



## DEPARTMENT OF THE NAVY

NAVAL SEA SYSTEMS COMMAND  
1333 ISAAC HULL AVE SE  
WASHINGTON NAVY YARD DC 20376-0001

IN REPLY TO

NAVSEAINST 4855.31A

Ser 04X/070

28 Mar 06

### NAVSEA INSTRUCTION 4855.31A

From: Commander, Naval Sea Systems Command

Subj: QUALITY SYSTEMS FOR NAVSEA LABORATORIES

1. Purpose. To provide the minimum requirements for documentation and implementation of Quality Systems in NAVSEA testing laboratories. These requirements will facilitate compliance with memorandum "Ensuring Quality of Information Disseminated to the Public by the Department of Defense" (10 Feb 2003).

2. Cancellation. This instruction supersedes NAVSEAINST 4855.31 of 14 December 1984.

3. Scope. The instruction is applicable to all NAVSEA chemical, metallurgical, and materials engineering laboratories. It is not intended to supersede more stringent requirements that may be invoked by other documents or users of NAVSEA laboratory services: such as the Environmental Protection Agency, the Navy Occupational Safety and Health Program, or the Navy Nuclear Propulsion Program.

#### 4. Background

a. Because of the importance of laboratory analyses and the resulting safety, medical, legal, and economic actions that they may produce, a program to ensure the reliability of the data reported is essential. It is recognized that all competent laboratories practice quality control to varying degrees, depending upon the training and professional pride of its staff and the awareness of the importance of the tests being performed. Therefore, an established, Quality Systems program is imperative to assure laboratory management and the users of laboratory services of the reliability of the results reported.

b. Reliability in laboratories is assured by providing trained and experienced personnel; knowledgeable management; adequate physical facilities; state-of-the-art instrumentation and equipment; periodic servicing and calibration of instrumentation; certified reagents and standards; the use of

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documented, proven, and accepted testing procedures; routine analysis of control samples; and, finally, demonstration of the laboratory's ability to produce acceptable results by requiring participation in proficiency testing programs.

c. This instruction provides the minimum requirements and recommendations for the control of the above factors in order to provide documented records to assure users of the laboratories services that a specified level of precision has been achieved. Documented records can provide laboratory management with an early warning when reagents, standards, instruments, or equipment begin to show deterioration of precision.

5. Mandatory Requirements and Recommendations. Mandatory requirements contained in this instruction are characterized by use of the word shall. Recommendations which are advisory in nature are indicated by the word should.

6. Requirements. All NAVSEA chemical, environmental, metallurgical, and materials engineering laboratories shall publish a Laboratory Quality Systems Manual (however named) and implement a Laboratory Quality System that meets the requirements of the international standard General requirements for the competence of testing and calibration laboratories, ISO/IEC 17025. The Quality Systems documentation shall be detailed enough to be used directly by the laboratory personnel and management; therefore, it should not merely reference other documents. The Laboratory Quality Systems Manual, and related quality documentation, shall state the laboratory's policies and operational procedures established in order to meet the requirements of ISO/IEC 17025. Quality documentation includes the Quality Systems Manual itself, Standard Operating Procedures (SOPs), and other appropriate reference documents and texts. In addition to the requirements of ISO/IEC 17025, the following topic areas shall be included in the laboratory's Quality Systems Manual:

a. Interlaboratory Testing Program: The section shall include requirements for participation in interlaboratory proficiency testing programs approved by the Laboratory Quality and Accreditation Office (LQAO) NAVSEA 04XQ (LABS) that are applicable to the laboratory's areas of testing.

b. Re-test Policy: This section shall include a procedure for handling out of specification or nonconforming samples. The procedure shall include requirements for a re-test policy, and review and approval by the appropriate supervisor, and methods

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of documentation.

c. Data Integrity: This section shall establish and maintain data integrity procedures and include data integrity training, periodic monitoring of data integrity, and data integrity procedure documentation.

7. Action

a. NAVSEA Laboratories shall take the necessary actions to implement the requirements of this instruction within one year of the date of issue.

b. NAVSEA Laboratories shall forward one (1) electronic copy of the Laboratory Quality Systems Manual to the Laboratory Quality and Accreditation Office (LQAO) NAVSEA 04XQ(LABS) for review and approval as required by this instruction.

Contact the LQAO at (843) 764-7337 for an email address or forward documents to:

Laboratory Quality and Accreditation Office  
(LQAO)  
NAVSEA 04XQ (LABS)  
Bldg 302, Room 208  
1661 Redbank Road  
Goose Creek, SC 29445

c. NAVSEA laboratories shall provide the LQAO with other quality systems documentation such as Standard Operating Procedures, Method Manuals and Policy Guidelines when requested by the LQAO.

d. The LQAO shall perform on-site assessments of NAVSEA laboratories when requested by NAVSEA or facility management, contingent upon funding availability.

e. Assessments may also be performed by the LQAO if deemed necessary to adequately assess the laboratory's quality system.



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