



# **PROB Medical and Licensing Issues**

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The guidance contained in ANSI/ANS-15.4-1988, “American National Standard for the Selection and Training of Personnel for Research Reactors” provide methods acceptable to the NRC staff for determining the medical qualifications of applicants for initial or renewal operator or senior operator licenses.

## Privacy Issues

Submission of Form 396 is a regulatory requirement as part of Form 398 for licensure and as such, is not covered under HIPAA. It does contain Privacy Act protected information and NRC does protect that information as required under the Act. If medical issues are identified during the required medical examinations that may require restrictions to the operator license, we are required to submit them to the NRC MROs.

## RECENT ISSUES

- Incomplete Medical Certification Form 396
- Conditions Not Reported
- License Renewal

# Medical Certification Form 396

## Discussion Topics

- General requirements and expectations
- NRC physician reviews –when and why?
- General feedback on medical submittals
- Recommendations for ensuring a smooth review
- Questions/comments?

# General Requirements

- 10 CFR 55.21 –medical exam by physician for initial license and every 2 years
- 10 CFR 55.23 –certification of physical exam and request for conditional license via Form 396
- 10 CFR 55.25 –new permanent disability or illness, request conditional license
- 10 CFR 55.27 –maintain documentation

## General Requirements

- 10 CFR 55.33(a)(1) –health, certification by facility licensee
- 10 CFR 55.33(b) –conditional license



## Physician responsibilities

- Be familiar with physical and mental demands of operators' job duties
- Evaluate operators' mental and physical fitness for the job considering the health requirements and disqualifying conditions is ANSI/ANS-15.4
- Recommend restrictions, as appropriate, to compensate for disqualifying conditions

## Physician responsibilities

- Administer practical tests, as necessary, to demonstrate complete capacity to perform duties and justify a waiver of the requirement.

## General Expectations

“The primary responsibility for ensuring that personnel are medically capable of fulfilling their duties rests with the facility licensee.”

Form 396 and accompanying medical evidence is the vehicle for communicating the facility’s assessment to the NRC so it can make the proper licensing decision.  
(Ref: 10 CFR 55.23, 25, 31, 33, 57)

## **Form 396 Reviews by NRC Physicians**

- When does the NRC obtain a medical review of a facility-submitted Form 396?
- –Facility recommends a new or changed (including removal of) condition/restriction on license
- –Request to approve a medical waiver
- –Typically corrective lenses, hearing aids not sent for review

## Form 396 Reviews by NRC Physicians

NRC uses internal form as a traveler to document our physician's review which contains:

- Instructions for [NRC] Doctor –“ Review the enclosed certification of medical examination by facility licensee and supporting medical evidence and provide your conclusions as to the applicant's physical condition...”

## **Form 396 Reviews by NRC Physicians**

- Report –“A review has been completed to determine if the physical condition and general health of the applicant are such that the applicant would not be expected to cause operational errors which might endanger public health and safety.”

## Food for thought.....

If you were a third party reviewer, what would you like to see to satisfy yourself before signing off?

## General Feedback on Form 396 Submittals

- Form 396 provides instruction to “Provide explanation and attach supporting medical evidence for NRC review” when requesting a conditioned license. Sometimes, little or no medical evidence is provided and the Form 396 Blocks for “RELATIONSHIP OF RESTRICTION TO DISQUALIFYING CONDITION” and “EXPLANATION(S)” are not being completed.



## General Feedback on Form 396 Submittals

- There have been cases where Form 396 block A.8, “OTHER RESTRICTION OR EXCEPTION,” has been checked, but with no (or overly brief) wording provided in “PROPOSED WORDING OF RESTRICTION (Block 8 above)” section.

## General Feedback on Form 396 Submittals

Sometimes there are conflicts between the physician narrative in attached documentation (letters, etc.) and the recommendation on the Form 396 with relation to ANSI/ANS disqualifying conditions. [For example, letter states that diabetes is not being controlled, constituting a disqualifying condition, yet licensing still recommended using “must take meds.”]

## General Feedback on Form 396 Submittals

- Some medical statements from physicians are informal notes on prescription pads and are difficult to read. Be mindful that information submitted to NRC becomes part of the file forming the basis for the licensing decision.

## General Feedback on Form 396 Submittals

- Some family doctor/personal physician notes state compliance with ANSI/ANS requirements. Are these physicians truly aware of ANSI requirements?

## Keys to successful reviews

The only basis the NRC's reviewing physician has to make an assessment is the medical evidence submitted by the facility via Form 396. The form explicitly states "PROVIDE EXPLANATION AND ATTACH SUPPORTING MEDICAL EVIDENCE FOR NRC REVIEW" in the restrictions section of Part A. The Form also contains blocks titled "RELATIONSHIP OF RESTRICTION TO DISQUALIFYING CONDITION (Briefly indicate how restriction will correct the disqualifying condition)"

## Keys to successful reviews

and “EXPLANATION(S).” These sections of Form 396 should be used to convey the appropriate medical evidence and its relation to the ANSI/ANS conditions and requirements

## Keys to successful reviews

- For the NRC's reviewing physician to perform a meaningful review, some basic information must be included:
  - Medical problem/issue (link to ANSI/ANS disqualifying condition)?
  - Related medical examination and diagnostic studies results?
  - Current diagnosis? (controlled?, stable?)
  - Treatment plan or license restriction to ensure ANSI/ANS and “not endanger public health and safety” are met?

## Keys to successful reviews

- NRC's reviewing physicians are not expecting a formal or lengthy report.
  - A simple statement addressing these elements (can be done in a few sentences) is sufficient.
  - Format is not important; content is.



## Keys to successful reviews

- “Must Take Medication as Prescribed to Maintain Medical Qualifications” is a common license condition. Some considerations to help these reviews go more smoothly:
- Identify why the medication is being prescribed, especially its relationship (or not) to an ANSI/ANS disqualifying condition
  - Identification of the specific medication, dosage and frequency

## Keys to successful reviews

- Describe interactions with other drugs, if applicable
- A statement of “no adverse side effects experienced/noted” is helpful in evaluating the issue of potential incapacity.

## Keys to successful reviews

Relevant critical laboratory data related to meeting ANSI/ANS conditions should be included:

- Blood pressure reading if hypertensive
- Fasting blood sugars and/or Hemoglobin A1C for diabetics to indicate stability/degree of control

Reminder: NRC reviewing physicians do not keep medical files on applicants. Each 396 must stand on its own.

## **§55.57 Renewal of Licenses**

- (a) Applicant for renewal shall:
  - (1) Complete and sign NRC Form 398
  - (2) File original NRC Form 398
  - (6) Provide certification by the facility license of medical condition and general health on Form NRC-396
- (b) License will be renewed if:
  - (1) Medical condition and general health of the licensee continue to be such as not to cause operational errors that endanger public health and safety.

Medical requirements are a condition of licenses and as such are a requirement for the license holder as well as the facility.

# Questions and Answers

