

09/09/06 200733-0

NVLAP ON-SITE ASSESSMENT SUMMARY

Please complete this summary and attach it to the original On-Site Assessment Report.
DO NOT LEAVE THIS SUMMARY WITH THE LABORATORY.

N/S
0/9
10/4/06

Laboratory Name: System Labs Incorporated Lab Code: INITIAL ASSESSMENT

Fields of Accreditation: VOTING SYSTEM TESTING

Assessor Name(s): RICHARD B. STUMP, STEVEN V. FREEMAN

Date of Pre-assessment Review of Quality Manual: APRIL 11, 12 & 13, 2006

Date(s) of On-Site Assessment: SEPTEMBER 20, 21 & 22, 2006

This report contains changes to the laboratory's Scope of Accreditation: additions; deletions; modifications. (Please describe in the On-Site Narrative Summary.)

RECEIVED
2006 OCT 4 P 12: 20
NVLAP
RECEIVED
2006 OCT 4 P 12: 20
NVLAP

SUMMARY AND RECOMMENDATIONS:

- The laboratory has no nonconformities and no written response to NVLAP is required.
- The laboratory has nonconformities in the following area(s). I have notified the laboratory of these nonconformities and the requirement to respond to NVLAP in writing about their resolution.

4 Management requirements

- 4.1 Organization
- 4.2 Management system
- 4.3 Document control
- 4.4 Review of requests, tenders and contracts
- 4.5 Subcontracting of tests and calibrations
- 4.6 Purchasing services and supplies
- 4.7 Service to the customer
- 4.8 Complaints
- 4.9 Control of nonconforming testing and/or calibration work
- 4.10 Improvement
- 4.11 Corrective action
- 4.12 Preventive action
- 4.13 Control of records
- 4.14 Internal audits
- 4.15 Management reviews

5 Technical requirements

- TO BE DETERMINED BY THE TECHNICAL EXPERT
- 5.1 General
 - 5.2 Personnel
 - 5.3 Accommodation and environmental conditions
 - 5.4 Test and calibration methods and method validation
 - 5.5 Equipment
 - 5.6 Measurement traceability
 - 5.7 Sampling
 - 5.8 Handling of test and calibration items
 - 5.9 Assuring the quality of test and calibration results
 - 5.10 Reporting the results
 - Annex A. Referencing NVLAP accreditation
 - Annex B. Implementation of traceability policy in accredited laboratories
 - Other (specify) NIST HB 150-22

Based on my findings regarding nonconformities, staff competence, and laboratory procedures, I recommend that another on-site assessment be performed before this laboratory is granted accreditation.

Richard B. Stump
Signature of Lead Assessor

24 SEP 2006
Date

National Institute of Standards and Technology
National Voluntary Laboratory Accreditation Program (NVLAP)

SIGNATURE SHEET

Laboratory Name: SysTest Labs Incorporated

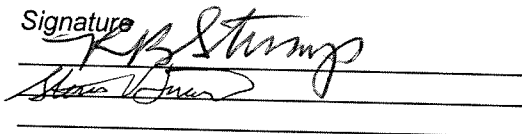
Field(s) of Accreditation: Voting System Testing

NVLAP Assessor(s):

Name

Richard B. Stump, Lead Assessor
Steven V. Freeman

Signature



On-Site Assessment Dates: 20, 21 & 22 SEP 2006

Type of Assessment (check one): Initial Renewal Monitoring Other

Note: Please list laboratory personnel present at exit briefing on the back of this page.

Instructions for the Laboratory

Respond in writing within 30 days of the date of this report, addressing all nonconformities documented by the assessor(s). All nonconformities must be satisfactorily resolved before accreditation may be granted. See page 2 for guidance and instructions on responding to nonconformities.

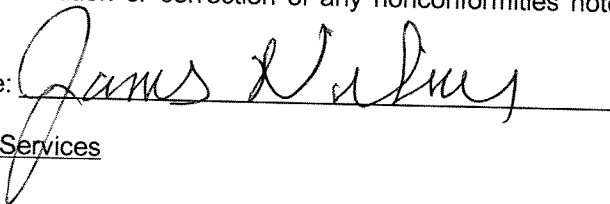
The On-Site Assessment Report, the information supplied by you, and the results of any required proficiency testing will be reviewed by NVLAP with the assistance of technical experts as necessary. NVLAP is solely responsible for the content of this report and reserves the right to change the findings of the assessor(s), based on the results of this review. The final evaluation of your laboratory, for the purpose of deciding whether to approve or deny an initial or a renewal accreditation, will be conducted by NVLAP. It is the responsibility of the Authorized Representative to understand and respond with sufficient information within the required timeframe. Failure to respond may result in the suspension of your laboratory's accreditation or, in the case of a new laboratory, may delay an accreditation decision. Questions concerning this response should be directed to NVLAP.

Send your response to: NVLAP
National Institute of Standards and Technology
100 Bureau Drive, Stop 2140
Gaithersburg, MD 20899-2140

Signed Statement

The assessor has discussed the contents of this report with members of the laboratory management who agree to respond in writing to NVLAP, regarding resolution or correction of any nonconformities noted, within 30 days of the date of this report.

Signature of Authorized Representative or designee:



Printed Name: James Nilius, Director, Compliance Services

Guidance and Instructions on Laboratory Responses

Resolving nonconformities: A laboratory's response shall include documentation that the specified nonconformities have been corrected and/or a plan of corrective actions. A corrective action plan must include a list of actions, target completion dates, and names of persons responsible for discharging those actions. All nonconformities must be satisfactorily resolved before accreditation may be granted. For accredited laboratories, this is interpreted to mean that nonconformities adversely affecting the outcome of calibrations or tests must be addressed and corrected immediately (within the 30 days). Evidence must be supplied which clearly demonstrates that actions taken fully resolve the nonconformities, thereby removing any concern as to the quality of results of the calibrations or tests conducted by the laboratory. In those cases where specified nonconformities do not directly affect the results of calibrations or tests, such as those related to record-keeping, NVLAP may accept a plan and a schedule, as previously described, as satisfactory resolution. When this occurs, laboratories are expected to submit sufficient objective evidence demonstrating that the nonconformities have, in fact, been resolved according to the schedule. All responses must be sent directly to the NVLAP office, not to the assessor(s).

Referencing nonconformities: Each nonconformity must be referenced in your response by item number as it is listed in the appropriate checklist. Cite the requirement against which the nonconformity is stated and, where more than one nonconformity was recorded against the same requirement, either restate the specific nonconformity, or indicate to which test/parameter the response is related.

Objective evidence: The laboratory may ask for clarification of a nonconformity either during the closing meeting or from the appropriate NVLAP Program Manager. It is required that objective evidence be submitted as proof that a nonconformity has been effectively resolved. Such evidence includes updated procedures, uncertainty analyses (where appropriate), corrected/updated sections of the quality documents associated with a stated nonconformity, copies of completed records, corrective action reports, etc. NVLAP reviews all responses, with the assistance of appropriate technical experts as necessary, and is solely responsible for the final decision regarding the resolution of a nonconformity and for the granting of initial or renewal accreditation.

ON-SITE ASSESSMENT NARRATIVE SUMMARY

CHANGES TO CURRENT OR REQUESTED SCOPE OF ACCREDITATION
(Additions, Deletions, Modifications)

N/A

4.1 ORGANIZATION

SysTest Labs Incorporated (STL) is preeminently positioned to deliver voting system testing laboratory certification. Two organization charts (file dated 13 SEP 2006) show the "Organization 2006" relationships for the overview of the company and "Organization 2006 Compliance Services" shows the structure for specific functions that will deliver the voting system testing for the certification body activities.

