QUALITY ASSURANCE DOCUMENTATION FOR NVLAP ACCREDITATION FOR E^3 LABORATORIES

A Quality Assurance Manual and a Calibration Manual promote consistent and accurate testing by E^3 laboratories.

Mike Howard, Liberty Labs, Inc., Cedar Rapids, IA

Successful Electromagnetic Compatibility (EMC) compliance programs or projects are highly dependent upon complete documentation. A requirement for this type of documentation exists under the National Institute of Standards & Technology (NIST) National Voluntary Laboratory Accreditation Program (NVLAP). The NVLAP program requires that a Quality Assurance System be in place at laboratories seeking accreditation.

The Quality Assurance System required by NIST is a key element in a properly functioning lab in that it maintains a system of procedures which ensure the technical integrity of analyses and adherence to quality assurance practices.

A large portion of the Quality System requires up-to-date documentation which thoroughly describes all its procedures and practices. The written documentation shall contain:

- Method of Implementation
- Responsible Personnel
- Record Keeping Systems
- Operating Procedures
- Procedures for Non-standard Circumstances and Scheduling

This information can then be developed into a Quality Assurance Manual, the bible for the EMC laboratory. It offers an excellent training tool for new employees and for ongoing training of lab personnel. This article focuses on the Quality Assurance Manual and the Calibration Manual that are required for NIST NVLAP EMC Laboratory Accreditation. This type of documentation is critical for any EMC laboratory whether an E^3 (Electromagnetic Environment Effects) laboratory seeks accreditation or not.

QUALITY ASSURANCE MANUAL

The QA Manual should be constructed to reflect a quality program in compliance with the requirements of documents such as NAVAIR Instruction 2410.1D, NIST NVLAP Program Requirements, MIL-Q-9858, and all other internal laboratory QA programs. The manual is to outline and describe procedures for establishing and maintaining the quality of analysis, research, inspection, and testing in the E^3 laboratory.

Quality control is a continuing process; consequently the QA Manual provides not only for the formation of a QA Program, but for its continuation through calibration, standardization and inspection programs.

An abbreviated outline of a sample QA Manual would include, as a minimum, the following titles:

1.0 Introduction
2.0 Administration of E^3 QA Program
3.0 Program Management
4.0 E^3 Test Facilities and Standards Control
5.0 Control of Purchases
6.0 Measurement Control
7.0 Receiving Inspection
8.0 Indication of Inspection Status
9.0 Sampling
10.0 Non-Conforming Products
11.0 Software
12.0 Final Inspection
13.0 Packing, Shipping and Storage
14.0 Government (Customer) Property

Annexes
A - Quality Bulletins
B - Staff
C - Equipment
D - Facilities
E - Software
F - Calibration
G - Test Methods and Procedures
H - Test Data and Reports
I - Forms
J - Laboratory Policies and Procedures
K - Test Standards
L - Reference Documents

The Administration of the QA Program provides instructions for the uniform preparation and/or revision of quality procedures, including the proper methods for securing appropriate approvals and distributed copies. Quality procedures are the directives issued by the E^3 laboratory's technical director for communicating the established methods for performing and administering the work relative to assuring the quality of the laboratory's products and services. Quality procedures also provide the summary level information required on a given subject. If this information must be described in further detail for a specific application, this detail is to be recorded in the Specific Operating Procedures (SOPs).

Program Management defines and describes the E^3 laboratory organization in terms of major units of operation and describes the responsibilities of each unit. Also included under program management are quality planning, SOPs, records and reports, and corrective actions.

E^3 Test Facilities and Standards Control address drawings and documentation control, measuring and test equipment, test system (multi) calibration control, and SOP developmental control. This section provides procedures for the review of the correctness and completeness of specifications, work instructions and process instructions. Responsibilities for controlling measurement accuracy and test equipment are assigned. Additional objectives are to assure that inspection and test equipment is adjusted, replaced or repaired before it becomes inaccurate. The main objectives -- guidelines and details pertaining to test and measurement equipment -- are addressed in the E^3 Calibration Manual, designed to meet the requirements of MIL-STD-45662.

