

NMRP MRO/Physicians Users Group NRC Medical Review Expectations

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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
- 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-3.4[15.4]
- Recommend restrictions, as appropriate, to compensate for disqualifying conditions
- 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 on-duty personnel are medically and psychologically capable of fulfilling their duties rests with the facility licensee."

- ANSI/ANS-3.4, section 3.1



General Expectations

 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
 - NRC regions can ask for review anytime if they need input for licensing decision
- Note: this is provided as background info and is not meant to change instances where facilities are required to submit Form 396 and report changes in medical conditions to the NRC.



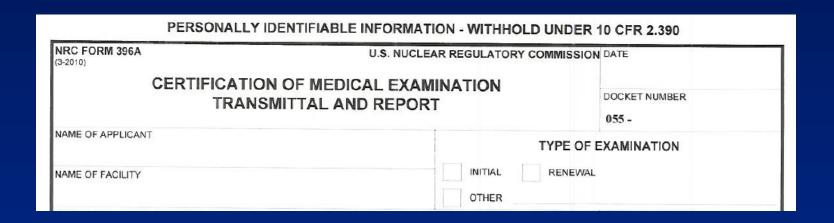
Form 396 Reviews by NRC Physicians

- What are the NRC's physicians trying to accomplish on behalf of the NRC?
 - NRC review physicians are looking for basic medical evidence to confirm the facility's recommendation for license conditions/restrictions and the suitability for licensing when reviewed against industry consensus standards (ANSI/ANS-3.4).
 - In addition to specific ANSI/ANS-3.4 requirements, the NRC physicians consider if the information submitted leads to a conclusion that "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."



Form 396 Reviews by NRC Physicians

NRC uses internal Form 396A as a traveler to document our physician's review





Form 396A Report

INSTRUCTIONS FOR 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 UNDER "REPORT" BELOW.			
	REF	PORT	
A REVIEW HAS BEEN COMPL APPLICANT WOULD NOT BE B RECOMMENDATION IS SUBM	ETED TO DETERMINE IF THE PHYSICAL CONDITION EXPECTED TO CAUSE OPERATIONAL ERRORS WHITTED:	ON AND GENERAL HEALTH OF THE HICH MIGHT ENDANGER PUBLIC H	APPLICANT ARE SUCH THAT THE EALTH AND SAFETY. THE FOLLOWING
THE PHYSICAL COND	ITION AND GENERAL HEALTH ARE SATISFACTOR	Y FOR LICENSING.	
NRC REVIEWING DOC	CTOR COMMENT(S):		
	DITION AND GENERAL HEALTH ARE SATISFACTOR SITION AND GENERAL HEALTH ARE NOT SATISFAC		
A DETERMINATION CA	ANNOT BE MADE UNTIL THE FOLLOWING ADDITIO	ONAL INFORMATION IS SUBMITTED):
SIGNATURE - MEDICAL DOCT	TOR		DATE



Form 396A Highlights

- 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…"
- 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?



SIGNATURE - MEDICAL DOCTOR



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.
- 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-3.4 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.
- Some family doctor/personal physician notes state compliance with ANSI/ANS requirements. Are these physicians truly aware of ANSI requirements? This would normally be under the facility physician's/medical department's purview.



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)" and "EXPLANATION(S)." These sections of Form 396 should be used to convey the appropriate *medical evidence* and its relation to the ANSI/ANS-3.4 conditions and requirements



- For the NRC's reviewing physician to perform a meaningful review, some basic information must be included:
 - Medical problem/issue (link to ANSI/ANS-3.4 disqualifying condition)?
 - Related medical examination and diagnostic studies results?
 - Current diagnosis? (controlled?, stable?)
 - Treatment plan or license restriction to ensure ANSI/ANS-3.4 and "not endanger public health and safety" are met?



- "SOAP notes" = <u>Subjective</u>, <u>Objective</u>,
 <u>Assessment</u>, <u>Plan can be a useful framework to meet these objectives
 </u>
- 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.