Leadership for the NVLAP Voting System Testing Laboratory Accreditation Program (VST LAP) has been outstanding for the progress displayed by STL for this initial NVLAP assessment. The NVLAP pre-assessment evaluation, conducted in April of this year, witnessed a strong indicator of STL's dedication to pursue NVLAP accreditation. This has continued and there has been additional visible drive to close on this accreditation during this NVLAP visit.

SysTest has an outstanding compilation of system documents – Quality System Manual (QSM), SysTest Labs Procedures (SLPs) and other associated items that address the NVLAP requirements of NIST Handbooks 150 General and 150-22 VST Program-Specific Checklist. SLI has provided two procedures SLP TR-01 and SLP TR-02 which describe the training tracking and competency records for all personnel involved with the delivery of certification body activities.

4.2 MANAGEMENT SYSTEM

Overall STL's documented management system addresses each of the Section 4.0 Management Requirements for accreditation for NIST Handbook 150. Its current quality manual was issued on 13 JUN 2006 and is Rev. 0.0.4.

SysTest Labs has published a Mission Statement and List of Values indicating its management commitments.

Some improvements are underway with the quality system management documentation (QSM) as a result of this NVLAP assessment and are documented in the "Comments and Nonconformities" sections of the individual checklists.

4.3 DOCUMENT CONTROL

SysTest Labs understands the requirements for tight document control and shows evidence of this in its overall documented program. Some items, such as Master Lists and a few SLPs, must be given more specific document control. These needs have been discussed and identified with SysTest management.

This is an area that requires some attention to put SysTest Labs into proper control of its VST LAP program documentation.

4.4 REVIEW OF REQUESTS, TENDERS AND CONTRACTS

Overall SysTest Labs has properly addressed this part of its initial dealing with customers. Some fine tuning occurred during the NVLAP assessment putting items needing attention into proper order.

The two major, controlling documents for SysTest Labs is its QSM Section 4.4 and SysTest Labs procedure SLPQS-11. SysTest Labs must make sure to conduct proposal reviews for its subcontractors; deviations; and changes to work after commencement of work.

4.5 SUBCONTRACTING OF TESTS AND CALIBRATIONS

SysTest Labs has challenges in this area of its VSTL program. It has associated with capable subcontracting test labs to perform special testing needs. But ensuring the capabilities of these labs will require specific determination of NVLAP needs, especially whether the subcontracting labs have proper credentials for the testing to be done.

This is a critical area for SysTest Labs as it is heavily dependent on its contractor labs for its complete array of testing. NVLAP is very interested in the outcome of SysTest Labs' decisions with the possibilities and final decisions arrived at by STL.

4.6 PURCHASING SERVICES AND SUPPLIES

This area is reported by SysTest Labs as a small part of the total program, considering the focus on the NIST HDBK 150 document and SysTest Labs' line of business. Discussion centered on the paper products used to test customer equipment and movers used to transport testing equipment.

SLP-QS-10 is the main document describing SysTest Labs' purchasing of services and supplies, and will be revised to include the current understanding of this area.

4.7 SERVICE TO THE CUSTOMER

SysTest Labs is on target with its approach to service to its customers. Documents providing direction for this area include SLP-QS-12 and QSM 4.7.

SysTest Labs is attentive in its involvement with its customers and has two surveys to gather input to improve its customer relationships. SLP-QS-12 also addresses SysTest Labs' approach to customer service.

4.8 COMPLAINTS

SysTest Labs has taken a very strong approach to addressing and handling customer complaints through establishing a program to further enhance its attention, through the Concerns_Discrepancy Report_Complaints (C_DR_C) Form. This form allows for proper documentation of complaints and ensures tracking and closure will be handled efficiently. SLP-QS-08 documents this program to aid in its further implementation.

One key manager was unaware of the existence of the C_DR_C Form, but referred to use of a SCRDF form that was not included in any other reviews of SysTest Labs' documentation. Another key manager was familiar with SysTest Labs initiation of the C_DR_C Form, but was not totally certain of all of its uses.

4.9 CONTROL OF NONCONFORMING TESTING WORK

SysTest Labs documents nonconforming testing work with Form QS-08 which provides very effective and complete attention to addressing this essential activity. The nonconformity program begins with the process described in SLP-QS-08.

4.10 IMPROVEMENT

SysTest Labs' focus on improvement is contained in SLP-QS-12. During this NVLAP assessment many improvements were witnessed that show SysTest Labs has given continuous attention to improvement, when considering such activities as:

- The use of the C_DR_C form
- The system to track personnel competency achievements (SLP-TR-02)

4.11 CORRECTIVE ACTION

SysTest Labs' corrective action program ties directly with its control of nonconforming testing work attention. SysTest Labs understands and has applied a strong approach to corrective action, mainly found in SLP-QS-09.

The current program emphasizes root cause analysis and the establishing of countermeasures. And, finally the evaluating the effectiveness of corrective action is included in the list of activities to give closure when the actions have produced the proper effect.

4.12 PREVENTIVE ACTION

SysTest Labs understands the differences and similarities between corrective action and preventive action. SysTest Labs is poised to properly apply preventive action to the potential problems that might come along. This activity is still in its infancy as far as application goes.

4.13 CONTROL OF RECORDS

Overall SysTest Labs has a strong control of records program. The program has been developed in SLP-QS-03. This is an area where several documents were found to be out of the current program either in identification or in a release that was not identified as final.

SysTest Labs understands the details of meeting the document control needs and will correct this as part of this assessment.

4.14 INTERNAL AUDITS

SysTest Labs must significantly strengthen its program for internal audits, beginning with comprehensive training in the structured program and attendant training required both from the outside and for SysTest Labs internal auditors.

SysTest Labs did not conduct an internal audit that met the NVLAP requirements prior to this assessment and must do so, following the exact details as one input to the corrective actions for this assessment.

SLP-QS-05 will require upgrading to address the details needed for a proper internal audit as well.

4.15 MANAGEMENT REVIEWS

SysTest Labs did not conduct a management review prior to this NVLAP assessment and will need to do so as part of its corrective actions to NVLAP. NIST Handbook 150 requirements for items to address at SysTest Labs' management reviews are very detailed, requiring considerable analysis of data.

SysTest Labs will have to upgrade its documents describing management reviews to stay on target for this activity.

5.1 GENERAL

There are no technical requirements for SysTest Labs in this section.

5.2 PERSONNEL

SysTest Labs' main documentation of its programs involving its personnel activities are found in QSM 5.2 AND SLPs TR-01 and TR-02. Overall, SysTest Labs' present a strong team to address the needs of the VST LAP Program. The interviews conducted by NVLAP were very impressive with respect to the knowledge and involvement of each one in the NVLAP program.

Interviews of Compliance Services personnel at SysTest Labs included:

- Mr. Jef Knutson, NVLAP Quality Manager
- Mr. Darrick Forester, NVLAP Team Leader – Hardware
- Ms. Jo Johnson, NVLAP Team Leader – Source Code Review
- Ms. Jenn Garcia, NVLAP Team Leader – Voting Specialists
- Mr. Mike Santos, NVLAP Team Leader – ITA Validations

(As taken from Organization Chart, "Organization 2006 Compliance Services," dated 13 SEP 2006.)

5.3 ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

Under the core requirements, SysTest operations are largely under standard office conditions. They need and have adequate space for the separation of clients and, under their document control program, provide separate storage of vendor files under secure conditions.

One core requirement, the Environmental Operating Temperature test, encompasses the Accuracy, Maintainability, and Reliability tests. The 48 hour operational environmental test component requires an environmental chamber adequate for SysTest personnel to perform the test in conditions of changing temperatures and voltages. SysTest subcontracts an environmental lab for the use of a chamber and technicians qualified to maintain and monitor the environmental conditions for the test. Within the subcontracting, processes required under NIST HDBK 150, Section 5.2 and this section need to be established, monitored, and recorded, and reported to ensure required control of the temperature, humidity, and power variations of this test the Mil-Std 810 criteria specified for the test.

