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Weights and Measures Division

Type Evaluation Laboratory Quality Manual Template

Developed for U.S. Type Evaluation Laboratories

NISTIR 7028
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Quality Manual Template

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Developed for U.S. Type Evaluation Laboratories

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July 2003

U.S. DEPARTMENT OF COMMERCE
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Preface

The National Institute of Standards and Technology (NIST) Weights and Measures Division (WMD) works with State weights and measures (W&M) programs and other federal agencies to promote uniformity in the U.S. commercial W&M system. Some State W&M programs and federal agencies maintain and operate type evaluation laboratories. These laboratories perform evaluations of commercial weighing and measuring devices to ensure their conformance to national (National Conference on Weights and Measures, NCWM Publication 14 test procedures), and international (International Organization of Legal Metrology, OIML recommendations) standards.

In accordance with ISO/IEC 17025 "General Requirements for the Competence of Testing and Calibration Laboratories, " 1999, U.S. type evaluation laboratories must establish, implement, maintain and document their laboratory quality system.

As part of its technical support to the U.S. commercial W&M system, NIST WMD created this quality manual template to assist type evaluation laboratories in documenting their quality systems. As such, this quality manual template is specifically designed for type evaluation testing laboratories. The quality manual template is based on ISO/IEC 17025 requirements. Although this manual is not numerically formatted identical to the ISO/IEC 17025 standard, the requirements of the standard are addressed in the quality manual. Each Section of the quality manual is cross-referenced to the ISO/IEC 17025 requirements so that auditors and others can locate where the requirements are addressed in the quality manual.

The U.S. type evaluation laboratories are encouraged to use the template to document their laboratory quality system. Other testing laboratories may also use this template to assist them in documenting their quality system.

Acknowledgments

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U.S. type evaluation laboratories

Introduction

The type evaluation quality manual template has 20 Sections followed by Appendices A through R. The appendices are referenced throughout the template. The table of appendices (page viii) cross-references each appendix to its section reference in the template. The following table (page ix) cross-references both ISO/IEC 17025 and NIST Handbook 150 "NVLAP Procedures and General Requirements," 2001, to the quality manual sections of the template.

Using the tables of cross-references, the laboratory should review and edit the sections so that they collectively represent the quality system of the laboratory in accordance with the ISO/IEC 17025 standard. In a situation where the laboratory policies or procedures differ from the ISO/IEC 17025 standard, the laboratory policies or procedures must be changed to ensure conformance to the standard. This template includes descriptions of how a laboratory may meet the requirements of ISO/IEC 17025, which may or may not be how your laboratory chooses to meet the requirements. As such, the template must be tailored to describe how your laboratory quality system meets the requirements of ISO/IEC 17025.

_____ Type Evaluation Laboratory
12345 Some St.
Special City, ST 54321

Adoption:

QUALITY MANUAL (Based on ISO/IEC 17025)	
Issued under the authority of the director of the State Bureau of Standards pursuant to Statute CXY.	
Adopted by:	
Title/Position:	
Signature:	
Date:	

Document Control:

Issue Date		
Issued to		
Controlled	Y	N
Copy No.		
No. of Pages		

Controlled issues of the Quality Manual may <u>not</u> be copied.

This quality manual is controlled in its entirety as updates or revisions are made.

_____Revisions to the appendices are controlled and each distributed separately as updates and revisions are made.

____Revisions to the appendices are controlled and maintained in the laboratory. Updates or revisions to appendices must be requested.

REVISIONS TO THE QUALITY MANUAL

DATE	SECTION NO.	PAGE NO.	PARAGRAPH NO.	COMMENTS	APPROVAL:	
					NAME	SIGNATURE

REVISIONS TO THE APPENDICES

DATE	APPENDIX NO.	PAGE NO.	PARAGRAPH NO.	COMMENTS	APPROVAL:	
					NAME	SIGNATURE

QUALITY MANUAL

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2.0 References and Definitions

All critical references cited in this quality manual are maintained on file in the laboratory and are accessible to all laboratory staff and management.

2.1 Critical References

2.1.1 ISO/IEC 17025, *General Requirements for the Competence of Testing and Calibration Laboratories,* 1999

2.1.2 National Conference on Weights and Measures, Publication 14 *NTEP Administrative Procedures, Technical Policy, Checklists and Test Procedures*, 2003.

2.1.3 NIST Handbook 44, *Specifications, Tolerances, and other Technical Requirements for Weighing and Measuring Devices,* 2003, Tina Butcher, Terry Grimes, Juana Williams, Richard Suiter

2.1.4 NIST Technical Note 1297, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results,* 1994, Barry N. Taylor and Chris E. Kuyatt

2.1.5 National Conference of Standards Laboratories (NCSL), *Recommended Practice (RP) No. 7, Laboratory Design,* 1993.

2.1.6 Applicable State laws and department policies and guidelines [NOTE: include State statutes, which denote the legal status of the type evaluation laboratory].

2.2 Additional References

2.2.1 NIST HB 130, *Uniform Laws and Regulations,* 2002, Thomas Coleman and Terry L. Grimes

[NOTE: This quality manual was written following the requirements of ISO/IEC 17025, 1999 and modified to promote a specific quality assurance program for a type evaluation laboratory.]

2.3 Definitions

Definitions are contained in Appendix A.

3.0 Quality Policy

3.1 Policy

3.1.1 This quality policy is issued under the authority of the chief executive [NOTE: enter title used].

3.1.2 The laboratory conducts all device type evaluations under laboratory and field conditions that are suitable for the test being conducted and by using techniques that are conducive to a high degree of reliability and follows recognized type evaluation procedures as noted in Appendix H. It is our policy to provide the highest reasonable quality type evaluation services attainable to clients through continuous improvement of the quality system. Quality in our services is a constant effort and focus.

3.1.3 The objective of this quality manual is to establish a documented quality system that provides for continuous improvement of that quality system to ensure reliable and accurate test results.

3.1.4 All laboratory personnel who perform type evaluation testing are familiar with the quality documentation, which is implemented in their work, policies and procedures. The laboratory quality manager provides copies of the quality documentation to the laboratory staff and/or informs the staff of its location. Laboratory staff review the documentation as part of their on-the-job training, which is recorded in their training records. The quality system documentation includes:

3.1.4.1 Laboratory quality manual;
3.1.4.2 Type evaluation test procedures: NCWM Publication 14 "NTEP Administrative Procedures, Technical Policy, Checklist, and Test Procedures referenced in Section 2 (see Appendix H), and OIML recommendations;
3.1.4.3 Administrative procedures as required by ISO/IEC 17025 (see Appendix H);
3.1.4.4 Work instructions;
3.1.4.5 Records, forms, and reports (see Section 13, Records)

3.1.4.6 Equipment instruction manuals (maintained in the laboratory).

3.1.5 The supporting documents and procedures are referenced in this quality manual, but are maintained separately from the quality manual.

3.2 Tests

3.2.1 The laboratory evaluates the devices listed in Appendix C in accordance with the procedures, practices, and conditions (hereafter referred to as "procedures") of the National Conference on Weights and Measures Publication 14 (see references, Section 2). The techniques used for specific tests are within the applicable State administrative guidelines and associated safety and cost-effective considerations.

