

NIST HANDBOOK 150 CHECKLIST

Instructions to the Assessor: This checklist addresses the general accreditation criteria prescribed in NIST Handbook 150, *NVLAP Procedures and General Requirements* (2006 edition). The checklist items are numbered to correspond to the requirements found in Clauses 4 and 5, and Annexes A and B of the handbook. Items marked with ♦ indicate a change in requirements from the 2001 edition of NIST Handbook 150.

Place an "X" beside each checklist item that represents a nonconformity. Place a "C" beside each item on which you are commenting for other reasons. Record the item number and written nonconformity explanation and/or comment on the comment sheet(s) at the end of the checklist. Write "OK" beside all other items you observed or verified as compliant at the laboratory.

4 Management requirements for accreditation

4.1 Organization

- X 4.1.1 The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.

A2LA Addendum, Section 1.1

Legal name of laboratory ownership: Wyle Laboratories

4.1.1 The laboratory shall establish and maintain policies and procedures for maintaining laboratory impartiality and integrity in the conduct of voting system testing. When conducting testing under HAVA, the laboratory policies and procedures shall ensure that:

a) the laboratory cannot perform both developmental testing and accredited testing of a particular voting system or system component

Procedure No. WHVS07 (Voting System Test Procedure) covers this issue with the third paragraph in the Executive Summary (paragraph 1.0).

b) the laboratory cannot provide consultation or other services to a voting system developer such that the independence, or appearance of independence, in the testing of a voting system or system component would be compromised.

No reference in the quality documentation to cover the "consultation" to a voting system developer.

- OK 4.1.2 It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this handbook and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition.

A2LA Addendum, Section 1.1

4.1.2 The laboratory shall have physical and electronic controls augmented with an explicit policy and set of procedures for maintaining separation, both physical and electronic, between the laboratory test personnel and laboratory consultants, product developers, system integrators, and others who may have an interest in and/or may unduly influence the outcome of the test.

Covered in Paragraph 6.1 (Facility Requirements) of Procedure No. WHVS07

(Voting System Test Procedure).

- OK 4.1.3 The management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.

A2LA Addendum, Section 1.1, Huntsville Facility Quality Program Manual, Section 2.0

- OK 4.1.4 If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest.

A2LA Addendum, Section 1.1, Huntsville Facility Quality Program Manual, Section 2.0, Quality Procedure ISO-QP-010.

NOTE 1 Where a laboratory is part of a larger organization, the organizational arrangements should be such that departments having conflicting interests, such as production, commercial marketing or financing do not adversely influence the laboratory's compliance with the requirements of this handbook.

NOTE 2 If the laboratory wishes to be recognized as a third-party laboratory, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgement. The third-party testing or calibration laboratory should not engage in any activities that may endanger the trust in its independence of judgement and integrity in relation to its testing or calibration activities.

4.1.5 The laboratory shall:

- OK a) have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2);

A2LA Addendum, Section 1.1, Huntsville Facility Quality Program Manual, Section 2.0, Quality Procedure ISO-QP-010 – Organization and Responsibilities (Revision: 1 - Effective June 9, 2007).

- OK b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;

A2LA Addendum, Section 1 – Management Requirements, Section 1.1 - Organization

- OK c) have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;

A2LA Addendum, Section 1 – Management Requirements, Section 1.1 - Organization; Internal Operating Procedure for the Contracts Department, Section 6.5 – Proprietary Information.

- OK d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity;

A2LA Addendum, Section 1 – Management Requirements, Section 1.1 - Organization

OK e) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services;

A2LA Addendum, Section 1 – Management Requirements, Section 1.1 - Organization plus Organization Charts. Also, Quality Procedure ISO-QP-010 - Organization and Responsibilities

OK f) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations;

Huntsville Facility Quality Program Manual, Section 2.0 and 5.5, Quality Procedure ISO-QP-010 – Organization and Responsibilities (Revision: 1 - Effective June 9, 2007).

OK g) provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results;

A2LA Addendum, Section 2.2 - Personnel

OK h) have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;

Quality Procedure ISO-QP-010 – Organization and Responsibilities (Revision: 1 - Effective June 9, 2007).

Name of person: Frank Padilla
 Area of responsibility: Test Supervisor, Voting System Test Lab
 Repeat as necessary: _____

OK i) appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources;

Quality Program Manual, Paragraph 2.3 – Quality Authority

Name of person: Raul Terceno

OK j) appoint deputies for key managerial personnel (see Note).

Name(s): Brenda Morse - Deputy Quality Manager, Bobby Hardy - Deputy VSTL Test Supervisor

OK♦ k) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.

Quality Program Manual, Paragraph 2.1 – Quality Policy and 5.5.3 – Internal Communication

NOTE Individuals may have more than one function and it may be impractical to appoint deputies for every function.

OK♦ **4.1.6** Top management shall ensure that the appropriate communication processes

are established within the laboratory and that communication takes place regarding the effectiveness of the management system.

Quality Program Manual, Paragraph 2.1 – Quality Policy and 5.5.3 – Internal Communication

4.2 Management system

4.2.1

OK a) The laboratory shall establish, implement and maintain a management system appropriate to the scope of its activities.

A2LA Addendum, Section 1.2 – Quality System

OK b) The laboratory shall document its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results.

A2LA Addendum, Section 1.2 – Quality System

X c) The system’s documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.

Quality Program Manual, Paragraph 2.1 – Quality Policy and 5.5.3 – Internal Communication

If both methods of documentation are used, one or the other will be identified as the primary source with the other having the status of a copy (historical, archive, working, distribution) – Primary Method__

Not apparent in the Quality documentation; no primary method was designated. __ Corrected on site – primary method is electronic storage – Wyle’s Storage Area Network Drive (SAND) will be used for the primary storage as shown n Paragraph 2.1 of WHVS07.A (Configuration Management Voting Systems Testing Data and documentation). _____

C **4.2.2** The laboratory’s management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named). The overall objectives shall be established, and shall be reviewed during management review.

Date of most recent quality manual: July 12, 2007

The quality policy statement shall be issued under the authority of top management. It shall include at least the following:

Wyle does not have a “concise” quality policy statement, rather, the entire section 2.1 (Quality Policy) of the Quality Program Manual.

OK a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers;

2.1 (Quality Policy) of the Quality Program Manual.

OK b) the management’s statement of the laboratory’s standard of service;

2.1 (Quality Policy) of the Quality Program Manual.

OK c) the purpose of the management system related to quality;

2.1 (Quality Policy) of the Quality Program Manual.

OK d) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and

2.1 (Quality Policy) of the Quality Program Manual.

OK◆ e) the laboratory management's commitment to comply with this handbook and to continually improve the effectiveness of the management system.

2.1 (Quality Policy) of the Quality Program Manual.

4.2.2 The following general management system procedures (required, but not limited to) should be available for assessor examination prior to the on-site visit (if requested) but in any event will be part of the on-site assessment process:

- a) internal audits and management review;
A2LA Addendum, Paragraphs 1.14 and 1.15
- b) writing and implementing system procedures;
ISO-QP-135 – Instructions, Procedures, Certification Reports
- c) writing and implementing system instructions;
ISO-QP-135 – Instructions, Procedures, Certification Reports
- d) staff training and individual development plans;
ISO-QP-320 – Training
- e) contract review;
ISO-QP-100 – Contract Review
- f) staff members who work at home and at alternate work sites outside the laboratory (e.g., telecommuting);
Not Applicable
- g) referencing NVLAP accreditation and use of the NVLAP symbol.
Procedure No. WHVS07 (Voting System Test Procedure) contains paragraph 13.0 entitled “Use of NVLAP Term, Logo and Symbol.”

NOTE The quality policy statement should be concise and may include the requirement that tests and/or calibrations shall always be carried out in accordance with stated methods and customers' requirements. When the test and/or calibration laboratory is part of a larger organization, some quality policy elements may be in other documents.

X◆ **4.2.3** Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improve its effectiveness.

4.2.1 (General) of the Quality Program Manual and 5.3 (Quality Policy) of the Quality Program Manual are appropriate.

4.2.3 The following program-specific procedures (required, but not limited to) should be available for assessor examination prior to the on-site visit (if requested) but in any event will be part of the on-site assessment process:

Note: This is expected to be done as part of the Technical Assessor review of the management system documentation before the on-site review.

- a) review of the vendor Technical Data Package (VSS-2002, Volume II, Section 2, VVSG-2005, Volume II, Section 2);
Procedure No. WHVS07 (Voting System Test Procedure), Paragraph 7.1
Technical Data Package Review)

b) selecting the laboratory staff for Certification test campaign;

Not apparent in the quality documentation – Corrected on site – Paragraph 6.0 (Test Reporting Procedure and Conditions) of Procedure No. WHVS07 (Voting System Test Procedure) was modified to address this issue.

c) writing a Certification Test Plan for first-time testing and testing of modified systems (VSS-2002, Volume II, Appendix A, VVSG-2005, Volume II, Appendix A);

Procedure No. WHVS07.13 – Master Test Plan exists.

d) writing Test Operation Procedures (VSS-2002, Volume II, Appendix A.6.4, VVSG-2005, Volume II, Appendix A 6.4);

ISO-QP-135 – Instructions, Procedures, Certification Reports

e) conducting testing at a customer's site (if the laboratory offers such services);

Procedure No. WHVS07 (Voting System Test Procedure), Paragraph 12 (Tests Conducted Outside of Wyle Laboratories)

f) writing a Certification Test Report (VSS-2002, Volume II, Appendix B, VVSG-2005, Volume II, Appendix B);

Procedure No. WHVS07 (Voting System Test Procedure), Paragraph 6.6 (Test Report)

g) reviewing the Configuration Management Plan (VSS-2002, Volume II, Section 2.11, VVSG-2005, Volume II, Section 2.11);

Procedure No. WHVS07 (Voting System Test Procedure), Paragraph 7.1 (Technical Data Package Review)

h) ensuring the protection of proprietary information against threat from persons outside the laboratory, from visitors to the laboratory, from laboratory personnel without a need to know, and from other unauthorized persons;

ISO-QP-180 (Control of Customer Furnished Material) covers this as well as 3.5 (Proprietary Data) and 6.1 (Facility Requirements) of the Voting System Test Procedure (WHSV07).

i) performing security testing; (VSS-2002, Volume I, 9.4.1.4, Volume II, Section 6.4, VVSG-2005, Volume II, Section 6.4)

Procedure No. WHVS07 (Voting System Test Procedure), Paragraph 7.8 (Security Testing)

j) cooperating with the EAC during test campaigns;

Procedure No. WHVS07 (Voting System Test Procedure), Paragraph 1.0 (Executive Summary)

k) witnessing of system build and installation

Procedure No. WHVS07.6 (VSTL Trusted Build of Voting Machines) covers this item

l) matrix cross-referencing the laboratory's test methods to the voting system standard. (provide sample in Annex). Specific test methods will be checked for compliance with the standard.
 Procedure No. WHVS07.13 – Master Test Plan and the Wyle Operating Procedures (WoPs) cover this item.

OK◆ 4.2.4 Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.

Sections 5.0 (Management Responsibility) and 5.5.3 (Internal Communication) of the Quality Program Manual are appropriate.

4.2.5

OK a) The quality manual shall include or make reference to the supporting procedures including technical procedures.

Quality Program Manual – Section 4.2 (Documentation Requirements)

OK b) It shall outline the structure of the documentation used in the management system.

Quality Program Manual – Section 4.2 (Documentation Requirements), Section 4.2.1 (General) covers the three levels of the Quality Management System.

OK 4.2.6 The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this handbook, shall be defined in the quality manual.

Section 1.2 (Quality System) of the ALA Addendum, Section 5.5 (Responsibilities, Authority, and Communication), and QP ISO-QP-010 (Organization and Responsibilities) are all appropriate.

OK◆ 4.2.7 Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.

1.15 (Management Reviews) of the A2LA Addendum and 5.6 (Management Review) of the QPM are appropriate.

4.3 Document control

4.3.1 General

OK The laboratory shall establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.

QPM, Section 4.2 (Documentation Requirements) and A2LA Addendum, Section 1.3 (Document Control) cover this item.

NOTE 1 In this context "document" could be policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written.

NOTE 2 The control of data related to testing and calibration is covered in 5.4.7. The control of records is covered in 4.13.