5.4 TEST AND CALIBRATION METHODS AND METHOD VALIDATION

SysTest has held a prior accreditation for testing to the Voting System Standards – 2002. In general, test methods and processes are in place for of the 2002 standards and many of them are well defined but require minor changes to bring them in compliance with NIST HDBK 150 and 150-22. Principle changes are:

- a. Provide and document test validation of methods and vendor supplied tests, diagnostics, and simulations
- b. Identifying sampling criteria where needed, especially for vendor test case review
- c. Identifying and reporting variations to the approved test methods.

Missing test cases/procedures

Availability (reporting the predicted Ai parameter)

New VVSG 2005 requirements and changes to old tests to meet 2005 criteria.

Operational Status Check procedure/test case

Corrections::

1. The parallel operation of the Accuracy, 48 Environmental, Reliability tests under the Hardware Environmental Test
2. Confirming accuracy for "This rate applies to the voting functions and supporting equipment that capture, record, store, consolidate, and report" to include ballot images and backup memory and consolidated reporting

5.5 EQUIPMENT

Equipment identified, other than the vendor supplied equipment for the test, is limited under the core requirements. The tests requiring extensive test equipment are under the tests which are subcontracted to accredited labs. (Note: however, the Environmental Operating test as an exception where SysTest will be performing the test under contracted services. At this time, the equipment requirements are expected to be supported by the subcontractor but additional attention may need to be paid in the subcontracting conditions).

An exception that is being developed is the use of a 'snifer' for telecommunications and security testing. As this and other more sophisticated test tools are adopted in the test methods and procedures, requirements for monitoring this equipment and its appropriateness will need to be developed but its use was not well enough defined in the current assessment to be included at this time.

5.6 MEASUREMENT TRACEABILITY

Measurement traceability is an requirement that is primarily the responsibility of accredited labs performing tests that are outside the VSTL core requirements. However, we include the need for the trace cross-references between requirements, test methods, and documents. SysTest has an extensive use of trace matrices to identify, track, and report test campaign components. The only significant issue is the need to complete the work to identify and complete the trace matrix analysis of the VVSG 2005 requirements to ensure completion of required procedures and test methods and to support test campaign reporting.

5.7 SAMPLING

Sampling has not been recognized in the past. SysTest has already identified that procedures need to be identified and applied to test cases and the reports but this needs to be completed. Sampling activity was identified for:

Reviewing and validating vendor tests.

Selecting combinations of voting ballot logic and variations for test cases that provide adequate coverage of all requirements.

5.8 HANDLING OF TEST AND CALIBRATION ITEMS

SysTest has strong procedures for the check-in, tracking, and configuration management of the units under test. There are relatively few test equipment and software items not provided by the client vendors for specific tests but SysTest needs review validation requirements for those items.

A minor item was noted in the Test Report to identify the condition of the equipment received.

The Operational Status Check is mentioned under Test Methods but this item is important through out the test campaign for verifying that the equipment used is fully operational and has not developed defects under the various tests, especially the more physically challenging hardware tests but also before major system or functional tests.

The configuration of COTS, especially the operating system, drivers, and utilities needed by the voting applications needs to be developed further. The procedures and test cases were missing the requirement to review and document the COTS installation choices and updates required for the installation of the application and that the COTS configuration needs to be reported in the final report. Growing security issues require that the test environment represented by the COTS elements be controlled and defined to detect changes and reduce security vulnerabilities. Although specific procedures in the Test cases were not found, some of the security items indicated an awareness to this problem is present.

5.9 ASSURING THE QUALITY OF TEST AND CALIBRATION RESULTS

Reviews and procedures are well establish to ensure the tracking. No current calibration is required under the VSTL core requirements but may become necessary under the development of the contracting for the environmental chamber for the core Environmental Operating tests. Also, procedures may need to be developed in the near future for the 'snifer' and other new tools being acquired for security and telecommunication testing.

5.10 REPORTING THE RESULTS

The Qualification Test Report Template matches closely with the Voting system standards (VSS 2002 and VVSG 2005) requirements but needs minor updates to reflect NIST HDBK 150 and 150-22 details requirements for the reporting. The NIST HDBK issues such 5.10.2 are simple administrative formatting guidelines that support better integrity of the reports and complement current formatting from the voting system requirements. Missing content identified are:

- System capacity,

- Identification of other equipment as needed not part of the system definition but providing support for the use in voting operations.

- Required statements on acceptability of the system design and construction and reporting Availability

- Identifying variations or changes to approved test methods used in the testing.

- Sampling criteria

- Test Data Analysis and raw test data (may require further development or interpretation of the requirement).

- For 2005 VVSG, development of the Trace Requirement matrix identified under Test Methods section above.

Recognizing branding restrictions (App A of HDBK 150) for variations of reports which may occur.

ANNEX A.
REFERENCING NVLAP ACCREDITATION

SysTest Labs will address these NVLAP requirements in references made in NIST Handbook 150-22, paragraph 4.2.2g).

ANNEX B.
IMPLEMENTATION OF TRACEABILITY POLICY IN ACCREDITED LABORATORIES

This Annex is N/A for SysTest Labs.

The Voting System Testing Laboratory Accreditation Program
 Certification Assessment Agenda

DAY 1 – Wednesday, September 20, 2006

TIME	LA	TE	NIST HDBK 150 (Clause) ³	Activities for VST LAP Accreditation	STL Contact(s)	Additional Support
8:30 AM	X	X		Opening Meeting / Introductions <ul style="list-style-type: none"> • SysTest Labs (STL) contact people • SysTest Labs organization • SysTest Labs scope of VST LAP accreditation • Establish SysTest Labs documents of record for this assessment • Review agenda for three days • Plans for Closing Meeting 	Brian Phillips	<ul style="list-style-type: none"> • SysTest Labs Team (software) • Precept Technology Representative (hardware)
9:30	X	X		Facilities Tour of Denver Operations	SysTest Labs Team	
10:30	X	X	4.1 & 4.2 ✓	Organization & Management System	Brian Phillips	STL Team
11:00		X	5.3 <i>Steve</i>	Accommodations & Environmental	STL Team	
		X	5.5 <i>OK</i>	Equipment & Software <i>? Item 5.5.3</i>	STL Team	Note: Power up & performance will be part of these steps ¹
		X	5.4 <i>Steve</i> Attachment A included	<u>Test and Method Validation</u>	STL Team	
	X		4.3 ✓	Document Control	Brian Phillips	
11:30	X		4.4 ✓	Review of Requests, tenders & contracts		
NOON	Lunch (prefer sandwiches, on-site)					
1:00 PM		X	5.3, 5.4 and 5.5 ↑	Continue on with topics from morning (includes 5.2 Personnel – performance)	SysTest Labs Team	
	(X)		4.6	Purchasing services and supplies	Brian Phillips	
	(X)		4.7	Service to the customer	Brian Phillips	
		X	5.7 <i>Default</i>	Sampling <i>C-DR-C</i>	STL Team	
	(X)		4.8	Complaints <i>Concerns - Dis Reps</i>	Brian Phillips	
	X		5.2 <i>Steve</i>	General & Personnel <i>Competency</i>	Brian Phillips	STL Team
	(150)	(150)		Records <i>INTERVIEWS</i>		
4:00	X	X	Recap	NVLAP Team		
4:30 PM	X	X	Briefing	NVLAP and STL – group meeting to review the activities of the day.	Brian Phillips & STL Team	
5:00 PM	Conclude the day at SysTest Labs.					
>>>>> PLEASE NOTE: All times listed are approximate <<<<<						

1. Power up and performance is dependent on a system being available to demonstrate some basic tests and methods to be used with voting systems. Software source code review is a specific test of interest.

3. If a clause in NIST Handbook 150 has additional requirements listed in Voting System Testing NIST Handbook 150-22, the additional requirements will be addressed when applicable, as well.