Control of Purchases establishes a system to ensure the control of purchased supplies and services in order to meet quality and contract requirements of MIL-Q-9858.

Measurement Control details procedures for the overall control during pre-test, test process, and post-test for repeatability, accuracy, completeness, efficiency, configuration, confidence, and environmental requirements. Measurement control must take into account the sources of measurement errors such as:

- Error attributable to variation within the measuring device
- Error attributable to the relationship between the tolerance spread of the product and the precision of the measuring device, commonly referred to as the "multiple"
- Error attributable to variation in the measurement method
- Error attributable to variation in operator performance
- Error attributable to environmental conditions and variations

The purpose of a QA System for measurement control is to achieve the proper balance between maximized measurement accuracy and minimized measurement cost, and secondly, to limit the loss of measurement accuracy from each of the error sources listed above.

A subcategory of Measurement Control, Pre-test addresses: incoming inspection; documentation; facility control; setup control; performance checks on all systems; and pre-test verification. A second subcategory, the Test Process includes: setup for E^3 test equipment for a specific test; system calibration; setup DUT for mode; performance test procedure; data acceptance (sanity check on data); discrepancy procedures; and test process verification. Post-test includes; post-test performance check/final inspection; removal and tear down of test; post-test verification; and writing of the final report.

Receiving Inspection provides a system to control inspection of all materials and items received by the E^3 laboratory and to verify compliance with specifications. The E^3 laboratory must maintain a positive system for identifying the inspection status of supplies, work-in-process, testing, calibration, etc. Identification can be accomplished by means of signatures, tags, travelers, and checklists.

Sampling procedures must be developed for the use of statistical sampling for the inspection of products and shall be applied to all deliverable products whether they are equipment, software or test samples.

Non-conforming Products establish a system to control the disposition of the non-conforming product. Documenting and establishing corrective action is also required.

Software is fast becoming one of the major tools used within the E^3 lab today. This software must be thoroughly documented and controlled. This includes software development, configuration control, baseline package, evaluation, software quality records, corrective action, software audits, and handling and storage of this software.

Final Inspection, Shipping, and Government (Customer) Property procedures are required to finalize the laboratory process.

The annexes of the QA Manual are intended to provide specific information on specific items relating to QA, the E^3 test laboratory, laboratory personnel, and other aspects of the E^3 facility. Many of these annexes can be utilized as a stand-alone document for reference and guidance for E^3 laboratory personnel.

CALIBRATION MANUAL

The E^3 Laboratory Calibration Manual defines the operation and procedures for the calibration of equipment maintained by the E^3 test laboratory both through an extended Certified Calibration Facility (subcontractor) and by the laboratory itself. The Calibration Manual provides the necessary basis to establish and maintain a level of measurement assurance consistent with the require-

ments of MIL-STD-45662 and commercial standards. An abbreviated outline of a sample Calibration Manual would include as a minimum the following titles:

1.0 Scope
2.0 Policy
3.0 Responsibilities
4.0 Calibration Systems Operating Procedures
5.0 Adequacy of Calibration Facilities and Equipment
6.0 Environmental Controls
7.0 E^3 Test Laboratory Calibration Schedules
8.0 Equipment Control
9.0 Internal and External Calibration Procedures
10.0 Calibration Records
11.0 Labels
12.0 Storage and Handling
13.0 Control of Calibration Sources
14.0 Traceability
15.0 Receiving Inspection
16.0 Program Evaluation
17.0 Recommended Supplements

The Calibration Manual sets forth minimum requirements for calibrations performed by the laboratory itself (i.e., antennas or cables done on-site) and for calibration organizations to which the E^3 laboratory regularly sends its equipment.

The accuracy ratio of primary standards to E^3 laboratory equipment (i.e., receivers, spectrum analyzers, etc.) must be 4:1 or greater. Accuracy ratios of less than 4:1 may be deemed necessary to be consistent with product requirements, cost, and state of the art considerations. Such ratios can be considered acceptable with the approval of the E^3 lab manager along with supporting documentation. The E^3 test laboratory environment (temperature, humidity, altitude, etc.) must be controlled within the manufacturer's defined operating limits for each piece of equipment.