3.3 Authorization and/or Accreditation
[NOTE: Edit this section as it applies to your laboratory.]

3.3.1 The type evaluation laboratory is authorized by _____ to demonstrate conformance to ISO/IEC 17025.

and/or

3.3.2 The type evaluation laboratory is accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) to demonstrate conformance to ISO/IEC 17025 (through *NIST HB 150*).

A current authorization and/or accreditation certificate is prominently displayed and maintained on the wall in the laboratory. The laboratory does not conduct type evaluation testing or issue reports for nonauthorized areas of evaluation.

4.0 Service to the Client and Review of Contract, Tenders, and Work Request

4.1 Service to the Client

4.1.1 As necessary, the laboratory works with the client to clarify test requests, device operation and test results. The client is provided controlled access to the laboratory to observe type evaluations of the device. To ensure confidentiality, information and devices of other clients are not visible during a client visit to the laboratory. The laboratory communicates with the client at any time prior to, during and after the type evaluation as needed to address any questions, changes and test results. The laboratory provides the client with a summary and conclusion of the test results. The laboratory may receive feedback from the client that might improve the laboratory quality system. As appropriate client feedback will be reviewed by the quality manager and used to improve the quality system (see Appendix H, AP No. 6).

4.2 Review of Contract, Tenders, and Work Request (Application)

4.2.1 Contracts, tenders, and work requests received by the laboratory are in the form of type evaluation applications. Applications are received by the type evaluation manager as a request for testing. Typically the type evaluation manager reviews the application, and in many cases the review involves an evaluation of the laboratory workload and other essential factors before the device is assigned to the laboratory. Procedures are maintained for the review of type evaluation applications that lead to an agreement for testing (see Appendix H, AP No. 21). The procedures ensure that:

4.2.1.1 The requirements and test used are defined and understood

4.2.1.2 The laboratory is capable of meeting the requirements and has the necessary resources; and

4.2.1.3 The work does not begin until there is agreement between the laboratory and the client.

4.2.2 Records of the application review and client discussions are maintained in the laboratory. (See Section 13 Records.)

4.2.3 Application reviews include any work that is subcontracted by the laboratory. The client is informed of any deviations from the application; if the application is amended after the work starts, the same review process is followed for an amendment to the application

4.2.4 The laboratory cooperates with the client to ensure that the application is understood. The laboratory calls the client upon receipt of the application and reviews the application with the client. Prior to testing the laboratory and the client discuss any abnormalities.

5.0 Organization and Management

5.1 Legal Status

5.1.1 The type evaluation laboratory is maintained under State statute XYZ [NOTE: enter State statute title, number, and/or article number].

OR

5.1.1 The type evaluation laboratory is maintained under NIST HB 130, Uniform Laws and Regulations, Uniform Regulation for National Type Evaluation, which is adopted by State statute XYZ.

5.2 Organization

5.2.1 The type evaluation laboratory is part of the State or Federal Government [NOTE: enter State or Federal agency and department of the State or Federal agency that the laboratory is a part of]. Authority, interrelation, and responsibilities of all laboratory personnel are on file in the form of job descriptions contained in Appendix M and organizational charts provided in Appendix B. The laboratory manager designates staff responsibilities of quality and technical managers and deputies. The quality and technical managers are designated based on knowledge of the quality system and technical activities of the laboratory. (See laboratory organization chart, Appendix B.) In the event that either the quality or technical manager is absent for an extended period, his/her duties are assigned to deputies.

5.2.2 Testing activities are conducted such that they meet the requirements of ISO/IEC 17025 and this quality manual, and satisfy the needs of the client and the regulatory authorities and/or organizations providing authorization and/or accreditation.

5.2.3 The laboratory performs some evaluations of weighing and measuring devices at sites that are outside the permanent laboratory facilities. These sites may be located at a device owner's facility or other site, either within a building or outdoors. Site evaluations are conducted in accordance with the laboratory management system.

5.2.4 The responsibilities of key personnel in the organization who perform other

activities and who have an involvement or influence on the testing activities of the laboratory are defined in order to identify potential conflicts of interest. A list of key personnel performing other activities is maintained in the laboratory. The list includes their current position, in the type evaluation laboratory, other activities conducted, and a statement as to whether or not any conflict exists. (See Quality Manual Section 13 Records, "List of Key Personnel Performing other Activities.") Laboratory personnel do not participate in activities that might adversely affect confidence in the type evaluation (see Appendix H, AP No. 24).

5.3 Responsibility

The managerial and technical personnel of the laboratory are equipped with the authority and resources to perform their duties. The laboratory personnel responsibilities are defined below.

[NOTE: The following is an example of laboratory personnel responsibilities. The type evaluation laboratories must edit this section so that the titles and responsibilities of your laboratory personnel are reflected in this section.]

5.3.1 Director

5.3.1.1 The Director is responsible for the overall compliance of the laboratory to this quality manual and has direct responsibility for the type evaluation laboratory, which includes final approval of all changes made to the quality manual. The Director participates in management reviews of the quality system

5.3.2 Management (Laboratory Manager, however named)

5.3.2.1 The management of the laboratory:

a. implements and enforces the applicable good laboratory practices described in reference documents;
b. provides resources, adjusts workloads, and provides training opportunities for laboratory staff to facilitate completion of assigned tasks in a safe work environment consistent with test requirements and personnel capabilities;
c. assigns deputies for both the technical and quality managers in

the case of an absence;
d. participates in management reviews of the quality system; and
e. supervises the activities of the laboratory

5.3.3 Technical Manager or Deputy [NOTE: The deputy may or may not have the same duties as the technical manager.]

5.3.3.1 The technical manager:
a. is a type evaluation laboratory person who has completed the appropriate level of type evaluation training as specified in the laboratory training procedures in the areas for which the laboratory is authorized;
b. is responsible for the overall administrative and technical operations of the laboratory;
c. specifies and/or approves all methodologies used;
d. implements good laboratory practices by providing instruction and training as needed, develops work plans and procedures, and requires that these be followed in all day-to-day operations;
e. verifies personnel training;
f. assigns only competent personnel to complete tests;
g. attests, by signature, to the validity of all laboratory tests performed and reports (a list of approved signatories is maintained in the laboratory (see Quality Manual Section 13 Records);
h. ensures continued authorization of the laboratory;
i. where necessary, identifies, develops, and implements improvement of the laboratory measurement capability to meet the requirements of ISO/IEC17025, department programs, and laboratory clients; and
j. participates in management reviews of the quality system.

5.3.4 Quality Manager or Deputy [NOTE: The deputy may or may not have the same duties as the quality manager.]

5.3.4.1 The quality manager:
a. is a type evaluation laboratory person who has completed the required level of training as specified in the laboratory training

procedures in the areas for which the laboratory is authorized;
b. coordinates internal audits of the laboratory in accordance with Section 6 of this quality manual;
c. participates in available and relevant proficiency tests, round robins, and/or interlaboratory collaborative studies;
d. maintains the quality manual;
e. has direct access to management and to the technical manager;
f. identifies departures from the quality system or from procedures, and initiate actions to prevent or minimize such departures,
g. coordinates and participates in management reviews of the quality system; and
h. supervises the quality activities of the laboratory.

