Contents

TSE

QUALITY CONTROL

REVISION RECORD

RETAIN THIS RECORD IN THE FRONT OF THE MANUAL. ON CREATION OF, AND APPROVAL OF REVISION, ENTER THE REVISION NUMBER, REVISION DATE, PAGES AND AUTHORITY (name / title) OF THE PERSON INCORPORATING THE REVISION IN THE APPROPRIATE BLOCK.

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PREFACE

This manual prescribes general instructions pertaining to the Operation and Quality Assurance for Charles S Sharp dba Trident Systems & Engineering also know as TSE. This manual is not intended to cover every contingency that may be an issue. Such instructions will be supplemented to this manual and will be considered as standard Inspection procedures.

This manual will be revised by page changes and additions and by complete editions. Comments and recommendations concerning this manual are encouraged. Extra copies are available from TSE Quality Assurance.

For further information please contact the Quality Manager or Laboratory Supervisor.

1.0 Scope and Parameters

1.1 Scope

1.1.1 This Quality Manual describes the quality assurance program used by Trident Systems & Engineering, Calibration laboratory and sets forth the established requirements to competently and effectively achieve the program objectives of the laboratory specifically for ANSI/ISO/IEC 17025-2017 accredited calibrations and performance verification, other non ANSI/ISO/IEC 17025-2017 accredited calibrations and performance verification will use the whole or parts of this manual as required. The objective of this Calibration laboratory is to:

1.1.1.1 Provide reliable performance verification services for devices operating within the scope of ANAB Certificate L2321 for accredited calibrations and or Appendix C for non-accredited calibrations, suited to the needs of its customers, program, and industry performed at TSE's permanent site or away from the permanent site including customer's sites.

1.1.2 Working standards are calibrated by an accredited or recognized laboratory whose measurement results, wherever applicable, are traceable to a national metrology institute or in house and will be calibrated against higher level standards having established values of at least four times the accuracy level of the standard being calibrated. These working standards are used to calibrate devices. The working standards are recalibrated periodically.

1.2 Parameters

1.2.1 Performance verifications performed by the laboratory that result in certificates, reports, or other summarizing statements are limited to the test parameters listed in ANAB Certificate L2321 for accredited calibrations and or Appendix C for non-accredited calibrations .

1.2.2 The laboratory quality manual is based on ANSI/ISO/IEC 17025-2005. The quality manual is used in conjunction with applicable portions of the reference documents, procedures, work instructions, records and forms maintained in the laboratory. These documents constitute the laboratory's quality control system applicable to the test parameters listed in ANAB Certificate L2321 for accredited calibrations and or Appendix C for non-accredited calibrations

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 ANSI/ISO/IEC 17025-2005, *General Requirements for the Competence of Testing and Calibration Laboratories*, 2005

2.1.2 NIST Hand Book 150 *Procedures and General Requirements* 2006 Edition.

2.1.3 National Conference of Standards Laboratories (NCSL), *Recommended Practice (RP) No. 12 Determining and Reporting Measurement Uncertainties* 1995.

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

2.2 Additional References

2.2.1 ANSI / NCSL Z540 – 1 - 1994

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 Charles S Sharp Owner the Chief Executive of Trident System & Engineering.

3.1.1.1 It is the Policy of Trident Systems & Engineering to avoid involvement in activities that diminish confidence in competence, impartiality, judgment or operational integrity.

3.1.1.2 It is the Policy of Trident Systems & Engineering that the integrity of the management system is maintained by top management when changes are made.

3.1.1.3 Employees of Trident Systems & Engineering will sign an agreement stating they understand these policies and will report any breach in these policies or conflict of interest.

3.1.2 The laboratory conducts all device performance 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 performance evaluation procedures as noted in . It is our policy to provide the highest reasonable quality performance evaluation services attainable to Customers 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 performance 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 Performance evaluation test procedures: Technical Policy, Checklist, and Test Procedures referenced in Section 2 ;
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.

3.0 Quality Policy

3.2 Tests

3.2.1 The laboratory evaluates devices within the test parameters listed in Appendix C in accordance with the procedures, practices, and conditions (hereafter referred to as "procedures") of the Original Equipment Manufacturer (OEM) performance test or calibration procedures supplied in the Maintenance and Repair section of the Instrument Operating and Service Manual or GIDEP (Navy / AF) Performance Verifications. When no procedure exists or when special calibrations are required which are not covered by present procedures the Lab Manager and The Quality Manager will write calibration procedures that will properly verify those calibrations as to specification, accuracy, resolution, and use within the TSE calibration system. Some calibration procedures may be entirely in software.

