



# **NMRP Users Group**

## **NRC Form 396 Reporting and Reviews**

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July 13, 2010



# Discussion Topics

- Form 396 Basic Requirements
- NRC physician reviews – when and why?
  - Have requirements changed?
- General feedback on 396 submittals
- Recommendations for ensuring a smooth review
- Questions/comments?



## Some NRC Form 396 Basics

- When should a Form 396 be submitted?
  - Certify medical fitness of a new license applicant (55.23 and 55.31)
  - Certify that a physician has examined any new permanent physical or mental condition, concluded that the operator meets the requirements of 55.21/33, and request a conditional license (55.25)
  - Certify the continued medical fitness of a license renewal applicant (55.57)



## 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 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

PERSONALLY IDENTIFIABLE INFORMATION - WITHHOLD UNDER 10 CFR 2.390			
NRC FORM 396A (3-2010)	U.S. NUCLEAR REGULATORY COMMISSION DATE		
<b>CERTIFICATION OF MEDICAL EXAMINATION TRANSMITTAL AND REPORT</b>			
NAME OF APPLICANT	DOCKET NUMBER  055 -		
NAME OF FACILITY	TYPE OF EXAMINATION		
	<input type="checkbox"/> INITIAL	<input type="checkbox"/> RENEWAL	
	<input type="checkbox"/> OTHER		



# 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.

**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. THE FOLLOWING RECOMMENDATION IS SUBMITTED:

THE PHYSICAL CONDITION AND GENERAL HEALTH ARE SATISFACTORY FOR LICENSING.

NRC REVIEWING DOCTOR COMMENT(S):

THE PHYSICAL CONDITION AND GENERAL HEALTH ARE SATISFACTORY FOR LICENSING WITH THE FOLLOWING CONDITIONS.

THE PHYSICAL CONDITION AND GENERAL HEALTH ARE NOT SATISFACTORY FOR LICENSING. THE ADVERSE CONDITION(S) IS (ARE):

A DETERMINATION CANNOT BE MADE UNTIL THE FOLLOWING ADDITIONAL INFORMATION IS SUBMITTED:

SIGNATURE – MEDICAL DOCTOR

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?

SUPPORTING MEDICAL EVIDENCE  
ENDANGER PUBLIC HEALTH AND SAFETY  
PHYSICAL CONDITION AND GENERAL HEALTH ARE SATISFACTORY FOR LICENSING  
OPERATIONAL ERRORS

**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 (*Briefly indicate how restriction will correct the disqualifying condition*)” and “EXPLANATION(S)” are not being completed.

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. (PROVIDE EXPLANATION AND ATTACH SUPPORTING MEDICAL EVIDENCE FOR NRC REVIEW).

RELATIONSHIP OF RESTRICTION TO DISQUALIFYING CONDITION (*Briefly indicate how restriction will correct the disqualifying condition*)

EXPLANATION(S)



## General Feedback on Form 396 Submittals

- Some cases where Form 396, Section A, block 8, “OTHER RESTRICTION OR EXCEPTION,” has been checked, but with nothing (or unclear wording) provided in “PROPOSED WORDING OF RESTRICTION (*Block 8 above*)” section.

<input type="checkbox"/> 8. OTHER RESTRICTION OR EXCEPTION
<input type="checkbox"/> 9. RESTRICTION CHANGE FROM PREVIOUS SUBMITTAL
<input type="checkbox"/> 10. INFORMATION ONLY
PROPOSED WORDING OF RESTRICTION ( <i>Block 8 above</i> )

Check **8. OTHER RESTRICTION OR EXCEPTION** if, in the physician's judgment, any other license condition is necessary to accommodate any identified medical or psychological situation that does not meet the minimum requirements in the applicable ANSI standard. Fill out the **PROPOSED WORDING OF OTHER RESTRICTION** block, briefly explain how the recommended restriction will correct or accommodate the disqualifying condition in the **RELATIONSHIP OF RESTRICTION TO DISQUALIFYING CONDITION** block, and attach the supporting medical evidence for review by the NRC. If an applicant fails to meet a medical requirement but can demonstrate complete capacity to perform assigned duties, as proven by a practical test administered by the physician, the physician may recommend, and similarly justify, a waiver (exception) of that portion of the applicable ANSI standard. In all cases, check Item 4.f.4 on the associated license application (NRC Form 398).



## General Feedback on Form 396 Submittals

- Some 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.