[NOTE: Type evaluation laboratories may be limited in staff. One person or a part-time person may operate these laboratories. In these cases, one person has the responsibilities of both technical and quality manager. Special care and precaution must be taken and documented to ensure that limited laboratory staff does not adversely affect the quality system and type evaluations.]

5.4 Independence

5.4.1 Management ensures that the laboratory is independent from any pressures – commercial, financial, or others, which adversely affect the quality of test and resulting reports. State policy provides guidelines to ensure laboratory independence. [NOTE: As appropriate the laboratory should reference the State policy.]

5.5 Confidentiality

5.5.1 The laboratory maintains the confidentiality and proprietary rights of all information, including the type of work performed and the results of tests to the extent allowable by State law and in accordance with the administrative procedures. [NOTE: The laboratory should include the specific State law in this statement and document the law in Section 2 of the quality manual.] All laboratory personnel and staff are informed of this policy. (See Appendix H, AP No. 1, Procedures for Client Confidentiality and Proprietary Rights.)

6.0 Quality System, Document Control, Internal Audits and Management Reviews

6.1 The type evaluation laboratory has established and maintains a quality system that supports the tests conducted by the laboratory. The quality system is described in this quality manual, the appendices, and applicable sections of the references named herein. These documents are readily available to all laboratory staff and serve as the basis for evaluating the integrity of the measurements and associated reports. The laboratory conducts internal audits of the laboratory quality system on behalf of management to ensure that the laboratory's policies and procedures as set forth in this quality manual are being followed. Management periodically reviews the quality system, including review of internal audit results (see Appendix H, AP No. 7, Procedures for Internal Audits and Management Review).

6.2 Quality System

6.2.1 The basic elements of the quality system include:

6.2.1.1 the quality manual;

6.2.1.2 NCWM Publication 14 test procedures (see Appendix H and also Section 11);

6.2.1.3 work instructions (maintained in the laboratory);

6.2.1.4 records, forms, reports (see section 13, Appendix O and Section 14); and

6.2.1.5 equipment instruction manuals (maintained in the laboratory)

6.2.2 To ensure proper operation of the quality system, there are:

6.2.2.1 Qualified personnel for each measurement (see Section 7, Personnel, Appendices L, Personnel Training & Competency and M, Job Descriptions and Duty Statements);

6.2.2.2 Management and senior personnel reviews and supervision (see

Section 5, Organization and Management, and Appendix B, Organization Chart);

6.2.2.3 Appropriately maintained and calibrated working standards, equipment, and associated apparatus (see Section 9, Standards, Equipment and Associated Apparatus, Appendices G, Standards and Reference Materials and F, Equipment and Materials);

6.2.2.4 Environmentally-controlled facilities, where appropriate, and/or proper accounting of relevant environmental factors (see Section 8, "Laboratory Facilities and Environment;" Appendices D, "Diagram of Facilities" and E, "Environmental Conditions"); and

6.2.2.5 Appropriate sampling procedures, where necessary (see Section 20).

6.2.3 All elements of the quality system are considered when developing test methods and procedures, training and qualification of personnel and in the selection and calibration of equipment.

6.3 Quality System Documentation

6.3.1 An outline of the laboratory quality system documentation is in Appendix Q, Documentation Outline.

6.3.2 Internal Document Control

6.3.2.1 General

6.3.2.1.1 Appendix N provides a detailed list of controlled documents with revision dates, retention periods, and locations. The procedures for document control include:

a. information on document control numbers,
b. designation of responsibility,
c. assurance that authorized editions of appropriate documents are available at all locations that are essential to the proper functioning of the laboratory,
d. periodic review and, as necessary, revision of the documents to ensure suitability and compliance with

e. applicable requirements,
f. removal of invalid or obsolete documents,
g. access and changes to hard and electronic document, and
h. marking obsolete documents used for legal purposes. (See procedures list in Appendix H, AP No. 3, Document Control.) Section 13 Records lists the records maintained by the laboratory, the location of the records, and the retention time. Handwritten documents are clearly marked, initialed, and dated.

6.3.2.1.2 All documents are reviewed and approved for use by authorized personnel prior to issuing the document to personnel in the laboratory. A control document distribution list is maintained in the laboratory, including the current revision status and distribution of the document. (See Appendix H, AP No. 3)

6.3.2.1.3 Document changes are reviewed and approved following the same procedures for the original review process (see Appendix H, AP No. 3). The altered and/or new text is identified in the document. Handwritten changes to hard copy documents are clearly marked, initialed and dated by laboratory staff authorized to make changes to the documents. Some laboratory documents are maintained on the computer and changes are made electronically. These documents require a password to access the file or are read-only files and must be saved with a different file name when changes are made. Changes in electronic documents are tracked by the word processing system and are accepted by authorized laboratory staff. Procedures and authorities are defined in Appendix H, AP No. 3, for handwritten and electronic changes.

6.3.3 Authority

6.3.3.1 Persons authorized to modify or update laboratory documents are included on the control document distribution list that is maintained

in the laboratory. The quality manager has the designated authority to modify or update the quality manual. The quality manual is annually reviewed and updated as needed by the end of September. The laboratory director is responsible for final approval of all changes made to the quality manual, and the revised document takes effect when signed and dated by the laboratory director.

6.3.3.2 This quality manual (along with associated appendices and references) is available to all laboratory staff and management. Management is responsible for providing the documented quality system to staff and ensuring that all staff familiarize themselves and comply with the policies and procedures established in the manual and associated documentation. The quality manager notifies staff of the most current and approved version of the quality manual through memorandums or e-mails.

6.3.4 Controlled Copies of the Quality Manual

6.3.4.1 Controlled copies of this quality manual are issued to the director, program manager, type evaluation manager, and authorization or accreditation bodies, and are made available to all laboratory personnel. All controlled copies are marked as controlled and are numbered and updated by the quality manager whenever changes are made. Recipients of controlled copies are issued the revised quality manual. It is the responsibility of the quality manager to ensure that the most current quality manual is issued and followed by all laboratory and administrative staff. A list of the names, control numbers, and
location of all controlled copies is maintained in the laboratory files.

6.3.5 Uncontrolled Copies of the Quality Manual

6.3.5.1 Uncontrolled copies of the quality manual are marked "uncontrolled", issued upon request, and are not updated.

6.4 Internal Audits and Management Reviews

6.4.1 Internal Audits

6.4.1.1 The internal audit program addresses all elements of the quality system, including testing. A review of the quality system in accordance with ISO/IEC 17025 is conducted and a checklist is completed. Internal audit reports are maintained in the laboratory. The internal audits include an audit of the laboratory:

a. Equipment
b. Standards
c. Staff (training needs)
d. Facilities
e. Quality documentation
f. Management action items
g. Test results
h. Statistical control data

The laboratory quality manager annually plans the internal audit to review the laboratory's quality system and testing activities to ensure its continuing suitability and effectiveness and to introduce necessary changes or improvements. Internal audits are conducted in August to verify that operations continue to comply with the quality system. Auditors are trained in auditing techniques, have technical insight concerning the laboratory's functions, and (wherever possible) are independent of the activity to be audited. The laboratory manager investigates any deficiencies found during the internal audit to determine appropriate actions. If necessary, the laboratory manager will notify any clients whose tests were affected by the deficiency. (See Section 13 Records and Appendix H, AP No. 7, “Internal Audits and Management Reviews”).