Concerns - Discrepancy Reports - Complaints
C - DR - C

The Voting System Testing Laboratory Accreditation Program - continued

DAY 2 - Thursday, September 21, 2006

TIME	LA	TE	NIST HDBK 150 (Clause) ³	Activities for VST LAP Accreditation	STL Contact(s)	Additional Support
8:00 AM	X	X	4.6-4.7 - 4.8	Opening Meeting • Plans for the day • Questions / comments	Brian Phillips	SysTest Labs Team
	X	X	4.9 ✓	Control of nonconforming testing work	Brian Phillips	
	X	X	4.10 ✓	Improvement	Brian Phillips	
	X	X	4.11 ✓	Corrective Action	Brian Phillips	
	X	X	4.12 ✓	Preventive Action	Brian Phillips	
	X	X	4.5 + 150-22	Subcontracting of Tests	Brian Phillips	
NOON Lunch (prefer sandwiches, on-site)						
1:00 PM	X	(X) ✓	5.9 Steve	Assuring the quality of test results	Brian Phillips	STL Team
1:30	X	X →	5.10 Sue	Reporting the results FRI	Brian Phillips	STL Team
1:45	(X)	X	4.13	Control of Records	Brian Phillips	STL Team
2:00		(X) →	5.6 NCR	Measurement Traceability FRI	STL Team	
	(X)		4.14	Internal Audits	Brian Phillips	
2:30		X →	5.8 Sue	Handling of test items	STL Team	
2:45	(X)		4.15	Management Reviews	Brian Phillips	
3:30	X	X	Recap	NVLAP Team		
4:30 PM	X	X	Briefing	NVLAP and STL - group meeting to review the activities of the day.	Brian Phillips & STL Team	
5:30 PM	Conclude the day at SysTest Labs.					

150-22 5.2.4 Roldres X

5.2.6 Training C

incl. Contract Empl. ? → STP-TR-02
#2.0 Scope

The Voting System Testing Laboratory Accreditation Program - continued

DAY 3 - Friday, September 22, 2006

TIME	LA	TE	NIST HDBK 150 (Clause) ³	Activities for VST LAP Accreditation	STL Contact(s)	Additional Support
8:00 AM	X	X	<i>Plan any catchup</i>	Opening Meeting <ul style="list-style-type: none"> • STL support/contact people • Overall status of NVLAP Assessment • Plans for Closing Meeting 	Brian Phillips	TBD
8:30 AM	X	X	All clauses needing additional attention	Tie off any open items and begin to draft the closing meeting materials	All SysTest participants must be available	
NOON	Lunch (prefer sandwiches, on-site)					
1:00 PM	X	X		Prepare for closing meeting		
3:30 PM	X	X	Closing Meeting	NVLAP and STL group meeting	Brian Phillips & STL Team	
5:00 PM	Close the NVLAP assessment					

Note: Clause 5.1 has no requirements to fulfill.

2. Power up & performance is dependent on a system being available to demonstrate some basic tests and methods to be used with voting systems at one or the other of the two sites. Operational Readiness Test prior/post non-operating tests is a specific test of interest.

For SysTest Labs, LLC, Denver:

For NVLAP:

Dick Stump

Date: _____

Date: 09-16-06

Mr. Brian T. Phillips,
President

Richard B. Stump
Lead Assessor

Jeff Stump
QA Mgr
on behalf of
Brian Phillips

9/22/06

SysTest

20 SEP 2006
Opening meeting

<u>Name</u>	<u>Position</u>	<u>Organization</u>
Dick Stump	Lead Assessor	NVLAP
Jef Knutson	QA Manager	SysTest Labs
Alicia Clay	XXXXX Sr. InfoSec Analyst	NIST
QUYNH DANG	Comp. Security Scientist	NIST
James Nilius	Lab Director	SysTest Labs
Jon Crickenberger	Program Manager	NIST/NVLAP
Steve Freeman	Technical Assessor	NIST /NVLAP
Mike Santos	ITA Project Manager	SYSTEST
DARRICK FORESTER	HW/PROJECT MANAGER	SYSTEST
KEVIN KELON	DIR. OF BUSINESS DEVELOPMENT	SYSTEST
Jo Johnson	Source Code Review Manager	Systest
Later Lesley Hoppert	Delivery Mgr/Technical Writer	Systest Support to Jef

22 SEP 2006 CLOSING MEETING

Dick Stump	Lead Assessor	NVLAP
Steve Freeman	Technical Assessor	NVLAP
James Nilius	Lab Director	SysTest Labs
Jef Knutson	QA Manager	SysTest Labs

SysTest Labs Incorporated
22 SEP 2006
Lead Assessor Assignments

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

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

Legal name of laboratory ownership: SysTest Labs Incorporated

OK
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.

OSM p. 15/73 listing
LISTED "NAVA" ↑

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.

Denver

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.

Name for VSLAP Subcontractor

Job Description provided

- QA mgr.
- Dir. of Compliance

Organization ← Compliance Services

Org charts 13 SEP 2006
Compliance Services

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 judgment. The third-party testing or calibration laboratory should not engage in any activities that may endanger the trust in its independence of judgment and integrity in relation to its testing or calibration activities.

System

22 SEP 2006

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);

Org. Chart 13 SEP 2006

also Job Descriptions -> 5.2

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;

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;

6.3.10 (BASED TIME FRAME)

LIST FORM NAMES IN VC-02

Done

OK d)

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

Rev. 04

SLP-VC-02

Facility: OFF SITE RECEIPT: PASSWORD

QSM 4th bullet p.12/73

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;

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;

Org. charts

Org. charts

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;

Job Descriptions - QA mgr. / Dir. Compliance Services

* C -> X

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;

org. chart / SLP-TR-01 SLP-TR-02 *

TR = Training * NOT FINAL APAD.

Name of person: Jim Nilas Earl Burba
Area of responsibility: Director, Compliance Services
Repeat as necessary: Chief Engineer

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;

Name of person: Jeff Knutson, Quality Manager

System

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OK j)

appoint deputies for key managerial personnel (see Note).

Name(s): Hardware - Darrick Furester
Software code Review - Jo Johnson

Name(s): Functional Test & Doc. Review - Jenn Garcia

Name(s): Q System, Tech Writing + Library Management
Lesley Hoppert.

ASK during interview

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.

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

draft on CD

RBS X-100

Project Mgt. SLP-VC-04 Proj. Mgt. for Assigned in Training Jacket

Excellent

Viewed Training Records

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.

OK See 4.1.5 above

SLP-QS-12

4.2

Management system

Needs closure

C-DR-C Form

Concern, Descrepancy Report

4.2.1

OK a)

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

allows input from employees - control # is log time which includes KY-HR-min

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.

Q System manual

Systemtest Labs Summary sheet

OK c)

The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.

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.

In training record - SLP = training element notified during a group mtg

Jenn Garcia was mtg input

4.2.2

QSM 1.3

Mission values

QSM 1.4

Date of most recent quality manual: QSM Rev. 0.0.4 NVLAP

13 JUN 2006

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

OK a)

Mission Statement

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

VSL QS Manual

OK b)

the management's statement of the laboratory's standard of service;

QSM 1.7

OK c)

the purpose of the management system related to quality;

QSM 1.7

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

QSM 1.5
QSM 1.7

X.
OK

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

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.

Add specific text

QSM 4.1.1 + 4.2.2 changed

X.
OK

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.

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

4.2.5

OK

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

OK

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

SLP-QS-01 - Document Structure

X

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.

Roles to be added to Q mgr.

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.

Signature Page = giving doc support

4.3 Document control

SLP-QS-05 Review sheet

Def - Jim-Brien Jenn - So

yearly review of QSM

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.

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.

Already established and in use with current customers

All SLPs must be in approved status before NVLAP acceptance for certification

Set For + For Jun 9/21

NVLAP LAB CODE:

SLJ

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4.3.2 Document approval and issue

4.3.2.1

SLP QS-02 4.5.3 = App'd Signatories
4.5.2.1 - 3

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.