## Keys to successful reviews

**Reminder** – the facility licensee is responsible for ensuring a physician\* conducts a medical examination and for certifying medical fitness of applicants/licensed operators

*[\* May delegate portions of exam to other licensed medical professionals per ANSI/ANS-3.4]*

**So.....What are the NRC doctors trying to confirm?**



# Keys to successful reviews

- The only basis the reviewing physician has to make an assessment is the **medical evidence** submitted via Form 396. The form explicitly states “*PROVIDE EXPLANATION AND ATTACH SUPPORTING MEDICAL EVIDENCE FOR NRC REVIEW*” in the restrictions section of Part A. Form 396 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 disqualifying conditions and minimum requirements



## Keys to successful reviews

- In order for the NRC reviewing physicians to perform a meaningful review, some basic information must be included:
  - Medical problem/issue (link to ANSI/ANS-3.4 disqualifying condition or minimum req'ts)?
  - Related medical examination and diagnostic studies results?
  - Current diagnosis? (controlled?, stable?)
  - Treatment plan or license restriction to ensure ANSI/ANS-3.4 requirements and “not endanger public health and safety” are met?



## Keys to successful reviews

- These elements have been referred to as “SOAP\* notes” in the medical community.
- 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.

\*SOAP = Subjective, Objective, Asessment, Plan



# 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-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]



## Keys to successful reviews

- If a medication is changed **and** facility chooses to report it (although it may not be required), there should be an explanation
- “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



# Keys to successful reviews

- 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]



# Keys to successful reviews

- “No solo” based on cardiac, mobility, respiratory conditions
  - Include brief description of the accommodations available (ref. ANSI/ANS-3.4, section 5.1)
  - Brief description of any job task analysis to show that individual can perform assigned duties despite otherwise disqualifying medical condition



## Keys to successful reviews

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



## Keys to successful reviews

3/6/12 month status reports:

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

# Keys to successful reviews

Actual 396 Examples





## 396 Example – potentially disqualifying conditions

Initial Licensed Operator Candidate, [REDACTED] 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:				
<input type="checkbox"/> ANSI/ANS 3.4 - 1996 <input checked="" type="checkbox"/> ANSI/ANS 3.4 - 1983 <input type="checkbox"/> ANSI/ANS 15.4 - 1988 (NON-POWER) <input type="checkbox"/> OTHER				
ON THE BASIS OF THE RECOMMENDATION OF THE PHYSICIAN, IT IS REQUESTED THAT THE APPLICANT'S OPERATOR LICENSE BE CONDITIONED AS FOLLOWS (PROVIDE EXPLANATION AND ATTACH SUPPORTING MEDICAL EVIDENCE FOR NRC REVIEW).				
<ul style="list-style-type: none"><li>1. NO RESTRICTIONS</li><li>2. CORRECTIVE LENSES MUST BE WORN WHEN PERFORMING LICENSED DUTIES</li><li>3. HEARING AID BE WORN WHEN PERFORMING LICENSED DUTIES</li><li>4. SOLO OPERATION IS NOT AUTHORIZED</li><li><input checked="" type="checkbox"/> 5. MUST TAKE MEDICATION AS PRESCRIBED TO MAINTAIN MEDICAL QUALIFICATIONS</li><li>6. MUST SUBMIT MEDICAL STATUS REPORT EVERY <input type="checkbox"/> 3, <input type="checkbox"/> 6, OR <input checked="" type="checkbox"/> 12 MONTHS</li><li>7. MUST NOT PERFORM LICENSED DUTIES REQUIRING A RESPIRATOR</li><li>8. OTHER RESTRICTION OR EXCEPTION</li><li><input checked="" type="checkbox"/> 9. RESTRICTION CHANGE FROM PREVIOUS SUBMITTAL</li><li>10. INFORMATION ONLY</li></ul>				
PROPOSED WORDING OF RESTRICTION (Block 8 above)				
RELATIONSHIP OF RESTRICTION TO DISQUALIFYING CONDITION (Briefly indicate how restriction will correct the disqualifying condition)				
<ul style="list-style-type: none"><li>•For what medical condition(s) are these being taken?</li><li>•Related to ANS-3.4?</li><li>•Side effects?</li></ul>				
EXPLANATION (S)				
#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. [REDACTED] 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 any 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 (although probably not required), but.....



## 396 Example – conflicting info (cont.)

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. (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 MUST BE WORN WHEN PERFORMING LICENSED DUTIES  
 4. SOLO OPERATION IS NOT AUTHORIZED  
 5. MUST TAKE MEDICATION AS PRESCRIBED TO MAINTAIN MEDICAL QUALIFICATIONS (This item is circled in red)  
 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  
 9. RESTRICTION CHANGE FROM PREVIOUS SUBMITTAL  
 10. INFORMATION ONLY

PROPOSED WORDING OF RESTRICTION (Block 6 above)

RELATIONSHIP OF RESTRICTION TO DISQUALIFYING CONDITION (Briefly indicate how restriction will correct the disqualifying condition)

EXPLANATION (S)

.....396 recommends  
“must take meds” with no  
other explanation ... ???