3.3 Authorization and/or Accreditation

3.3.1 The performance evaluation laboratory is authorized by ___ANAB_____ to demonstrate conformance to ISO/IEC 17025.

3.4 Improvement

3.4.1 The laboratory shall use the quality policy and objectives, audit results, data analysis, corrective and preventive actions and management review to improve its management system

4.0 Service to Customer & Review of Contract, Tenders, and Work Request

4.1 Service to the Customer

4.1.1 As necessary, the laboratory works with the Customer to clarify test requests, device operation and test results. The Customer is provided controlled access to the laboratory to observe performance evaluations of the device. To ensure confidentiality, information of other Customers are not visible during a Customer visit to the laboratory. The laboratory communicates with the Customer at any time prior to, during and after the performance evaluation as needed to address any questions, changes and test results. The laboratory provides the Customer with a summary and conclusion of the test results and/or a complete set of point by point data as requested . The laboratory may receive feedback from the Customer that might improve the laboratory quality system. As appropriate Customer 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

4.2.1 Contracts, tenders, and work requests received by the laboratory are in the form of request for calibration. Calibration request are received by the Operation manager. Typically the Operation manager reviews the request with the TSE Service Guide for reference of adequacy and capabilities. Should said equipment not be listed then said equipment is referred to the Lab Manager and/or QA Manager for disposition. Calibration Request may be verbal. The procedures ensure that:

4.2.1.1 The type of calibration and requirements are adequately 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 Customer.

4.2.1.4 Calibration request may include work that is subcontracted by the laboratory. The Customer is informed of any subcontracted work and the Customer approves before it is accepted.

4.2.1.5 The laboratory cooperates with the Customer to ensure that the application is understood. The laboratory contacts the Customer upon receipt of equipment and or the PO and reviews the application with the Customer. Prior to testing the laboratory and the Customer discuss any abnormalities. Unless inherent in the requested specification or standard, the decision rule is communicated to, and agreed with, the customer.

5.0 Organization and Management

5.1 Legal Status

5.1.1 This organization is a sole proprietorship, Charles S Sharp dba Trident Systems & Engineering licensed for business in the State of California.

5.2 Organization

5.2.1 Authority, interrelation, and responsibilities of all laboratory personnel are on file in the form of an organizational charts provided in Appendix B . The laboratory manager designates staff responsibilities of quality, technical and operation. The Quality and Laboratory 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 Laboratory 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/or NCSL Z540-1 and this quality manual, and satisfy the needs of the Customer and/or organizations providing authorization and/or accreditation.

5.2.3 This laboratory performs some performance evaluations of measuring and testing 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. Laboratory personnel do not participate in activities that might adversely affect confidence in the Performance Verification.

5.3 Responsibility

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

5.0 Organization and Management

5.3.1 Owner

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

5.3.2 Laboratory Manager

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; assigns deputies for both the technical and quality managers the case of an absence;
c. participates in management reviews of the quality system; and
d. supervises the activities of the laboratory
e. is a Calibration laboratory person who has completed the appropriate level of Performance Verification training as specified in the laboratory training procedures in the areas for which the laboratory is authorized;
f. is responsible for the overall administrative and technical operations of the laboratory;
g. specifies and/or approves all methodologies used;
h. 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;
i. verifies personnel training;
j. assigns only competent personnel to complete tests;
k. 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);
l. ensures continued authorization of the laboratory;
m. where necessary, identifies, develops, and implements improvement of the laboratory measurement capability to meet the requirements of ISO/IEC17025, department programs, and laboratory Customers; and
h. participates in management reviews of the quality system.

5.0 Organization and Management

5.3.3 Quality Manager

5.3.3.1 The Quality manager:

a. is a Calibration laboratory person who has completed the required level of training as required by the laboratory 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 Laboratory 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 supervises the quality activities of the laboratory

5.3.4 Calibration Technician

5.3.4.1 The Calibration technician is

(Under the direction of the Laboratory Supervisor or Quality Manager)

a. is a Calibration laboratory person who has completed the required level of training as required by the laboratory in the areas for which they have been selected for and which laboratory is authorized in.
b. Responsible for performing test and reporting results.
c. Responsible for troubleshooting, installing and repairing devices as required.
d. Perform other Laboratory related task as required.