6.4.2 Management Reviews

6.4.2.1 The laboratory director and manager conduct annual management reviews of the quality system (see Appendix H, AP No. 7, “Internal Audits and Management Reviews”.

6.4.2.2 Laboratory staff participate in the review meetings. The management review includes:

6.4.2.2.1 Identification of problems that arise as a result of any client-discovered errors and/or discrepant results from the analysis of the laboratory test data (see Section 17).

6.4.2.2.2 Evidence from internal audits and statistical control data and/or charts, where appropriate. (See Section 13, and Appendices J and N.);

6.4.2.2.3 Evidence from proficiency tests, round robins, and/or interlaboratory collaborative experiments. (See Section 13, and Appendices J and K.);

6.4.2.2.4 Review of policies and procedures;

6.4.2.2.5 Reports of managerial and supervisory personnel;

6.4.2.2.6 Preventive and corrective actions;

6.4.2.2.7 Assessments by external bodies; and

6.4.2.2.8 Changes in volume and type of work, staff needs, facility and equipment needs.

6.4.3 Authorization Review

6.4.3.1 The laboratory submits updated authorization material annually to _____ [NOTE: Insert authorization body, as appropriate.] for review. The material that is submitted for review depends upon the request from the authorization body and may consist of:

a. General laboratory information;
b. Equipment and standard information;
c. Internal audit information;
d. Management reviews
e. Scope or laboratory activities;

f. Staff assignments and training records; and
g. Updated quality manual

6.4.4. All internal audit and authorization review findings, and any corrective actions that arise from them, are promptly settled within the agreed time, documented by the quality manager, and maintained in the laboratory files.

7.0 Personnel

7.1 Members of the laboratory staff are selected for employment based on their professional qualifications, including education and relevant experience (See Appendix H, AP No. 17). The basic qualifications for type evaluation staff include:

7.1.1 knowledge of the operation of legal for trade weighing and measuring instruments;

7.1.2 experience in applying NIST Handbook 44 requirements for the inspection and test of commercial weighing and measuring devices;

7.1.3 knowledge of statistics and uncertainty analysis; and

7.1.4 completion of field weights and measures training.

Staffing is sufficient to maintain the timely processing of the client workload, laboratory internal monitoring, quality control, traceability activities, and staff training. New staff is hired as the need arises and is trained in an on-the-job training program that ensures that personnel understand the metrological concepts of legal for trade weighing and measuring device and apply them in their testing of the devices. Laboratory managers, supervisors, and/or senior staff train staff on how to conduct the evaluations according to documented test procedures. Training is verified by the laboratory technical manager, who also ensures that staff is qualified to perform device testing. Additional laboratory training is discussed in Section 7.4. Job descriptions for laboratory personnel are contained in Appendix M (or are on file in the laboratory).

Type evaluations are performed by personnel who are employed or contracted by the laboratory. Personnel who are in the process of training are supervised until their on-the-job training is completed. Contracted personnel are also trained or experienced in testing legal-for-trade weighing and measuring devices.

7.2 Adequately trained staff is a key factor in good type evaluations. The type evaluation laboratory personnel have the necessary background in weights and measures and science as appropriate to ensure comprehension of the laboratory tests and operations. Training is documented and maintained in Appendix L. Procedures for identifying

training needs and providing training and qualifying laboratory personnel are maintained in the laboratory (see Appendix H, AP No. 17).

7.3 The laboratory supervisor(s), utilizing staff resources to meet policy goals:

7.3.1 Implements and applies the procedures contained in the referenced documents as listed in Section 2;

7.3.2 Provides ongoing training to ensure proficiency in type evaluation testing;

7.3.3 Develops work plan schedules and requires that the staff follow the procedures in day-to-day operations; and

7.3.4 Assigns and authorizes staff to perform tasks based on personnel training and verified competence. Records of authorizations are maintained in the laboratory files. (See Section 13 Records.)

7.4 Other Training

7.4.1 The laboratory staff attend and participate in several training opportunities to include the National Type Evaluation Technical Committee (NTETC) Sector Meetings and NTEP Laboratory Meetings. All training is documented and maintained in the laboratory (see Appendix L).

8.0 Laboratory Facilities and Environment

8.1 Facilities and Environment

8.1.1 The laboratory facilities are maintained to support good laboratory practices and accurate type evaluation test results. Equipment and other items that are no longer used for testing are discarded or removed from the laboratory and placed into storage to prevent clutter in the laboratory. Portable equipment and materials used for testing are returned to the appropriate location (s) after use, and test weights are returned to storage kits. (See Appendix D, Diagram of the Laboratory Facilities, and Appendix H, AP No. 11.)

8.1.2 The laboratory facilities, test areas, energy sources, lighting, heating, and ventilation facilitate proper type evaluation testing. The laboratory ensures that dust, electromagnetic interference, humidity, line voltage, temperature, and vibration levels (i.e., vibration sources due to surrounding equipment or improper support tables and temperature changes) do not affect the test and are appropriate for the device under test. The laboratory staff observes the device under test to determine if any conditions of the facility affect the test or if the environmental conditions are outside the limits specified in Appendix E.

8.1.3 Environmental conditions maintained by the laboratory are appropriate for the type evaluation testing. The environment in the laboratory where testing is performed does not invalidate results nor adversely affect the test results. The environmental conditions of the laboratory are listed in Appendix E. The laboratory environmental conditions are monitored using a chart recorder, controlled, and recorded if required by the test procedures or if they influence the quality of the results. The laboratory technical manager will stop testing if the environmental conditions jeopardize the test results (see Appendix H AP No. 27). The laboratory staff ensures that the facilities are adequate for testing by:

8.1.3.1 verifying that air conditioning, lighting, heating, and ventilation do not adversely affect the environmental conditions or device being tested (The environmental conditions of the laboratory are as listed in Appendix E. See Appendix H AP No. 27.),

8.1.3.2 maintaining good housekeeping practices to promote a clean, uncluttered laboratory according to procedures listed in Appendix H, AP No. 11.,

8.1.3.3 having sufficient space to minimize the risk of injury to staff and/or damage to standards or equipment due to activities around test setup (see Appendix D, laboratory diagram and dimensions),

8.1.3.4 maintaining a convenient and efficient work environment with effective separation of incompatible activities (see Appendix D laboratory diagram and dimensions), and

8.1.3.5 controlling access to and use of areas affecting the quality of tests (see QM section 18.2).