4.3.2 Document approval and issue

4.3.2.1

- OK a) All documents issued to personnel in the laboratory as part of the management system shall be reviewed and approved for use by authorized personnel prior to issue.

QPM, Section 4.2 (Documentation Requirements) and A2LA Addendum, Section 1.3 (Document Control) cover this item. Also, QP-120 (Document Control) is also appropriate.

- OK b) A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

Level 1 documentation is the QPM and the A2LA Addendum. The Table of Contents for the Quality Procedures is a master summary list of the Level 2 procedures with a document number, Revision status, and Description. A Level 3 summary is the Voting System Controlled Documentation Index (WHVS07.IND).

4.3.2.2 The procedure(s) adopted shall ensure that:

- OK a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed;

Section 4.2.3 (Control of Documents) of the QPM, Section 1.3 (Document Control) of the A2LA Addendum and QP-120 (Document Control) are all appropriate.

- OK b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;

Section 4.2.3 (Control of Documents) of the QPM, Section 1.3 (Document Control) of the A2LA Addendum and QP-120 (Document Control) are all appropriate.

- OK c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

Section 4.2.3 (Control of Documents) of the QPM, Section 1.3 (Document Control) of the A2LA Addendum and QP-120 (Document Control) are all appropriate.

- OK d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

Section 4.2.3 (Control of Documents) of the QPM, Section 1.3 (Document Control) of the A2LA Addendum and QP-120 (Document Control) are all appropriate.

4.3.2.3 Management system documents generated by the laboratory shall be uniquely identified. Such identification shall include:

OK

- OK a) the date of issue and/or revision identification,

Section 1.3 (Document Control) of the A2LA Addendum covers this item.

- OK b) page numbering,

Section 1.3 (Document Control) of the A2LA Addendum covers this item

- OK c) the total number of pages or a mark to signify the end of the document, and

Section 1.3 (Document Control) of the A2LA Addendum covers this item

- OK d) the issuing authority(ies).

Section 1.3 (Document Control) of the A2LA Addendum covers this item

4.3.3 Document changes

OK 4.3.3.1 Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.

Section 1.3 (Document Control) of the A2LA Addendum covers this item

OK 4.3.3.2 Where practicable, the altered or new text shall be identified in the document or the appropriate attachments.

Section 1.3 (Document Control) of the A2LA Addendum covers this item

4.3.3.3

OK a) If the laboratory's document control system allows for the amendment of documents by hand pending the reissue of the documents, the procedures and authorities for such amendments shall be defined.

ISO-QP-120, Paragraph 4.12 covers this.

OK b) Amendments shall be clearly marked, initialed and dated. A revised document shall be formally reissued as soon as practicable.

ISO-QP-120, Paragraph 4.12 covers this.

OK 4.3.3.4 Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.

CM VST Data and Documentation (WHVS07.A5) is appropriate for the voting system documentation.

4.4 Review of requests, tenders and contracts

OK 4.4.1 The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that:

The QPM calls out Section 7.2 (Customer-related Processes), the A2LA Addendum calls out 1.4 (Review of Requests, Tenders, and Contracts) plus ISO—QP-100 (Contract Review), and Internal Operating Procedure for the Contracts Department are appropriate procedures.

OK a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2);

The QPM calls out Section 7.2 (Customer-related Processes), the A2LA Addendum calls out 1.4 (Review of Requests, Tenders, and Contracts) plus ISO—QP-100 (Contract Review), and Internal Operating Procedure for the Contracts Department are appropriate procedures.

OK b) the laboratory has the capability and resources to meet the requirements;

The QPM calls out Section 7.2 (Customer-related Processes), the A2LA Addendum calls out 1.4 (Review of Requests, Tenders, and Contracts) plus ISO—QP-100 (Contract Review), and Internal Operating Procedure for the Contracts Department are appropriate procedures.

OK c) the appropriate test and/or calibration method is selected and is capable of meeting the customers' requirements (see 5.4.2).

The QPM calls out Section 7.2 (Customer-related Processes), the A2LA Addendum calls out 1.4 (Review of Requests, Tenders, and Contracts) plus

ISO—QP-100 (Contract Review), and Internal Operating Procedure for the Contracts Department are appropriate procedures.

OK d)

Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to the laboratory and the customer.

The QPM calls out Section 7.2 (Customer-related Processes), the A2LA Addendum calls out 1.4 (Review of Requests, Tenders, and Contracts) plus ISO—QP-100 (Contract Review), and Internal Operating Procedure for the Contracts Department are appropriate procedures.

4.4.1 The procedures for review of contracts shall include procedures to ensure that the customer understands that its products and systems must meet the requirements of HAVA, the VSS-2002, VVSG-2005, and the EAC.

Paragraph 14.0 (Review of requests, tenders and contracts) of Procedure No. WHSV07 (Voting System Test Procedure).

NOTE 1 The request, tender and contract review should be conducted in a practical and efficient manner, and the effect of financial, legal and time schedule aspects should be taken into account. For internal customers, reviews of requests, tenders and contracts can be performed in a simplified way.

NOTE 2 The review of capability should establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests and/or calibrations in question. The review may also encompass results of earlier participation in interlaboratory comparisons or proficiency testing and/or the running of trial test or calibration programs using samples or items of known value in order to determine uncertainties of measurement, limits of detection, confidence limits, etc.

NOTE 3 A contract may be any written or oral agreement to provide a customer with testing and/or calibration services.

OK **4.4.2** Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract.

Contracts IOP, Section 6.3 is appropriate.

4.4.2 The review shall include (but is not limited to): laboratory competencies and resources to provide the service, vendor-supplied documentation, tests to be conducted, test requested in addition to Certification Testing, and subcontracting

Paragraph 14.0 (Review of requests, tenders and contracts) of Procedure No. WHSV07 (Voting System Test Procedure).

NOTE For review of routine and other simple tasks, the date and the identification (e.g., the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for ongoing routine work performed under a general agreement with the customer, provided that the customer's requirements remain unchanged. For new, complex or advanced testing and/or calibration tasks, a more comprehensive record should be maintained.

OK 4.4.3 The review shall also cover any work that is subcontracted by the laboratory.

QPM, Section 4.1; IOP for Purchasing, and ISO QPs 140, 160, and 170 are all appropriate.

4.4.3 Procedures for the review of requests, tenders, and contracts should include provisions to ensure that any State Certification Testing does not replace or dilute the Qualification/National Certification Testing requirements.

Paragraph 14.0 (Review of requests, tenders and contracts) of Procedure No. WHSV07 (Voting System Test Procedure).

OK 4.4.4 The customer shall be informed of any deviation from the contract.

QPM Section 7.2 and Section 8.3 are appropriate.

4.4.4 When conducting a contract review, the VSTL should determine if there are any special or changed requirements from the EAC or from state or local election authorities.

Paragraph 14.0 (Review of requests, tenders and contracts) of Procedure No. WHSV07 (Voting System Test Procedure).

OK 4.4.5 If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.

QPM, Section 7.2.2 (Review of Requirements related to the product) is appropriate.

4.5 Subcontracting of tests and calibrations

OK 4.5.1 When a laboratory subcontracts work whether because of unforeseen reasons (e.g., workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g., through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this handbook for the work in question.

A2LA Addendum, paragraph 1.5 (Subcontracting of Test and Calibrations) covers this item.

4.5.1 Subcontracting of tests is the use of laboratory services outside of the VSTL to perform tests, e.g., electromagnetic compatibility testing, environmental testing, shock and vibration testing, FIPS 140 validation, and physical test instrument. The word subcontracting is not used to describe a

mechanism by which the laboratory employs staff members (see 5.2.7)

Paragraph 10.0 (Subcontracting of Tests) Procedure No. WHVS07 covers this item.

OK 4.5.2 The laboratory shall advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer, preferably in writing.

A2LA Addendum, paragraph 1.5 (Subcontracting of Test and Calibrations) covers this item.

4.5.2 All core voting system testing shall be conducted by a VSTL. If the VSTL subcontracts testing for any test within its scope of accreditation, the subcontracted laboratory shall also be an EAC-accredited VSTL authorized to do business in the United States.

Paragraph 10.0 (Subcontracting of Tests) Procedure No. WHVS07 covers this item.

OK 4.5.3 The laboratory is responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.

A2LA Addendum, paragraph 1.5 (Subcontracting of Test and Calibrations) covers this item.

4.5.3 Subcontractors for non-core testing do not need to be accredited under the VST LAP.

a. If laboratories accredited in another LAP are available for non-core testing, VSTLs shall use accredited laboratories.

Paragraph 10.0 (Subcontracting of Tests) Procedure No. WHVS07 covers this item.

b. When an accredited laboratory is not available for non-core testing, the VSTL shall conduct an audit of the subcontracted laboratory and shall document that the laboratory is competent and qualified for use.

Paragraph 10.0 (Subcontracting of Tests) Procedure No. WHVS07 covers this item.

OK 4.5.4 The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this handbook for the work in question.

A2LA Addendum, paragraph 1.5 (Subcontracting of Test and Calibrations) covers this item. Also, a register of competent subcontractors is available; it is part of the Approved Suppliers List (Level A).

4.5.4 When a VSTL subcontracts to another laboratory, the VSTL is responsible for ensuring that setup, configuration, testing, and reporting is competent, appropriate, and conducted by qualified people. The VSTL shall ensure:

a. The VSTL shall ensure that there are no gaps in the knowledge required to conduct the testing.
Paragraph 10.0 (Subcontracting of Tests) Procedure No. WHVS07 covers this item.

b. The VSTL is responsible for ensuring that the entire voting system is properly tested.
Paragraph 10.0 (Subcontracting of Tests) Procedure No. WHVS07 covers this item.

4.6 Purchasing services and supplies

OK **4.6.1** The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.

Quality Program Manual, Section 7.4 is the policy and paragraph 1.6 of the A2LA Addendum is the procedure for this issue.

4.6.2

OK a) The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements.

Quality Program Manual, Section 7.4 is the policy and paragraph 1.6 of the A2LA Addendum is the procedure for this issue.

OK b) Records of actions taken to check compliance shall be maintained.

Quality Program Manual, Section 7.4 is the policy and paragraph 1.6 of the A2LA Addendum is the procedure for this issue.

OK **4.6.3** Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.

The Quality Program Manual, Section 7.4 (Purchasing) and paragraph 1.6 (Purchasing Services and Supplies) are appropriate.

NOTE The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required and the management system standard under which they were made.

4.6.4

OK a) The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and
The Quality Program Manual, Section 7.4 (Purchasing) and paragraph 1.6 (and Purchasing Services and Supplies) are appropriate. Also, IOP for Purchasing and Subcontracting, Section 10 is pertinent.

OK b) shall maintain records of these evaluations and list those approved.
The Quality Program Manual, Section 7.4 (Purchasing) and paragraph 1.6 (and Purchasing Services and Supplies) are appropriate. Also, IOP for Purchasing and Subcontracting, Section 10 is pertinent.

4.7 Service to the customer

OK 4.7.1 The laboratory shall be willing to cooperate with customers or their representatives in clarifying the customer’s request and in monitoring the laboratory’s performance in relation to the work performed, provided that the laboratory ensures confidentiality to other customers.
Paragraph 5.2 (Customer Focus) of the QPM is appropriate. Also, 7.2 (Customer-Related Processes) and 8.2 (Monitoring and Measurement) of the QPM are pertinent. Also, Section 1.7 (Service to the Customer) of the A2LA Addendum is significant.

NOTE 1 Such cooperation may include:

- a) providing the customer or the customer's representative reasonable access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the customer;
- b) preparation, packaging, and dispatch of test and/or calibration items needed by the customer for verification purposes.

NOTE 2 Customers value the maintenance of good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the customer, especially in large assignments, should be maintained throughout the work. The laboratory should inform the customer of any delays or major deviations in the performance of the tests and/or calibrations.

OK◆ 4.7.2 The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analyzed to improve the management system, testing and calibration activities and customer service.
Paragraph 5.2 (Customer Focus) of the QPM is appropriate. Also, 7.2 (Customer-Related Processes) and 8.2 (Monitoring and Measurement) of the QPM are pertinent. Also, Section 1.7 (Service to the Customer) of the A2LA Addendum is significant

NOTE Examples of the types of feedback include customer satisfaction surveys and review of test or calibration reports with customers.