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.

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 law and in accordance with the administrative procedures. . (See Appendix H, AP No. 1, Procedures for Customer Confidentiality and Proprietary Rights.)

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

6.1 This Calibration laboratory has established and maintains a quality system that supports the tests conducted by this 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 work instructions (maintained in the laboratory);

6.2.1.3 records, forms, reports (see section 13, and Section 14)

6.2.1.4 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, and Training Records)

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 Appendix 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;" Appendix D, "Diagram of Facilities" and Appendix 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 list of controlled documents. 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, periodic review and, as necessary, revision of the documents to ensure suitability and compliance with
d. applicable requirements, Uniquely indentified.
e. removal of invalid or obsolete documents,
f. access and changes to hard and electronic document, and 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.(See Appendix H, AP No. 3 and Appendix N)

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

6.3.2 Internal Document Control

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). 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 revision number 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 December. The laboratory Manager 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 Manager.

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, e-mails or verbally. Staff will acknowledge reading the QA Manual by signing DOC-001, it will then be placed in their training record.

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

6.3.4 Controlled Copies of the Quality Manual

6.3.4.1 Controlled copies of this quality manual are issued in digital form. It is provided to accreditation bodies and is posted on our website, it is made available to all laboratory personnel. 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. When the Quality Manual is updated the accrediting body will be notified. A list of the names of any other person requiring notification is kept in Appendix N.

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

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

6.4 Internal Audits and Management Reviews

6.4.1.1

The Quality Manager 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 monthly 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 Customers 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

The Laboratory Manager conducts annual management reviews of the quality system (see Appendix H, AP No. 7. "Internal Audits and Management Reviews".

6.4.2.1 Laboratory staff are encouraged to participate in the review meetings. The management review includes:

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

6.4.2.1.2 Evidence from internal audits and statistical control data and/or charts, where appropriate. (See Section 13, and Appendix J and Appendix K.);

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

6.4.2.1.4 Review of policies and procedures;

6.4.2.1.5 Reports of managerial and supervisory personnel;

6.4.2.1.6 Preventive and corrective actions;

6.4.2.1.7 Assessments by external bodies; and

6.4.2.1.8 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 LAB 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 review
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 Performance Verification staff include:

7.1.1 normal and customary Calibration techniques

7.1.2 will be familiar and have some knowledge of ANSI/ ISO / IEC 17025

7.1.3 will be familiar and have some knowledge of ANSI / NCSL Z540

Staffing is sufficient to maintain the timely processing of the Customer 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 measuring device and apply them in their testing of the devices. The Laboratory manager, 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. .

Performance evaluations are performed by personnel who are employed or contracted by the laboratory. Personnel who are in the process of training are supervised until training is completed. Contracted personnel are also trained or experienced in testing measuring and testing devices.

Adequately trained staff is a key factor in good Performance Verification test. The 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).

7.0 Personnel

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 Performance Verification 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 Measurement Science Conference (MSC) and American Society for Quality (ASQ) . 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 Performance Verification 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. (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 Performance Verification 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 Performance Verification 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 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:

8.3.1 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),

8.0 Laboratory Facilities and Environment

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 section 18.2).

8.2 Environmental Records

8.2.1 Laboratory device testing

8.2.1.1 Environmental conditions are recorded with the use of a 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 Performance Verifications. Corrective actions are taken when the environmental conditions affect the quality of test (see Appendix E, Environmental Conditions and Appendix H, AP No. 27.)

8.2.2 Onsite 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.).

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 Laboratory manager investigates any equipment or standards that are suspected in contributing to out-of-control conditions (see Appendix F, Equipment List). Records of corrective actions for discrepancies are maintained in the laboratory (see Section 13 Records,). _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. 13).

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

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,;

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 / Firmware version affecting the calibration;

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.

9.0 Standards, Equipment, and Associated Apparatus

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-calibration 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 Library (See 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 laboratory (see Section 13 Records). 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. using 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).

9.0 Standards, Equipment, and Associated Apparatus

9.3.1.8 All equipment having an effect 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 (Tamper proof seals 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.