8.2 Environmental Records

8.2.1 Laboratory device testing

8.2.1.1 Environmental chamber conditions are recorded with the use of a strip-chart recording device while testing is being conducted. The laboratory environmental conditions are maintained and documented to ensure that they are conducive to the various type evaluations. Corrective actions are taken when the environmental conditions affect the quality of test (see Appendix E, Environmental Conditions, and Appendix O, Complaints/Corrective Actions form).

8.2.2 Field device testing

8.2.2.1 Typically field tests are not performed when the environmental conditions are such that they may adversely affect the test results, and these conditions are documented on the data sheets (see Appendix H, AP No. 27).

[NOTE: Environmental monitoring devices are periodically verified against accurate and traceable standards.]

9.0 Standards, Equipment, and Associated Apparatus

9.1 Laboratory standards, equipment, and associated apparatus are maintained suitable for the correct performance of tests and are maintained in accordance with the laboratory procedures (see Appendix H, AP No. 13), equipment maintenance and operational manuals, and this quality manual. The equipment, standards and associated apparatus are protected from dirt, dust, corrosion, and other causes of deterioration. The technical manager investigates any equipment or standards that are suspected in contributing to out-of-control conditions (see Appendix G, Standards List, and Appendix F, Equipment List). Records of corrective actions for discrepancies are maintained in the laboratory (see Section 13 Records, and Appendix O, Forms). Procedures for safe handling, transport, storage, use and planned maintenance of test equipment to ensure proper functioning are maintained in the laboratory (see Appendix H, AP No. 14).

9.2 Maintenance and calibration records for equipment and standards include the following as appropriate (see Section 13, Records, and Appendix O, Forms):

9.2.1 Item name and manufacturer; model, serial, and other identification numbers;

9.2.2 Date and condition of receipt, date placed in service, and current location;

9.2.3 History of calibration, maintenance, malfunction, modification, and repair;

9.2.4 Calibration status, recertification date and maintenance plan, where appropriate;

9.2.5 Identification of any software affecting the calibration and quality assurance of the program;

9.2.6 Copy of manufacturer's instructions, where available;

9.2.7 Verification that equipment complies with specifications;

9.2.8 Verification of equipment used which is outside the control of the laboratory.

9.3 Operation and Maintenance

9.3.1 Equipment and Associated Apparatus

9.3.1.1 Laboratory equipment is properly maintained in accordance with procedures for calibration, verification, and maintenance (see Appendix H, AP No. 14). These procedures are located in the laboratory files.

9.3.1.2 Equipment used by the laboratory staff are handled and maintained in accordance with Appendix H, AP No. 14. The equipment is maintained so that it operates according to the manufacturer's specifications for device evaluations. The following activities are conducted to ensure that the equipment operates according to manufacturers specifications:

a. maintenance and service of the equipment by trained technicians,
b. operation by laboratory staff that have been trained,
c. protection from factors that may affect the operation, such as drafts, dirt, dust, and extreme temperatures, and
d. when not operating correctly, labeling the equipment with an out-of-service tag, removing the equipment from service, and whenever possible storing it in the laboratory storage room (see Appendix D) returning it to service only when its satisfactory performance has been verified.

9.3.1.3 The laboratory examines any previous tests that might have been affected by the equipment that was taken out of service (see Appendix H, AP No. 18, Procedure for Control of Nonconforming Work, and AP No. 14).

9.3.1.4 Operation manuals and instructions for proper maintenance of equipment are available and located in the laboratory files (See QM Section 13 Records for location of the files in the laboratory).

9.3.1.5 Newly installed equipment and software programs are tested to verify that they perform satisfactorily before they are placed into

service. Documentation of this verification is maintained in the laboratory (see Section 13 Records and Appendix O, Forms). The laboratory maintains procedures for testing newly installed equipment (see Appendix H, AP No. 14).

9.3.1.6 Equipment is used only when it is in a safe and reliable condition and only by personnel who have been appropriately trained and are qualified. Safe and reliable conditions include:

a. Stable support for equipment,
b. Use of electrical outlets in accordance with equipment specifications, and
c. loading equipment in accordance with equipment specifications.

9.3.1.7 Use of equipment outside the laboratory's control is verified prior to use to ensure that it meets the same requirements of the laboratory quality system (see Appendix H, AP No. 14).

9.3.1.8 All equipment having an affect on the test is calibrated and is labelled, coded or otherwise identified to indicate the status of calibration, including date calibrated and recalibration due date (see Appendix H, AP No. 14).

9.3.1.9 The laboratory uses and maintains procedures for the intermediate checks of equipment calibration status when needed (see Appendix H, AP No.14).

9.3.1.10 The laboratory follows procedures to ensure that correction factors that arise from the calibration of equipment are correctly updated, including updates to any computer software data (see Appendix H, AP No.14).

9.3.1.11 The laboratory ensures that test equipment is safeguarded from adjustments that can cause invalid test results (See Appendix H, AP No. 14).

9.3.2 Standards (See Section 10, Measurement Traceability and Calibration)

9.3.2.1 To maintain integrity of the standards, all maintenance operations are performed according to documented procedures (see Appendix H, AP No. 13). The laboratory standards are:

a. selected for use according to the level of precision, accuracy, and uncertainty required;
b. limited in access and use to trained and authorized laboratory staff only; and
c. handled and safely stored according to good laboratory practices.

[NOTE: Appendix H AP No. 13 should define how Section 9.3.2.1 a through c above are met or define your laboratory activities for maintaining the integrity of your standards]

9.3.2.2 All standards having an affect on the test, are calibrated by an accredited or recognized laboratory with traceability to a national laboratory, and calibration reports are maintained in the laboratory files.

[NOTE: In section 9.3.2.2, identify the calibration of your laboratory standards and how the calibration results are traceable to a national or recognized laboratory, e.g., "The laboratory standards of mass and volume are tested by our state metrology laboratory. The State metrology laboratory maintains a measurement traceability certificate from NIST WMD recognizing that the laboratories measurements are traceable to NIST (see Appendix H, AP No. 4 and Appendix R).]"

10.0 Measurement Traceability and Calibration

10.1 Policy

10.1.1 Standards and measuring and test equipment significantly affecting the integrity of the measurements conducted by the laboratory are monitored for stability as part of the measurement control program. Standards and equipment are calibrated and/or verified before use to ensure the recall or removal from service of any equipment or standards that are unreliable or that have exceeded the calibration interval. The laboratory maintains procedures for safe handling, transport, storage and use of reference standards, materials and equipment (see Appendix H, AP Nos. 13 and 14).

10.2 Measurement Traceability

10.2.1 Measurements of the laboratory are traceable to the international system of measurements (SI) through an unbroken chain of measurements. Measurement traceability for the laboratory test are documented in traceability charts (see Appendix R).

10.2.2 The laboratory has a program of calibration and verification of measuring and test equipment that has an affect on the test results. The program is designed to ensure that the tests are valid and that the measurements made by the laboratory are traceable to national standards of measurement (see Appendix H, AP No. 14).

10.2.3 To provide external evidence of traceability, the laboratory participates in interlaboratory and collaborative experiments, as available (see Appendix K and Appendix H, AP No. 4).