X 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.
SLPs + Forms - on-line approved

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; QSM 4.3.3

X b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements; Needs to address annual review
invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

OK c) SLP QS-02 4.5.2.4.4
obsolete documents retained for either legal or knowledge preservation purposes are suitably marked. SLP-QS-02 4.5.2.4.4

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

OK a) the date of issue and/or revision identification, And observed as such

OK b) page numbering,

OK c) the total number of pages or a mark to signify the end of the document, and QSM 4.3.4

OK d) the issuing authority(ies).

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. Role

OK 4.3.3.2 Where practicable, the altered or new text shall be identified in the document or the appropriate attachments. SLP-QS-02 4.5.3

Current - QSM

Document history "Tracking table" - Observed as working

SLI

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4.3.3.3

N/A

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.

N/A

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

OK

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

Not doing a) ; not doing b)

SLP-QS-02 all

Defento.
Jim/Brian

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:

Revising to clean notes

SLP QS-11 Leslie
revising
9-21-06

OK

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

QSM 4.4.4 SLP QS-11 SLPs listed 4.4.3 QSM

OK

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

QSM 4.4.4.1 Given through VSS

OK

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

QSM 4.4.4.1 QSM p. 38/74

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.

QSM 4.4.1 All VSS specified methods understood

Wm...
KBE

QSM 4.4.1 put in

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.

QSM 4.4.1 put in

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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.

Jim
Brian

- OK 4.4.3 The review shall also cover any work that is subcontracted by the laboratory.
- OK 4.4.4 The customer shall be informed of any deviation from the contract. *SLP-VC-24 #5.1.1*
- 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. *QSM 4.4.2.4 add Account Manager #5.4*

QSM 4.4.2 add partition

Kevin Keeland

STEVEN

- 4.5 Subcontracting of tests and calibrations
- X 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. *QSM #4.5*
- 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. *Percept has A2LA for EMC SLP-VC-24 APT - has no HDX150 coverage*
- X 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. *QSM #4.4.1*
- X 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. *Not addressed*

Not formal with subcontractors

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.

QSM #4.6 p. 42+43/74 SLP-VC-02

- 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. *SLP-OS-10 SLP-VC-02 #5.4*



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OK
OK

QSM #4.6 put in
Records of actions taken to check compliance shall be maintained. SLP-VC-02 #5.4
Needs Form # Form = Equipment Traveler

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. ~~QSM RBS~~ SLP-QS-10 → QSM 4.6

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

X
X

a) → NOT ADDRESSED
The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and
b) → WM cover in SLP QS-10 — add
" " " " " "

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.

NOTE 1 Such cooperation may include: QSM #4.7 SLP-QS-12 #5.2 RBS needed add to QSM 4.7

- 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.

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

QSM #4.2.1 Feedback
• STL Survey 1
• STL Survey 2
use of C-DR-C
SLP-QS-12 esp. #5.2
#5.3.3 analyze

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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.

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).

SLP-QS-12 C-DR-C QSM 4.8 complaints
SLP-QS-12 C-DR-C

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:

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;

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

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

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

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

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.

LINKS
SLP-QS-08 -> Form QS-09
SLP-QS-09

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.

QSM 4.2.2 SLP-QS-12
p.29/74

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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. SLP-QS-09 A2.2

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. SLP-QS-09 A2.3.1

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.

OK b) Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem. Form QS-09 Root Cause Analysis

OK c) The laboratory shall document and implement any required changes resulting from corrective action investigations. Form QS-09 Corrective Steps

4.11.4 Monitoring of corrective actions

OK The laboratory shall monitor the results to ensure that the corrective actions taken have been effective. JEF SLP-QS-09 A5.2.4 Closing by the QA mgr

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. Needs to be added to SLP-QS-09

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.

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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.
- OK b) *SLP-QS-09 45.3.2 + 5.3.3*
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.

OK 4.12.2 *Form QS-09*
Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective.

SLP-QS-09 3.4
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.

SLP QS-03 Config Mgmt + Record control

4.13.1.2

OK a) *all electronic 45.2.3.3*
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.

OK b) *5.2.3.4 [only legal docs in hard copy]*
Retention times of records shall be established.

SLP QS-03 45.2.3.6 - indefinite basis
NOTE Records may be in any media, such as hard copy or electronic media.

OK 4.13.1.3 *5.2.3.4*
All records shall be held secure and in confidence.

OK 4.13.1.4 *SLP QS-03 Legal + Server (Flow diagram)*
The laboratory shall have procedures to protect and back up records stored electronically and to prevent unauthorized access to or amendment of these records. *CSMA 4.3.7*

SLP-VC-024 5.3
Staff access
Basic Network v. 0.9.1 (need to identify page with this info)
~~*SLP-QS-14 KBR*~~

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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. SLP QS-03 # 5.2.3.1
- X 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. *Due to nature of business*
- OK c) The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results. *Not addressed in total* See SLP QS-03 # 5.2.3.1

NOTE 1 In certain fields it may be impossible or impracticable to retain records of all original observations. *LNA - SLP-QS-23 # 5.1* SLP QS-05 # 5.2.3.3

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.

4.13.2.3 *SLP QS-05 # 5.2.3.3* Form for each test.

- X 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.
- X b) In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data. *Address all - Systest + subcontractors*

4.14 Internal audits

4.14.1

OK a) *Document* 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.

X *Practice* Dates of most recent internal audit: *COMPLETE SLPs 6 SEP 2006 10 SEP 2006*

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

SLP QS-05

22 SEP 2006

NVLAP LAB CODE:

SLI

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

NOTE Upgrade SLP-QS-05 for total inter The cycle for internal auditing should normally be completed in one year.

X 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.

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

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

SLP-QS-05 Form QS-05 SLP-QS-05 AS.2.2.4

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.

SLP-QS-06

QSM 4.15 p49/74

X Date(s) of most recent management review: NOT OCCURRED

Practice What is the review schedule? 1 Q 2007 - planned For NMAP assessment - W/IN 30 DAYS SLP-QS-06

RAB/OK

The review shall take account of:

OK a) the suitability of policies and procedures; 4 4.15 p49/74

OK b) reports from managerial and supervisory personnel; 4 5.2.1 + 5.2.2

OK c) the outcome of recent internal audits; 4 5.1.2

OK d) corrective and preventive actions; 4 5.1.7

X e) assessments by external bodies;

NA f) the results of interlaboratory comparisons or proficiency tests; System is the only lab in this category

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

OK h) customer feedback; QSM 4.14

OK i) complaints; 4 5.1.5

OK j) recommendations for improvement; SLP-QS-06 4 5.2.1

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SLI

OK^{k)}

other relevant factors, such as quality control activities, resources and staff training. QSM 44.15

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.

OK b)

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

SLP-QS-06715, 2.2

SLP-QS-06715, 2.2

5 Technical requirements for accreditation

5.1 General

TA-TE

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).

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.

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5.2 Personnel

5.2.1

SLP TR-01

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.

OK b)

ITA TRAINING CURRICULUM [SKILL LEVELS FORM]

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. QSM 5.2

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;
- ii) knowledge of the general requirements expressed in the legislation and standards; and
- iii) an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc. concerned.

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.

OK b)

SLP TR-01 SLP INCLUDES TRAINING RECORD
The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel.

OK c)

SLP TR-01
The training program shall be relevant to the present and anticipated tasks of the laboratory.

OK d)

ITA TRAINING CURRICULUM (EXCEL SHEET)
The effectiveness of the training actions taken shall be evaluated.

5.2.3

OK a)

↓ SLP TR-02
+ COMPETENCY
The laboratory shall use personnel who are employed by, or under contract to, the laboratory.

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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

SCP-TR-01 & 02 SCOPE
The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.