9.3.2.2 All standards having an effect 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. (see Appendix H, AP No. 4, SOP 1006 and Appendix R).

10.0 Measurement Traceability and Calibration

10.1 Policy

10.1.1 Standards, 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 program is reviewed and adjusted as necessary in order to maintain confidence in the status of the standard or equipment used for calibrations. The laboratory maintains procedures for safe handling, transport, storage and use of reference standards, materials and equipment (see Appendix H, AP No. 13and AP No. 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 and SOP 1006).

10.2.2 The laboratory has a program of calibration and verification of measuring and test equipment that has an effect 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 No. 13).

10.0 Measurement Traceability and Calibration

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 Performance Verification 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, usage, and repair history. The Laboratory Manager conducts the review and makes the final determination(see Appendix H, AP No. 14).

10.4 Measurement of Uncertainty

The laboratory is a Performance Verification laboratory that performs testing and evaluation of measuring and testing equipment (MTE). A variety of tests are performed on each device under test to include accuracy, influence factors, and permanence testing. For 17025 calibrations 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 TN 1297 "Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results and MSC T11-2011 training are used as the basis for the expression of uncertainty in measurement (see Appendix I, "Assessment of Uncertainties")

11.0 Performance Verification 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. Equipment manuals, operating instructions, reference data, specifications, and tolerance tables relevant to the laboratory are maintained in the laboratory and are readily available.

11.2 The selected test procedures are appropriate for the device under test, and the appropriate 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 all concerned parties. 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). 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 Performance Verification Testing Procedures

11.3.1 The laboratory follows the procedures and checklist for measuring and testing instruments listed in the TSE Service guide.

11.3.2 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 MSC T11-2011 training. The device under test must meet of the tolerances and specification of OEM recommendations or customer required specifications. Performance Verifications of measuring and testing equipment 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.

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 K1990-PC / Libraries / Documents / Public Documents / Quality/ SOP 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.

11.0 Performance Verification Test Methods and Procedures

11.4.2 The Laboratory 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 Performance Verification.. 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 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

11.5.1.3 Computer equipment is maintained in accordance with the procedures for maintenance of equipment (see Appendix H AP No. 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.

The Laboratory 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 Section 13 Records, and Appendix P, 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 Customer 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 Customer.

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).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 Customer. (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. The staff has access to all data and information required to perform their duties (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 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. Performance Verification data is recorded at the time of test on standard forms on file. Data is inputted directly to an excel file and a pdf copies is made to ensure original data is preserved or in the case no excel file has been created by the QA Manager(or his designee) 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. The Performance Verification test number is included on the data sheets to ensure that the data and calculations are identifiable to the specific job. Performance Verification 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 Title - Certificate Of Calibration
13.2.2 Name of the Calibration Lab
13.2.3 Unique Identification **Certificate Number**
13.2.4 Name of the customer
13.2.5 Model number of the calibration Item
13.2.6 Serial number (if appropriate)
13.2.7 Asset number (if appropriate)
13.2.8 Before or after status if necessary
13.2.9 Date Calibration performed
13.2.10 Procedure used
13.2.11 Measurement results and/or data if necessary
13.2.12 Identity of person responsible (i.e. Tech #)

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).

14.0 Performance Verification Test Reports (Certificates of Calibration)

14.1 Performance Verification tests reports (Certificates of Calibration) 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 Certificates of Calibration based on the test results. The Certificate of Calibration is reviewed by the Operations Manager, or the Laboratory Manager, and the Quality Assurance Manager, or their designee, before issuance. The Certificate of Calibration contains the results from the test. Test reports and calibration certificates include 17025 listed information, unless they have a valid reason for not doing so.

14.2 The laboratory follows the accrediting agency policy for displaying their name and 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 Certificate of Calibration. The test report includes all information requested by the Customer as appropriate in accordance with the test procedures and necessary for the interpretation of the test results and required by the method. If requested by the customer, the test results are reported in a simplified way.

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 Customer are documented on the test report.