10.3 Calibration/Verification (See Procedure for Calibration Intervals, Appendix H, AP No. 13)

10.3.1 Calibration of Standards

10.3.1.1 An accredited or approved laboratory with traceability to a national laboratory calibrates working standards.

10.3.1.2 Working standards are calibrated on a periodic basis, are monitored, and are under the custody of trained laboratory personnel (see Appendix H, AP No. 13). Records of the calibrations are maintained in the laboratory.

10.3.1.3 Standards are recalibrated if there is damage to the standards or any significant change is observed in the monitoring program (see Appendix H, AP 13).

10.3.1.4 If measurement traceability to SI units is not possible, there is traceability to certified reference materials or agreed methods and/or consensus standards (see Appendix H, AP No. 4).

10.3.2 Verification of Standards

10.3.2.1 Standards are continuously monitored to ensure the integrity of the test (see Appendix H, AP No. 13).

10.3.2.2 Measurement assurance procedures and standard and reference material monitoring results are maintained in the laboratory files (see Appendix H, AP No. 13 and Appendix J, Control Charts).

10.3.3 Calibration of Measuring and Test Equipment (M&TE)

10.3.3.1 Type evaluation test equipment that might affect test results is calibrated by a national laboratory, or by a laboratory whose traceability to a national laboratory has been validated through a verification process. A calibration interval is established for the equipment and the equipment is labeled, marked, or otherwise identified to indicate its calibration status (see Appendix H, AP No. 14).

10.3.3.2 Procedures for setting and changing M&TE calibration intervals are maintained in the laboratory files (see Appendix H, AP No. 14).

10.3.3.3 Calibration of equipment is conducted at a frequency to ensure that the equipment remains in tolerance during its use in the laboratory.

Frequency of calibration is based on a review of calibration, maintenance, and repair history. The technical manager conducts reviews and the records of the review are maintained with the internal audit records in the laboratory files (see Appendix H, AP No. 14).

10.4 Measurement of Uncertainty

10.4.1 The laboratory is a type evaluation laboratory that performs testing and evaluation of weighing and measuring devices. A variety of tests are performed on each device under test to include accuracy, influence factors, and permanence testing. The laboratory identifies all components of the test uncertainty that might affect the integrity of the test results, makes a reasonable estimation, and ensures that the form of reporting the results does not give a wrong impression of the uncertainty. NIST Technical Note 1297 "Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results and the ISO Guide to the Uncertainty in Measurement are used as the basis for the expression of uncertainty in measurement (see Appendix I, "Assessment of Uncertainties").

11.0 Type Evaluation Test Methods and Procedures

11.1 The administrative and test procedures are maintained in the laboratory files. The procedures are available to the laboratory staff and are followed to ensure the integrity of the test results, and that the administrative and test procedures are conducted uniformly in the laboratory (see Appendix H, Procedures List). Equipment manuals, operating instructions, reference data, specifications, and tolerance tables relevant to the laboratory are maintained in an up-to-date file in the laboratory and are readily available.

11.2 The selected test procedures are appropriate for the device under test, and the latest edition of the procedure is used to test the device. When documented or published procedures are unavailable, or when deviations from documented procedures occur, procedures for a specific test are developed, validated, and agreed to by the laboratory and the type evaluation body. The extent of the validation meets the needs of the application. The results of the validation are maintained in the laboratory and include the validation procedures used and a statement that the method is fit for its intended use (see Appendix H, AP No. 19 and Section 13, Records). Before a new test is conducted, the laboratory reviews the test procedure to ensure that the test can be performed adequately. If the test procedure is revised, the review is repeated. The test report states the procedure used to perform the test. Records regarding departures from documented policies and procedures or from standard specifications are initiated by laboratory management and are maintained in the laboratory files (see Section 13, Records and Appendix O, Forms). Procedures for departure from documented policies and procedures are maintained in the laboratory (see Appendix H, AP No. 15 and AP No. 19).

11.3 Type Evaluation Testing Procedures

11.3.1 The laboratory follows the procedures and checklist in NCWM Publication 14 (see Appendix H, Measurement Procedures List).

11.3.2 The type evaluation procedures of NCWM Publication 14 include specific technical policy and specific references to NIST HB 44.

11.3.3 The laboratory identifies all the components of the uncertainty that might affect the integrity of the test results in accordance with the NIST TN 1297 and the ISO Guide to the Uncertainty in Measurement. The device under test must meet

the tolerances and specifications of NIST HB 44 according to the test methods of NCWM Publication 14 (and/or must meet the tolerances and specification of OIML recommendations). Type evaluations of weighing and measuring devices are conducted by using standards to verify the accuracy of the device and other tests are performed to ensure that the device meets the required specifications. Laboratory staff are trained before they may conduct the test. Test methods and reporting instructions are followed when conducting the test (see Appendix H, measurement procedures list).

11.4 Administrative Procedures

11.4.1 The administrative procedures required by ISO/IEC 17025 are developed by the laboratory and listed in Appendix H. Additional administrative procedures are located in NCWM Publication 14 and are maintained in the laboratory. The administrative procedures ensure that the overall operations of the laboratory promote the quality and integrity of the test results and test items.

11.4.2 The technical manager maintains the procedures for the purchase, receipt and storage of consumable materials used for the technical operations of the laboratory (see Appendix H, AP No. 9).

11.5 Control of Data

11.5.1 As a minimum, laboratory staff review data, calculations, and test results to ensure the integrity of the type evaluation. Checks or quality control procedures include interlaboratory or proficiency testing and replicate tests or retesting, as appropriate for the device under test. Records are maintained regarding feedback and corrective action whenever testing discrepancies are detected. (See Section 13 Records, Appendix O, Forms, Appendix H, AP No. 6, Feedback, Corrective and Preventive Actions, Appendix H, AP No. 20, Monitoring the Validity of Test Results and Appendix H, AP No. 8 Control of data and Software Data Integrity.) Where computers are involved in data recording, retrieval, processing, calculation, analysis, or reporting, the laboratory ensures that:

11.5.1.1 The requirements of this manual are maintained;

11.5.1.2 Computer software developed by the laboratory has been documented and verified by using data sets. (See Section 13 Records and Appendix O, Forms); and

11.5.1.3 Computer equipment is maintained in accordance with the procedures for maintenance of equipment (see Appendix H AP 14) and is used in suitable environmental and operating conditions.

11.5.2 The laboratory procedure for software data integrity, Appendix H, AP No. 8, includes guidance on how to:

11.5.2.1 Protect the integrity and confidentiality of stored test data, test data entry or collection;

11.5.2.2 Limit access to maintain security of the programs in use;

11.5.2.3 Backup programs and test records;

11.5.2.4 Revise the software if updates occur;

11.5.2.5 Protect test data transmission and processing.

11.5.3 The technical manager maintains the procedures for software documentation and verification, which are located in the laboratory files (see Appendix H, AP No. 8).