## 396 Example – potentially disqualifying condition

ON THE BASIS OF THE RECOMMENDATION OF THE PHYSICIAN, IT IS REQUESTED THAT THE APPLICANT'S FOLLOWS: Check all that apply. PROVIDE EXPLANATION AND ATTACH SUPPORTING MEDICAL EVIDENCE

- 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  12 MONTHS
- 7. MUST NOT PERFORM LICENSED DUTIES REQUIRING A RESPIRATOR
- 8. OTHER RESTRICTION OR EXCEPTION
- 9. RESTRICTION CHANGE FROM PREVIOUS SUBMITTAL
- 10. INFORMATION ONLY

PROPOSED WORDING OF RESTRICTION (Block 8 above)

- No other info attached
- What cardiac condition?
  - ANS 3.4 qualification?
  - What medication?
  - Is “no solo” appropriate?

RELATIONSHIP OF RESTRICTION TO DISQUALIFYING CONDITION (Briefly indicate how restriction will correct the disqualifying condition)

Operator must take medication to maintain cardiac risk at acceptable levels.

EXPLANATION (S)



## 396 Example – potentially disqualifying conditions

ON THE BASIS OF THE RECOMMENDATION OF THE PHYSICIAN, IT IS REQUESTED THAT THE APPLICANT FOLLOWS: Check all that apply. PROVIDE EXPLANATION AND ATTACH SUPPORTING MEDICAL EVIDENCE

- 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  12 MONTHS
- 7. MUST NOT PERFORM LICENSED DUTIES REQUIRING A RESPIRATOR
- 8. OTHER RESTRICTION OR EXCEPTION
- 9. RESTRICTION CHANGE FROM PREVIOUS SUBMITTAL
- 10. INFORMATION ONLY

PROPOSED WORDING OF RESTRICTION (Block 8 above)

RELATIONSHIP OF RESTRICTION TO DISQUALIFYING CONDITION (Briefly indicate how restriction will control disqualification)

Prescriptions to maintain cardiac risk within acceptable level.

EXPLANATION (S)

Removing medical report requirement: Demonstrating better control of diabetes.

No other info included  
•How is diabetes being controlled?  
•Meds?  
•What about cardiac condition?

## 396 Example – potentially disqualifying conditions

Mr. [REDACTED] licensed operator at [REDACTED] a. He has restrictions for blood pressure medication and medication for control of diabetes mellitus. In addition, for information he takes Lipitor for lipid management and Levoxyl for thyroid management.

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 condition**

[REDACTED] is a licensed operator at [REDACTED]. Recently, he was 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.

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

**Medical data**

**Treatment**

**Co-morbidity**

**Link to ANS 3.4**

**Addresses side effects**



# 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, atenolol 100 mg daily, and triamterene/hctz 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. [redacted].  
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

[REDACTED] is currently taking Toprol XL 100mg daily, Lisinopril 20mg daily, and Metformin 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, [REDACTED] 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.

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.

[REDACTED] 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).

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”.

**Brief history of condition**

**Assessment and meds summary**

**Medical evidence**



# Good summary – multiple conditions

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

1. Obstructive Sleep Apnea – [REDACTED] 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, [REDACTED] 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. [REDACTED] will continue to follow up with his pulmonologist, on an annual basis, and provide [REDACTED] 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.
2. Hypertension – [REDACTED] 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.
3. Corrective Lenses – [REDACTED] 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

A [REDACTED] has reported he is being treated for glaucoma suspect. His condition is stable and well controlled with the use of Xalatan 0.005% ophthalmic drops, 1 drop every night into left eye. His intraocular pressures measured by [REDACTED] S O are OD: 14 and OS: 17. I have personally evaluated [REDACTED] P and feel he continues to meet the criteria for licensed operator per the ANSI/ANS 3.4 standard.

I recommend that [REDACTED] continue to perform licensed duties with the previously assigned restriction of "you shall wear corrective lenses as prescribed while performing the activities for which you are licensed." In addition, I also recommend the restriction of "you shall take medication as prescribed to maintain medical qualification."

I will continue to monitor this case and make notifications as needed.

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



## Good example – multiple conditions

Mr. [REDACTED] Docket Number 5 [REDACTED] 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. [REDACTED] 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. [REDACTED]'s 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



## Key to successful reviews

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 49-51 discuss Form 396 reviews:
  - <http://www.nrc.gov/reactors/operator-licensing/op-licensing-files/ol-feedback.pdf>



# Summary

- The basic requirements really haven't changed
- Relate conditions/restriction to ANSI/ANS-3.4 requirements
- Medical evidence is key to allow NRC's doctors to make their determination



## Summary

What would  
YOU  
need to see to make a  
determination?



# Your feedback

- Questions?
- Comments?
- Frustrations?