NOTE
be defined:

Under Presented "System Test Labs" with Charts & Position Descriptive
Master Document List 02

- i) the responsibilities with respect to performing tests and/or calibrations;
- ii) the responsibilities with respect to the planning of tests and/or calibrations and evaluation of results;
- iii) the responsibilities for reporting opinions and interpretations;
- iv) the responsibilities with respect to method modification and development and validation of new methods;
- v) expertise and experience required;
- vi) qualifications and training programs;
- vii) managerial duties.

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.

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.

OK c)

Training SCP-TR-02 OBSERVED JEP'S RECORDS
This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.

SCP-TR-02 RECORDED IN INDIVIDUAL TRAINING RECORDS
NVLAP Note: This requirement also applies to Approved Signatories (see 1.5.2).

5.3 Accommodation and environmental conditions

TA
5.3.1

- 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.

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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.

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

5.3.2

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

___ **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.

___ **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.

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

5.4 Test and calibration methods and method validation

TA - JE

5.4.1 General

- ___ 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.
- ___ 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.
- ___ 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).

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

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

- ___ 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.
- ___ b) When necessary, the standard shall be supplemented with additional details to ensure consistent application.
- ___ 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.
- ___ d) The customer shall be informed as to the method chosen.
- ___ 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.
- ___ f) The laboratory shall inform the customer when the method proposed by the customer is considered to be inappropriate or out of date.

5.4.3 Laboratory-developed methods

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

5.4.4 Non-standard methods

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

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;
- b) scope;
- c) description of the type of item to be tested or calibrated;
- d) parameters or quantities and ranges to be determined;
- e) apparatus and equipment, including technical performance requirements;
- f) reference standards and reference materials required;
- g) environmental conditions required and any stabilization period needed;
- h) description of the procedure, including:
 - i) affixing of identification marks, handling, transporting, storing and preparation of items,
 - ii) checks to be made before the work is started,
 - iii) checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use,
 - iv) the method of recording the observations and results,
 - v) any safety measures to be observed;
- i) criteria and/or requirements for approval/rejection;
- j) data to be recorded and method of analysis and presentation;
- k) the uncertainty or the procedure for estimating uncertainty.

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.

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5.4.5.2

- _____ 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.
- _____ 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.

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

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.

- _____ **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.

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.

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5.4.6 Estimation of uncertainty of measurement

- _____ **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.
- _____ **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.

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

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).

- _____ **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.

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

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

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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:

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

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

TA — TE
5.5.1

- ___ 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).
- ___ 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.

5.5.2

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

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- ___ 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.
- ___ 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.
- ___ 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:
 - ___ a) the identity of the item of equipment and its software;
 - ___ b) the manufacturer's name, type identification, and serial number or other unique identification;
 - ___ c) checks that equipment complies with the specification (see 5.5.2);
 - ___ d) the current location, where appropriate;
 - ___ e) the manufacturer's instructions, if available, or reference to their location;
 - ___ f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;
 - ___ g) the maintenance plan, where appropriate, and maintenance carried out to date;
 - ___ h) any damage, malfunction, modification or repair to the equipment.
- ___ 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.

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

5.5.7

- ___ 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.
- ___ 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).

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- ___ 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.
- ___ 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.
- ___ 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.
- ___ 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.
- ___ 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.

5.6 Measurement traceability

TA — TE
5.6.1 General

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

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

- ___ 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*).

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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.

- _____ 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.
- _____ 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.

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- ___ **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:
- ___ a) the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;
 - ___ b) the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.
 - ___ c) Participation in a suitable program of interlaboratory comparisons is required where possible.

5.6.2.2 Testing

- ___ **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.

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.

- ___ **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).

5.6.3 Reference standards and reference materials

5.6.3.1 Reference standards

- ___ a) The laboratory shall have a program and procedure for the calibration of its reference standards.
- ___ b) Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1.
- ___ 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.

5.6.3.2 Reference materials

- ___ 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.

5.6.3.3 Intermediate checks

____ 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.

5.6.3.4 Transport and storage

____ 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.

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

TA — TE
 5.7.1

____ 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.

____ 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.

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.

____ **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.

____ **5.7.3** 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.

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5.8 Handling of test and calibration items

TA
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.

5.8.2

- a) The laboratory shall have a system for identifying test and/or calibration items.
- b) The identification shall be retained throughout the life of the item in the laboratory.
- 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.
- d) The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory.

5.8.3

- 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.
- 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.

5.8.4

- 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.
- b) Handling instructions provided with the item shall be followed.
- c) When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.
- 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.

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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

TA — TE
5.9.1

- ___ a) The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken.
- ___ 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.
- ___ c) This monitoring shall be planned and reviewed and may include, but not be limited to, the following:
 - ___ 1) regular use of certified reference materials and/or internal quality control using secondary reference materials;
 - ___ 2) participation in interlaboratory comparison or proficiency-testing programs;
 - ___ 3) replicate tests or calibrations using the same or different methods;
 - ___ 4) retesting or recalibration of retained items;
 - ___ 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.

- ___ ♦ **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.

5.10 Reporting the results

TA — TE
5.10.1 General

- ___ 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.

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- ___ 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.
- ___ 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.

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:

- ___ a) a title (e.g., "Test Report" or "Calibration Certificate");
- ___ 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;
- ___ 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;
- ___ d) the name and address of the customer;
- ___ e) identification of the method used;
- ___ f) a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated;
- ___ 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;
- ___ 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;
- ___ i) the test or calibration results with, where appropriate, the units of measurement;

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- ___ j) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate;
- ___ k) where relevant, a statement to the effect that the results relate only to the items tested or calibrated.

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:

- ___ a) deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions;
- ___ b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications;
- ___ 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;
- ___ d) where appropriate and needed, opinions and interpretations (see 5.10.5);
- ___ e) additional information which may be required by specific methods, customers or groups of customers.

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:

- ___ a) the date of sampling;
- ___ 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);
- ___ c) the location of sampling, including any diagrams, sketches or photographs;
- ___ d) a reference to the sampling plan and procedures used;
- ___ e) details of any environmental conditions during sampling that may affect the interpretation of the test results;

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- ___ 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:

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

5.10.4.2

- ___ a) The calibration certificate shall relate only to quantities and the results of functional tests.
- ___ b) If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met.
- ___ 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.
- ___ d) When statements of compliance are made, the uncertainty of measurement shall be taken into account.

___ **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.

___ **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

___ 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.

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.

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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;
- ii) fulfillment of contractual requirements;
- iii) recommendations on how to use the results;
- iv) guidance to be used for improvements.

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

- ___ a) When the test report contains results of tests performed by subcontractors, these results shall be clearly identified.
- ___ b) The subcontractor shall report the results in writing or electronically.
- ___ 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

___ 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).

5.10.8 Format of reports and certificates

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

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

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

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- _____ 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.

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Annex A (normative)

Referencing NVLAP accreditation

System will address with reference in QSM.

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.

- ___ 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.
- ___ b) The laboratory shall have a policy and procedure for controlling the use of the term *NVLAP* and the NVLAP symbol.
- ___ 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.
- ___ d) When the term *NVLAP* is used to reference a laboratory's accredited status, it shall be accompanied by the NVLAP Lab Code.
- ___ e) When the NVLAP symbol 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:

- ___ 1) The logo shall stand by itself and shall not be combined with any other logo, symbol, or graphic.
- ___ 2) The aspect ratio (width to height) shall be 2.25 to 1.
- ___ 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.
- ___ 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.

___ 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)

- ___ 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.
- ___ 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.
- ___ 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)

- ___ 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.
- ___ 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.

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- ___ 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.
- ___ 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.
- ___ 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.
- ___ 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.
- ___ 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*.

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Annex B (normative)

Implementation of traceability policy in accredited laboratories

B.1 Policy overview

THIS ANNEX IS N/A FOR
SYSTEMS LABS INCORPORATED

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.
- 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.

