Regulatory Basis of Licensed Operator Medical Requirements:

Subpart C, "Medical Requirements," of 10 CFR Part 55, Section 55.23, "Certification," requires certification that a physician has examined licensed reactor operators and senior operators in accordance with NRC's regulatory guidance. Form NRC-396, "Certification of Medical Examination by Facility Licensee," must be completed by an authorized representative of the facility licensee and must certify that a physician has conducted the medical examination of the applicant as required by 10 CFR 55.21. The physician should determine that the examinee'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 intent of these requirements is to have the facility licensee certify the health of its operators.

The facility licensee is expected to maintain the records on operators or senior operators that may be requested and reviewed by the NRC. Therefore, 10 CFR 55.27 requires the facility licensee to document and maintain the medical qualifications data, test results, and each operator's medical history.

There are two instances in which medical information must be sent to the NRC. One is when a conditional license based on medical evidence is requested under the provisions of 10 CFR 55.23(b) and 55.33(b). The second instance is when a licensed individual has become mentally or physically unable to perform licensed duties. In this case, the facility licensee must notify the NRC within 30 days after learning of the diagnosis. If a conditional license is requested, the facility licensee must forward the medical evidence on Form NRC-396. This documentation is required by 10 CFR 55.27 to be maintained by the facility.

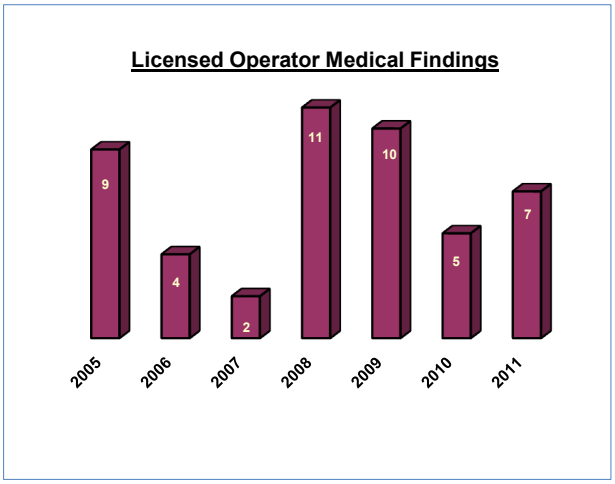
American National Standard developed by the American Nuclear Society, ANSI/ ANS-3.4-1996, "Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants," prescribes minimum requirements necessary to determine that the medical condition and general health of nuclear reactor operators will not cause operational errors. The criteria presented in this standard provide an examining physician a basis for determining whether a potentially disqualifying abnormal health condition exists. Although it is the physician's responsibility to identify and evaluate any potentially disqualifying medical conditions, the NRC makes the final determination of the operator's medical fitness. Regulatory Guide 1.134; Revision 3, March 1998; (“Medical Evaluation Of Licensed Personnel At Nuclear Power Plants, endorses ANSI/ANS 3.4-1996, “Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants,”) with exceptions. However, facility licensees may continue to use the 1983 version of ANSI/ANS 3.4, which was previously endorsed in its entirety by Revision 2 of RG 1.134, dated April 1987. A reactor part 50 licensee can update their commitment to a more recent approved edition of the standard by revision to their current commitment.

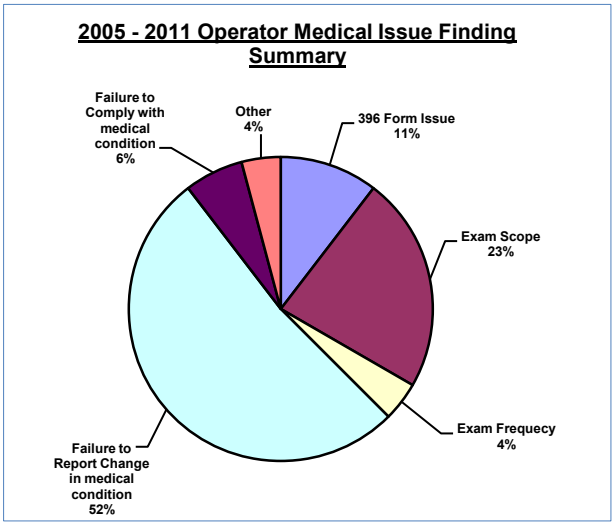
The Licensed Operator Medical Standard Dilemma

Why not implement the 1996 Standard? Currently, 94 of the 104 of the operating units continue to use the 1983 version. One major reason that 90 percent of the industry has not implemented the 1996 version of the standard is that it requires "Stamina shall be evaluated through the use of a treadmill, bicycle ergometer, or other valid and reliable testing method for measuring aerobic capacity. The minimum passing criterion for this requirement shall be a maximum aerobic capacity of at least 25 cm3 (CC) of oxygen per kilogram per minute. Exercise testing shall assess aerobic capacity and fitness and shall not be used specifically to determine the presence of ischemic heart disease."