- "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 it's relationship (or not) to an ANSI/ANS-3.4 disqualifying condition
 - Identification of the specific medication, dosage and frequency
 - 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 as described in section 5.3.9 [5.4.9] of ANSI/ANS-3.4-1983 [1996]



- If a medication is changed **and** facility chooses to report it (although it may not be required), there should be an explanation. Otherwise, it may be unclear if there is any impact on medical qualification.
- "Information Only" helpful to state why the information is being submitted and how it does/does not relate to ANS requirements. Side effects and "potential for incapacity" good to address if applicable



- Relevant critical laboratory data related to meeting ANSI/ANS-3.4 conditions should be included:
 - Blood pressure reading if hypertensive
 - Fasting blood sugars and/or Hemoglobin A1C for diabetics to indicate stability/degree of control
- Thyroid function study when using replacement therapy to compensate for normal function per section 5.4.9 [5.4.3] of ANSI/ANS-3.4-1983 [1996]



- "No solo" based on cardiac, mobility, respiratory conditions
 - Include brief description of the accommodations available
 - Brief description of any job task analysis to show that individual can perform assigned duties despite otherwise disqualifying medical condition



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



3/6/12 month status reports:

- MRO should recommend when appropriate
- Can be added by NRC doctor
- Removal needs recommendation by facility MRO, supported by medical evidence that medical condition is corrected or no longer relevant



Some selected examples from medical certifications submitted since October 2009 to illustrate these points:



396 Example – potentially disqualifying conditions

Initial Licensed Operator Candidate, diagnosed with Diabetes Mellitus and Hypertension.

Employee's medical status is under control with use of medication and dietary restriction.

2 potentially disqualifying conditions, but no medical evidence to show:

- Diabetes controlled blood sugars, hemoglobin A1C?
- Hypertension controlled blood pressure readings?
- What medications? Any adverse side effects?



396 Example - medications

GUIDANCE USED:				
ANSI/ANS 3.4 - 1996 X ANSI/ANS 3.4 - 1983 ANSI/ANS 15.4 - 1988 (NON-POWER) OTHER				
ON THE BASIS OF THE RECOMMENDATION OF THE PHYSICIAN, IT IS REQUESTED THAT THE APPLICANT'S OPERATOR LICENSE BE CONDITIONED AS FO (PROVIDE EXPLANATION AND ATTACH SUPPORTING MEDICAL EVIDENCE FOR NRC REVIEW).				
1. NO RESTRICTIONS				
2. CORRECTIVE LENSES MUST BE WORN WHEN PERFORMING LICENSED DUTIES				
3. HEARING AID BE WORN WHEN PERFORMING LICENSED DUTIES				
4. SOLO OPERATION IS NOT AUTHORIZED				
X 5. MUST TAKE MEDICATION AS PRESCRIBED TO MAINTAIN MEDICAL QUALIFICATIONS				
6. MUST SUBMIT MEDICAL STATUS REPORT EVERY 3, 6, OR 12 MONTHS				
7. MUST NOT PERFORM LICENSED DUTIES REQUIRING A RESPIRATOR				
8. OTHER RESTRICTION OR EXCEPTION				
X 9. RESTRICTION CHANGE FROM PREVIOUS SUBMITTAL				
•For what medical				
PROPOSED WORDING OF RESTRICTION (Block & above) condition(s) are these				
RELATIONSHIP OF RESTRICTION TO DISQUALIFYING CONDITION (Briefly Indicate how distriction will correct the disqualifying condition)				
•Related to ANS-3.4?				
explanation (s) Side effects?				
#5 medications (Singulair, 10 mg) (Vytorin, 10-20 mg) (Benazepril, 10-12.5 mg)				



396 Example - medications

has been prescribed Zolpidem 10mg and Chantix 0.5mg. He has been informed of side effects of these medications both verbally and written. If he experiences any problems with these medications, he is to discontinue them immediately and inform his physician and the Medical Department.

For what medical condition(s) are these being taken? Related to ANS-3.4?



396 Example – conflicting info

Mr. presented for his interval respirator examination. He reports that he is taking Allegra D prn for his seasonal allergies as prescribed by his primary care physician. He denies and side effects from this medication.

This is being presented for informational only.

"Info Only" – non-ANS 3.4 medical condition for seasonal allergies

OK if facility chooses to report, but.....