In order to maintain a desired accuracy and quality level, all E^3 test laboratory primary standards and equipment must be calibrated at fixed calendar intervals. The Certified Calibration Facility must maintain control of the test and measurement equipment (T&ME) used for calibration. The control system must provide records giving a maintenance profile on all primary standards and T&ME.

Whenever calibration of T&ME is performed, approved calibration procedures shall be followed. These calibration procedures may be prepared by the certified calibration facility. Alternatively, published standard practices or written instructions that accompany the purchased equipment may be utilized. When available, published Army, Navy, or Air Force procedures may also be used.

Calibration records/certificates shall be maintained at the E^3 test laboratory for all equipment calibrated within the laboratory as well as all equipment calibrated by a subcontractor working for the laboratory. All calibration standards used in the calibration system shall be supported by certificates attesting to the date, accuracy, and environmental or other conditions under which the results were obtained. Labels must be used for *Calibration*, *No Calibration Required*, *Performance Check*, *Limited Calibration*, and *Property Identification Asset*.

All T&ME shall be handled, stored, and transported in a manner which shall not adversely affect the calibration or condition of the equipment. Facility protection and personal controls shall provide adequate safeguards so that equipment may be left unattended on workbenches.

Primary standards and T&ME shall be calibrated by the subcontractor using approved techniques and procedures. The calibration capabilities of the source must first be evaluated and approved by the E^3 laboratory manager. All primary standards and T&ME utilized in or calibrated by the certified calibration facility must be traceable to NIST. This traceability must be verifiable by examination of records for the equipment used in the calibration process.

All equipment received as calibrated by the E^3 laboratory shall undergo an inspection to verify its compliance with any specified requirements. The inspection shall include but not be limited to the completeness of subcomponents, transit damage, and proper and complete documentation as required by the Calibration Manual.

If the E^3 laboratory manager elects to utilize a commercial subcontractor, the facility shall be subject to review and approval by the E^3 laboratory director. The facility shall be subject to this review at the time of the initial approval survey inspection and during later audits. The E^3 laboratory manager shall request the subcontractor's written procedure for evaluation and to be open for on-site inspection when requested by the E^3 laboratory manager.

REFERENCE DOCUMENTS

The documents listed below may be of assistance in developing calibration and quality assurance manuals, although some were not specifically written for testing laboratories and therefore may not be directly applicable. At the time of the writing of this article, a model document for both the QA and Calibration Manual have been submitted to NIST for acceptance as NIST documents. Information on how to obtain copies of the model QA and Calibration Manuals listed below is available from the author at (319) 390-3646 or the NIST NVLAP program director at (301) 975-4016.

- MIL-STD-45662A -- Calibration System Requirements
- MIL-Q-9858 -- Quality Program Requirements
- MIL-I-45208A -- Inspection System
- ACIL LA(62)-1-76 -- Quality Con-

trol System, Requirements for a Testing and Inspection Laboratory
- EIA Standard QB4 -- Calibration System Requirements
- EIA Standard IS-7 -- Quality System Requirements for IECQ System
- MIL-STD-109B -- Quality Assurance Terms & Definitions
- MIL-HDBK-50 -- Evaluation of a Contractor's Quality Program
- MIL-HDBK-52B -- Evaluation of a Contractor's Calibration System
- DOD-STD-2168 -- Defense System Software Quality Program

SUMMARY

Quality assurance programs are strongly recommended for all E^3 laboratories to define minimum requirements and standards for operation and control of its products and services. The QA system and documentation effected is only useful to the extent that the holders of these manuals follow and implement the directives. ■

ACKNOWLEDGEMENT

The author wishes to acknowledge the team effort by PMTC E^3 personnel at Pt. Mugu, CA, NRL and NAVAIR personnel, and NIST in the establishment of the model QA and Calibration Manuals. Their efforts and assistance in the development of these manuals will be of a lasting benefit to the E^3 labs that undertake a QA program.