14.5 Test reports (Certificate of Calibration) include the following information

14.5.1 A report title;

14.5.2 Name and address of the laboratory and location where the test was conducted . Unique identification of the test (Certificate of Calibration Number) on every page of the Certificate of Calibration, identification which shows page number and total number of pages;

14.5.3 Name and address of Customer;

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

14.5.5 Test date; and Date the report is issued

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

14.5.7 Identification of the test method used;

14.0 Performance Verification Test Reports (Certificate of Calibration)

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

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

14.5.10 Test results with units of measure and accuracy and tolerance conformity including before and after any adjustment or repair, if available; as appropriate.

14.5.11 Signature of the Operation Manager, Laboratory Manager, AP No 26 or other official who accepts responsibility for the validity of the results and the content of the report;

14.5.12 Where relevant, a statement that the report relates only to the items listed in the report "at the time of test;"

14.5.13 The estimated uncertainty in the same unit, or relative term as the measurand;

14.5.14 Clear identification of reported results or test if performed by subcontractors. 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.

14.5.15 A statement that the Certificate of Calibration shall not be reproduced, except in full, without the written approval of the laboratory;

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

14.5.17 Special limitations of use if necessary;

14.5.18 Traceability statement, as appropriate;

14.5.19 Date test item received, test complete (this information is kept on file; not placed on the Certificate of Calibration); and

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

14.5.21 Where relevant, a statement of conformity with requirements or specifications

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

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

14.0 Performance Verification Test Reports (Certificate of Calibration)

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 Customer is notified and the work is recalled. Persons responsible for authorizing the work to continue are identified; and

14.6.5 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. . .) the change of information is clearly identified and, where appropriate, the reason for the change included in the report. 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. All Amendments shall meet the requirements of 17025.

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).

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 are clear and understandable including customer supplied data.

14.13 TSE is responsible for all the information provided in the report, except when information is provided by the customer, In addition a disclaimer put on the report when the information is supplied by the customer that could affect the validity of results.

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15.0 Subcontracting

15.1 The laboratory subcontracts in the special circumstances where technical, safety, or efficiency issues dictate. Subcontracting is only conducted with the OEM or authorized laboratories capable of performing the Performance Verification. 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 Approved Vendors and Section 13 Records).

15.2 The laboratory is responsible for the subcontractor's work and notifies the Customer 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.

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 Laboratory 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.

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 Laboratory Manager or designee, upon receipt of the service or supply, examines the supply or quality of the service. If the services or supplies are not of adequate quality, the procedure for the control of nonconforming 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 is a member of NCSL and participates in Quality events such as MSC and ASQC. Discussion at these meetings includes the interpretation of Performance Verification 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, internal reviews and Customer Surveys, we use this information 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).

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 Quality Manager examines all documents and records associated with complaints, and the Laboratory Manager investigates adverse audit findings and other circumstances. 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) Records of deficiencies and corrective actions are maintained in the laboratory (see Section 13, Records).

18.0 Site Security

18.1 The laboratory is located 2646 Palma Drive Suite 130 Ventura CA 93003 The Laboratory Manager is responsible for security directly related to the laboratory and designates the specific duties of on-site security to the laboratory staff. Security of the laboratory premises includes the following:

18.1.1 Locking laboratory doors in specific areas when not in use;

18.1.2 Securing all doors and perimeter at the close of the day;

18.1.3 Notifying the police of disturbances and suspicious activity as appropriate;

18.1.4 Securing entrances to the laboratory when disturbance during testing affects the integrity of the Performance Verification; and

18.1.5 Securing all areas where standards and equipment are stored or maintained.

18.2 Access

18.2.1 Access to and use of all Calibration areas are controlled and defined by the Laboratory Manager. It is restricted to personnel and invited guest.

18.2.2 Laboratory building keys are given to administrative staff members and laboratory personnel.

19.0 Safety

19.1 Safe working conditions are prerequisite to good laboratory practices. Laboratory personnel are instructed in safe working practices and are encouraged to look for hazardous conditions and repair or report them to the Quality Manager, as well as to recommend and implement accident prevention. The Quality Manager documents hazardous conditions and the actions taken to eliminate the hazardous condition.

19.2 Management provides safe-working conditions, complies with safety regulations, and, along with supervisors, ensures that the staff complies with these regulations.

19.3 It is the responsibility of all staff to be familiar with and comply with all safety guidelines and requirements. The laboratory staff takes proper precautions in the laboratory.

20 Sampling

20.1 The laboratory does not use sampling as part of the Performance Verification testing