12.0 Handling and Storage of Test Items

12.1 Items received for test are recorded in a laboratory work log and assigned a number that uniquely identifies the item during its stay in the laboratory. Work logs are maintained in the laboratory. A work order is completed to include: the item or items received for test, name of company submitting the test items, and date of receipt. Work orders are attached to and, if possible, are kept with the test item during its stay in the laboratory (see Appendix O, "Forms," Section 13 Records, and Appendix P, Type Evaluation Process Flowcharts, Appendix H, AP No. 5, Handling Calibration and Test Items).

12.2 Incoming test items are evaluated by laboratory staff to ensure that standards, equipment, staff, facilities, and procedures necessary to perform testing are available. Procedures for the review of all incoming work are maintained in the laboratory files (see Appendix H, AP No. 5.).

12.3 Prior to testing incoming items, the laboratory communicates to the client any significant abnormalities (see Appendix H, AP No. 5) including:

12.3.1 Departures from required standard conditions and necessary preparations;

12.3.2 Doubt as to the test items suitability for testing; and

12.3.3 Nonconformance of the test item with the description (application information) provided by the client.

Records of these client discussions are maintained in the laboratory (see QM Section 13, Records)

12.4 The laboratory handles, prepares, and stores test items in its custody in a safe manner to protect them from loss, deterioration, damage, and destruction of required chains of evidence. Documented procedures for the receipt and retention of the test items are maintained in the laboratory files (see Appendix H, AP No. 5).

12.5 If a test item requires specific environmental conditions for storage, the conditions are maintained, monitored and recorded (see Appendix H, AP No. 5).

12.6 Test items to be held for any reason, including safety, value, to perform check testing, etc., are stored and secured to protect the item's condition (see Appendix H, AP No. 5).

12.7 Upon completion of testing, the test items will be retained no longer than necessary, and will be safely returned to the client. (See Appendix H, AP No. 5, The Return of Test Items, which includes procedures for shipping.)

13.0 Records

13.1 The laboratory maintains procedures for the identification, collection, indexing, access, filing, storage, maintenance and disposal of administrative and measurement-related records. All records are readily retrievable and maintained in a suitable environment. (See Appendix H, AP No. 22.)

13.2 To ensure that the laboratory records are secure and to prevent destruction or tampering, the laboratory records are kept in locked cabinets and access to the files are limited to the laboratory staff. Records include information required by regulation or associated with original test observations, calculations, and reported results. Type evaluation data is recorded in permanent form at the time of test, in bound notebooks, or on standard forms on file (see Appendix O, Forms). Permanent ink is used to record the actual data, and no erasures or whiteouts are made. Any corrections to data are made by drawing a single line through the entry and initialing the change with a note as to why the change was made. The type evaluation test number is included on the data sheets to ensure that the data and calculations are identifiable to the specific job. Type evaluation records contain sufficient detail to permit any necessary repetition of the evaluation and identification of the components of uncertainty. Records of original data include the following:

13.2.1 Test Procedure used;

13.2.2 Description of, and reason for, any deviation from the standard operating procedure (SOP);

13.2.3 Identity of the personnel performing testing;

13.2.4 Identity and description of objects under test;

13.2.5 Identity of equipment or apparatus used;

13.2.6 Identity of standards used and reference to traceability;

13.2.7 Date of test;

13.2.8 Original test data;

13.2.9 Derived data;

13.2.10 Type evaluation control number and State test number if appropriate;

13.2.11 Environmental data during test when applicable (see Section 8 Laboratory Facilities and Environment); and

13.2.12 Work order.

13.3 Records, including those in computer files, are accessible only to authorized personnel. Computer files are backed-up for protection against loss (see Appendix H, AP No. 22 Record Maintenance). [NOTE: Include a brief explanation of how your files are backed-up and how access to your electronic records are controlled.]

13.4 Two categories of records are maintained by the laboratory: administrative and measurement-related. The laboratory maintains and retains the following records in the locations stated for the specified amount of time. [Note: Laboratories should include a statement addressing the specific retention time of records according to State or laboratory policy.]

Administrative		
List of Records	**Location**	**Retention Time**
Audit		
Complaints/ Feedback/ Preventive and Corrective Action		
Deviations from Accepted Procedure		
Management Review		
List of Approved Signatories		
Subcontractors and Outside Suppliers (evidence of compliance to the quality system)		
List of Key Personnel Performing Other Duties		
Controlled Document Distribution List		
Personnel Training and Competency		
Contract (Application) Review and Client Discussions		
Internal Audits		
Validation of Test Methods		
Management Staff Authorization and Assignment for Testing		
Inspection and Verification of Support Services and Supplies and Resulting Actions		

Measurement-Related		
List of Records	**Location**	**Retention Time**
Test Reports (Certificates)* and Amendments to Test Reports (Certificates)		
Original Test Data		
Environmental Conditions/Deviations Log		
Calibration and Maintenance (Standards and Equipment)		
Software Verification		
Working Standards Calibration Reports		
Equipment Assessment		
Assessment of Uncertainties		
Interlaboratory/Proficiency Test Results		
Equipment Operation and Instruction Manuals		

*Certificates are Certificates of Conformances (CC)

14.0 Type Evaluation Test Reports (Certificates of Conformance)

14.1 Type evaluation tests reports (Certificates of Conformance) are reviewed by the laboratory staff to correct any inconsistencies in the report, supporting data, and calculations (see Section 13 Records for the location of calibration and test reports). Upon successful completion of testing, the laboratory drafts a Certificate of Conformance (CC) based on the test results. The CC is reviewed by the device manufacturer, the laboratory technical manager, and the type evaluation manager before issuance (see Appendix P, page 5 of 10). The CC contains the results from the test report.

14.2 *If accredited by NVLAP,* the laboratory follows the NVLAP policy (NIST HB 150 Annex A) regarding the use of the NVLAP logo, (see Appendix H, AP No. 25).

14.3 Test results and data are reported accurately, clearly, unambiguously and objectively in accordance with any specific instructions in the test methods.

The test results are initially provided in a test report, and information from the test report is included in a CC. The test report includes all information requested by the client as appropriate in accordance with the test procedures and necessary for the interpretation of the test results and required by the method. If tests are performed for internal clients, or as requested in a written agreement with the client, the test results are reported in a simplified way, but all information that is usually included in the test report is available in the laboratory.

14.4 Any opinions and interpretations included in test reports are clearly marked as such and indicate the basis upon which the opinions and interpretations were made. Any opinions and interpretations that are communicated through conversation with the client are documented on the test report.

14.5 Test reports (Certificate of Conformance) include the following information:
[NOTE: Laboratories should edit this section following the guidelines in ISO/IEC 17025 Section 5.10.2 and 5.10.3.]

