



DEPARTMENT OF THE NAVY

NAVAL SEA SYSTEMS COMMAND

WASHINGTON D C 20382

IN REPLY REFER TO

NAVSEAINST 4855.31

Ser 07Q/200

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NAVSEA INSTRUCTION 4855.31

From: Commander, Naval Sea Systems Command

Subj: QUALITY CONTROL MANUAL FOR SHIPYARD LABORATORIES

1. Purpose. To provide a quality control program in shipyard material testing laboratories and to provide the minimum requirements for a Shipyard Quality Control Manual for Laboratories.

2. Scope. The instruction is applicable to all naval shipyard chemical, metallurgical, and materials engineering laboratories. It is not intended to supersede more stringent requirements which may be invoked by other documents or users of shipyard laboratory services; such as the Environmental Protection Agency, the Navy Occupational Safety and Health (NAVOSH) Program, or the Navy Nuclear Propulsion Program.

3. Background.

a. Because of the importance of laboratory analyses and the resulting safety, medical, legal, and/or economic actions which 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 analysis/tests being performed. Therefore, an established, routine control program is important 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; a knowledgeable management; adequate physical facilities; state-of-the-art instruments and equipment; periodic servicing and calibration of instruments; certified reagents and standards; the use of established, proven, and accepted analytical/testing procedures; routine analysis of control samples; and, finally, documentation of the laboratory's ability to produce acceptable results by requiring analyses of reference samples.

c. This instruction provides the minimum requirements and recommendations for the controls of the above factors in order to provide documented records to assure users of the laboratories services that a specified level of precision is achieved in the routine performance of its analyses/tests, and that the results reported were obtained from the samples submitted. It also provides laboratory management with an early warning when methods, instruments, or equipment begin to develop biases or show deterioration of precision.

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4. 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.

5. Requirements. All naval shipyards shall publish and implement a Shipyard Laboratory Quality Control Manual. The manual shall be detailed enough to be used directly by the laboratory personnel; therefore, it should not merely reference other documents. The manual shall include the following sections and controls:

a. Purpose. This section shall state the reasons for implementing the quality control manual.

b. Scope. This section shall define the extent of coverage and applicability of the manual and its specific limitations.

c. Background or Introduction. This section is optional. It may include a discussion on the need, significance, and use of a quality control system in laboratories.

d. Definitions. All uncommonly used, abbreviated, and technical terms must be defined in this section.

e. Responsibilities.

(1) This section shall include the basic duties and responsibilities of the laboratory division head; branch heads; supervisors and laboratory analysts as related to quality control.

(2) Quality control coordinator(s) should be designated in writing and should have the responsibility and authority to monitor quality and establish procedures for assuring quality. The coordinator(s) should have a technical education, be familiar with laboratory work, and the techniques of statistical quality control.

f. Quality Control Principles. This section shall include a general discussion on the quality control principles used in laboratories. The discussion shall provide guidance on precision and accuracy, statistical approach, methods of least squares, determinate and indeterminate errors, and quality control charts.

g. Sample Accountability. This paragraph shall include a requirement for a sample accountability system to assure that the results reported refer directly to the sample submitted.

h. Instruments and Equipment.

(1) The calibration of instruments and equipment shall be in accordance with local METCAL requirements.

(2) This section shall include instructions to ensure that local operating procedures and/or the manufacturer's instrument operating instructions are easily accessible to the user at all times for major analytical equipment.

i. Reagents and Reference Standards. This section shall include instructions for the control of reagents and reference standards. Requirements for the labeling of reagents shall be included in this section. As a minimum, the label must show the name and concentration of the reagent or reference standard solution. The date of preparation and the name of the preparer should be shown, if applicable. Also, if the solution is one which breaks down with time, the shelf life criteria or expiration date of the solution must be indicated. Other characteristics and information should be shown, where applicable.

j. Methods of Analyses and/or Testing.

(1) This section shall include instructions to ensure that all analyses/testing performed are in accordance with the specification of the material being analyzed/tested or established procedures, if applicable. If established procedures are modified, the changes must be documented and approved by the supervisor.

(2) Before adopting a new standard procedure, laboratories must perform an evaluation of the procedure's effectiveness in supplying reliable results by testing a series of known samples or comparison with a NBS standard, if available. The evaluation must be documented and approved by the supervisor.

k. Quality Control. This section shall include instruction to ensure that quality control of analytical and test methods provide the information needed and that procedures, instruments, equipment, and personnel are performing at the levels of precision and accuracy required by the intended use of the data. As a minimum, laboratories shall maintain control charts. Instruments or methods should be included in the control chart program as usage and data indicates.

l. Interlaboratory Testing Program. This section shall include requirements for participation in an interlaboratory proficiency testing program.

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

n. Documentation. This section shall include requirements for documentation of laboratory analytical test results. Included shall be instructions for recording raw data; rounding-off; correction of errors; and retention of data and reports.

o. Training Policy. This section shall include requirements to ensure that all personnel involved in any function affecting data quality should have sufficient training in their assigned jobs and the provisions of the Quality Control Manual for the shipyard laboratory.

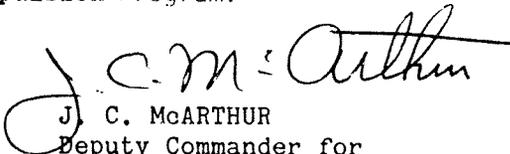
p. Audits. This section shall include provision for internal self audits by the laboratory divisions.

6. Action.

a. Naval shipyards shall take the necessary actions to implement all requirements of this instruction within one year of the date of issue.

b. All shipyards shall forward to NAVSEA 07Q (SY LABS) one copy of the Laboratory Quality Control Manual required by this instruction.

7. Exceptions. This instruction shall not modify any existing requirements related to the Naval Nuclear Propulsion Program.


J. C. McARTHUR
Deputy Commander for
Industrial and Facility
Management

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