4.8 Complaints

OK 4.8.1 The laboratory shall have a policy and procedure for the resolution of complaints received from customers or other parties.

Paragraph 5.2 (Customer Focus) of the QPM is appropriate. Also, 7.2 (Customer-Related Processes) and 8.2 (Monitoring and Measurement) of the QPM are pertinent. Also, Section 1.8 (Complaints) of the A2LA Addendum is significant. Also, section 6.2.9 of the Internal Operating Procedure for Contracts covers customer complaints. ISO-QP-330 (Servicing of Customer Complaints) gives the responsibility to Contracts Administration for keeping the record of complaints.

- OK 4.8.2 Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also 4.11).

Paragraph 5.2 (Customer Focus) of the QPM is appropriate. Also, 7.2 (Customer-Related Processes) and 8.2 (Monitoring and Measurement) of the QPM are pertinent. Also, Section 1.8 (Complaints) of the A2LA Addendum is significant. Furthermore, section 6.2.9 of the Internal Operating Procedure for Contracts covers customer complaints. ISO-QP-330 (Servicing of Customer Complaints) gives the responsibility to Contracts Administration for keeping the record of complaints.

4.9 Control of nonconforming testing and/or calibration work

- OK 4.9.1 The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer. The policy and procedures shall ensure that:

Paragraph 8.3 (Control of Nonconforming Product) of the QPM is appropriate. ISO-QP-260 (Notice of Anomaly) is a pertinent procedure. Furthermore, Section 1.9 (Control of Nonconforming Testing and/or Calibration Work) lists other Wyle documentation that are appropriate.

- OK a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified;

ISO-QP-260 (Notice of Anomaly) is a pertinent procedure

- OK b) an evaluation of the significance of the nonconforming work is made;

ISO-QP-260 (Notice of Anomaly) is a pertinent procedure

- OK c) correction is taken immediately, together with any decision about the acceptability of the nonconforming work;

ISO-QP-260 (Notice of Anomaly) is a pertinent procedure

- OK d) where necessary, the customer is notified and work is recalled;

ISO-QP-260 (Notice of Anomaly) is a pertinent procedure

- OK e) the responsibility for authorizing the resumption of work is defined.

ISO-QP-260 (Notice of Anomaly) is a pertinent procedure

NOTE Identification of nonconforming work or problems with the management system or with testing and/or calibration activities can occur at various places within the management system and technical operations. Examples are customer complaints, quality control, instrument calibration, checking of consumable materials, staff observations or supervision, test report and calibration certificate checking, management reviews and internal or external audits.

- OK 4.9.2 Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its

own policies and procedures, the corrective action procedures given in 4.11 shall be promptly followed.

Paragraph 5.2.1 of ISO-QP-260 (Notice of Anomaly) is a specific pertinent procedure

4.10 Improvement

OK◆ The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

Paragraph 1.10 (Improvement) of the A2LA Addendum is appropriate. Also, Section 8.5 (Improvement) of the QPM addresses the issue as does 8.5.1 (Continual Improvement). Paragraph 5.4.2 (Quality Management System Planning) of the QPM addresses “other improvement opportunities.”

4.11 Corrective action

4.11.1 General

OK The laboratory shall establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.

Paragraph 8.5.2 (Corrective Action) of the Quality Program Manual addresses this comment. Also, 8.2.2 (Internal Audit) of the QPM addresses “corrective” actions. ISO-QP-270 is the Corrective and Preventive Action procedure that is appropriate. Paragraph 1.11 of the A2LA Addendum is entitled “Corrective Action” and it outlines appropriate quality documents that address this item.

NOTE A problem with the management system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, feedback from customers and from staff observations.

4.11.2 Cause analysis

OK The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

ISO-QP-270 is the Corrective and Preventive Action procedure that is appropriate.

NOTE Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration.

4.11.3 Selection and implementation of corrective actions

OK a) Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.

ISO-QP-270 is the Corrective and Preventive Action procedure that is appropriate. ISO-QP-270 includes a sample Corrective Action Request Form.n

- OK b) Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.

ISO-QP-270 is the Corrective and Preventive Action Procedure and it addresses this issue.

- OK c) The laboratory shall document and implement any required changes resulting from corrective action investigations.

ISO-QP-270 is the Corrective and Preventive Action Procedure and it addresses this issue.

4.11.4 Monitoring of corrective actions

- OK The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.

Paragraph 8.2.2 (Internal Audits) specifies that “Verification of corrective, preventive and other actions taken shall be performed and documented.”

4.11.5 Additional audits

- X Where the identification of nonconformities or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this handbook, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible.

No evidence in the quality documentation that the finding of a serious nonconformity drives the initiation of an internal audit.

NOTE Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit should be necessary only when a serious issue or risk to the business is identified.

4.12 Preventive action

4.12.1

- OK a) Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified.

Paragraph 8.5.3 (preventive action) of the QPM addresses this issue. ISO-QP-270 (Corrective and Preventive Action) goes into detail and it references a Preventive Action Plan/Request and Preventive Action Plan/Request Control Log; both of these were reviewed in detail in the May-2007 pre-assessment and found to be acceptable.

- OK◆ b) When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

Paragraph 8.5.3 (preventive action) of the QPM addresses this issue. ISO-QP-270 (Corrective and Preventive Action) goes into detail and it references a Preventive Action Plan/Request and Preventive Action Plan/Request Control Log; both of these were reviewed in detail in the May-2007 pre-assessment and found to be acceptable

OK 4.12.2 Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective.

Paragraph 8.5.3 (preventive action) of the QPM addresses this issue. ISO-QP-270 (Corrective and Preventive Action) goes into detail and it references a Preventive Action Plan/Request and Preventive Action Plan/Request Control Log; both of these were reviewed in detail in the May-2007 pre-assessment and found to be acceptable

NOTE 1 Preventive action is a proactive process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

NOTE 2 Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analyses and proficiency-testing results.

4.13 Control of records

4.13.1 General

OK 4.13.1.1 The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.

Paragraph 4.2.3 (Control of Documents) in the Quality Program Manual covers this issue as well as Paragraph 1.13 (Control of Records) in the A2LA Addendum. Appropriate procedures are QP ISO-QP-120 (Document Control) and QPISO-QP-130 (Control of Quality Records).

4.13.1.2

OK a) All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

Paragraph 4.9 of ISO-QP-130

OK b) Retention times of records shall be established.

Paragraph 4.10 of ISO-QP-130

NOTE Records may be in any media, such as hard copy or electronic media.

OK 4.13.1.3 All records shall be held secure and in confidence.

Paragraphs 4.6 and 4.7 of ISO-QP-130 cover this issue.

OK 4.13.1.4 The laboratory shall have procedures to protect and back up records stored electronically and to prevent unauthorized access to or amendment of these records.

Paragraph 4.13 of the A2LA Addendum specifies that “quality and technical records stored on the facility’s T-drive are backed up nightly Monday through Friday.”

4.13.2 Technical records

4.13.2.1

- OK a) The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period.

Covered in Paragraph 1.13 of the A2LA Addendum. Records are kept a minimum of two years as per 4.10 of ISO-QP-130. For the VSTL program, records will be kept a minimum of 5 years after the latest test report revision (Procedure No. WHVS07 – Paragraph 6.6 – Test Report)

- OK b) The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original.

Covered in Paragraph 1.13 of the A2LA Addendum. Records are kept a minimum of two years as per 4.10 of ISO-QP-130.

- C c) The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.

ISO-QP-220 (Quality Assurance Hold Points) and ISO-QP-200 (Test and Process Control) both cover this issue using the Test Control Record. The terms Test Control Record, traveler-type document, and Holdpoint should be defined in the Quality Program Manual.

NOTE 1 In certain fields it may be impossible or impracticable to retain records of all original observations.

NOTE 2 Technical records are accumulations of data (see 5.4.7) and information which result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, check sheets, work notes, control graphs, external and internal test reports and calibration certificates, customers' notes, papers and feedback.

- OK **4.13.2.2** Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.

Paragraph 1.13 (Control of Records) of the A2LA Addendum covers this issue.

4.13.2.3

- OK a) When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction.

Paragraph 1.13 (Control of Records) of the A2LA Addendum covers this issue.

- OK b) In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.

Paragraph 1.13 (Control of Records) of the A2LA Addendum covers this issue.

4.13.3 The Certification Test Report plus the laboratory's records of the certification test shall contain sufficient information to allow repeating, reproducing and/or auditing the entire certification test.

Paragraph 6.0 (Test Reporting Procedure and Conditions) and 6.6 (Test Report) of Procedure WHVS07 (Voting System Test Procedure) cover this item.

4.14 Internal audits

4.14.1

- OK a) The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this handbook. The internal audit program shall address all elements of the management system, including the testing and/or calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management.

Dates of most recent internal audit: July -2007; the internal audit schedule for 2007 was reviewed and found to be acceptable

Note to assessor: Attach a copy of the full internal audit schedule.

Paragraph 8.2.2 (Internal Audit) of the QPM was reviewed and found to cover this issue. Also, Paragraph 1.13 of the A2LA Addendum was reviewed and found to list the appropriate quality documentation covering this item.

- OK b) Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

Quality Procedure ISO-QP-310 (Certification of Auditors/Qualifications) covers this issue in paragraphs 4.2 and 4.3.

4.14.1 The internal audit shall cover the laboratory management system and the application of the management system to all laboratory activities, including compliance with NVLAP, HAVA, VSS-2002, VVSG-2005, contractual, laboratory management system, and any additional EAC requirements.

A2LA Addendum (Section 1.14) and ISO-QP-300 (Quality Audits) cover this issue.

NOTE The cycle for internal auditing should normally be completed in one year.

- OK **4.14.2** When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify customers in writing if investigations show that the laboratory results may have been affected.

Covered in paragraph 8.2.2 (Internal Audit) of the QPM.

- OK **4.14.3** The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.

Paragraphs 4.5, 4.6, and 4.7 of the ISO-QP-300 (Quality Audits) cover this item.

OK 4.14.4 Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

Covered in paragraph 8.2.2 (Internal Audit) of the QPM.

4.15 Management reviews

OK 4.15.1 In accordance with a predetermined schedule and procedure, the laboratory's top management shall periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements.

Date(s) of most recent management review: March 15, 2007

What is the review schedule? Annually

The review shall take account of:

Paragraph 1.15 of the A2LA Addendum covers the items below. And 5.6 (Management Review) of the QPM also covers the topic.

OK a) the suitability of policies and procedures;

Paragraph 1.15 of the A2LA Addendum

OK b) reports from managerial and supervisory personnel;

Paragraph 1.15 of the A2LA Addendum

OK c) the outcome of recent internal audits;

Paragraph 1.15 of the A2LA Addendum

OK d) corrective and preventive actions;

Paragraph 1.15 of the A2LA Addendum

OK e) assessments by external bodies;

Paragraph 1.15 of the A2LA Addendum

OK f) the results of interlaboratory comparisons or proficiency tests;

Paragraph 1.15 of the A2LA Addendum

OK g) changes in the volume and type of the work;

Paragraph 1.15 of the A2LA Addendum

OK h) customer feedback;

Paragraph 1.15 of the A2LA Addendum

OK i) complaints;

Paragraph 1.15 of the A2LA Addendum

OK♦ j) recommendations for improvement;

Paragraph 1.15 of the A2LA Addendum

OK k) other relevant factors, such as quality control activities, resources and staff training.

Paragraph 1.15 of the A2LA Addendum

4.15.1 The laboratory shall perform at least one management review prior to the first on-site assessment.

Management Review was completed March 15, 2007.

NOTE 1 A typical period for conducting a management review is once every 12 months.

NOTE 2 Results should feed into the laboratory planning system and should include the goals, objectives and action plans for the coming year.

NOTE 3 A management review includes consideration of related subjects at regular management meetings.

4.15.2

OK a) Findings from management reviews and the actions that arise from them shall be recorded.

Paragraph 1.15 of the A2LA Addendum

OK b) The management shall ensure that those actions are carried out within an appropriate and agreed timescale.

Paragraph 1.15 of the A2LA Addendum

5 Technical requirements for accreditation

5.1 General

5.1.1 Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from:

- i) human factors (5.2);
- ii) accommodation and environmental conditions (5.3);
- iii) test and calibration methods and method validation (5.4);
- iv) equipment (5.5);
- v) measurement traceability (5.6 and Annex B);
- vi) sampling (5.7);
- vii) the handling of test and calibration items (5.8).

