to NEI RROAR submission (Slide 2 of 2)

- From SECY-21-0056, Enclosure 1 ([ML21012A439](#)):
  - “The NRC staff will consider ways to apply a risk-informed approach to the medical requirements for licensed operators at nonpower production and utilization facilities.”
  - “This activity will include an evaluation of the current rule and applicable industry standards to determine existing flexibilities that may allow risk insights to be considered through the development or endorsement of guidance.”

# Discussion

- The NRC is interested in any feedback regarding the medical exam component of the operator licensing process, such as:
  - Does the current process meet your needs?
    - Hurdles encountered?
    - Other concerns?
  - Ideas for possible flexibilities or improvements to the current approach?

# And now we will hear from the National Organization of Test, Research, and Training Reactors

Ayman I. Hawari, Ph.D.  
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North Carolina State University

# How to Comment

- Submit questions or comments via Chat and we will read them aloud.
- Click on the hand icon at the top of your Teams screen to “raise your hand.”
  - We will enable your microphone.
  - You must then unmute yourself to speak.
  - You can mute yourself when you are finished (or we can mute you).

We are taking a short break.

**We will resume at 3:15 p.m. EDT.**