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.

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.

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:

- a) document that an appropriate accredited calibration service provider is not available;
- 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:
 - 1) information regarding assessment of the quality system used by the calibration service provider,
 - 2) the calibration procedure(s) used by the calibration service provider,
 - 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),
 - 4) information regarding the calibration intervals of relevant standards or other test and measurement equipment,
 - 5) the environmental conditions of the laboratory,

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

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.

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SystemST Labs Incorporated

**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).

Item No.	C or X	Comments and/or Nonconformities
4.1.2	X	SLI DID NOT ADDRESS THIS REQUIREMENT, BUT WAS CORRECTED - NO FURTHER C/A NEEDED,
4.1.5c	X	SLI DID NOT ADDRESS THIS REQUIREMENT, BUT WAS CORRECTED - NO FURTHER C/A NEEDED
4.1.5g	X	SLI PRESENTED SLP-TR-01 & 02 WHICH WERE NOT FINAL APPROVED - ALSO SEE 4.3 DOCUMENT CONTROL. SEARCH FOR ALL OTHER VST LAP DOCUMENTS NOT FINAL APPROVED,
4.1.6	PRB X	THE C-DR-C FORM HAS NOT REACHED CLOSURE FOR USE (SAW IN INTERVIEWS AS WELL - SEE 5.2)
4.2.2e	X	NEEDED SPECIFIC TEXT - DONE - NO FURTHER C/A NEEDED
4.2.3	X	SEE 4.1.6 ABOVE AND COMBINE THIS. Ref. SLP-QS-12
4.2.4	X	NEEDED SPECIFIC TEXT - DONE - NO FURTHER C/A NEEDED
4.2.6	X	ROLE OF QA MANAGER IS INCOMPLETE, PROVIDED IN BINDER - DONE - NO FURTHER C/A NEEDED UNLESS WANT TO ADD IN QSM 4.1.1.4 AS WELL
4.3.2.1 b)	X	A CONTROLLED MASTER LIST IS REQUIRED FOR ALL VST LAP DOCUMENTS
4.3.2.2 b)	X	SLI DOES NOT ADDRESS PERIODIC REVIEW

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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).

Item No.	C or X	Comments and/or Nonconformities
4.5.1	X	SLI MUST ADDRESS THE LISTED NEEDS
4.5.3	X	FOR ITS SUBCONTRACT LABS PROGRAM
4.5.4	X	AND APPLY ITS COMMITMENTS
4.6.4	a) X b) X	SLI MUST ADDRESS EVALUATION OF SUPPLIERS AND KEEP RECORDS
4.11.5	X	SLI MUST ADDRESS ADDITION OF AUDITS WHEN DETERMINED ARE TO NONCONFORMITIES.
4.13.1.4	C	SLI SHOULD IDENTIFY THE BASIC NETWORK PAGE WITH INFO
4.13.2.1	b) X	SLI MUST ADDRESS THIS RECORD REQUIREMENT RELATING TO UNCERTAINTY
4.13.2.3	a) X b) X	SLI HAS NOT ADDRESSED CROSSCHECKS TO CORRECT MISTAKES IN RECORDS
4.14.1	a) X b) X	SLI DID NOT CONDUCT AN INTERNAL ACCORDING TO NVLAP REQUIREMENTS
4.14.2	X	SLI DOES NOT ADDRESS THE TIMELY CORRECTIVE ACTION FOR AUDIT FINDINGS
4.15.1	X	SLI HAS NOT CONDUCTED A MANAGEMENT REVIEW (SEE HB 150-22 4.15)
4.15.1g)	X	SLI NEEDS TO ADD CHANGES IN VOLUME

4.5 Subcontracting of tests and calibrations

Def. **4.5.1** Subcontracting of tests and calibrations is the use of laboratory services outside of the VSTL to perform tests and calibrations, e.g., electromagnetic compatibility testing, environmental testing, shock and vibration testing, FIPS 140 validation, and physical test instrument calibration. The word subcontracting is not used to describe a mechanism by which the laboratory employs staff members (see 5.2.7).

SLP-VC-24

X

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

4.5.3 If the VSTL subcontracts voting system testing that is outside of its scope of accreditation, the subcontracted laboratory must be:

N/A

- a. located in the United States,
- b. an accredited laboratory under NVLAP (preferred) or another LAP with which NVLAP has signed a Mutual Recognition Arrangement (MRA). *Receipt has AZLA for EMC - APT not 18012025*
- c. accredited under the appropriate scope of accreditation for the testing which is subcontracted.

X

d. If the VSTL needs to subcontract voting system testing outside of the core requirement scope of accreditation, the VSTL shall include in their application and Quality Management procedures a list of validated test labs and the tests for which they will used.

X

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 equipment under test is the same production design models as that presented to and used by the VSTL for Qualification/National Certification Testing

b. The equipment operations used in the subcontracted testing are based on the operations as a voting system component. Where appropriate, the VSTL shall provide test procedures or perform the Operational Status Test or operations based on the Operational Status Test (Ref VSS Vol II,

Note1: For example, a VSTL subcontracting with another laboratory to conduct temperature cycling tests should conduct the functional testing itself rather than allowing the subcontractor to do so. The VSTL is responsible for ensuring that the entire voting system is properly tested.

4.6 Purchasing services and supplies

There are no requirements additional to those set forth in NIST Handbook 150.

4.7 Service to the customer

There are no requirements additional to those set forth in NIST Handbook 150.

4.8 Complaints

There are no requirements additional to those set forth in NIST Handbook 150.

4.9 Control of nonconforming testing and/or calibration work

4.9.1 (Draft) The procedures shall include a requirement for reporting to the EAC when non-conforming work is identified as having occurred on previous campaigns.

4.10 Improvement

There are no requirements additional to those set forth in NIST Handbook 150.

4.11 Corrective action

There are no requirements additional to those set forth in NIST Handbook 150.

4.12 Preventive action

There are no requirements additional to those set forth in NIST Handbook 150.

4.13 Control of records

OK 4.13.1 The laboratory shall set policies and procedures on the retention of records that meet the requirements of HAVA and the EAC and meet the needs of its customers as agreed in a contract. Volume I, Section 2.2.11 of the VSS-2002, "Data Retention," does not apply to the retention of records of testing by the VSTL.

OK 4.13.2 The laboratory shall maintain a functional record-keeping system that is used to track each product or system. *SLP QS-03 4.5.2.3, 6 indefinite retention Retention = 2 yrs*

OK a. Records shall be easily accessible and contain complete information for each Qualification/National Certification test. *SLP - QS-03 -> Life Cycle Approach*

OK b. Required records of testing activities shall be traceable to requirements in the VSS-2002. *SLP QS-03 4.5.2.3, 2*
NOTE: Technical reviewers of the Qualification/National Certification Test Reports have requested that the report include a standardized test requirement matrix against the VSS 2002/VVSG 2005 requirements showing which tests/reviews were performed, whether the results were accepted, and, if based on reports from earlier tests or laboratories, the reference for the report of the test.

OK c. Computer-based records shall contain entries indicating the date created and the individual(s) who performed the work, along with any other information required by the management system. *SLP QS-03 4.5.2.3, 3 Auto Journaling*

X d. Entries in laboratory notebooks shall be dated and signed or initialed. *Not addressed*

OK e. All records shall be maintained in accordance with laboratory policies and procedures and in a manner that ensures record integrity. *SLP-QC-03*

N/A f. There shall be appropriate backups and archives

X 4.13.3 Laboratory records shall be maintained, released, or destroyed in accordance with the laboratory's policy on proprietary information and contractual agreements with customers. *SLP QC-03 4.5.2.3, 6*

X 4.13.4 The Qualification/National Certification Test Report plus the laboratory's records of the Qualification/National Certification test shall contain sufficient information to allow repeating, reproducing and/or auditing the entire Qualification/National Certification test.