The quality manual shall contain, or refer to, documentation that describes and details the laboratory's implementation of procedures covering all of the technical requirements in NIST Handbook 150 and this handbook (150-22).

N/A **5.1.2** The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations. The laboratory shall take account of these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.

A2LA Addendum, Section 2.1, policy statement, The last sentence is improperly formed (corrected)

5.2 Personnel

5.2.1

- OK a) The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates.

Paragraph 6.2.2 (Competence, Awareness, and Training) of the Quality Program Manual covers this item as well as Section 2.2 (Personnel) of the A2LA Addendum. ISO-QP-320 (Training) is also appropriate.

- OK b) When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

Paragraph 6.2.1 (General) is appropriate as well as Section 2.2 of the A2LA Addendum

5.2.2 The laboratory shall maintain a list of personnel designated to fulfill NVLAP requirements including

**Laboratory Director: Joe Hazeltine, Senior Director TE&R (East) (leaving soon)
 Technical Directory: Frank Padilla, Voting Systems Program Manager/Project Engineer**

Authorized Representative:

- a. Frank Padilla, Voting Systems Program Manager/ Project Engineer**

Approved Signatories:

- a. For Test Plans and Reports, Bobby Hardy, Manager EMI/EMC, Product Safety, & Voting Sy**
b. For Test Campaign Contracts, Dawn Bates
c. For General Contracts: Bruce Bateman, Contracts (Manager)

Team Leaders: (not used) See Project Engineers on WHVS07.A1 Voting Systems Organization Chart.

Quality Manager: Raul Terceno, Manager Quality (East)

NOTE 1 In some technical areas (e.g., nondestructive testing) it may be required that the personnel performing certain tasks hold personnel certification. The laboratory is responsible for fulfilling specified personnel certification requirements. The requirements for personnel certification might be regulatory, included in the standards for the specific technical field, or required by the customer.

NOTE 2 The personnel responsible for the opinions and interpretation included in test reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing carried out, also have:

- i) relevant knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service;

Covered in the A2LA Addendum, Section 2.2 (Personnel)

5.2.3 The laboratory shall notify both NVLAP and the EAC within 30 days of any change in key personnel. When key personnel are added to the staff, the notification of changes shall include a current resume for each new staff member.

Covered in Procedure No. WHVS07 (Voting System Test Procedure), Paragraph 1.0 (Executive Summary).

OK

- ii) knowledge of the general requirements expressed in the legislation and standards; and

OK

- iii) an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc. concerned.

OK

5.2.2

- OK a) The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel.

Covered in the A2LA Addendum, Section 2.2 (Personnel)

- OK b) The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel.

Policy Covered in the A2LA Addendum, Section 2.2 (Personnel)
QA holds a list of Minimum Employee Training Requirements for Dept 545 for general training requirements.
WHSVS07.T22 Training and Qualification Matrix

- OK c) The training program shall be relevant to the present and anticipated tasks of the laboratory.

Covered in the A2LA Addendum, Section 2.2 (Personnel)

- C♦ d) The effectiveness of the training actions taken shall be evaluated.

A2LA Addendum, Section 2.2 (Personnel) on a policy level. The procedures are not documented but expected to be recovered as part of the reviews (management, anomaly requests, non-conformance, complaints, etc) and corrective actions process. Only documented instructions are in Quality Directive XVI Tac 1, Atch 7.1 Sec 5.3 (corrective action report resolution).

5.2.3

- OK a) The laboratory shall use personnel who are employed by, or under contract to, the laboratory.

Covered in the A2LA Addendum, Section 2.2 (Personnel)

- OK b) Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's management system.

- OK **5.2.4** The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.

Covered in the A2LA Addendum, Section 2.2 (Personnel).Also, WHVS07.A2 (Voting System Job Descriptions) is also pertinent.

5.2.4 Laboratories shall document the required qualifications for each staff position.. The staff information may be kept in the official personnel folders or in separate, official folders that contain only the information that the NVLAP assessors need to review.
WHVS07.T22 provides the Wyle 545 Training Matrix

NOTE Job descriptions can be defined in many ways. As a minimum, the following should be defined:

- i) the responsibilities with respect to performing tests and/or calibrations;

Covered in the A2LA Addendum, Section 2.2 (Personnel). Verified in Job Description for Project Engineer
- ii) the responsibilities with respect to the planning of tests and/or calibrations and evaluation of results;
X

Covered in the A2LA Addendum, Section 2.2 (Personnel) Not documented in Job Description/Task (corrected)
- iii) the responsibilities for reporting opinions and interpretations;

Covered in the A2LA Addendum, Section 2.2 (Personnel) Verified in Job Description for Project Engineer
- iv) the responsibilities with respect to method modification and development and validation of new methods;

Covered in the A2LA Addendum, Section 2.2 (Personnel)
- v) expertise and experience required;

Covered in the A2LA Addendum, Section 2.2 (Personnel) Provided under 'Qualifications'
- vi) qualifications and training programs;

Covered in the A2LA Addendum, Section 2.2 (Personnel)
- vii) managerial duties.

Covered in the A2LA Addendum, Section 2.2 (Personnel)

5.2.5

- OK a) The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment.

ISO-QP-010, A2LA Addendum, Section 2.2 Policy.
- OK b) The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel.

ISO-QP-130 and 320, The Quality Assurance Manager has responsibility to direct and control identification of qualification of individuals.
WHVS07.T22
- C c) This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.

5.2.6
X
5.2.7
OK
5.2.8
OK
5.2.9
OK

ISO-QP-130 and 320. Confirmed on Training Record (WH-1145) and Qualification and Training Matrix.
5.2.5 a. The laboratory shall have documented a detailed description of its training program for new and current staff members.

545 Minimum Qualifications, Training for all employees in Dept 545.
Systems Training Matrix, Training specific to Voting Systems testing
Program Manual ISO-QP-320. Trainings are defined in WHVS067.Tx for Accuracy Testing, Acoustic Testing, Anomaly Report, EMI, Environmental Testing, FCC, Functional Configuration Audit, Physical Configuration Audit, Product Safety Testing, Receipt and Inspection, Security, Source Code Review, Systems Integration, Technical Data Package, Telecommunications, Test Plan Development, Witness Build, WOPS, Wyle Time Keeping, Voting Systems Required Reading, and Security Training. *WHVS07.T11 and T23 Security Training are identical.*

b. Each new staff member shall be trained for assigned duties.

Voting Systems Training Matrix WHVS07.t22
Quality Program Manual ISO-QP-320

c. The training program shall be updated and current staff members shall be retrained when the VSS-2002 and VVSG-2005 changes, or when the individuals are assigned new responsibilities

Provided through a Required Reading List in Quality Program Manual ISO-QP-320. Also, WHVS07, Section 1 provides for general updates and changes. *Does not provide a planned response for cover major changes such as a move to VVSG-200x.*

5.2.6 a. The laboratory shall review annually the competence of each staff member for each test method the staff member is authorized to conduct

HR, Wyle Employee Handbook.. *Challenged by Voting Systems Program Manager. The review administered at the test method level but at the Core areas identified in the WHVS07.T22. M claims an undue burden for over 140 test methods in current test method program. However ever Core Area/Test Method is currently required of every Project Engineer.*

5.2.6 b. A record of the annual review of each staff member shall be dated and signed by the supervisor and the employee.

Reviewed records for Frank Padilla and two interviewees.

5.2.7 Individuals hired to perform testing activities are sometimes referred to as *subcontractors*. NVLAP does not make a distinction between full-time laboratory employees and individuals hired on a contract. NVLAP requires that the VSTL maintain responsibility for and control of any work performed within its scope of accreditation.

To that end, the VSTL shall ensure all individuals performing testing activities satisfy all NVLAP requirements, irrespective of the means by which individuals are compensated (e.g., the VSTL shall ensure all test personnel receive proper training and are subject to annual performance reviews, etc.).

WGVS96 Sec 11, policy

5.2.8 The records for each person having an effect on the outcome of the testing shall include:

a) position description;
 HR and QA

b) resume/CV/bio to match the person to the position;
 HR

c) duties assigned;
 HR

d) annual competence review;

Quality

Test Control Rec

Does not

HR
 e) training records and training plans.
 Training , Reviewed for Frank Padilla,

NVLAP Note: This requirement also applies to Approved Signatories (see 1.5.2).

5.3 Accommodation and environmental conditions

5.3.1

- OK a) Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations.

Section 6.4 (Work Environment) of the QPM is appropriate as well as Paragraph 2.3 (Accommodation and Environmental Conditions) in the A2LA Addendum. Additional documentation includes Section 6.3 (Infrastructure) of the QPM and ISO-QP-230 (Control of Measuring and Test Equipment) and Safety Procedure SP-G-007 (Safety and Housekeeping Inspections).

The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility.

Section 6.4 (Work Environment) of the QPM is appropriate as well as Paragraph 2.3 (Accommodation and Environmental Conditions) in the A2LA Addendum. Additional documentation includes Section 6.3 (Infrastructure) of the QPM and ISO-QP-230 (Control of Measuring and Test Equipment) and Safety Procedure SP-G-007 (Safety and Housekeeping Inspections).

- OK b) The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented.

Section 6.4 (Work Environment) of the QPM is appropriate as well as Paragraph 2.3 (Accommodation and Environmental Conditions) in the A2LA Addendum. Additional documentation includes Section 6.3 (Infrastructure) of the QPM and ISO-QP-230 (Control of Measuring and Test Equipment) and Safety Procedure SP-G-007 (Safety and Housekeeping Inspections).

5.3.1 The laboratory shall have adequate facilities to conduct the voting system testing that it offers. If testing activities are conducted at more than one location, all locations shall meet the NVLAP requirements.
WHVS07 Section 6.1 (Facility Requirements) and 12 (Tests Conducted outside of Wyle Laboratories) cover this item.

5.3.2

- OK a) The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where

they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned.

Section 6.4 (Work Environment) of the QPM is appropriate as well as Paragraph 2.3 (Accommodation and Environmental Conditions) in the A2LA Addendum.

- OK b) Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.

A2LA Addendum, Section 2.3. ISO-QP-230 for conditions out of tolerance.

[5.3.2 A protection system shall be in place to safeguard customer proprietary hardware, software, test data, electronic and paper records, and other materials. This system shall protect the proprietary materials and information from personnel outside the laboratory, visitors to the laboratory, laboratory personnel without a need to know, and other unauthorized persons.](#)

WHVS07 Section 6.1 (Facility Requirements) also WHVSP01 (Policy – Acceptable Computer and Network Use) and WHVSP02 (Policy- Network Security).

- C 5.3.3 There shall be effective separation between neighboring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.

Paragraph 2.3 (Accommodation and Environmental Conditions) in the A2LA Addendum covers this.

[5.3.3 Laboratories shall have systems \(e.g., firewall, intrusion detection\) in place to protect internal systems from untrusted external entities. The laboratory shall have regularly updated protection for all systems against viruses and other malware.](#)

WHVS07, Section 6.1 (Facility Requirements) and also also WHVSP01 (Policy – Acceptable Computer and Network Use) and WHVSP02 (Policy- Network Security) cover this item.

A tour of the computer server was done; it is located in a separate building on the Wyle 145-acre site. It is part of the corporate financial building (Building 33). The front door to the building was unlocked and no electronic security is available at the building in non-business hours. Although the computer server for the voting system program is in a computer room that has a locked (cyber locked) access with limited personnel entry, the offices going to that room appeared empty and there was a delay before anyone appeared to challenge our entry

- OK 5.3.4 Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances.

Paragraph 2.3 (Accommodation and Environmental Conditions) in the A2LA Addendum covers this item.

[5.3.4 If the laboratory is conducting multiple, simultaneous tests, it shall maintain a system of separation between the products of different customers.](#)

This includes the product itself, the test platform, peripherals, documentation, electronic media, manuals, and records.

WHVSP01 (Policy – Acceptable Computer and Network Use) and WHVSP02 (Policy- Network Security) cover this item.

OK 5.3.5 Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.

5.3.6 OK **Section 2.3 of the A2LA Addendum addresses this. Also, Safety Procedure SP-G-007 (Safety and Housekeeping Inspections) is appropriate.**

5.3.5 If testing activities will be conducted outside of the laboratory, the management system shall include procedures for conducting activities at customer sites or other off-site locations. For example, procedures may explain how to secure the site, where to store records and documentation, and how to control access to the test facility.