396 Example – conflicting info (cont.)

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FOLLOWS Check all that apply IPROVIDE EXPLANATION AND ATTACH SUI 1. NO RESTRICTIONS	JESTED THAT THE APPLICANT'S OPERATOR LICENSE BE CONDITIONED AS PPORTING MEDICAL EVIDENCE FOR NRC REVIEWS
7. MUST NOT PERFORM LICENSED DUTIES REQUIRING A RES	EDICAL QUALIFICATIONS
■ 8. OTHER RESTRICTION OR EXCEPTION 9. RESTRICTION CHANGE FROM PREVIOUS SUBMITTAL 10. INFORMATION ONLY PROPOSED WORDING OF RESTRICTION (Block & above)	396 recommends — "must take meds" with no
	other explanation ???
RELATIONSHIP OF RESTRICTION TO DISQUALIFYING CONDITION (Briefly INCRESS FOR 181	Sisten will correct the disqualifying condition?
EXPLANATION (S)	
April Designation of the Control of	



396 Example – potentially disqualifying condition

ON THE BASIS OF THE RECOMMENDATION OF THE PHYSICIAN, IT IS REQUESTED TH FOLLOWS: Check all that apply. (PROVIDE EXPLANATION AND ATTACH SUPPORTING	AT THE APPLICANTS			
1. NO RESTRICTIONS				
2. CORRECTIVE LENSES MUST BE WORN WHEN PERFORMING LICENSED DUTIES				
3. HEARING AID MUST BE WORN WHEN PERFORMING LICENSED DUTIES				
4. SOLO OPERATION IS NOT AUTHORIZED				
5. MUST TAKE MEDICATION AS PRESCRIBED TO MAINTAIN MEDICAL QUALIFICATIONS				
6. MUST SUBMIT MEDICAL STATUS REPORT EVERY 3, 6, OR				
7. MUST NOT PERFORM LICENSED DUTIES REQUIRING A RESPIRATOR	No other info attached			
8. OTHER RESTRICTION OR EXCEPTION	•What cardiac condition?			
9. RESTRICTION CHANGE FROM PREVIOUS SUBMITTAL				
10. INFORMATION ONLY	•ANS 3.4 qualification?			
PROPOSED WORDING OF RESTRICTION (Block 8 above)	What medication?			
	• Is "no solo" appropriate?			
RELATIONSHIP OF RESTRICTION TO DISQUALIFYING CONDITION (Briefly indicate how restriction will co	rrect the disqualitying con-			
Operator must take medication to maintain cardiac risk at acceptable levels	. 2			
EXPLANATION (S)				



396 Example – potentially disqualifying conditions

Removing medical report requirement: Demonstrating better control of diabetes.				
RELATIONSHIP OF RESTRICTION TO DISQUALIFYING CONDITION (Briefly indicate how restriction will a Prescriptions to maintain cardiac risk within acceptable level.	•What about cardiac condition?			
PROPOSED WORDING OF RESTRICTION (Block & above)	controlled? •Meds?			
9. RESTRICTION CHANGE FROM PREVIOUS SUBMITTAL 10. INFORMATION ONLY	No other info included •How is diabetes being			
☐ 4. SOLO OPERATION IS NOT AUTHORIZED ☐ 5. MUST TAKE MEDICATION AS PRESCRIBED TO MAINTAIN MEDICAL QUALIFICATIONS ☐ 6. MUST SUBMIT MEDICAL STATUS REPORT EVERY ☐ 3, ☐ 6, OR ☐ 12 MONTHS ☐ 7. MUST NOT PERFORM LICENSED DUTIES REQUIRING A RESPIRATOR ☐ 8. OTHER RESTRICTION OR EXCEPTION				
 ✓ 2. CORRECTIVE LENSES MUST BE WORN WHEN PERFORMING LICENSED DUTIES ✓ 3. HEARING AID MUST BE WORN WHEN PERFORMING LICENSED DUTIES ✓ 4. SOLO OPERATION IS NOT AUTHORIZED 				
FOLLOWS: Check all that apply. (PROVIDE EXPLANATION AND ATTACH SUPPORTING MEDICAL EVIDENC 1. NO RESTRICTIONS				
ON THE BASIS OF THE RECOMMENDATION OF THE PHYSICIAN, IT IS REQUESTED THE	HAT THE APPLICANT			



396 Example – potentially disqualifying conditions

Mr. Licensed operator at Licen

He continues to require corrective lens, medication for blood pressure control and diabetes control to meet the requirements of ANSI/ANS 3.4.

- •Evidence to show control of diabetes? hypertension? thyroid function?
- •Meds? side affects?

We are requesting a review to determine if this license will need to be amended to reflect this change in his medical status.