4.14 Internal audits *SLP-QS-03 4.5.2.3, 5*

OK 4.14.1 Internal audits shall be performed on a schedule prescribed by the laboratory policies and procedures. Recent internal audit reports shall be available for review during NVLAP on-site assessments. *4.5.2.2, 2, 3, 4 CA/PA SLPs*

OK 4.14.2 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, contractual, laboratory management system, and any additional EAC requirements. *SLP-QS-03 4.5.2.3, 1*

Def. 4.14.3 In the case where only one member of the laboratory staff is competent to conduct a specific aspect of a test method, and performing an audit of work in this area would result in that person auditing his or her own work, then the audit may be conducted by another staff member. External experts may also be used in these situations. *SLP QS-05 Process QC + Internal Audits WILL NOT APPLY*

OK The audit shall cover the methodology for that test method and shall include a review of documented procedures and instructions, adherence to procedures and instructions, and review of previous audit reports *SLP QS-05 4.5.2.1, 2*

X 4.14.4 The laboratory shall perform at least one complete internal audit of its management system prior to the first on-site assessment. *WILL DO W/in 30 DAYS*

OK 5.2.6 The laboratory shall review annually the competence of each staff member for each test method the staff member is authorized to conduct. The staff member's immediate supervisor, or a designee appointed by the laboratory director, shall conduct annually an assessment and an observation of performance for each staff member. A record of the annual review of each staff member shall be dated and signed by the supervisor and the employee. A description of competency review programs shall be maintained in the management system.

OK 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.).

SLP TR-01-02 RE "LEASED WORKERS"

X { 5.2.8 The records for each person having an effect on the outcome of the testing shall include:
a) position description;
b) resume/CV/bio to match the person to the position;
c) duties assigned;
d) annual competence review;
e) training records and training plans.

Being done not complete

5.2.9 In order to maintain confidentiality and impartiality, the laboratory shall maintain proper separation between personnel conducting testing and other personnel inside the laboratory or outside the laboratory, but inside the parent organization.

5.3 Accommodation and environmental conditions

TA 5.3.1 The laboratory shall have adequate facilities to conduct the voting system testing that it offers. This includes facilities for staff training, record keeping, document storage, and software storage. If testing activities are conducted at more than one location, all locations shall meet the NVLAP requirements, and mechanisms shall be in place to ensure secure communication between all locations.

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.

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. The laboratory shall have an effective backup system to ensure that data and records can be restored in the event of their loss.

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.

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.

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.

Note: See NASED Guideline 4 for specific requirements on witnessed builds at customer sites.

5.4 Test and calibration methods and method validation

Def. 5.4.1 The test methods for this program are given in the VSS-2002 approved by the Federal Election Commission on April 30, 2002, and adopted in the HAVA. In the VSS-2002, there are specific test methods, references to test methods, and provisions for laboratory-developed test methods. The EAC may amend and augment the VSS-2002.

_____ 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.

_____ 5.4.2 For each test in the Test Plan, the laboratory shall document all aspects of the test including the test method. The level of detail shall be such that the laboratory can repeat the test or another laboratory can reproduce the test and the results of the test will be equivalent to the original test.

_____ Where the laboratory has developed test methods to meet the requirements of the VSS-2002, validation of the test methods shall be included in the documentation.

_____ 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.

_____ 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.

_____ 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.

Note: This is to include the configuration of COTS software installed to support the system.

_____ 5.4.5 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.

_____ 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.

5.5 Equipment

TA _____ 5.5.1 The laboratory shall document and maintain records on all test equipment or test suites used during testing. Test equipment includes software and hardware products or other assessment mechanisms used by the laboratory to support the testing of products and systems. The laboratory shall also know how to configure and operate all equipment within its control.

_____ 5.5.2 Computer systems, and other platforms used during the conduct of testing shall be under configuration control. The laboratory shall have procedures to ensure that any equipment (hardware and software) used for testing is in a known state prior to use for testing.

Note: The procedures for the Test Report shall include a report of the configuration of the operational voting system equipment including COTS component versions used in the actual test.

_____ 5.5.3 Test equipment shall be properly calibrated. For test equipment, calibration means verification of correctness and suitability. 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, Volume II, Section B.3 requires the documentation of the tested software and supporting hardware.

_____ 5.5.4 Laboratories shall have procedures that ensure appropriate configuration of all test equipment. Laboratories shall maintain records of the configuration of test equipment and all analyses to ensure the suitability of test equipment to perform the desired testing.

_____ 5.5.5 For software testing, calibration is used to mean that all hardware, software, interfaces, etc. have been brought under configuration management and that the laboratory can reproduce the conditions under which each specific test was conducted. Where an operating system, user applications, test tools, and customer software are loaded onto a platform, calibration covers the hardware platform, all software, and the order in which the software was loaded.

5.6 Measurement traceability

- Def. **5.6.1** For this NVLAP program, *traceability* is used in two different ways. The first applies to classical test and measurement equipment. The second to software and system testing.
- Def. **5.6.2** The classical definition of *traceability* is a comparison of a measured value to a stated reference through an unbroken chain of comparisons all having stated uncertainties. For example, a micrometer is calibrated using a gauge block that has been assigned a value that is traceable through the national standard to the International System of Units (SI).
- Def. **5.6.3** For software and some systems testing, *traceability* means that the operations performed by a test or test tool have been demonstrated to embody the assertions contained in the documentary standard. This means that test tools and test methodology demonstrate that the tests conducted by the tools and the test assertions they make are traceable to specific criteria and methodology.

_____ **The Test Plan and Report shall include test requirement matrix identifying the requirements that are being satisfied.**

Note: Reference

5.7 Sampling

- TA _____ **5.7.1** The laboratory shall use documented procedures for sampling. When sampling is used during a test campaign, the laboratory shall document its sampling strategy, the decision-making process, and the nature of the sample. Sampling may include (but is not limited to):
 - _____ a) hardware items;
 - _____ b) software;
 - _____ c) system configuration;
 - _____ d) test methods;
 - _____ e) system states at time of test.
- _____ **5.7.2** The VSS-2002 requires that the laboratory document its plan for the minimum number of combinations or alternatives of input and output conditions that can be exercised to constitute an acceptable test of the parameters involved (VSS-2002, Volume II, A.5.2).
- _____ **5.7.3** Sampling shall be part of the test record.

5.8 Handling of test and calibration items

- TA _____ **5.8.1** The laboratory shall protect products and systems under test and calibrated tools from modification, unauthorized access, and use. The laboratory shall also maintain separation between and control over the items from different tests, to include the product being tested, its platform, peripherals, and all documentation.
- _____ **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.
- _____ **5.8.3** The laboratory shall have procedures to ensure proper retention, disposal or return of software and hardware after the completion of the test.

5.9 Assuring the quality of test and calibration results

- _____ The laboratory shall have procedures for conducting final review of testing, Qualification/National Certification Test Reports and any other test reports it issues, and laboratory records of the testing prior to submission to the customer and/or the EAC.

5.10 Reporting the results

TA-

- _____ **5.10.1** The laboratory shall issue test reports of its work that accurately, clearly, and unambiguously present the test plan, test conditions, test setup, test methods, test results, and all other required information. Test reports shall provide all necessary information to permit the same or another laboratory to reproduce the test plan and obtain comparable results.
- _____ **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 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.
- _____ **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.
- _____ **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.
- _____ **5.10.6** **The section of a Qualification/National Certification Test Report that meets the VSS-2002 requirement for a summary or the recommendation section of a test report for a customer shall also meet the requirements of NIST Handbook 150 on opinions and interpretations under Reporting the results.**

6 Additional requirements

N/A

There are no additional requirements beyond NIST Handbook 150 and its associated normative annexes, and any other normative references previously cited in this handbook.