WHVS07 Section 6.1 (Facility Requirements) and 12 (Tests Conducted outside of Wyle Laboratories) cover this item

5.3.6 If the laboratory is conducting its tests at a customer site or other location outside the laboratory facility, the environment shall conform, as appropriate, to the requirements for a laboratory environment. If a customer's system on which a test is conducted is potentially open to access by unauthorized entities during test, the VSTL shall control the test environment. This is to ensure that the systems are in a defined state compliant with the requirements for the test before starting to perform testing work and that the systems ensure that unauthorized entities do not gain access during testing.

WHVS07 Section 6.1 (Facility Requirements) and 12 (Tests Conducted outside of Wyle Laboratories) cover this item

5.4 Test and calibration methods and method validation

5.4.1 General

OK a) The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.

In the QPM, 8.0 (Measurement, Analysis, and Improvement), 8.1 (General), and 8.2.3 (Monitoring and Measurement of Processes) are all pertinent. Also, paragraph 2.4 (Test and Calibration Methods and Method Validation) of the A2LA Addendum is appropriate.

OK b) The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations.

Paragraph 2.4 (Test and Calibration Methods and Method Validation) of the A2LA Addendum is appropriate

- OK c) All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel (see 4.3).

Paragraph 2.4 (Test and Calibration Methods and Method Validation) of the A2LA Addendum is appropriate

- OK d) Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.

Paragraph 2.4 (Test and Calibration Methods and Method Validation) of the A2LA Addendum is appropriate

5.4.1 The test methods for this program are given in the VSS-2002 and VVSG-2005. In the VSS-2002 and VVSG-2005, there are specified test methods, test methods that require adaptation, and requirements for which the laboratory shall have to develop test methods. When the EAC publishes amendments or augmentations to the standards or guidelines the laboratory shall develop procedures for implementation of the new requirements
The laboratory shall develop procedures for implementation of the new requirements when the EAC amends or augments the VSS-2002

Note: VVSG 2005 is an amendment to the VSS-2002.

WHVS07 (Voting System Test Procedure), Section 1 (Executive Summary) covers this issue. Procedures are provided by WHVS07.A5

NOTE International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used as published by the operating staff in a laboratory. It may be necessary to provide additional documentation for optional steps in the method or additional details.

5.4.2 Selection of methods

- OK a) The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so.

A2LA Addendum, Section 2.4 (Test and Calibration Methods and Method Validation) is appropriate. ISO-QP-230 (Control of Measuring and Test Equipment) also covers this item.

- OK b) When necessary, the standard shall be supplemented with additional details to ensure consistent application.

A2LA Addendum, Section 2.4 (Test and Calibration Methods and Method Validation) is appropriate.

- OK c) When the customer does not specify the method to be used, the laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Laboratory-developed methods or methods

adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated.

A2LA Addendum, Section 2.4 (Test and Calibration Methods and Method Validation) is appropriate

OK d) The customer shall be informed as to the method chosen.

A2LA Addendum, Section 2.4 (Test and Calibration Methods and Method Validation) is appropriate

OK e) The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated.

A2LA Addendum, Section 2.4 (Test and Calibration Methods and Method Validation) is appropriate. WHSV07 Section 6.5 also.

OK f) The laboratory shall inform the customer when the method proposed by the customer is considered to be inappropriate or out of date.

A2LA Addendum, Section 2.4 (Test and Calibration Methods and Method Validation) is appropriate

5.4.2 Where the laboratory has developed or modified test methods to meet the requirements of the VSS-2002 and VVSG-2005, validation of the test methods shall be referenced in the test report.

WHVS07 (Voting System Test Procedure) covers this in Section 6.6 (Test Report).

5.4.3 Laboratory-developed methods

OK a) The introduction of test and calibration methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources.

A2LA Addendum, Section 2.4 (Test and Calibration Methods and Method Validation) is appropriate.

OK b) Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured.

A2LA Addendum, Section 2.4 (Test and Calibration Methods and Method Validation) is appropriate

5.4.3 For the purposes of achieving product certification under HAVA, laboratories shall comply with interpretations of the test methods as provided by the EAC.

WHVS07 (Voting System Test Procedure) covers this in Section 6.6 (Test Report).

When exceptions to the testing methodology may be necessary for technical reasons, the laboratory shall ask the EAC for an interpretation, the customer shall be informed and details of an interpretation shall be described in the test report.

WHVS07 (Voting System Test Procedure), Section 6.4 (Test Operations Procedures)

5.4.4 Non-standard methods

- OK a) When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test and/or calibration.

A2LA Addendum, Section 2.4 (Test and Calibration Methods and Method Validation) is appropriate

- X b) The method developed shall have been validated appropriately before use.

A2LA Addendum, Section 2.4 (Test and Calibration Methods and Method Validation) is appropriate.

5.4.4 As a part of the testing procedure, the laboratory shall describe by whom and how the voting system will be configured. If the customer configures any part of the voting system, then the laboratory shall verify the configuration, including all software.

WHVS07 (Voting System Test Procedure), Section 6.0 (Test Reporting Procedure and Conditions) cover this item. The information block indicating the condition of the equipment when received was missing. Corrected on site.

NOTE For new test and/or calibration methods, procedures should be developed prior to the tests and/or calibrations being performed and should contain at least the following information:

- a) appropriate identification;
OK
- b) scope;
OK, labeled as Applicability in the WOPs.
- c) description of the type of item to be tested or calibrated;
OK, labeled as Applicability in the WOPs
- d) parameters or quantities and ranges to be determined;
OK, example found in WOP 29, Electrical Supply
- e) apparatus and equipment, including technical performance requirements;
Example in WOP 21, "Requires a test chamber" needs to be more specific and provide reference to requiring access to the equipment during the test.
- f) reference standards and reference materials required;
OK, example in WOP 1
- g) environmental conditions required and any stabilization period needed;
OK, example in WOP 21 Environmental Operating Test Procedures
- h) description of the procedure, including:
 - i) affixing of identification marks, handling, transporting, storing and preparation of items,
OK
 - ii) checks to be made before the work is started,
OK
 - iii) checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use,
OK

	iv) the method of recording the observations and results,
	OK
	v) any safety measures to be observed;
	None have been identified.
i)	criteria and/or requirements for approval/rejection;
	OK
j)	data to be recorded and method of analysis and presentation;
	OK
k)	the uncertainty or the procedure for estimating uncertainty.
	None has been identified at this time

5.4.5 Validation of methods

5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

5.4.5.2

C

a) The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.

A2LA Addendum, Paragraph 2.4 (Test and Calibration Methods and Method Validation) and QPM Section 7.5.2 provide general policy. WHVS07, Section 6.5 directs that the method should be tried before used and validated by a review of the procedure by two qualified observers. The validation procedures are not defined at a level to determine if the test method is appropriate to reveal the characteristics expected of the product by objective evidence See the note 2 below and note 1 and 2 after 5.4.5.3 below

X

b) The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

Quality Directive Number IX-1(Control of Special Processes and Validation of Non-Standard Methods), Attachment 7.2 (Instructions for Validation of Non-Standard Methods) covers t his item. WHVS07 Section 6.6 requires the validation be reported but the WOPs do not record the “results obtained, the procedure used for validation, and a statement as to whether the method is fit for intended use.” [svf][Corrected on-site: WHVS07.16, Sec 2]

5.4.5 Testing may be conducted at the customer site, the laboratory or another location that is mutually agreed to by the laboratory and the customer. When testing activities are conducted outside the laboratory, the laboratory shall have additional procedures to ensure the integrity of all tests and recorded results. These procedures shall also ensure that the same requirements that apply in the laboratory and its facility are maintained at the non-laboratory site.

WHVS07 Sectlion 12 (Tests Conducted outside of Wyle Laboratories), Procedures are not well defined beyond performing an inspection of the location

NOTE 1 Validation may include procedures for sampling, handling and transportation.

NOTE 2 The techniques used for the determination of the performance of a method should be one of, or a combination of, the following:

- i) calibration using reference standards or reference materials;
OK
- ii) comparison of results achieved with other methods;
OK
- iii) interlaboratory comparisons;
OK
- iv) systematic assessment of the factors influencing the result;
OK
- v) assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.
OK

NOTE 3 When some changes are made in the validated non-standard methods, the influence of such changes should be documented and, if appropriate, a new validation should be carried out.

OK **5.4.5.3** The range and accuracy of the values obtainable from validated methods (e.g., the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the customers' needs.

A2LA Addendum, Section 2.4 (Test and Calibration Methods and Method Validation) covers this item.

NOTE 1 Validation includes specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity.

NOTE 2 As method-development proceeds, regular review should be carried out to verify that the needs of the customer are still being fulfilled. Any change in requirements requiring modifications to the development plan should be approved and authorized.

NOTE 3 Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g., accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information.

5.4.6 Estimation of uncertainty of measurement

OK **5.4.6.1** A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.

A2LA Addendum, Section 2.4 (Test and Calibration Methods and Method Validation) covers this item.

OK **5.4.6.2** Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.

A2LA Addendum, Section 2.4 (Test and Calibration Methods and Method Validation) covers this item.

NOTE 1 The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:

- i) the requirements of the test method;
OK
- ii) the requirements of the customer;
OK
- iii) the existence of narrow limits on which decisions on conformity to a specification are based.
OK

NOTE 2 In those cases where a well recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (see 5.10).

C **5.4.6.3** When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.

A2LA Addendum, Section 2.4 (Test and Calibration Methods and Method Validation) covers this item. Also, Paragraph 6.5 (Test Method Validation) of Procedure No. WHVS07 addresses this issue.

5.4.4 As a part of the testing procedure, the laboratory shall describe by whom and how the voting system will be configured. If the customer configures any part of the voting system, then the laboratory shall verify the configuration, including all software.

WHVS07, Sec 6.0 specifies that the voting system shall be installed by Wyle personnel.

5.4.6 The laboratory shall clearly identify any test methods included in the test campaign that are outside of the laboratory's scope of accreditation. .

WHVS07, Sec 6.6 3rd para references specific case of state unique test requirements are to be labeled. Location for identifying test methods (format, what to include such as this status) in the Test Plan in WHVS07.13 sec 1.3 WHVS07TR Test Report sec 5.1

Cross reference listed this incorrectly as N/A. WHVS07, Sec 6.6 3rd paragraph references specific case of state unique test requirements

are to be labeled but needs to be expanded for state or vendor requested.

NOTE 1 Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator.

NOTE 2 The predicted long-term behavior of the tested and/or calibrated item is not normally taken into account when estimating the measurement uncertainty.

NOTE 3 For further information, see ISO 5725 and the Guide to the Expression of Uncertainty in Measurement (see 1.4).

NVLAP Note: *ANSI/NCSL Z540-2-1997 and NIST Technical Note 1297, 1994 edition, are considered to be equivalent to the Guide to the Expression of Uncertainty in Measurement (GUM).*

5.4.7 Control of data

X 5.4.7.1 Calculations and data transfers shall be subject to appropriate checks in a systematic manner.

Not apparent in the quality documentation.

5.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:

OK a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;

ISO-QP-235 (Software Control) covers this item. Paragraph 7.6(Control of Monitoring and Measuring Devices) in the QPM covers this issue.

OK b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;

WHVSP01 (Policy – Acceptable Computer and Network Use) covers this issue for Voting Systems.

OK c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.

WHVSP01 (Policy – Acceptable Computer and Network Use) covers this issue for Voting Systems.

NOTE Commercial off-the-shelf software (e.g., word processing, database and statistical programs) in general use within their designed application range may be considered to be sufficiently validated. However, laboratory software configuration/modifications should be validated as in 5.4.7.2 a).

5.5 Equipment

5.5.1

- OK a) The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data).

Covered in the QPM, Section 7.6 (Control of Monitoring and Measuring Devices). Also, covered under Paragraph 2.5 (Equipment) in the A2LA Addendum.

- OK b) In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this handbook are met.

Covered in the QPM, Section 7.6 (Control of Monitoring and Measuring Devices). Also, covered under Paragraph 2.5 (Equipment) in the A2LA Addendum.