NRC physician review is not as a consultant for licensees – facility needs to make recommendations on Form 396 and provide supporting medical evidence



Good example - hypertension

Medical data

Medical condition

Treatment

is a licensed operator at discovered to have hypertension. He is taking Amlodipine 5 mg. He has no side effects. His blood pressure on 2/11/2010 was 120/70. In addition, he takes Simvastatin for cholesterol management.

requires blood pressure medication to meet the requirements of ANSI/ANS 3.4. He continues to require corrective lens.

Co-morbidity

Addresses side effects

Link to ANS 3.4



Another good hypertension example

presents for his biennial licensed medical examination. He continues with a diagnosis of hypertension for which he takes lisinopril 10mg daily, atended 100 mg daily, and triamterene/hetz one tablet daily. His blood pressure at the time of this exam is 104/72, HR 72, EKG normal. He denies any fatigue, dizziness, or other side effects from this medication.

He is obese with a BMI of 44.2. The remainder of his physical examination is unremarkable.

He further denies any new medical problems. He is not taking any other prescription medication.



Good thyroid disease example

Medical evidence in the form of lab data was included so NRC doctor could see that thyroid disease was being controlled

has a diagnosis of Hypothyroidism and is currently taking
Levothyroxine 150 mcg 1 po QD per his primary care physician Dr. i
current thyroid panel was drawn on 27APR10. These lab results have been
attached to this letter dosage is at therapeutic TSH and free T4 levels.

I will be adding "must take medication as prescribed to maintain medical qualifications" to NRC Form 396.



Good combined diabetes and HTN example

is currently taking Toprol XI 100mg daily. Lisinopril 20mg daily, and metrormin 500mg daily for hypertension and diabetes mellitus, respectively. His blood pressure is under control as evidenced by blood pressure readings of 136/84 and 121/86 obtained on April 15, 2010. His diabetes mellitus also shows reasonable control with a HgbA1C of 8.1% obtained on March 12, 2010. He will be submitting HgbA1C levels every three months to the medical department for review. He exhibits no untoward side effects on his current regimen.

Diagnoses, meds, lab test/exam results, control, side effects... all good info!



Good example – heart condition

On March 19, 2010, had an acute coronary syndrome requiring emergency single-vessel coronary angioplasty and coronary stent placement. He has been administratively removed from licensed duties. I have evaluated him today to determine whether he is fit to resume licensed duties as a nuclear operator.

Brief history of condition

He has recovered remarkably well from his illness. His blood pressure is well controlled (132/78) while taking Toprol XL 25 mg qd. He also takes Plavix 75 mg qd and aspirin 162 mg qd. His only other ongoing medication is Lipitor 40 mg qd.

Assessment and meds summary

underwent a stress echocardiogram on April 29, 2010 (see attached study results). He has normal left ventricular wall motion. PVCs noted during the examination were well-controlled with the above Toprol therapy (see attached EKG).

Medical evidence

I recommend his license be conditioned to require that he "must take medication as prescribed". Though there is no evidence of compromise to his ability to safely and effectively perform licensed duties, I recommend a precautionary restriction that "solo operation is not authorized".



Good summary – multiple conditions

To maintain licensure, is currently monitored at Health Services for the following conditions:

- 1. Obstructive Sleep Apnea has been symptomatically stable after undergoing a UP-3 procedure with a medical regimen of Provigil 200 mg BID. He, additionally, uses an oral appliance at night. Based on this condition, I has been restricted to a permanent "No Solo" status. Also, at the direction of his pulmonologist, he has been administratively restricted to a goal of no greater than 60 hours of work per week and daylight shift only.

 Will continue to follow up with his pulmonologist, on an annual basis, and provide

 3 a narrative of the findings. Based on his current treatment status and response, it is my opinion that an event of sudden incapacitation is unlikely.
- Hypertension N is currently prescribed HCTZ 25 mg QD for blood pressure control. His most recent measurement was 140/90 on April 10, 2010. Typical measurements, over the past year, have been generally stable; with a range 120-136/78-84. His license restriction is must take medication as prescribed.
- Corrective Lenses continues to require corrective lenses. His
 most recent visual acuity check, on January 15, 2010, documented a far
 point measurement of OS 20/22, OD 20/20 and OU 20/20 and near point of
 OS 20/20, OD 20/20 and OU 20/20. His license restriction is shall wear
 corrective lenses while performing the activities for which you are
 licensed.