14.5.1 A report title;

14.5.2 Name and address of the laboratory and location where the test was conducted if different from the laboratory;

14.5.3 Unique identification of the test (CC Number) on every page of the CC, identification which shows the end of the page, and page number and total number of pages;

14.5.4 Name and address of client;

14.5.5 Item identification including: description, manufacturer, model, and serial number (where available);

14.5.6 Test date;

14.5.7 Condition and characterization of the item (where relevant);

14.5.8 Identification of the test method used;

14.5.9 Additions, exclusions or deviations from the test method and other relevant information including environmental conditions existing during test (when applicable);

14.5.10 Tables, graphs, and other supporting information when necessary for the interpretation of the report;

14.5.11 Test results with units of measure and accuracy and tolerance conformity as appropriate.

14.5.12 Date of issue and signature of the technical manager, laboratory staff, or other official who accepts responsibility for the validity of the results and the content of the report;

14.5.13 Where relevant, a statement that the report relates only to the items listed in the report “at the time of test;”

14.5.14 The estimated uncertainty if the uncertainty affects compliance to specification limits;

14.5.15 Clear identification of reported results or test if performed by subcontractors;

14.5.16 Where relevant, reference to sampling procedures, date of sampling, identification of samples, sampling location, environmental conditions, during sampling, that can affect the test results, and standards or specifications for sampling.

14.5.17 A statement that the CC shall not be reproduced, except in full, without the written approval of the laboratory;

14.5.18 Statement that the client shall not use the report to claim product endorsement by the laboratory accrediting body, as appropriate;

14.5.19 Signature of an approved signatory for all test and calibration reports endorsed with the accreditation status or NVLAP logo (see Section 13 Records, List of Approved Signatories);

14.5.20 Special limitations of use;

14.5.21 Traceability statement, as appropriate;

14.5.22 Date test item received, test complete and draft CC complete (this information is kept on file; not placed on the CC); and

14.5.23 Opinions and interpretations, and any additional information required by the test method, where appropriate.

14.6 The laboratory follows a failure process and procedures to address tests or test results that do not conform to the test requirements (see Appendix P). The procedures ensure that:

14.6.1 Management responsibilities and authorities for addressing nonconforming work and the actions to be taken are identified;

14.6.2 The significance of the nonconformance is evaluated;

14.6.3 Remedial actions are addressed and decision are made quickly;

14.6.4 The client is notified and the work is recalled;

14.6.5 Persons responsible for authorizing the work to continue are identified; and

14.6.6 When there is indication that non-conforming work could recur, the laboratory follows the corrective action procedure (see Appendix H, AP No. 18).

14.7 The laboratory notifies its customers in writing of any events that cast doubt on the validity of the results given in any test report or amendment to a report.

14.8 Amendments are made in the form of an additional document or data transfer and the Certificate is labeled with an amendment number for each amendment (e.g., A1, A2, A3. . .). If a new document is issued, it contains a reference to the original that it replaces. Records of these documents are maintained by the laboratory staff and located in the laboratory files (see Section 13 Records, Test Reports (Certificates)/Supplements to Test Reports (Certificates).

14.9 Tests performed by subcontractors are clearly identified on the test report by including a note that states the data and results were received from a subcontractor (see QM Section 15). [NOTE: Edit QM section 14.9 to describe how your laboratory would identify subcontracted work on a test report; delete this section if you do not subcontract.]

14.10 Opinions and interpretations are clearly identified on the test report by writing notes on the test report adjacent to the test results for each test of the device, which includes the basis upon which the opinions and interpretations are made.

14.11 When test results are transmitted by telephone or electronically the procedures for the control of data are followed (see QM Section 11.5 and Appendix H, AP No. 8).

14.12 The test reports (certificates) are clear and understandable. The test report formats are included in NCWM Publication 14 (see QM Section 2, References and Definitions).

15.0 Subcontracting

15.1 The laboratory performs tests within its documented capability. The laboratory does not subcontract.

OR

15.1 The laboratory subcontracts in the special circumstances where technical, safety, or efficiency issues dictate. Subcontracting is only conducted with authorized type evaluation laboratories or State Weights and Measures officials capable of performing type evaluation testing. The laboratory maintains a list of all subcontractors used by the laboratory, along with evidence of their compliance to the laboratory's quality system (see Section 13 Records).

15.2 The laboratory is responsible for the subcontractor's work and notifies the client in writing of the arrangements for subcontracting.

15.3 The laboratory receives the subcontractor's data in writing or electronically. The data is included in the test report and is identified with a note that states that the data was received from a subcontractor. [NOTE: Edit QM section 15.3 to describe how your laboratory would identify subcontracted work. If NVLAP accredited, follow the requirements of NVLAP as found in NIST Handbook 150.]

16.0 Outside Support Services and Supplies

16.1 The laboratory uses services and supplies of adequate quality where the specifications of outside services and supplies are relevant to the integrity of tests. The laboratory maintains procedures for the purchase, storage, and evaluation of supplies and services (see Appendix H, AP No. 9).

16.2 The purchasing orders contain data that describe the services and supplies ordered; they are reviewed and approved before release. The technical manager completes the purchasing order, which includes the following information:

16.2.1 description of the service or supply,
16.2.2 service provider or supplier name address and phone number,
16.2.3 cost of the service or supply, and
16.2.4 date of request.

The technical manager reviews the purchase order and the director approves the order before it is released.

16.3 Where assurance of the quality of outside support services or supplies is unavailable, the laboratory uses these items only after they have been inspected or otherwise verified for adequate quality. The suppliers of critical supplies and services that affect the quality of testing are evaluated. The technical manager, upon receipt of the service or supply, examines the supply or quality of the service and records the findings on the "Inspection and Verification of Support Services and Supplies and Resulting Action Form." If the services or supplies are not of adequate quality, the procedure for the control of non-conforming work is initiated (see Appendix H, AP No. 18). The records of inspections, and verification of suppliers and services and actions are maintained in the laboratory (see Appendix H, AP No. 9 and Section 13 Records).

17.0 Preventive Action / Complaints and Corrective Action

17.1 Preventive Action

17.1.1 The laboratory participates in annual NTEP laboratory meetings. Discussion at these meetings includes the interpretation of type evaluation test procedures. The information from these meetings is documented and used to improve the quality of test in the laboratory. The laboratory obtains information from laboratory meetings and internal reviews and uses this information to examine its technical and quality system to identify needed improvements and potential sources of nonconformance. If preventive action is required, action plans are developed, implemented, and monitored. Procedures for preventive action are maintained in the laboratory (see Appendix H, AP No. 6).

[NOTE: If the laboratory has a control chart process, this can be referenced in this section as a means of preventive action]

17.2 Complaints and Corrective Action

17.2.1 The laboratory promptly investigates complaints, adverse findings during audits, or any other circumstance that raises doubts concerning the laboratory's competence or compliance with required procedures. The laboratory determines the root cause, identifies potential corrective actions, and follows a corrective action procedure to resolve the adverse situation promptly and, where necessary, conducts a retest. Procedures for handling complaints are maintained in the laboratory (see Appendix H, AP No. 6, AP No. 10, and AP No. 16).

17.2.2 The laboratory quality manager examines all documents and records associated with complaints, and the laboratory technical manager investigates adverse audit findings and other circumstances. If deficiencies are discovered during these reviews, they are documented. After review of the deficiencies with the laboratory staff and management, corrective actions are documented for each deficiency appropriate to the magnitude and risk of that deficiency and likely to eliminate or prevent recurrence. Deadlines are set for each corrective action. The laboratory manager monitors the corrective action to ensure that it is effective (see Appendix H, AP No. 6).