5.5.1 For the purposes of this section “equipment” is defined as test equipment used in the testing process. Test equipment includes software and hardware products or other assessment mechanisms used by the laboratory to support the testing of products and systems.

Definition for 150-22 purposes.

5.5.2

- OK a) Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned.

Covered in the QPM, Section 7.6 (Control of Monitoring and Measuring Devices). Also, covered under Paragraph 2.5 (Equipment) in the A2LA Addendum.

- OK b) Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on the results.

Covered in the QPM, Section 7.6 (Control of Monitoring and Measuring Devices). Also, covered under Paragraph 2.5 (Equipment) in the A2LA Addendum.

- OK c) Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use (see 5.6).

Covered in the QPM, Section 7.6 (Control of Monitoring and Measuring Devices). Also, covered under Paragraph 2.5 (Equipment) in the A2LA Addendum.

5.5.2 The laboratory shall document and maintain records on all test equipment used during testing. The laboratory shall have procedures to configure and operate all equipment within its control.

WHVS07 Sec 6.1 policy. WHVS07.T10, WOP 2 cover this.

OK 5.5.3 Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.

Covered in the QPM, Section 7.6 (Control of Monitoring and Measuring Devices). Also, covered under Paragraph 2.5 (Equipment) in the A2LA Addendum.
5.5.3 Equipment used during the conduct of testing shall be under configuration control. The laboratory shall have procedures to ensure that any equipment used for testing is in a known state prior to use for testing. WHVS07 Sec 6.1 policy. WOP 25 Procedures Configuration Control/Management.

OK 5.5.4 Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.

Covered in the QPM, Section 7.6 (Control of Monitoring and Measuring Devices). Also, covered under Paragraph 2.5 (Equipment) in the A2LA Addendum.
5.5.3 Any software test tools shall be validated to be sure that they are accurately testing to the standard. They shall also be examined to ensure they do not interfere with the conduct of the test and do not modify or impact the integrity of the product under test in any way. VSS-2002 and VVSG-2005 require the documentation of the test software and supporting hardware in the certification.

 WHVS07, Section 3, Materials required for testing – not supported?.
 WHSV10 ?

OK 5.5.5 Records shall be maintained of each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following:

Covered in the QPM, Section 7.6 (Control of Monitoring and Measuring Devices). Also, covered under Paragraph 2.5 (Equipment) in the A2LA Addendum.

OK a) the identity of the item of equipment and its software;

OK b) the manufacturer's name, type identification, and serial number or other unique identification;

OK c) checks that equipment complies with the specification (see 5.5.2);

OK d) the current location, where appropriate;

OK e) the manufacturer's instructions, if available, or reference to their location;

OK f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;

OK g) the maintenance plan, where appropriate, and maintenance carried out to date;

OK h) any damage, malfunction, modification or repair to the equipment.

OK 5.5.6 The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.

QPM, Paragraph 7.6 covers this.

NOTE Additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations or sampling.

5.5.7

OK a) Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly.

Covered in the QPM, Section 7.6 (Control of Monitoring and Measuring Devices). Also, covered under Paragraph 2.5 (Equipment) in the A2LA Addendum.

OK b) The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure (see 4.9).

Covered in the QPM, Section 7.6 (Control of Monitoring and Measuring Devices). Also, covered under Paragraph 2.5 (Equipment) in the A2LA Addendum.

OK 5.5.8 Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

Covered in the QPM, Section 7.6 (Control of Monitoring and Measuring Devices). Also, covered under Paragraph 2.5 (Equipment) in the A2LA Addendum.

OK 5.5.9 When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

Covered in the QPM, Section 7.6 (Control of Monitoring and Measuring Devices). Also, covered under Paragraph 2.5 (Equipment) in the A2LA Addendum.

OK 5.5.10 When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure.

Covered in the QPM, Section 7.6 (Control of Monitoring and Measuring Devices). Also, covered under Paragraph 2.5 (Equipment) in the A2LA Addendum.

OK 5.5.11 Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e.g., in computer software) are

correctly updated.
Covered in the QPM, Section 7.6 (Control of Monitoring and Measuring Devices). Also, covered under Paragraph 2.5 (Equipment) in the A2LA Addendum.

OK 5.5.12 Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.

Covered in the QPM, Section 7.6 (Control of Monitoring and Measuring Devices). Also, covered under Paragraph 2.5 (Equipment) in the A2LA Addendum.

5.6 Measurement traceability

5.6.1 General

OK a) All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service.

Covered in the QPM, Section 7.6 (Control of Monitoring and Measuring Devices). Also, covered under Paragraph 2.6 (Traceability) in the A2LA Addendum.
 a. All developed test methods and tests performed within the test campaign must be traceable to the V and VVSG-2005.
Defined within WOP

X b) The laboratory shall have an established program and procedure for the calibration of its equipment.

Covered in the QPM, Section 7.6 (Control of Monitoring and Measuring Devices). Also, covered under Paragraph 2.5 (Equipment) in the A2LA Addendum.
 b. This validation shall be documented (e.g. cross-reference matrix).
 WOP 24a creates a cross-reference matrix as a base for showing how requirements are to be met but n show which method is to be used)

NOTE Such a program should include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform tests and calibrations.

NVLAP Note: See Annex B for requirements for the implementation of traceability policy in NVLAP-accredited laboratories.

5.6.2 Specific requirements

5.6.2.1 Calibration

5.6.2.1.1

N/A a) For calibration laboratories, the program for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements

made by the laboratory are traceable to the International System of Units (SI) (*Système international d'unités*).

A calibration laboratory establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute.

N/A b) When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability.

N/A c) The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also 5.10.4.2).

NOTE 1 Calibration laboratories fulfilling the requirements of this handbook are considered to be competent. A calibration certificate bearing an accreditation body logo from a calibration laboratory accredited to this handbook, for the calibration concerned, is sufficient evidence of traceability of the calibration data reported.

NOTE 2 Traceability to SI units of measurement may be achieved by reference to an appropriate primary standard (see VIM:1993, 6.4) or by reference to a natural constant, the value of which in terms of the relevant SI unit is known and recommended by the General Conference of Weights and Measures (CGPM) and the International Committee for Weights and Measures (CIPM).

NOTE 3 Calibration laboratories that maintain their own primary standard or representation of SI units based on fundamental physical constants can claim traceability to the SI system only after these standards have been compared, directly or indirectly, with other similar standards of a national metrology institute.

NOTE 4 The term "identified metrological specification" means that it must be clear from the calibration certificate which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification.

NOTE 5 When the terms "international standard" or "national standard" are used in connection with traceability, it is assumed that these standards fulfill the properties of primary standards for the realization of SI units.

NOTE 6 Traceability to national measurement standards does not necessarily require the use of the national metrology institute of the country in which the laboratory is located.

NOTE 7 If a calibration laboratory wishes or needs to obtain traceability from a national metrology institute other than in its own country, this laboratory should select a national metrology institute that actively participates in the activities of BIPM either directly or through regional groups.

NOTE 8 The unbroken chain of calibrations or comparisons may be achieved in several steps carried out by different laboratories that can demonstrate traceability.

N/A **5.6.2.1.2** There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:

[Redacted]

N/A a) the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;

[Redacted]

N/A b) the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.

[Redacted]

N/A c) Participation in a suitable program of interlaboratory comparisons is required where possible.

[Redacted]

5.6.2.2 Testing

OK **5.6.2.2.1** For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.

Paragraph 2.6 (Measurement Traceability) of the A2LA Addendum covers this issue.

NOTE The extent to which the requirements in 5.6.2.1 should be followed depends on the relative contribution of the calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements should be strictly followed.

OK **5.6.2.2.2** Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required as for calibration laboratories (see 5.6.2.1.2).

Paragraph 2.6 (Measurement Traceability) of the A2LA Addendum covers this issue

5.6.3 Reference standards and reference materials

5.6.3.1 Reference standards

N/A a) The laboratory shall have a program and procedure for the calibration of its reference standards.

[Redacted]

N/A b) Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1.

[Redacted]

N/A c) Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.

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5.6.3.2 Reference materials

N/A Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.

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5.6.3.3 Intermediate checks

N/A Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules.

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5.6.3.4 Transport and storage

N/A The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

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NOTE Additional procedures may be necessary when reference standards and reference materials are used outside the permanent laboratory for tests, calibrations or sampling.

5.7 Sampling

5.7.1

OK a) The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration.

Paragraph 2.7 (Sampling) of the A2LA Addendum covers this.

OK b) The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the test and calibration results.

Paragraph 2.7 (Sampling) of the A2LA Addendum covers this.

NOTE 1 Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing or calibration of a representative sample of the whole. Sampling may also be required by the appropriate specification for which the substance, material or product is to be tested or calibrated. In certain cases (e.g., forensic analysis), the sample may not be representative but is determined by availability.

NOTE 2 Sampling procedures should describe the selection, sampling plan, withdrawal and preparation of a sample or samples from a substance, material or product to yield the required information.

N/A **5.7.2** Where the customer requires deviations, additions or exclusions from the

documented sampling procedure, these shall be recorded in detail with the appropriate sampling data and shall be included in all documents containing test and/or calibration results, and shall be communicated to the appropriate personnel.

- OK 5.7.3 **Paragraph 2.7 (Sampling) of the A2LA Addendum covers this.**
 The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.
Paragraph 2.7 (Sampling) of the A2LA Addendum covers this.

5.8 Handling of test and calibration items

- OK 5.8.1 The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer.

Section 7.5.3 (Identification and Traceability) of the QPM addresses this issue.
 5.8.1 The laboratory shall maintain separation between and control over the items from different tests, to include the product being tested, its platform, peripherals, and all documentation.
 Quality Program Manual A2LA 2.5, ISO-QP-150, 280, WHVS07
 Section 6, policy

5.8.2

- OK a) The laboratory shall have a system for identifying test and/or calibration items.

Section 7.5.3 (Identification and Traceability) of the QPM addresses this issue

- OK b) The identification shall be retained throughout the life of the item in the laboratory.

Section 7.5.3 (Identification and Traceability) of the QPM addresses this issue

- OK c) The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents.

Section 7.5.3 (Identification and Traceability) of the QPM addresses this issue

- OK d) The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory.

Section 7.5.3 (Identification and Traceability) of the QPM addresses this issue

 5.8.2 When the product being tested includes software components, the laboratory shall ensure that configuration management mechanisms are in place to prevent inadvertent modifications to the software components during the testing process. This includes the customer's software, test tools, and commercial off-the-shelf (COTS) software.

 WHVS07.05 (Configuration Management VST Data and Documentation covers this item.

5.8.3

- OK a) Upon receipt of the test or calibration item, abnormalities or departures from normal or specified conditions, as described in the test or calibration method, shall be recorded.

Section 7.5.4 (Customer Property) in the QPM covers this issue.

- OK b) When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult the customer for further instructions before proceeding and shall record the discussion.

Section 7.5.4 (Customer Property) in the QPM covers this issue

5.8.4

- OK a) The laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation.

Section 7.5.5 (Preservation of Product) in the QPM covers this issue

- OK b) Handling instructions provided with the item shall be followed.

Section 7.5.5 (Preservation of Product) in the QPM covers this issue

- OK c) When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.

Section 7.5.5 (Preservation of Product) in the QPM covers this issue

- OK d) Where a test or calibration item or a portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.

Section 7.5.5 (Preservation of Product) in the QPM covers this issue

NOTE 1 Where test items are to be returned into service after testing, special care is required to ensure that they are not damaged or injured during the handling, testing or storing/waiting processes.

NOTE 2 A sampling procedure and information on storage and transport of samples, including information on sampling factors influencing the test or calibration result, should be provided to those responsible for taking and transporting the samples.

NOTE 3 Reasons for keeping a test or calibration item secure can be for reasons of record, safety or value, or to enable complementary tests and/or calibrations to be performed later.

5.9 Assuring the quality of test and calibration results

5.9.1

- OK a) The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken.

Section 8.2.3 (Monitoring and Measurement Processes) in QPM and Paragraph 2.9 (Assuring the Quality of Test and Calibration Results) are appropriate.

- OK b) The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results.

Section 8.4 (Analysis of Data) of the QPM is appropriate.

- OK c) This monitoring shall be planned and reviewed and may include, but not be

limited to, the following:

A2LA Addendum, Paragraph 2.9 (Assuring the Quality of Test and Calibration Results) covers this issue.