Good summary – multiple conditions

He has a history of ulcerative colitis which was diagnosed in 2003. I am including his physician's letter detailing his disease course and prognosis. He is currently taking Azathioprine 200mg daily, Prednisone 35mg daily, and Apriso 1500mg daily in attempt to control this disease process. He will be placed on no solo operation on his NRC form 396 due to the unpredictability of his disease. He states he currently has fecal urgency 3-4 times daily.

He has a history of hypertension for which he takes lisinopril 10mg daily. His blood pressure at this exam is 116/60, HR 80 bpm.

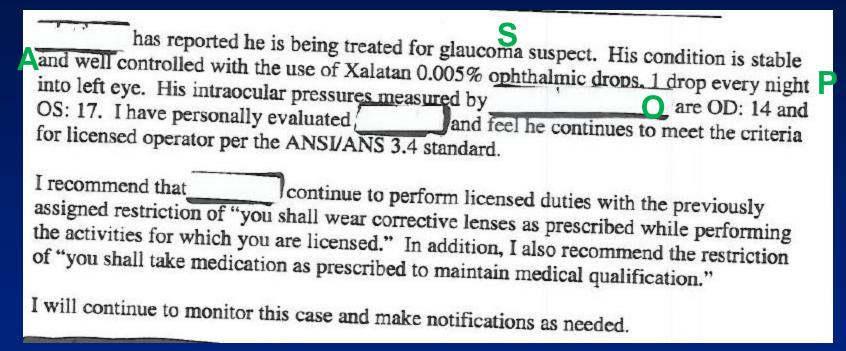
He has low bone density from the steroid use, for which he takes alendronate 70mg weekly.

He has anxiety from his concern about his ulcerative colitis for which he began taking Lexapro 10mg daily on 2/15/2010, with good response thus far and no side effects.

He requires corrective lenses for near and far vision. The remainder of his physical exam is normal.



Good example - vision



Medical condition (S), test results (O), assessment (A), treatment plan (P)



Good example – multiple conditions

Mr Docket Number 5 is a Licensed Operator. He recently had a myocardial infarction and had angioplasty and stent placement on 12/7/2009. He had an exercise nuclear stress test done on 1/6/10 which revealed good exercise capacity, no provocation of angina or arrhythmias and a calculated EF of 61%. He has been released to return to work effective 1/20/10, light duty. We will monitor him and return him to full duty when cleared by his cardiologist.

Brief history of condition

His current medications include: Carvedilol 6.25 mg BID, Lipitor 80 mg QD, Plavix 75 mg QD, Aspirin 325 mg QD, Allopurinol 300 mg QD, and Men's multivitamin QD. He reports no side effects from the medications including dizziness, fatigue, cough or orthostatic hypotension. He has noted good effect from the medications, his blood pressure during the stress test was 120/80 and today it is 127/84.

Summary of meds

He has been counseled on modifying his risk factors including smoking cessation, weight loss and he is going to start cardiac rehabilitation later this month. We will address the effects of shift work on his medical condition when he returns to full duty.

General outlook and related health issues (weight, smoking)

Additionally, Mr. now requires corrective lenses for near vision. His near vision without glasses was right eye 20/70 and left eye 20/100. With corrective lenses his near vision is 20/20 bilaterally. Distance vision is 20/30 bilaterally without correction.

After reviewing the ANSI/ANI-3.4-1983 standards, specifically 5.3.2, it is my professional opinion that Mr.' 'license be amended to include the following restrictions, corrective lenses, no-solo operation and he must continue to take his medications to maintain his qualifications.

Specific ANS-3.4 reference



A "common sense" perspective:

 "If I were a third party reviewer, what information would I need to be able to conclude that the applicant meets the ANSI/ANS-3.4 requirements, that the recommended license conditions address these requirements and that the reported physical condition and general health would not be expected to cause operational errors endangering public health and safety?"



Available Guidance

- NUREG-1021, ES-605, C.3, "Medical Standards"
- "FAQs" on NRC public website General Questions discuss medical issues:
 - http://www.nrc.gov/reactors/operatorlicensing/op-licensing-files/olfeedback.pdf



Summary

 Relate conditions/restriction to ANSI/ANS-3.4 requirements

Provide medical evidence to back up recommendations/conclusions



Summary

What would YOU

need to see to make a determination?