The stamina testing requirement is extremely onerous not only because of the expense due to the testing, purchase of equipment, or requiring that the testing to be done off-site, but also because of additional qualifications of the medical staff to perform the testing because of the risks associated with performance of the cardiac stress testing. According to American Heart Association data, about 65% of men and 47% of women have as their first symptom of cardiovascular disease a heart attack or sudden cardiac arrest. Stress tests, carried out shortly before these events, are not relevant to the prediction of cardiac event in the majority of individuals tested. Over the past two decades, better methods have been developed to identify atherosclerotic disease before it becomes symptomatic. The 1983 and 1996 versions of the standard do not reflect progressions in medical science regarding terminology, criteria for normality, and risk assessment with respect to risk factors associated with heart valves, conduction, and coronary arteries. The changes proposed in the revised standard reflect the consensus within the occupational medical community that the use of absolute or blanket disqualifications based upon diagnosed medical conditions 1) may disqualify individuals with low or no risk of sudden or subtle incapacitation (OPM's terminology) 2) may fail to recognize the high risk of individuals with multiple risk factors. Incorporating a risk assessment methodology directly into the standard empowers licensees to make the most medico legally valid decisions and provides transparency in decision-making for those operators subject to medical assessments. Risk assessment of coronary artery disease and heart attack was absent from both versions and incorporated into the current version through application of the Framingham Points System established by the National Institutes of Health, thus enabling licensees to recommend/require operator evaluation by cardiac specialists/testing.

The vast majority of the industry needs to balance the belief that the 1983 version of the standard does not reflect the current medical practices in that it doesn't adequately address overall cardiac risk factors against the 1996 version of the standard which requires onerous stamina testing with increased risks and significant increased cost and liability with minimal diagnostic benefit.





The confusion of the current standards - The industry continues to struggle with the implementation of ANSI/ANS 3.4 with an average of seven violations/findings per year since 2005 (48 total violations). The number of violations is relatively consistent and does not show an improving trend of performance. Reporting failures (either failure to report a change in medical conditions or error in form 396) and medical exam issues comprise 90 percent of these violations. The high number of violations is directly related to unclear criteria within the 1983 version of the standard. The working group represents 22 commercial nuclear sites, numerous Department of Energy (DOE) nuclear facilities and has reviewed and continues to review NRC violations associated with Operator Medical issues. The team members have also been involved with numerous audits of other facilities and have an in-depth understanding of the issues identified. Finally, the NRC and DOE representatives are highly experienced and have provided operating experience from their perspective and the perspective of the NRC and DOE physicians.

How the Proposed Standard Solves these issues - As opposed to the ANS/ANSI 1996, the proposed standard, balances the current progression in medical science which utilizes overall risk factors to determine the need for additional cardiac testing to assure that an operator is medically qualified to perform all licensed duties.

Additionally, the proposed revision to the standard has incorporated significant improvements including providing definitions such as Administrative Controls, Administrative Hold, Administrative Conditional Restriction, Conditional license, Examining Physician, Facility licensee, Licensed Duties, Marker Gas, No Solo Operations, Operator, Licensed Reactor operator, Licensed Senior Operator, Permanent Medical Condition, Sudden Incapacitation, and Temporary Medical Condition. The incorporation of these specific definitions will eliminate much of the confusion which currently exists.

This revision also provides comprehensive medical guidance to improve industry's consistent implementation of the standard. The major changes made as a result of the revision include Specific Minimum Requirements, Disqualifying Conditions, Conditional Restrictions, Exam Methods and Monitoring Methods are provided for each medical area; Incorporation of nuclear

industry operating experience and consideration of other industry medical standards including Department of Transportation (DOT) and Federal Aviation Administration (FAA); and the medical criterions reflect progressions in medical science that include updated terminology, current medical practices, criteria for normality, and risk assessments. For example, Tactile testing was unclear and testing was administered with considerable variability among facilities. In the proposed revision, tactile deficit testing is addressed by standard neurological or orthopedic testing.

The revised standard also provides additional specific guidance to reduce unnecessary reporting of medical conditions. For example, the 1983 and 1996 standards malignant neoplasm (cancer) requirements are too broad which made it necessary to report all cancers to the NRC. The revised standard includes an ANNEX to provide the examining physician guidance when determining operator fitness and when to notify the NRC.

How can we get the whole industry on the current standard? – While there is no specific commitment from the NRC, the NRC has been significantly involved in the preparation of the new draft standard and there is a very high probability that the NRC will approve the use of this standard with a revision to Regulatory Guide 1.134. There are many benefits in having the entire industry adopt the proposed standard. These include (but are not limited to) providing a medical basis consistent with current medical modalities for determining the medical fitness of a licensed operator to perform all licensed duties and significantly reduced industry and NRC confusion regarding the technical requirements of the guidance leading to improved implementation and reduced findings and violations. The working group represents 19 commercial nuclear sites. Several of the more significant changes were evaluated against the current population of licensed operators and while minor changes in the type and number of conditional restrictions would be anticipated, this standard (based upon their current medical condition) is not expected to eliminate any currently licensed operators from medical qualification.

The working group is having difficulty determining the best method to align the industry to commit to the updated standard. From a medical perspective, as opposed to the current standard, this standard provides a much sounder medical basis for assuring that the licensed operators are medically qualified. In addition, it also provides more specific guidance and leaves less room for interpretation and potential NRC violations and enforcement. However, there is no defined regulatory requirement (e.g., regulatory backfit of the new requirement) that requires a part 50 licensee to update their commitment from an outdated standard to the revised standard and therefore the change would have to be “voluntary”.

The ANS 3.4 working group has begun discussions with NEI (Scott Bauer) to see if the Licensed Operator Task Force will be willing to drive this change.