- OK 1) regular use of certified reference materials and/or internal quality control using secondary reference materials;
- OK 2) participation in interlaboratory comparison or proficiency-testing programs;
- OK 3) replicate tests or calibrations using the same or different methods;
- OK 4) retesting or recalibration of retained items;
- OK 5) correlation of results for different characteristics of an item.

NOTE The selected methods should be appropriate for the type and volume of the work undertaken.

- OK◆ **5.9.2** Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported.

A2LA Addendum, Paragraph 2.9 (Assuring the Quality of Test and Calibration Results) covers this issue. Also, ISO-QP-260 (Notice of Anomaly) is appropriate.

5.10 Reporting the results

5.10.1 General

- OK a) The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.
- C b) The results shall be reported, usually in a test report or a calibration certificate (see Note 1), and shall include all the information requested by the customer and necessary for the interpretation of the test or calibration results and all information required by the method used. This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4.

A2LA Addendum, Section 2.10

5.10.2 There may be more than one type of test report issued by the VSTL, including:

- a) Qualification/National Certification Test Reports (VSS-2002, Volume II, Appendix B) that are to be submitted to the EAC-designation certification body;
- b) test reports submitted to a state for its use in Certification Testing;
- c) test reports that are produced under contract and intended for use by the customer.

5.10.3 Qualification/National Certification Test Reports created for submission to the EAC shall meet the requirements of the VSS-2002 [Comment: should be extended to include VVSG 2005] and any additional EAC requirements. The report shall contain sufficient information for the exact test conditions and results to be reproduced at a later time if a re-examination or retest is necessary. Reports shall be submitted in the form and by the method specified by VSS-2002. Information required to reproduce the test but not included in the Qualification/National Certification Test Report shall be kept by the laboratory as part of the testing records. WHVS07 Sec 6.6. The official NCTR has a required format that should not be modified by the customer agreement as the target audience is not the customer but official government agencies

- OK c) In the case of tests or calibrations performed for internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way. Any information listed in 5.10.2 to 5.10.4 which is not reported to the customer shall be readily available in the laboratory which carried out the tests and/or calibrations.

A2LA Addendum, Section 2.10. policy statement.

5.10.4 Reports intended for use only by the customer shall meet customer-laboratory contract obligations and be complete, but need not necessarily meet all VSS-2002 requirements. Information required to reproduce the test but not included in the test report shall be kept by the laboratory as part of the testing records.

NOTE 1 Test reports and calibration certificates are sometimes called test certificates and calibration reports, respectively.

NOTE 2 The test reports or calibration certificates may be issued as hard copy or by electronic data transfer provided that the requirements of this handbook are met.

5.10.2 Test reports and calibration certificates

Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so:

- OK a) a title (e.g., "Test Report" or "Calibration Certificate");
- A2LA Addendum, Section 2.10, policy. ISO-QP-135, WHVS07TR, “Test Report” “National Certification Test Report”**
- OK b) the name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory;

- | | | |
|------------|----|---|
| | | A2LA Addendum, Section 2.10, WHVS07TR on front page and sec 2.1, ISO-QP-135, does not require address (may not have been updated from an earlier version of 17025) |
| <u>OK</u> | c) | unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate; |
| | | WHVS07TR Report number Txxxxxx ISO-QP-135 Purchase Order and serial numbers if applicable |
| <u>OK</u> | d) | the name and address of the customer; |
| | | WHVS07TR , front page and sec 1.5, ISO-QP-135 customer name only |
| <u>OK</u> | e) | identification of the method used; |
| | | WHVS07TR 5.1, also references the Functional Chart. "Test methods" are identified as "WOP" or "tests" in the Test Report ISO-QP-135 specifies Procedures |
| <u>X</u> | f) | a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated; |
| | | WHVS07TR Section 3.1 gives a description of the models to be tested, 3.4 lists the models and serial numbers of equipment delivered for testing, does not show that the condition of the units under test are reported, WOP 02 specifies the equipment will be checked in with a Wyle Receiving Inspection Form WL-218. ISO-QP-150 inspects received equipment for shipping damage but does not report the condition otherwise., ISO-QP-135, 4.1 refers to Specimen Title,sec 4.9 refers to Test Specimen Description. |
| <u>OK</u> | g) | the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration; |
| | | ISO-QP-150, Shipping and receiving,Wyle Receiving Inspection Form WL 218 and attaches an identification sticker which identifies the date, |
| <u>N/A</u> | h) | reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results; |
| | | ISO-QP-135, not currently required but basic procedures are included if needed. |
| <u>OK</u> | i) | the test or calibration results with, where appropriate, the units of measurement; |
| | | ISO-QP-135, 4.1 Results and 4.9 Notice of Anomalies, WHVS07.13 Sec 6.0. Includes specific statements and findings required by VVS-2002/VVSG-2005 Vol II App B |
| <u>OK</u> | j) | the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate; |
| | | ISO-QP-135, WHVS07.13 Front page (Project Engineer, Senior Project Manager, QA Manager) |
| <u>OK</u> | k) | where relevant, a statement to the effect that the results relate only to the items tested or calibrated. |

A2LA Addendum, Section 2.10, ISO-QP-135

5.10.5 The test reports shall clearly indicate that the test results apply to the product or system as tested. Testing of products or systems that have been modified may or may not produce the same test results.

WHVS07TR, "This evaluation report is valid only for the items listed in Section 3 of this report. Any changes, revisions, or corrections made to the product after this evaluation shall be reevaluated, and a revised report shall be issued."

NVLAP Note: NVLAP defines the person(s) who authorizes the test report or calibration certificate as the Approved Signatory (see 1.5.2).

NOTE 1 Hard copies of test reports and calibration certificates should also include the page number and total number of pages.

NOTE 2 It is recommended that laboratories include a statement specifying that the test report or calibration certificate shall not be reproduced except in full, without written approval of the laboratory.

5.10.3 Test reports

5.10.3.1 In addition to the requirements listed in 5.10.2, test reports shall, where necessary for the interpretation of the test results, include the following:

- OK a) deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions;
WHVS07.13, App A, Anomaly (for deviations, other questions) App B Functional Requirement Matrix shows excluded requirements and reason excluded
- OK b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications;
WHVS07.13 Sec 6, Includes specific statements required by VVS-2002/VVSG-2005 App B National Certification Test Report
- N/A c) where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the uncertainty affects compliance to a specification limit;
- OK d) where appropriate and needed, opinions and interpretations (see 5.10.5);
A2LA Addendum, 2.10, second paragraph. Not normally needed or used but policy is available as needed.
- OK e) additional information which may be required by specific methods, customers or groups of customers.
A2LA Addendum, 6.0

5.10.3.2 In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling shall include the following, where necessary for the interpretation of test results:

- N/A a) the date of sampling;
Sampling at this time is considered not applicable.

- N/A b) unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate);
- N/A c) the location of sampling, including any diagrams, sketches or photographs;
- N/A d) a reference to the sampling plan and procedures used;
- N/A e) details of any environmental conditions during sampling that may affect the interpretation of the test results;
- N/A f) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.

5.10.4 Calibration certificates

5.10.4.1 In addition to the requirements listed in 5.10.2, calibration certificates shall include the following, where necessary for the interpretation of calibration results:

- N/A a) the conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results;
- N/A b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof;
- N/A c) evidence that the measurements are traceable (see Note 2 in 5.6.2.1.1).

5.10.4.2

- N/A a) The calibration certificate shall relate only to quantities and the results of functional tests.
- N/A b) If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met.
- N/A c) When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference.
- N/A d) When statements of compliance are made, the uncertainty of measurement shall be taken into account.
- N/A **5.10.4.3** When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, shall be reported.

N/A **5.10.4.4** A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the customer. This requirement may be superseded by legal regulations.

5.10.5 Opinions and interpretations

OK When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.

A2LA Addendum, 2.10

NOTE 1 Opinions and interpretations should not be confused with inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC Guide 65.

NOTE 2 Opinions and interpretations included in a test report may comprise, but not be limited to, the following:

i) an opinion on the statement of compliance/noncompliance of the results with requirements;

as needed

ii) fulfillment of contractual requirements;

as needed

iii) recommendations on how to use the results;

as needed

iv) guidance to be used for improvements.

N/A

NOTE 3 In many cases it might be appropriate to communicate the opinions and interpretations by direct dialogue with the customer. Such dialogue should be written down.

5.10.6 Testing and calibration results obtained from subcontractors

OK a) When the test report contains results of tests performed by subcontractors, these results shall be clearly identified.

WHVS07TR, Sec 2.1

OK b) The subcontractor shall report the results in writing or electronically.

Not found,[svf] Corrected on site in WHVS07 Sec 10 on site

N/A c) When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory.

5.10.7 Electronic transmission of results

OK In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this handbook shall be met (see also 5.4.7).

WHVS07 Sec 1 (applies EAC directed procedures for transmitting test documents)

5.10.8 Format of reports and certificates

OK The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.

A2LA Addendum, Section 2.10, ISO-QP-135, VVS-2002/VVSG-2005 AppB.

NOTE 1 Attention should be given to the layout of the test report or calibration certificate, especially with regard to the presentation of the test or calibration data and ease of assimilation by the reader.

NOTE 2 The headings should be standardized as far as possible.

5.10.9 Amendments to test reports and calibration certificates

OK a) Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement:

"Supplement to Test Report [or Calibration Certificate], serial number . . . [or as otherwise identified]," or an equivalent form of wording.

A2LA Addendum, Section 2.10, ISO-QP-135 Sec 5.4. "Rev A" (letter designator)

OK b) Such amendments shall meet all the requirements of this handbook.

A2LA Addendum, Section 2.10, ISO-QP-135, Sec 5

C c) When it is necessary to issue a complete new test report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces.

A2LA Addendum, Section 2.10, ISO-QP-135, Sec 5. A new report is not allowed replace an early report but is a completely new report reporting a new configuration or system

Annex A (normative)

Referencing NVLAP accreditation

A.1 Conditions for referencing the NVLAP term, logo, and symbol

The term *NVLAP* and the NVLAP logo are registered marks of the Federal Government, which retains exclusive rights to control the use thereof. Permission to use the term and symbol (NVLAP logo with approved caption) is granted to NVLAP-accredited laboratories for the limited purpose of announcing their accredited status, and for use on reports that describe only testing or calibration within the scope of accreditation. NVLAP reserves the right to control the quality of the use of the NVLAP term, logo, and symbol.

In order to become and remain accredited, laboratories shall comply with the following conditions pertaining to the use of the term *NVLAP*, the NVLAP logo, and NVLAP symbol. Failure to comply with these conditions may result in suspension or revocation of a laboratory's accreditation.

- OK a) An applicant laboratory that has not yet achieved accreditation may make reference to its applicant status. If the NVLAP Lab Code is used, it shall be accompanied by a statement accurately reflecting the laboratory's status. An applicant laboratory shall not use the NVLAP term, logo or symbol in a manner that implies accreditation.

Procedure No. WHVS07 (Voting System Test Procedure) – Paragraph 13 (Use of the NVLAP Term, Logo and Symbol) covers this Annex A.

- OK b) The laboratory shall have a policy and procedure for controlling the use of the term *NVLAP* and the NVLAP symbol.

- OK c) The term and/or symbol shall not be used in a manner that brings NVLAP into disrepute or misrepresents a laboratory's scope of accreditation or accredited status.

- OK d) When the term *NVLAP* is used to reference a laboratory's accredited status, it shall be accompanied by the NVLAP Lab Code.

- OK e) When the NVLAP symbol is used to reference a laboratory's accredited status, it shall be comprised of the NVLAP logo and the NVLAP Lab Code in an approved caption. The caption shall appear below and in close proximity to the logo. The following captions have been approved by NVLAP:

- "For the scope of accreditation under NVLAP Lab Code 000000-0"

- "NVLAP Lab Code 000000-0".

See Annex A of NIST Handbook 150 for examples of the logo with captions.

- f) When the NVLAP symbol is used, the form of the NVLAP logo must conform to the following guidelines:

- OK 1) The logo shall stand by itself and shall not be combined with any other logo, symbol, or graphic.
- OK 2) The aspect ratio (width to height) shall be 2.25 to 1.
- OK 3) The logo and caption shall be of a size that allows the caption to be easily read. The size of the caption shall not exceed the size of the logo itself.
- OK 4) The logo shall appear in black, blue, or other color approved by NVLAP, and may be filled or unfilled. In the case of a filled logo, the same color shall be used for the outline and the fill.

OK g) The name of at least one Approved Signatory shall appear on a test or calibration report that displays the NVLAP symbol or references NVLAP accreditation. A computer-generated report may have the Approved Signatory's name printed along with the test or calibration results, as long as there is evidence that there is a system in place to ensure that the report cannot be generated without the review and consent of the Approved Signatory. There may be legal or contractual requirements for original signatures to appear on the report.

- h)**
- OK 1) When the term and/or symbol are used on test or calibration reports, such use shall be limited to reports in which some or all of the data are from tests or calibrations performed by the laboratory under its scope of accreditation.
 - OK 2) A test or calibration report that contains both data covered by the accreditation and data not covered by the accreditation shall clearly identify the data that are not covered by the accreditation.
 - OK 3) The report must prominently display the following statement at the beginning of the report: "This report contains data that are not covered by the NVLAP accreditation."

- i)**
- OK 1) When the term and/or symbol are used on test or calibration reports that also include work done by subcontracted laboratories, such use shall be limited to reports in which some or all of the data are from tests or calibrations performed by the laboratory under its scope of accreditation.
 - OK 2) A test or calibration report that contains both data covered by the accreditation and data provided by a subcontractor shall clearly identify the data that were provided by the subcontracted laboratory.

- OK 3) The report must prominently display the following statement at the beginning of the report: "This report contains data that were produced under subcontract by Laboratory X." If the subcontracted laboratory is accredited by NVLAP, then its Lab Code should also be stated.
- OK 4) If the subcontracted laboratory is accredited by a body other than NVLAP, then the name of the accreditation body and the laboratory's number or other unique identifier should also be stated. If the subcontracted laboratory is not accredited, then this must be stated.
- OK j) Each test or calibration report bearing the term and/or symbol shall include a statement that the report must not be used by the client to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the Federal Government.
- OK k) When used in a contract or proposal, the term and/or symbol shall be accompanied by a description of the laboratory's scope of accreditation and current accreditation status.
- OK l) Laboratories shall not use the terms *certified* or *registered* when referencing their NVLAP accreditation or conformance to ISO/IEC 17025 requirements. The correct term is *accredited*.

Annex B (normative)

Implementation of traceability policy in accredited laboratories

B.1 Policy overview

It is a fundamental requirement that the results of all accredited calibrations and the results of all calibrations required to support accredited tests shall be traceable to the SI (the International System of Units) through standards maintained by the National Institute of Standards and Technology (NIST) or other internationally recognized national metrology institutes (NMIs). NIST Handbook 150 (and ISO/IEC 17025) details the specific requirements for traceability to be met by testing and calibration laboratories. This annex provides guidance as to how these requirements may be met and how traceability of measurement can be assured by an accredited laboratory.

Internationally recognized NMIs are those that are signatory to the Comité International des Poids et Mesures (CIPM) Mutual Recognition Arrangement (MRA) titled “Mutual recognition of national measurement standards and of calibration and measurement certificates issued by national metrology institutes” and that have the necessary calibration services listed in Appendix C of the MRA, Calibration and Measurement Capabilities (CMC). For more details on the CIPM MRA and the CMC database, please see <<http://www.bipm.org/en/convention/mra/>> or visit the NVLAP web site.

B.2 General

- N/A a) Laboratories shall be able to demonstrate proper use of traceable standards and test and measurement equipment by competent laboratory personnel in a suitable environment in performing the tests for which accreditation is desired or held. This demonstration will include the determination of the appropriate measurement uncertainty.

- N/A b) Calibration certificates received by NVLAP-accredited testing and calibration laboratories with new or recalibrated equipment shall meet the requirements of ISO/IEC 17025. The certificates must include the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof.

Note to assessor: The NVLAP assessor(s) must, for each measurement parameter, indicate which method the laboratory has employed to achieve traceability. Select from B.3.1, B.3.2, B.3.3, B.3.4, or B.3.5 below. If B.3.4 or B.3.5 is selected, supporting documentation is also required as indicated.

B.3 Demonstration of traceability

N/A **B.3.1** NVLAP-accredited laboratories may submit appropriate physical standards and test and measurement equipment directly to NIST or, when appropriate, to another national metrology institute. Accredited laboratories may obtain certified reference materials from NIST (called Standard Reference Materials under copyright) or from another national metrology institute. Use of a national metrology institute other than NIST shall be documented and will be assessed by NVLAP.

[Redacted]

N/A **B.3.2** Testing laboratories that perform calibrations only for themselves do not need to be accredited as calibration laboratories. Calibration laboratories that perform specific calibrations only for themselves to support their accredited services do not need to be accredited for those calibrations. For the purpose of assuring traceability, an accredited laboratory may calibrate its own equipment if the appropriate requirements of NIST Handbook 150 have been met.

[Redacted]

N/A **B.3.3** NVLAP-accredited laboratories that do not demonstrate traceability as described in B.3.1 or B.3.2, shall use accredited calibration laboratory services wherever available. Accredited calibration laboratories are those accredited by NVLAP or by any accrediting body with which NVLAP has a mutual recognition arrangement. A listing of NVLAP-accredited calibration laboratories and of accreditation bodies with which NVLAP currently has agreements is available from NVLAP.

[Redacted]

N/A **B.3.4** If a NVLAP-accredited laboratory submits physical standards or test and measurement equipment to a calibration service provider that is not accredited by NVLAP or by an accrediting body with which NVLAP has a mutual recognition arrangement, the laboratory shall:

[Redacted]

N/A a) document that an appropriate accredited calibration service provider is not available;

[Redacted]

N/A b) audit the claim of traceability of the provider of the calibration service and document the following areas related to the calibration and claim of traceability of its standards and test and measurement equipment:

[Redacted]

N/A 1) information regarding assessment of the quality system used by the calibration service provider,

[Redacted]

N/A 2) the calibration procedure(s) used by the calibration service provider,

[Redacted]

N/A 3) the physical standards or other test and measurement equipment used by the calibration service provider (including evidence of traceability to standards maintained by NIST or an appropriate national metrology institute and copies of relevant calibration certificates),

[Redacted]

N/A 4) information regarding the calibration intervals of relevant standards or other test and measurement equipment,

[Redacted]

- N/A 5) the environmental conditions of the laboratory,
- N/A 6) the method(s) by which uncertainties are determined (e.g., Guide to the Expression of Uncertainty in Measurement (GUM), and
- N/A 7) the relative uncertainties achieved at all steps of the process;

N/A c) pursue the traceability chain until traceability to appropriate stated references is completely validated, when a calibration service provider submits physical standards and/or test and measurement equipment used in the calibration to another laboratory(s) not accredited by NVLAP;

N/A d) enter the audit documentation, including all findings of nonconformance and resolutions of those findings, into the laboratory's quality management record-keeping system.

NOTE An on-site visit to the provider of the calibration service is encouraged, but is not required as long as the information listed above is obtained and otherwise verified. Self-declaration of compliance to ISO/IEC 17025 or other relevant standards by a calibration service provider is not acceptable evidence of verification of traceability. Citation of a NIST Test Number by the calibration service provider likewise is not acceptable evidence of verification of traceability.

N/A **B.3.5** If traceable calibration services are not available or appropriate, laboratories may demonstrate comparison to a widely used standard that is clearly specified and mutually agreeable to all parties concerned, particularly in measurements where NIST does not maintain a U.S. national standard. For example, NIST does not maintain a standard for all hardness testing scales. There are several widely used commercial standards available for hardness. However, these standards may not all give equivalent measurement results; therefore, it is important to specify which standard is used and to obtain agreement among all parties involved that the choice made is acceptable.

**NIST HANDBOOK 150 CHECKLIST
COMMENTS AND NONCONFORMITIES**

Instructions to the Assessor: Use this sheet to document comments and nonconformities. For each, identify the appropriate item number from the checklist. Identify comments with a "C" and nonconformities with an "X." If additional space is needed, make copies of this page (or use additional blank sheets).

<i>Item No.</i>	<i>C or X</i>	<i>Comments and/or Nonconformities</i>
4.4.1	X	<u>No reference in the quality documentation to cover the "consultation" to a voting system developer.</u>
4.2.1c)	X	Not apparent in the Quality documentation; no primary method was designated. <u>Corrected on site – primary method is electronic storage – Wyle’s Storage Area Network Drive (SAND) will be used for the primary storage as shown n Paragraph 2.1 of WHVS07.A (Configuration Management Voting Systems Testing Data and documentation).</u>
4.2.3	X	Not apparent in the quality documentation – Corrected on site – Paragraph 6.0 (Test Reporting Procedure and Conditions) of Procedure No. WHVS07 (Voting System Test Procedure) was modified to address this issue.
4.11.5	X	No evidence in the quality documentation that the finding of a <u>serious nonconformity drives the initiation of an internal audit.</u>
4.13.2.1 c)	C	ISO-QP-220 (Quality Assurance Hold Points) and ISO-QP-200 (Test and Process Control) both cover this issue using the Test Control Record. The terms Test Control Record, traveler-type document, and Holdpoint should be defined in the Quality Program Manual
5.2.2 d)	C	A2LA Addendum, Section 2.2 (Personnel) on a policy level. The procedures are not documented but expected to be recovered as part of the reviews (management, anomaly requests, non-conformance, complaints, etc) and corrective actions process. Only documented instructions are in Quality Directive XVI Tac 1, Attch 7.1 Sec 5.3 (corrective action report resolution).
5.2.4 ii	X	Test Planning responsibility not documented in Job Description/Task (corrected)
5.2.6 (150-22)	X	Challenged by Voting Systems Program Manager. The review <u>is not</u> administered at the test method level but at the Core areas identified in the WHVS07.T22. Manager claims an undue burden for over 140 test methods in current test method program. However, not every Core Area/Test Method is currently required of every Project Engineer - Corrected on Site

5.3.3. (150-22)	C	A tour of the computer server was done; it is located in a separate building on the Wyle 125-acre site. It is part of the corporate financial building (Building 33). The front door to the building was unlocked and no electronic security is available at the building in non-business hours. Although the computer server for the voting system program is in a computer room that has a locked (cyber locked) access with limited personnel entry, the offices going to that room appeared empty and there was a delay before anyone appeared to challenge our entry
5.4.4	X	WHVS07 (Voting System Test Procedure), Section 6.0 (Test Reporting Procedure and Conditions) cover this item. The information block indicating the condition of the equipment when received was missing from the test report template. - Corrected on site.
5.4.5.2	X	The WoPS do not record the “results obtained, the procedures used for validation, and a statement as to whether the method is fit for general use” [Corrected on site in WHVS07.16, Section 2]
5.4.5.2 a)	C	The validation procedures are not defined at a level to determine if the test method is appropriate to reveal the characteristics expected of the product by objective evidence See the note 2 below and note 1 and 2 after 5.4.5.3 below
5.4.5.2 b)	X	Quality Directive Number IX-1(Control of Special Processes and Validation of Non-Standard Methods), Attachment 7.2 (Instructions for Validation of Non-Standard Methods) covers t his item. WHVS07 Section 6.6 requires the validation be reported but the WOPs do not record the “results obtained, the procedure used for validation, and a statement as to whether the method is fit for intended use.” [svf][Corrected on-site: WHVS07.16, Sec 2]
5.4.4 e)	C	Example in WoP 21, “Requires a test chamber” needs to be more specific and provide reference to requiring access to the equipment during the test
5.4.4 (150-22)	X	Procedures not provided to describe by whom and how the voting system will be configured when the customer installs – Corrected on site.
5.4.5 (150-22)	X	Procedures WHVS07 Section 12 (Tests Conducted outside of Wyle Laboratories) only list an inspection of the location.- Corrected on site.
5.4.6.3	C	Cross reference listed this incorrectly as N/A. WHVS07, Sec 6.6 3rd paragraph references specific case of state unique test requirements are to be labeled but needs to be expanded for state or vendor requested.
5.4.7.1	X	Not apparent in the quality documentation
5.6.1.b (150-22)	X	WoP 24a creates a cross-reference matrix as a base for showing how requirements are to be met but needs to show which method is to be used.
5.10.1 b)	C	The official NCTR has a required format that should not be modified by the customer agreement as the target audience is not the customer but official government agencies

